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# Optimising the Bariatric Perioperative Journey

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# **ABSTRACT**

## **Aim**

To evaluate whether bariatric surgery can be made more cost-effective and to improve early and long-term outcomes

## **Methods**

The bariatric procedure offered at Counties Manukau District Health Board (CMDHB), Auckland, is laparoscopic sleeve gastrectomy (LSG). Therefore this thesis deals solely with surgical recovery and outcomes after LSG. To determine the current status of LSG at CMDHB, a retrospective review describing the outcomes of the first 400 patients to have LSG at our institution was performed, the results of which would be used to measure the effect of clinical interventions described in later chapters. The thesis was then divided into two distinct phases. The first phase was to determine whether optimised and standardised perioperative care would lead to improved surgical recovery, improved clinical outcomes and reduced perioperative costs. Implementation of an Enhanced Recovery After Surgery (ERAS) programme was hypothesised to be an effective way to achieve this. A bariatric ERAS programme was therefore formulated by performing an extensive review of the literature evaluating perioperative care interventions in major abdominal surgery. In this review, prehabilitation was identified as an intervention which could be investigated in later chapters as a means to improve surgical recovery. Once formulated, the ERAS programme was evaluated within a randomised controlled trial. The second phase of the thesis was to determine whether improved exercise behaviour would

lead to improved surgical outcomes. A prospective study was first performed to describe the long-term efficacy of LSG at our institution in order to determine the extent to which outcomes could be improved. A systematic review was then performed to determine whether a text-message intervention could be used to improve exercise adherence in order to optimise preoperative exercise behaviour. The efficacy of text-messages and preoperative exercise were then investigated within a randomised controlled trial.

## **Results**

Whilst the results of LSG at our institution were comparable with other published studies, it was shown that the benefits could occur at the expense of significant morbidity and prolonged convalescence. A bariatric specific ERAS programme was then formulated and safely implemented with the results of the randomised controlled trial showing a significant reduction in hospital length of stay (3 days to 1 day;  $p<0.001$ ) and perioperative costs. However, there was no improvement in clinical outcomes. The early term results described in Chapter 2 were not maintained at long-term follow-up. In the final randomised controlled trial, the implementation of text-messages led to a significant improvement in adherence to exercise behaviour (77.3% to 56.8%;  $p=0.041$ ). However, this did not correlate with improved clinical outcomes. The improvement in exercise behaviour was not maintained postoperatively.

## **Conclusion**

The principles of ERAS can be successfully applied to the perioperative management of patients undergoing bariatric surgery. Within an established ERAS programme, despite optimised adherence, preoperative exercise does not improve clinical outcomes or postoperative exercise behaviour.

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## ABBREVIATIONS

1-RM	1-Repetition Maximum
6MWT	6 Minute Walk Test
%BMIL	Percentage BMI Loss
%EBMIL	Percentage Excess BMI Loss
%EWL	Percentage Excess Weight Loss

### A

ACSM	American College of Sports Medicine
ASA	American Society of Anesthesiologists'

### B

BAROS	Bariatric Reporting Outcome System
BMI	Body Mass Index
BMR	Basal Metabolic Rate
BPD/DS	Biliopancreatic Diversion with or without Duodenal Switch

### C

CG	Control Group
CI	Confidence Intervals
cm	Centimetres
CMDHB	Counties Manukau District Health Board
CO <sub>2</sub>	Carbon Dioxide
COF	Clear Oral Fluid
CONSORT	Consolidated Standard of Reporting Trials
COX-2	Cyclo-oxygenase 2

	CSF	Cerebrospinal Fluid
	CT	Computer Tomography Scan
D		
	Dex	Dexamethasone
E		
	EG	Exposure Group
	ERAS	Enhanced Recovery After Surgery
F		
	Fr	French
G		
	g	Grams
	GDFT	Goal Directed Fluid Therapy
	GLP-1	Glucagon Like Peptide 1
	GP	General Practitioner
H		
	H <sub>2</sub> O	Water
	HbA <sub>1c</sub>	Haemoglobin A1c
	HCG	Historic Control Group
	HDL	High-Density Lipoprotein
	Hyperchol	Hypercholesterolaemia
	HTN	Hypertension
	HVLP	High Volume, Low pH
I		
	ICU	Intensive Care Unit

IDC	Indwelling Catheter
IPAQ	International Physical Activity Questionnaire
IPLA	Intraperitoneal Local Anaesthetic
IQR	Interquartile Range
IVC	Inferior Vena Cava
IVF	Intravenous Fluid
IV GC	Intravenous Glucocorticoids
K	
kg	Kilograms
L	
L	Litre
LAGB	Laparoscopic Adjustable Gastric Band
LDL	Low-Density Lipoprotein
LOS	Length of Hospital Stay
LRYGB	Laparoscopic Roux-En-Y Gastric Bypass
LSG	Laparoscopic Sleeve Gastrectomy
LTEQ	Leisure Time Exercise Questionnaire
M	
MET	Metabolic Equivalent Task
METmin <sup>-1</sup>	Metabolic Equivalent Task Minutes
mHealth	Mobile Health
m	Metres
ml	Millilitres



## N

NGT	Nasogastric Tube
NIH	National Institutes of Health
NZD	New Zealand Dollars
NZPAQ	New Zealand Physical Activity Questionnaire

## O

OSA	Obstructive Sleep Apnoea
-----	--------------------------

## P

PE	Pulmonary Embolism
PEEP	Positive End Expiratory Pressure
Postop	Postoperatively
Preop CHO	Preoperative Carbohydrate
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PYY	Gut Hormone Peptide YY

## R

RCT	Randomised Controlled Trial
-----	-----------------------------

## S

SD	Standard Deviation
SRS	Surgical Recovery Scale
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
SWET	Self Reported Walking and Exercise Table

## T

T2DM      Type 2 Diabetes Mellitus

TC      Total Cholesterol

## V

VTE      Venous Thromboembolism

## W

WHO      World Health Organisation



# Chapter 1

## **INTRODUCTION**

## **1.1 Obesity**

### ***1.1.1 The Health Burden of Obesity***

Obesity is an increasing global epidemic. It is associated with an increase in the burden of both acute and chronic disease which has led to excess demand and consumption of limited health resource.<sup>1</sup> Once thought of as a condition of the old and wealthy, recent figures detailing obesity prevalence have demonstrated a frighteningly indiscriminate side to the problem with increasing prevalence being seen amongst children and in non-developed countries.<sup>2, 3</sup> New Zealand has the third highest rate of obesity in the developed world with over 25% of adults classified as obese. There are also disproportionate rates of obesity amongst Maori and Pacific populations.<sup>4</sup>

### ***1.1.2 Definition***

Obesity is defined as a body mass index (BMI) of greater than or equal to  $30\text{kg/m}^2$ . This is further classified into mild (BMI  $30\text{--}34.9\text{kg/m}^2$ ), moderate ( $35\text{--}39.9\text{kg/m}^2$ ) and severe (greater than or equal to  $40\text{kg/m}^2$ ).<sup>5</sup> It is the result of chronic energy imbalance where energy intake exceeds energy expenditure and involves a complex interplay of genetic predisposition and environmental risk factors.<sup>6</sup>

### ***1.1.3 Neuro-Hormonal Regulation of Energy Homeostasis***

Energy homeostasis is the biological process of balancing energy expenditure with energy intake. This occurs through central assimilation and integration of taste information with long and short-term humoral signals which are either transmitted through the vagus nerve or which cross the blood brain barrier. These signals

transmit information regarding nutritional state to promote stability in the amount of body fuel stored as fat.<sup>7, 8</sup> This integration occurs within the hypothalamus where the arcuate nucleus projects both stimulatory and inhibitory neurones to other hypothalamic nuclei within the lateral hypothalamic area to induce hunger or the ventromedial hypothalamus to induce satiety.<sup>9</sup> There are also neuronal projections to the paraventricular nucleus within the hypothalamus which regulates pituitary function and autonomic nervous system outflow.<sup>9</sup>

#### ***1.1.4 Pathophysiology***

Despite acknowledging the important contribution of genetics to obesity, the search for causative genes has been largely unsuccessful. However, what is known suggests that obesity is primarily a neuro-behavioural disorder as opposed to a disorder of adipose tissue.<sup>8</sup> The body has evolved adaptive neuronal mechanisms to protect against weight loss and weight gain which effect meal initiation and termination.<sup>7</sup> It is thought that mutations in key molecules involved in these adaptive mechanisms, such as leptin and insulin, lead to an increased vulnerability to severe obesity. This suggests that it is the protection of an elevated body weight rather than the absence of regulation which interacts with environmental cues to cause obesity.<sup>7</sup>

Another postulated mechanism includes a defect in the dopaminergic mesolimbic pathway, also termed the 'reward pathway'. Here, obesity is thought to be a consequence of reward deficiency secondary to deficiency in dopamine signalling which leads to compensatory overeating.<sup>9</sup>

### **1.1.5 Obesogenic Environment**

Whilst the physiology and genetics of obesity are well described, they alone are not enough to explain the continued rise and scale of the epidemic. It is now widely accepted that the driving force for obesity is the obesogenic environment which society has fostered.<sup>10</sup> It is characterised by easy access to energy-dense food with low nutritional value and an unwavering trend towards an increasingly sedentary lifestyle.<sup>11</sup> The obesogenic environment defines the indiscriminate nature of obesity which is no longer confined to adults in the first world. Hence, society has created a self-sustaining and perpetual cycle and this makes obesity one of the largest and most difficult global health problems facing health professionals and legislators.

## **1.2 Treatment of Obesity**

The treatment of obesity can be classified as either non-surgical or surgical. Non-surgical treatment options include behavioural modification and pharmacotherapy.

### **1.2.1 Behavioural Modification**

Behavioural modification is the mainstay of obesity treatment. It aims to manipulate energy balance by creating a net energy deficiency which is achieved through dietary interventions and increased physical activity.<sup>6</sup> Alone, behavioural modification can achieve mild to moderate weight loss with therapeutic goals set at 5-10% of body weight loss at 6 months.<sup>12, 13</sup> However, long-term efficacy is severely affected by non-compliance.<sup>12</sup>

#### *1.2.1.1 Dietary interventions*

Though there are various dietary strategies, most work on the principle of caloric restriction in order to achieve a net negative energy balance. By definition, all dietary interventions are hypocaloric and aim to restrict caloric intake by between 500 and 1000 kilocalories per day less than what would be considered eucaloric based on body weight.<sup>6</sup> This correlates to weight loss of approximately 0.5kg/week.<sup>6, 12</sup> In addition to this, other diets manipulate the metabolism equation by increasing the thermic effect of food by implementing diets which specifically reduce fat or carbohydrates with or without restriction of caloric intake.<sup>14-16</sup>

#### *1.2.1.2 Increased physical activity*

Increased physical activity achieves net negative energy balance by increasing total energy expended in activity. It also increases energy expended at rest by increasing lean muscle mass which accounts for the majority of energy expenditure through the basal metabolic rate (BMR).<sup>6, 17</sup> This is likely the most significant contributor to weight loss associated with increased physical activity with BMR being responsible for 60-70% of total energy expenditure.<sup>18</sup> Increased physical activity has well documented additional health benefits independent of weight loss which help reduce the cardiovascular risk profile.

#### **1.2.2 Pharmacotherapy**

Initiation of pharmacotherapy is recommended in patients with mild or moderate obesity who have failed to lose more than 5% body weight after 6 months.<sup>6</sup> Of the various agents available, orlistat (in conjunction with hypocaloric diet and exercise)

and sibutramine are the only two agents which have been approved by the US Food and Drug Administration for the long-term treatment of obesity. Both have demonstrated modest weight loss results of less than 5kg.<sup>19, 20</sup>

### **1.3 Bariatric Surgery**

#### **1.3.1 Definition**

Bariatric is a term derived from the greek work 'Baros' meaning weight and is used to described a branch of medicine which focuses on the causes, prevention and treatment of obesity.<sup>21</sup> Bariatric surgery is a therapeutic arm of this branch of medicine which is defined in a limited capacity by the Oxford dictionary as removal of part of the stomach or small bowel to induce weight loss. However, this definition fails to encapsulate more recent understanding of bariatric surgery which includes the resolution of metabolic conditions, such as type 2 diabetes mellitus (T2DM), whose pathogenesis and therefore risk is strongly associated with the presence of obesity. The term bariatric surgery is now synonymous with 'metabolic surgery', and in clinical practice is used as an inclusive term for a variety of procedures which are performed for the purpose of weight loss and resolution of obesity related metabolic conditions.<sup>21</sup> Currently, it remains the only evidence-based method of treating severe obesity and curing obesity related comorbidity.<sup>22-24</sup>

#### **1.3.2 Indication for Bariatric Surgery**

Bariatric surgery is for the treatment of severe obesity ( $BMI \geq 40 \text{ kg/m}^2$ ) or obesity with related comorbidity.<sup>25</sup> It is considered only after failure of conventional non-surgical therapeutic approaches. There are well established international criteria



which aid in appropriate patient selection. In the United States of America, the criteria defining indications and contraindications to surgery are detailed in the American National Institutes of Health (NIH) Consensus Statement on Gastrointestinal Surgery for Severe Obesity.<sup>26</sup> Similarly in Europe, criteria are detailed in the Interdisciplinary European Guidelines for Surgery for (Morbid) Obesity.<sup>27</sup>

### **1.3.3 Bariatric Procedures**

As mentioned previously, bariatric surgery is an inclusive term for a variety of different procedures. Each procedure exists along a spectrum of invasiveness and utilises one or a mixture of mechanisms of weight loss. The large majority of bariatric procedures are now performed using a laparoscopic approach which has been associated with a significantly reduced risk of wound infection and incisional hernia.<sup>28</sup> Some of the procedures and their mechanisms of weight loss are detailed in *Table 1.1*. Of these, vertical banding gastroplasty and jejunal-ileal bypass are now obsolete procedures.

The most common bariatric procedures performed today are the laparoscopic adjustable gastric band (LAGB) and Laparoscopic Roux-en-Y gastric bypass (LRYGB), though laparoscopic sleeve gastrectomy (LSG) is becoming increasingly popular as a stand-alone bariatric procedure.<sup>29</sup> A systematic review by Franco et al reported that both LRYGB and LSG produce greater weight loss results than LAGB. However, LAGB has a lower incidence of postoperative morbidity.<sup>29</sup> Despite efforts to develop standardised criteria to aid the choice of surgical procedure for each individual

patient, there has been no consensus reached within the literature as to which surgical procedures are best for specific obesity profiles.<sup>30-32</sup>

#### ***1.3.4 Mechanism of Action***

Traditionally, weight loss and comorbidity resolution after bariatric surgery have been attributed to caloric restriction, nutrient malabsorption, or a combination of both secondary to anatomic reconfiguration. Restrictive procedures primarily cause weight loss by reducing the stomach size and storage capacity. In comparison, malabsorptive procedures cause weight loss by rerouting gut contents thereby reducing intestinal food absorption. It is now known that the mechanisms of action are far more complex and involve an override of the biological process of energy homeostasis.<sup>8</sup> The anatomical reconfiguration of surgery leads to a modification of nutrient partitioning and absorption which affects local stimulation of the gastrointestinal (GI) tract.<sup>8</sup> This leads to an adaptation of neural, hormonal and nutrient signals sent from the GI tract, adipose tissue and liver which are assimilated centrally to regulate energy homeostasis. This in turn resets 'stable body weight' and overcomes the addictive self-gratifying motivation to eat.<sup>8</sup>

These adaptations include transient inhibition of the vagus nerve during division of the stomach which plays a key role in the functionality and secretion of the orexigenic gut hormone ghrelin.<sup>33-36</sup> Circulatory levels of ghrelin are also affected by resection of the gastric fundus where ghrelin is produced and, to a lesser extent, by the acute weight loss induced by bariatric surgery.<sup>37</sup>

*Table 1.1.* Bariatric procedures and their mechanism of weight loss

Procedure	Mechanism of Weight Loss	Open or Laparoscopic
Roux-En-Y Gastric Bypass	Restrictive	Open or laparoscopic
Laparoscopic Adjustable Gastric Banding	Restrictive	Mostly laparoscopic
Laparoscopic Sleeve Gastrectomy	Restrictive <sup>§</sup>	Mostly laparoscopic
Biliopancreatic Diversion with or without duodenal switch	Mixed restrictive and malabsorptive	Open or laparoscopic
Vertical Banding Gastroplasty <sup>‡</sup>	Restrictive	Open or laparoscopic
Jejunal-Ileal Bypass <sup>‡</sup>	Malabsorptive	Open

<sup>§</sup> Weight loss is also attributed to reduction of plasma levels of ghrelin which is thought to regulate satiety; <sup>‡</sup> Historical procedures which are now obsolete

The circulating levels of the potent anorectic gut hormone peptide YY (PYY) are significantly increased after some bariatric procedures such as LRYGB likely as a result of the expedition of nutrient rich chyme to the L-cells of the terminal ileum. This mechanism is further augmented by gut adaptation with enteroendocrine cell hypertrophy and hyperplasia as demonstrated in animal models.<sup>8, 38</sup> Similarly, increased serum plasma levels of incretins such as glucagon like peptide 1 (GLP-1) are thought to be a result of the anatomical rerouting of the gut contents, with the increased circulating incretins playing a major role in the surgically induced modification of the enteroinsular axis that is thought to be responsible for the weight-loss independent resolution of T2DM.<sup>8, 39, 40</sup>

Bariatric surgery is also thought to affect the adipokine leptin which is a potent anorectic.<sup>40</sup> Surprisingly, serum levels of leptin are decreased after bariatric surgery.

However, in patients having bariatric surgery the ratio of leptin in cerebrospinal fluid (CSF) to that in serum is increased compared to obese patients who do not have bariatric surgery which is reflective of what is seen in patients of lean body size. The effect of bariatric surgery on CSF leptin is not well characterised in the literature.<sup>9</sup>

### **1.3.5 Reporting Weight Loss**

Absolute weight loss after bariatric surgery is variable and represents an unreliable measure for comparison across centres and surgery types. All studies reporting weight loss after bariatric surgery therefore report either percentage excess weight loss (%EWL) or change in BMI which is reported as either percentage BMI loss (%BMIL) or percentage excess BMI loss (%EBMIL).<sup>41, 42</sup> The formulae for each measure are as follows:

$$\%EWL = \frac{(Operative\ Weight) - (Follow - Up\ Weight)}{(Excess\ Operative\ Weight)} \times 100$$

$$\%BMIL = \frac{(Operative\ BMI) - (Follow - Up\ BMI)}{(Operative\ BMI)} \times 100$$

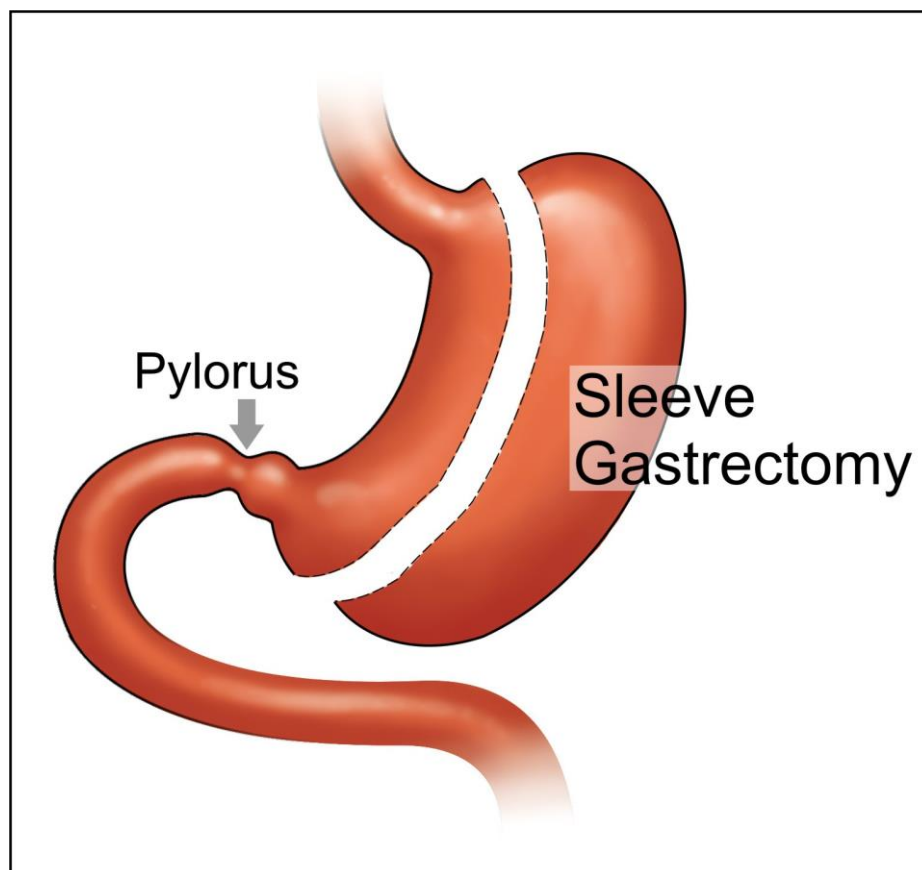
$$\%EBMIL = 100 - \left( \frac{(Follow - Up\ BMI) - 25}{(Beginning\ BMI) - 25} \times 100 \right)$$

For %EWL, excess operative weight is equal to a patient's operative weight minus their ideal body weight. Ideal body weight is calculated as described by Deitel et al.<sup>42</sup>

## 1.4 Laparoscopic Sleeve Gastrectomy

The bariatric procedure offered at Counties Manukau District Health Board (CMDHB) is LSG and is where the data for this thesis has come from. LSG is a vertical gastrectomy to create a tubular stomach approximately 100-150ml in volume (*Figure 1.1*), and is classified as a restrictive procedure.<sup>43</sup>

*Figure 1.1.* Diagram of laparoscopic sleeve gastrectomy



### 1.4.1 History of the LSG

The concept of LSG was initially developed in the setting of anti-reflux surgery by Lawrence Tretbar who was able to demonstrate weight loss following fundoplication.<sup>44</sup> In 1988, Doug Hess modified this concept by substituting plication

with a vertical gastrectomy to develop a sleeve which later become part of the Biliopancreatic Diversion with or without duodenal switch (BPD/DS) and had the advantages of leaving an intact pylorus, which prevented dumping syndrome, and utilising a duodenal-enteric anastomosis which helped prevent marginal ulcers.<sup>45-47</sup> BPD/DS was first attempted laparoscopically in 1999 on pigs.<sup>48</sup> With this proving to be feasible, it was attempted in humans. However, it was noticed that for patients with higher BMI, there was an increased incidence of postoperative morbidity. In order to solve this, it was decided to split the restrictive and malabsorptive components of the procedure by performing LSG as the first stage followed by the laparoscopic enteric anastomosis as the second stage. Eighteen cases were performed between September 2000 and September 2001 and there was noted to be a drastic reduction in the incidence of major morbidity.<sup>46</sup>

LSG as a primary procedure was first reported in the literature in 2003 and showed excellent weight loss results.<sup>49, 50</sup> These results have been compared to other more established bariatric procedures and have been shown to be comparable to LRYGB and BPD/DS with less morbidity and superior weight loss results compared to laparoscopic adjustable gastric banding LAGB.<sup>51-54</sup>

### ***1.4.2 Surgical Technique***

#### ***1.4.2.1 Positioning***

Patients are placed in the reverse Trendelenburg position, which involves the bed being tilted head-up, with the surgeon standing between the patients legs. The surgeon assistant and scrub nurse stand on the left and right of the patient

respectively with the display monitor placed directly above the patient in the line of sight of the surgeon.<sup>55</sup>

#### *1.4.2.2 Access to the stomach*

Depending on the surgeon, between four and seven trocars are utilised to access the abdomen.<sup>56, 57</sup> Once pneumoperitoneum is achieved using carbon dioxide insufflation, the liver is retracted cranially to facilitate greater exposure of the stomach. The gastro-colic ligament is then dissected beginning at the distal end with the harmonic scalpel.<sup>58</sup> This includes division of the short gastric vessels.

#### *1.4.2.3 Bougie size*

A bougie is placed trans-orally into the stomach to calibrate the dissection of the stomach.<sup>58</sup> Bougie size is measured in French (Fr) units, where 1 Fr is equivalent to 0.33mm, and contributes to the size of the remnant stomach after dissection. However, there is very little consensus amongst bariatric surgeons on optimal bougie size.<sup>59</sup> Smaller bougies leave smaller gastric remnants which augment the caloric restriction component of the LSG. However, the smaller tubular stomach left with smaller bougies have increased gastric pressures which may increase the risk of staple line leak.<sup>60, 61</sup> This is supported by a recent systematic review and meta-analysis which demonstrated a significant reduction in risk of staple line leak with larger bougies (>40 Fr).<sup>62</sup> Studies have utilised bougie sizes from 32 Fr up to 60 Fr which correlates to a difference in diameter of the catheters of around 9mm.<sup>63-66</sup> Despite the controversy surrounding optimal bougie size, the current literature would suggest that it has little effect on percentage excess weight loss after LSG.<sup>59</sup>

#### ***1.4.2.4 Gastrectomy***

The vertical stapled gastrectomy begins distally near the pylorus. This starting position is not standardised in the current literature and has varied from as little as 2cm through to around 7cm.<sup>59</sup> Starting positions closer to the pylorus amplify the restrictive mechanism of the LSG by creating smaller gastric remnants.<sup>67</sup> However, this may lead to distal stenosis and increase the pressure within the stomach increasing the risk of leak. Most surgeons begin approximately 4cm from the pylorus.<sup>59,68</sup> Once the gastrectomy is complete, reinforcement of the staple line is performed selectively as a means of reducing the risk of leak secondary to mechanical failure. Various reinforcing techniques have been employed in the literature including running sutures and fibrin based sealants. However, these techniques do not protect against ischaemic causes of staple line leak.<sup>59</sup>

### ***1.4.3 Efficacy of Laparoscopic Sleeve Gastrectomy***

#### ***1.4.3.1 Weight loss***

There is an increasing amount of literature to support the use of LSG as a stand-alone single-stage procedure. Studies have demonstrated that LSG produces weight loss results in the short-term which are comparable to, and in some cases superior to, other more established bariatric procedures.<sup>69-72</sup>

Though there is good evidence demonstrating excellent early to mid-term weight loss results after LSG, there is a lack of long-term data to show the durability of these results. Himpens et al reported follow-up data for 41 out of 53 patients who underwent LSG out to six years and showed a mean %EWL of 57.3%, though this had decreased



from 72.8% at three years.<sup>73</sup> Similarly, in a series of 26 patients who underwent LSG, Bohidjalian et al found a reduction in %EWL from a peak of 60.3% at two year follow-up to 55% at five year follow-up.<sup>74</sup> The longest follow-up data available from Sarela et al reports %EWL in 19 patients assessed at up to nine years postoperatively of which 11 had sustained %EWL greater than 50%.<sup>75</sup>

It is thought that, though LSG affects early term weight loss, there is a tendency towards long-term weight-regain which has been demonstrated in series that report follow-up greater than 5 years.<sup>76</sup> With this in mind, it is unclear whether a second stage procedure is required for patients who undergo LSG and longer follow-up data are required to clarify this.

#### *1.4.3.2 Comorbidity resolution*

The current literature suggests that LSG is effective at resolving obesity related comorbidity. In their systematic review, Shi et al reported comorbidity resolution rates of between 45% and 95.3% in patients with T2DM, hypertension (HTN), obstructive sleep apnoea (OSA), hypercholesterolaemia (hyperchol), osteoarthritis, gastroesophageal reflux, depression and peripheral oedema at 12 to 24 months follow-up.<sup>77</sup> Resolution of urinary incontinence in women after LSG has also been reported by Srinivasa et al who found a resolution rate of 90% at 12 months.<sup>78</sup>

The majority of the literature describes the efficacy of LSG at resolving T2DM. Reported resolution rates for T2DM are in the range of 63-100%.<sup>79-81</sup> LSG has been shown to be not only comparable, but often superior, to other laparoscopic bariatric

procedures with regards to T2DM resolution. Abbatini et al reported that T2DM resolution after LSG was 80.9% at three months. This result was comparable to LRYGB at 81.2% and superior to LAGB at 60.8%.<sup>80</sup> Omana et al demonstrated significant resolution of T2DM after LSG with a result of 100%. This was again vastly superior to LAGB (46%).<sup>81</sup> How this resolution occurs in LSG is not well understood. Initially, resolution was attributed to weight loss. However, biochemical improvement has been shown to occur well before weight loss and is likely due to the neuro-hormonal adaptations described previously.

There is also substantial evidence describing the efficacy of LSG with regards to resolution of HTN and OSA. Complete resolution of HTN ranges from 55% through to 93% at 6 to 18 month follow-up with a mean resolution rate of 71.7% out to 24 months. Similarly, resolution rates of OSA range between 52.6% and 100% with a mean rate of 83.6% at 24 months follow-up.<sup>77</sup>

#### *1.4.3.3 Efficacy in the super-obese*

Surgical risk is thought to increase significantly with BMI greater than 50kg/m<sup>2</sup>. It is recognised as an independent predictor of postoperative morbidity and mortality, and this has been attributed to a greater burden of obesity-related comorbidity.<sup>82-84</sup> Previous studies have investigated postoperative morbidity in super-obese patients after laparoscopic bariatric surgery and found increased rates of postoperative complications.<sup>85, 86</sup> Though it is thought that LSG is safe in the super-obese population, it is unclear whether it is effective in producing satisfactory weight loss in these patients.

Several studies have demonstrated that, although LSG affects excellent absolute weight loss in this group of patients, a large proportion remain with a BMI of more than 40kg/m<sup>2</sup> at follow-up of 12-18 months.<sup>51</sup> According to current guidelines, these patients would still qualify for bariatric surgery which may suggest that LSG might be more effective as a staging procedure in this select group of patients.<sup>26, 27</sup> This is supported by a recent systematic review which found that studies identifying patients as super-obese or high risk were likely to have a second stage procedure approximately two years after the initial LSG.<sup>64</sup> More long-term follow-up data are required to clarify this.

#### **1.4.4 Associated Morbidity**

As with other bariatric procedures, the established benefits of LSG often come at the expense of significant short-term morbidity. The rate of morbidity reported in the literature varies from 1% to 29%.<sup>87</sup> This may depend on surgical technique (bougie size, amount of antrum excised, staple-line re-inforcement etc), patient factors, complication definitions, the follow-up period, and the mechanisms of reporting. This complication rate is comparable to other more established bariatric procedures.

The major complications associated with single stage LSG are listed in *Table 1.2*.<sup>51, 77, 88, 89</sup> This is not an exhaustive list and the incidence of each of these complications is low. The Michigan Bariatric Surgery Collaborative reported on the largest LSG series. This included 854 patients who underwent LSG between 2006 and 2009 across 25 hospitals and 62 surgeons and they reported a major complication rate of 2.2%.<sup>89</sup>

#### 1.4.4.1 Staple-line leak

The risk of staple line leak is the greatest concern for bariatric surgeons and patients. Leak rates range between 0-7% with a mean occurrence of 2.4%.<sup>90</sup> Staple line leak is associated with significant morbidity, prolonged convalescence and increased risk of mortality. It is difficult to manage with little consensus in the current literature regarding an optimal treatment approach. Most leaks occur relatively early after surgery which often makes surgical management difficult due to poor tissue quality and inflammation.<sup>91</sup> The placement of endoscopic stents and percutaneous drains in conjunction with gut rest and parenteral nutrition is generally the preferred management option though resolution often takes an extended period of time.<sup>90</sup>

*Table 1.2.* Major postoperative complications associated with LSG

Major Complications	Incidence (%)
Staple line leak	2.4%
Intraabdominal haemorrhage	3.6%
Symptomatic cholelithiasis	3.8%
Wound infection	2.2%
Stricture	0.6%
Respiratory failure	0.5%
Pulmonary embolism	0.3%
Intraabdominal abscess	0.1%
Splenic injury	0.1%
Trocar site hernia	0.1%
Bowel obstruction	0.1%
Death	0.3%

### 1.5 Perioperative Care

Obesity is associated with an increased burden of disease affecting nearly all organ systems.<sup>92</sup> In obese patients undergoing surgery, the increased disease burden is

associated with an increased risk of postoperative morbidity, prolonged surgical recovery and increased perioperative costs. It may also affect both early and long-term surgical outcomes.<sup>93, 94</sup> Achieving the best outcome after surgery in obese patients may be accomplished by optimising the physiological and functional capacity of a patient and this could potentially occur by modifying and optimising perioperative care.

#### ***1.5.1 Enhanced Recovery after Surgery Programmes***

Enhanced Recovery after Surgery (ERAS) programmes have been utilised in other surgical settings as a means of preparing patients for the physiological stress of surgery by standardising and optimising perioperative care. Initially pioneered by Kehlet et al in the setting of colorectal surgery, ERAS has been shown to improve surgical recovery by reducing postoperative morbidity and hospital length of stay (LOS).<sup>95, 96</sup> It has also been shown in a recent systematic review to reduce perioperative costs.<sup>97</sup> An additional benefit of ERAS is the creation of a standardised perioperative environment which can be used as a platform for the evaluation of further clinical interventions.

#### ***1.5.2 Text-messaging***

Several methods have been considered to address the issue of adherence to interventions which are aimed at behavioural modification in the short-term. One method which is gaining increasing popularity is the use of mobile health interventions, more commonly termed mHealth. This encompasses all digital frameworks which increase accessibility to health information and the form which

has gained the most interest is text-messaging. In the setting of bariatric surgery, text-messaging may be used to optimise lifestyle behaviours in order to improve both early and long-term results after surgery.

### **1.6 Aim of the Thesis**

The obesity epidemic is showing no sign of slowing down, leading to insatiable consumption of increasingly precious health resources. With bariatric surgery remaining the only evidence-based method of treating severe obesity and curing obesity related comorbidity, the numbers of bariatric procedures continue to rise. In order to optimise the resource utilisation and increase the likelihood of success of surgery, this thesis focuses on:

1. Optimising perioperative care in order to improve outcomes and decrease costs associated with surgery.
2. Improve exercise behaviour as a means of improving early and long-term outcomes after bariatric surgery.

# Chapter 2

## **LAPAROSCOPIC SLEEVE GASTRECTOMY AT COUNTIES MANUKAU DISTRICT HEALTH BOARD**

## **2.1 Introduction**

As mentioned previously, the bariatric procedure that has been offered at CMDHB since 2007 is the LSG. Initially used as the first stage in a two stage approach for high risk patients undergoing bariatric surgery, it is now commonly used as a definitive operation producing comparable results to more established procedures.<sup>64, 69, 71, 98, 99</sup>

This chapter is a retrospective review evaluating prospectively collected weight loss outcomes and complications rates of patients who underwent LSG at our institution.<sup>100</sup> The aim of this chapter is to characterise the current state of LSG at CMDHB to determine the safety and efficacy of this bariatric procedure within this unique population. The results of the study will also be used as baseline data for sample size calculations for studies described in later chapters.

## **2.2 Method**

A retrospective review of prospectively collected data was performed for all patients who had undergone LSG at the institution from March 2007 to September 2010.

### ***2.2.1 Preoperative Characteristics and In-Hospital Outcomes***

Preoperative characteristics collected were sex, age, ethnicity, mean preoperative weight and BMI, excess weight, and presence of obesity related comorbidities including T2DM, HTN, hyperchol and OSA. The LOS and 30 day complication rate were recorded. Complications were classified from grade one to five according to the Clavien-Dindo classification system.<sup>101, 102</sup> The definition of each grade of complication is detailed in *Table 2.1*.



*Table 2.1.* Definitions of complication grade according to the Clavien-Dindo Classification system

Grade of Complication	Definition
Grade 1	Deviation from the normal course of recovery not requiring pharmacological treatment or surgical or radiological intervention
Grade 2	Complications requiring pharmacological treatment
Grade 3	Complication requiring reoperation or radiological intervention
Grade 4	Admission to the Intensive Care Unit (ICU)
Grade 5	Death

### **2.2.2 Outcomes**

The outcomes recorded were mean time of postoperative follow-up, mean absolute weight loss, mean %EWL and comorbidity improvement and resolution. For the purposes of this study, improvement in comorbidity was defined as a decrease in medication dose or improvement in biochemical parameters. Resolution was defined as cessation of all medications in the presence of normal biochemical parameters. The %EWL calculation has been described previously above.<sup>42</sup>

### **2.2.3 Super-Obese Patients**

As mentioned previously, super-obese patients ( $\text{BMI} > 50\text{kg/m}^2$ ) are at increased risk of postoperative morbidity and mortality. Therefore, following collection of data, patients were stratified into super-obese and non super-obese. The weight loss outcomes and complication rates were compared between the two groups to evaluate safety and efficacy of LSG in the super-obese.

#### 2.2.4 Statistical Analysis

Statistical analysis was performed using SPSS (SPSS V13 Inc, Irvine CA). The two tailed Student's t-test and Fisher's exact test were used to analyse parametric data as required. A logistic regression model was created to control for known potential confounders with the independent effect of each variable subsequently evaluated. Results were considered significant when  $p \leq 0.05$ . All data were analysed on an intention to treat basis.

#### 2.3 Results

There were 400 consecutive patients included in the analysis. This was the number of eligible patients who had surgery at the time of the study. The preoperative characteristics are detailed in *Table 2.2*.

*Table 2.2.* Preoperative characteristics

Characteristic	Value
Mean Age (range)	44 years (20-64)
Female Gender (%)	291 (73)
Ethnicity (%)	
European	232 (58)
Maori	88 (22)
Pacific	60 (15)
Other	20 (5)
Weight Characteristics	
Mean weight (kg) [SD]	140 (31)
Mean BMI (kg/m <sup>2</sup> ) [SD]	49 (9)

Preoperative characteristics. BMI=Body Mass Index; SD=Standard Deviation

### 2.3.1 In-Hospital Outcomes

The median LOS was three days. In total, there were 67 complications within a 30 day follow-up period (16%). There were 20 grade one complications, 18 grade two complications, 23 grade three complications, five grade four complications and one grade five complication. Major complications ( $\geq$ grade three) are detailed in *Table 2.3*. The rates of staple line leakage and staple line bleeding were 2% and 2.5% respectively. A logistic regression model was constructed and found no association between the rates of total complications, major complications, staple line leakage and staple line bleeding with age, gender, surgical experience or BMI (*Table 2.4*).

*Table 2.3.* The complication rate on 400 patients after LSG using the Clavien-Dindo grading system

Clavien-Dindo Grade	Complication Description
Grade 3	7 staple line leaks requiring stenting (3) or laparoscopy (4) 6 bleeds requiring laparoscopy (4) or laparotomy (2) 4 strictures requiring endoscopic dilatation Stricture requiring laparotomy Inadvertent bowel injury requiring laparotomy Volvulus requiring endoscopic correction Intra-abdominal collection requiring CT guided drainage Renal calculi requiring ureteric stent Caecal ulceration with pneumostasis requiring colonoscopy
Grade 4	ICU admission for labile postoperative blood pressure Postoperative bleed with secondary MI requiring ICU Staple line lead requiring laparotomy and ICU 2 postoperative bleeds requiring laparotomy and ICU
Grade 5	Death from unknown cause – presumed cardiac event

CT=Computer Tomography Scan; ICU=Intensive Care Unit

*Table 2.4. Association with complication – logistic regression*

Outcome Association	Variable	Odds Ratio	<i>p</i> value
Total complication	Age	1.0	0.86
	Male Gender	1.0	0.96
	One year experience doing LSG	0.5	0.15
	BMI	1.2	0.45
Major complication	Age	1.0	0.15
	Male Gender	0.6	0.33
	One year experience doing LSG	0.9	0.77
	BMI	1.2	0.59
Staple line leakage	Age	1.0	0.44
	Male Gender	1.7	0.49
	One year experience doing LSG	2.1	0.39
	BMI	1.3	0.75
Staple line bleed	Age	1.0	0.42
	Male Gender	0.7	0.63
	One year experience doing LSG	1.5	0.65
	BMI	0.9	0.87

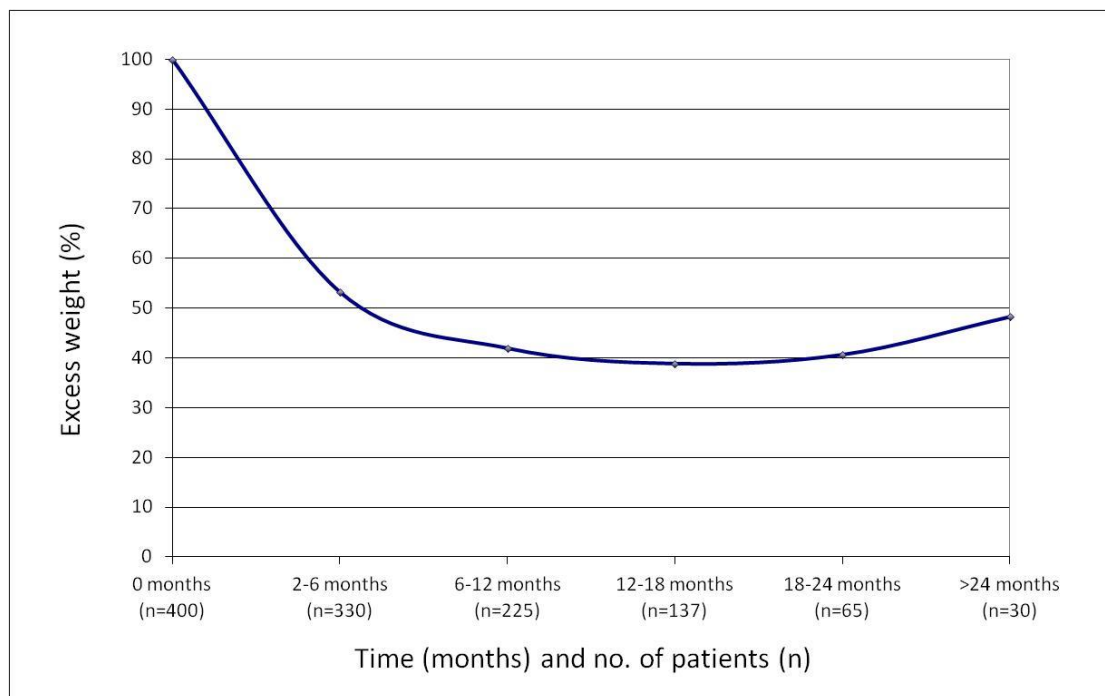
BMI=Body Mass Index; LSG=Laparoscopic Sleeve Gastrectomy

### **2.3.2 Outcomes**

The mean follow-up period was 12 months (range 1-41months). One-hundred and thirty-seven patients, 65 patients and 30 patients had follow-up at 12-18 months, 18-24 months and  $\geq 24$  months respectively. Of the 400 patients, all were eligible for follow-up up to one year whilst 259 were eligible for follow-up at  $\geq 24$  months. Missing data were due to patients either being discharged from the service or non-attendance at follow-up appointments. The mean weight loss was 42kg (SD, 23) with a mean %EWL of 51.5% (SD, 32).

The mean absolute weight loss at 12-18 months, 18-24 months and  $\geq 24$  months was 46.7kg (SD, 24), 44.3kg (SD, 23) and 41kg (SD, 20) respectively. %EWL was 61.1% (SD, 19), 59.3% (SD, 16) and 51.7% (SD, 40) respectively. %EWL remaining postoperatively (with respect to follow-up in months) is shown in *Figure 2.1*.

*Figure 2.1.* Percentage of excess weight remaining postoperatively



Preoperative comorbidity status and postoperative improvement and resolution are shown in *Table 2.5*.

*Table 2.5. Preoperative comorbidity status and postoperative improvement and resolution*

Comorbidity	Number of Patients	Comorbidity Improved	Comorbidity Resolved
T2DM	164 (42.5%)	34 (20%)	117 (71%)
HTN	210 (52%)	52 (24%)	100 (47%)
Hyperchol	193 (48.3%)	34 (17%)	76 (39%)
OSA	79 (20%)	17 (21.5%)	25 (32%)

OSA=Obstructive Sleep Apnoea; T2DM=Type 2 Diabetes Mellitus; HTN=hypertension; Hyperchol=hypercholesterolaemia. Resolution of T2DM and hyperchol is defined as biochemical resolution and cessation of medical therapy. Resolution of hypertension and OSA is defined as cessation of medical therapy. Improvement of comorbidity is defined as reduction in medical therapy.

### **2.3.3 Super-Obese**

There were 170 (43%) super-obese patients. The mean follow-up for these patients was one year. The mean postoperative BMI was 38.9kg/m<sup>2</sup>. Absolute weight loss (59kg vs. 36.7kg;  $p<0.01$ ) and %EWL (58.9% vs. 45.9%;  $p<0.01$ ) were significantly higher in super-obese patients compared to non super-obese. However, 66 (39%) super-obese patients still had a postoperative BMI $\geq$ 40.

The difference in 30 day complication rates was not statistically significant between super-obese patients and non super-obese (17% vs. 16%;  $p=0.69$ ). There was no difference in the incidence of major complications (8.2% vs. 6.5%;  $p=0.56$ ). There was one death (41 year old female, BMI 52kg/m<sup>2</sup>, asthmatic with history of several courses of oral prednisone) in our series of 400 which occurred 19 days after surgery. The death occurred suddenly after an uneventful hospitalisation and recovery. Autopsy revealed no specific cause and the death was attributed to a sudden cardiac

arrhythmia. *Table 2.6* details the comparison of results between the super-obese and non super-obese.

*Table 2.6.* Summary of results – super-obese vs. non super-obese

	Super-Obese	Non Super-Obese	<i>p</i> value
Weight loss (mean)			
Absolute weight (kg)	59	36.7	<0.01
%EWL (%)	58.9	45.9	<0.01
Complications (%)			
Total complications	17	16	0.69
Major complications	8.2	6.5	0.56
Comorbidity Resolution (%)			
T2DM	71	71	1.00
HTN	51	45	0.48
Hyperchol	43	46	0.76
OSA	37	40	1.00

Super-obese defined as BMI≥50; %EWL=percentage excess weight loss; T2DM=type two diabetes mellitus; HTN=hypertension; Hyperchol=hypercholesterolaemia; OSA=obstructive sleep apnoea

## 2.4 Discussion

This study evaluated the outcomes of 400 consecutive patients who underwent LSG at CMDHB. It found LSG to be a safe and effective procedure at the institution. LSG was also found to produce comparable satisfactory results in super-obese patients.

This study demonstrated that for all patients, at a mean follow-up of one year, LSG as a stand-alone bariatric procedure is safe and produces satisfactory weight loss which is comparable to other published series.<sup>56, 63, 83, 103</sup> Comorbidity resolution was

also satisfactory and comparable to other reported series, particularly for T2DM.<sup>79-81</sup>

Hutter et al reported findings from the American College of Surgeons Bariatric Surgery Center Network, which included 28,616 patients undergoing bariatric surgery at 109 accredited hospitals. They showed that after one year follow-up, LSG was a safe and effective definitive bariatric procedure. When compared to other bariatric procedures, it compared favourably to other popular procedures such as LAGP and LRYGB.<sup>104</sup> Despite favourable early to mid-term results, the long-term efficacy and safety of LSG is yet to be established in a large cohort of patients.

This case series describes weight loss at a mean follow-up of one year after LSG. Of the 400 patients included in this series, 137 patients had recorded follow-up at 12-18 months and demonstrated a mean %EWL of 61.1% (SD, 19). This series also includes 30 patients who had follow-up of more than two years with mean %EWL of 51.7% (SD, 40). In a systematic review by Shi and colleagues, case series reporting one year follow-up demonstrated a range of %EWL of 46% to 83.3%. For follow-up of two years or more, %EWL ranged from 56.1% to 67.9%.<sup>77</sup> Bellanger and colleagues reported on a case series of 529 patients where 68% and 63% had follow-up at one and two years respectively and demonstrated %EWL of 65.9% and 66.1% respectively.<sup>68</sup>

Both absolute weight loss and %EWL were significantly higher in the super-obese. However, whilst the mean postoperative BMI for super-obese patients was 38.9kg/m<sup>2</sup> at a mean follow-up of one year, a significant proportion of super-obese patients still remained severely obese. Of 170 super-obese patients, 66 (39%) had a



postoperative BMI  $\geq 40 \text{ kg/m}^2$  and therefore, according to European guidelines, would still qualify for bariatric surgery. This is consistent with other published studies.<sup>51, 105</sup>

Our major complication rate in the super-obese patients was no different to the other patients (8.2% vs. 6.5%;  $p=0.56$ ).<sup>78</sup> Birkmeyer and colleagues reported on the results of The Michigan Bariatric Surgery Collaborative (a registry including 854 LSG patients across 35 hospitals). The median BMI for their series was  $50 \text{ kg/m}^2$  (range 44-56) and the major complication rate was 2.2%.<sup>89</sup> Though we cannot directly compare this with the complication rate of the super-obese patients reported here, Birkmeyer's low complication rate does support our finding that there is no undue elevation in risk in performing LSG on super-obese patients.

There appeared to be a tendency for weight regain in patients with longer follow-up. Few series have reported on follow-up longer than three years. One such series is D'Hondt and colleagues who reported on a series of 23 patients with follow-up at six years. They demonstrated %EWL of 55.9% though there appeared to be a tendency for weight regain at five years.<sup>76</sup> Though it appears that LSG leads to early weight loss, there may be a tendency for weight regain in patients with longer follow-up.

This study has limitations. It has relatively short-term follow-up and the number of patients seen at follow-up of more than 18 months is low. This makes it difficult to draw conclusions regarding long-term efficacy and safety of LSG. It may also exaggerate the difference in weight loss results between the obese and super-obese.

Based on the model of health care utilised at our institution, where patients who are progressing well are discharged from our service within six to eighteen months, the patients seen at follow-up of more than 18 months may reflect those who have had a complicated postoperative course. This may account for the reduction in weight loss after eighteen months.

In conclusion, this study shows that the postoperative results of LSG performed at CMDHB as a stand-alone bariatric procedure are comparable to other international series published in the peer-reviewed literature. This supports the use of LSG as treatment option in the severely obese. The results will now be used as a baseline for interventions aimed at clinical improvement in later chapters.

# Chapter 3

## **DEVELOPMENT OF A BARIATRIC-SPECIFIC ENHANCED RECOVERY AFTER SURGERY PROGRAMME**

### 3.1 Introduction

This chapter in the thesis describes the design and the establishment an evidence-based bariatric-specific ERAS programme at CMDHB, the aim of which is to reduce costs associated with LSG, improve short-term outcomes, and act as a platform for the clinical evaluation of other perioperative care interventions.

ERAS (or fast-track) programmes incorporate multiple evidence-based perioperative interventions to standardise and optimise patient care.<sup>95, 96</sup> There is a large volume of literature supporting ERAS in various types of surgery, but comparatively little in bariatric surgery. Mechanick et al have previously proposed optimal perioperative interventions for bariatric patients.<sup>106</sup> Grantcharov et al published a prospective review looking at laparoscopic gastric resection within an enhanced recovery programme and found that it was associated with a lower morbidity and LOS.<sup>107</sup> McCarty et al published a review of 2000 consecutive patients who had undergone LRYGB and found that they were able to improve postoperative recovery by incorporating standardised sequential modifications to intraoperative and postoperative care.<sup>108</sup> Bamgbade et al published a series of 406 patients having LRYGB within a fast-track programme and found a reduction of LOS from two days to one day.<sup>109</sup>

By implementing the principles of ERAS into bariatric surgery, there is the potential to improve short-term recovery and long-term outcomes. Through the standardisation of care, ERAS can also create a platform for the clinical evaluation of other perioperative interventions. The purpose of this chapter is to review the

existing literature describing the safety and efficacy of evidence-based perioperative care interventions which should be included in a bariatric-specific ERAS programme.

### **3.2 Method**

A systematic review was conducted using search terms which included 'bariatric surgery', 'weight loss surgery', 'gastric bypass', 'ERAS', 'enhanced recovery', 'enhanced recovery after surgery', 'fast track surgery', 'perioperative care', 'postoperative care', 'intraoperative care' and 'preoperative care'. Multiple medical databases were utilised including MEDLINE, Scopus, EMBASE, the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials. Interventions recovered by the database search, as well as interventions garnered from clinical experience in ERAS, were also used as individual search terms.

### **3.3 Results**

Due to the paucity of data evaluating ERAS interventions in bariatric surgery, this review predominantly details perioperative interventions currently used in the management of patients who undergo major abdominal surgery and how they may be applied to a bariatric surgery specific ERAS programme. When available, literature specific to evidence-based perioperative care in bariatric surgery was evaluated. The data are presented chronologically through the perioperative patient journey beginning in the preoperative period, moving through to the intraoperative period and finally to the postoperative period.

### **3.3.1 Preoperative**

#### **3.3.1.1 Preoperative education**

It is important to prepare a patient for the physical and behavioural changes induced by bariatric surgery.<sup>110</sup> In the setting of colorectal surgery, observational studies show that patients who are well informed in the preoperative period have less anxiety, greater compliance to postoperative instructions, improved recovery and superior long-term outcomes.<sup>111</sup> A preoperative visit to the ward familiarises patients to their environment and is thought to give them a greater sense of security and independence.<sup>111</sup> Specific guidelines exist detailing the multidisciplinary information that should be provided to bariatric surgery patients.<sup>106, 112</sup>

#### **3.3.1.2 Prehabilitation**

Prehabilitation is preparing patients for the stress of major surgery by initiating the recovery process before surgery and hence enhancing their preoperative functional capacity.<sup>113</sup> There are very limited data investigating the efficacy and safety of prehabilitation in bariatric surgery. The current studies have been conducted in the setting of orthopaedic, cardiothoracic and colorectal surgery in patients who may be older and more physically frail than those having bariatric surgery. However, there is no reason to suggest that recovery following bariatric surgery would not be amenable to the potential benefits of prehabilitation seen in other types of surgery. The primary focus of prehabilitation is improving preoperative physical ability through aerobic exercise and resistance training, optimisation of nutrition and smoking and alcohol cessation.

### *3.3.1.3 Prehabilitation – exercise*

Preoperative exercise is theorised to improve cardio-respiratory function by improving stroke volume (manifested as decreased maximal heart rate), enhancing endothelial function and improving maximal oxygen consumption (VO<sub>2</sub>max).<sup>113, 114</sup>

The improvement in VO<sub>2</sub>max is particularly important as it is acknowledged as a predictor of postoperative mortality. The addition of resistance training improves preoperative strength by increasing muscle and neuronal mass, and this has been shown to decrease falls, prevent angina and improve functionality and quality of life.<sup>113, 115, 116</sup>

The benefits of prehabilitation exercise programmes have been demonstrated in colorectal, cardiovascular and orthopaedic surgery with randomised controlled trials showing decreased rates of postoperative complications and mortality, decreased LOS and faster return to baseline level of functioning.<sup>113, 117-119</sup> However, these patients are often older and medically frailer than patients awaiting bariatric surgery which limits the conclusions which can be drawn and applied to a cohort of patients awaiting bariatric surgery. There is recognition that dependent level of functional status is an independent predictor of postoperative morbidity in bariatric surgery.<sup>82</sup> With no studies investigating the safety and efficacy of prehabilitation in bariatric surgery candidates, there remains a need for further research on this topic.

The minimum period of exercise to show benefit is four weeks.<sup>113</sup> However, studies suggest that patients should undergo up to three months of exercise in order to

optimise the chance of gaining benefit with patients engaging in a formal prehabilitation programme whilst waiting for surgery.<sup>113, 120</sup>

#### *3.3.1.4 Prehabilitation – aerobic exercise*

Most exercise programmes insist on the inclusion of aerobic and strength exercises. Aerobic exercises aim to achieve 40-70% of heart rate reserve (HRR; the difference between resting and maximal heart rate) with sessions lasting between 20 and 40 minutes per day for one to three months preoperatively.<sup>113, 120</sup> Strength exercises normally involve weight training. Programmes are defined by the number of repetitions at a percentage of the maximal weight at which a person is able to perform one successful repetition prior to fatigue prohibiting further repetitions (1-RM). A review by Carli et al suggested that the optimal weight regimen for a local muscle group should be 60% of 1-RM which equates to 15 repetitions until fatigue.<sup>113</sup>

#### *3.3.1.5 Prehabilitation – adherence to exercise*

It is important to consider the effects of physical capability and adherence which can impact the efficacy of such programmes.<sup>121</sup> Preoperative exercise programmes are severely limited by high rates of non-adherence. Carli et al compared a structured bike and strengthening programme to a simpler walking and breathing programme and found no clinically significant difference in postoperative outcomes. One of the main reasons though to be responsible for this result was lack of adherence to the structured programme with only 16% of subjects remaining compliant to the protocol.<sup>118</sup> It is important to reiterate to patients the importance of prehabilitation



and this may require regular follow-up in the community by a primary care physician or physiotherapist. Due to the lack of current evidence, these exercise programmes should not be considered a compulsory component of preoperative care. Effectively, these exercise programmes should be designed to be self-sustaining and it is important to recognise the need to train the patients in how to perform these activities correctly and safely and to tailor exercises to a patient's physical capability and comorbidity status.

#### *3.3.1.6 Prehabilitation – nutrition*

Obese patients may be nutritionally deficient. This is thought to occur due to the consumption of foods which are energy-rich but nutrient-deplete.<sup>122</sup> Several studies have been published demonstrating obesity-related nutritional deficiency with the most commonly depleted nutrients being vitamins D, B6 and B12, folate, and trace minerals magnesium, iron and zinc.<sup>123-126</sup> Nutritional deficiencies may also occur secondary to bariatric procedures, especially with fat dependent vitamins and trace minerals such as iron, selenium, zinc and copper.<sup>127</sup> The procedures may also induce hypervitaminosis, which has been described with laparoscopic sleeve gastrectomy.<sup>128</sup> Assessment by a dietician should be performed routinely. Supplementation of nutritional deficiencies is essential in the perioperative management of bariatric patients.

#### *3.3.1.7 Prehabilitation – smoking and alcohol*

Smoking (one or more cigarettes per day) and hazardous drinking (three alcoholic drinks per day; 12g of ethanol per drink) increases the risk of postoperative

complications two to four times after major surgery.<sup>129, 130</sup> The European guidelines for bariatric surgery list alcohol abuse and substance dependence as contraindications for surgery.<sup>27</sup> Current literature recommends abstinence for a minimum period of four to six weeks preoperatively but this time period may require extension in bariatric surgery.

#### *3.3.1.8 Preoperative weight loss*

Bariatric patients are routinely advised to lose weight preoperatively. This has been shown to promote rapid early weight loss.<sup>131-133</sup> Livhits et al published a systematic review detailing predictors of positive outcome after surgery and found preoperative weight loss to be the only factor positively associated with postoperative weight loss.<sup>134</sup> However, given that these findings were in only seven of the 14 papers included in their analysis, further evaluation is required to confirm these results. Weight loss may also be effective in decreasing liver volume which helps to improve visualisation during the operation. For this reason, implementation of an anorectic supplement has been previously recommended, two to four weeks preoperatively, in conjunction with the patients exercise programme.<sup>106</sup>

#### *3.3.1.9 Environment*

In their review of optimised care in colorectal surgery, Zargar-Shoshtari et al suggested that the hospital environment influences postoperative recovery.<sup>111</sup> Favourable hospital environments, such as those which are well lit and promote social interaction, are thought to decrease anxiety and modify patient behaviour. There are few data on the type of environment which would be best suited to ERAS,

but the suggestion is that in the elective-surgery setting, the presence of ERAS trained nurses improves recovery. This concept could potentially be utilised in a bariatric specific ERAS programme.

#### *3.3.1.10 Preoperative fasting*

The traditional approach to preoperative care is to fast patients up to six hours prior to surgery to minimise the risk of pulmonary aspiration.<sup>135</sup> However, there is a mounting body of evidence to suggest that fasting for this period is unnecessary and in fact detrimental to optimal postoperative recovery.<sup>135, 136</sup> Harter et al found that obese patients have acceptably low residual gastric fluid volumes compared to lean patients, as demonstrated by low volume of gastric contents at time of intubation, following fasts of eight to ten hours.<sup>137</sup> When given clear fluid up to two hours prior to surgery, Maltby et al showed no difference in gastric fluid volume in patients who received clear fluid and those that did not.<sup>138</sup> This suggests that the preoperative fasting regime of obese patients should not differ to non-obese patients and that regimes used in ERAS programmes for other types of surgery may be utilised. The studies by Harter et al and Maltby et al are summarised in *Table 3.1*.

Preoperative carbohydrate loading is often practiced in other types of surgery to avoid the fasting state and this has been shown to improve postoperative glucose metabolism.<sup>111</sup> The benefits of preoperative carbohydrate loading have yet to be shown in bariatric surgery but have been shown to be safe in patients with diabetes.<sup>139</sup>

*Table 3.1. Preoperative fasting obese patients*

Author	Type of Study	Number of Patients	Main Outcome	Result
Harter et al (1998)	Prospective cohort comparison study (obese vs. lean)	232	HVLP	Significantly less patients with HVLP in obese cohort (26%) when compared to lean cohort (42%) [ $p<0.05$ ]
Maltby et al (2004)	RCT	136	Volume and pH of gastric contents at induction of anaesthesia following 300ml of COF 2 hours preoperatively	Having COF two hours preoperatively did not significantly alter the volume or pH of the gastric contents

HVLP=High-volume, low pH gastric contents (as proxy for risk of aspiration); RCT=Randomised controlled trial; COF=Clear oral fluid

### **3.3.2 Intraoperative**

#### *3.3.2.1 Glucocorticoids*

In a recent systematic review and meta-analysis, the administration of intravenous glucocorticoids (IV GC) has been shown to decrease complications and LOS by attenuating the inflammatory response to major abdominal surgery.<sup>140</sup> Though this is true of other types of surgery, there is comparatively less evidence in bariatric surgery. A retrospective review of a prospective database on LRYGB outcomes was performed by McCarty et al, within which a group of patients received intraoperative steroid as part of a transitional experience to reduce postoperative nausea and vomiting. Using multivariate analysis, they were able to demonstrate that

administration of a steroid bolus in bariatric surgery was an independent predictor of optimal postoperative outcomes.<sup>108</sup>

However, there is a risk of inducing hyperglycaemia with Hans et al showing that maximum glucose concentration after administration of 10milligrams (mg) intravenous dexamethasone at induction of anaesthesia was linearly correlated with BMI.<sup>141</sup> The current literature would suggest that administering 8mg of intravenous dexamethasone at the time of induction is safe with the proviso that blood sugar levels are closely monitored intraoperatively and postoperatively. It should be noted that 4mg of dexamethasone is routinely given for antiemetic prophylaxis but this dose is ineffective in attenuating surgical inflammation.<sup>140</sup> The optimal time to administer IV GC is thought to be at 90 minutes prior to induction of anaesthesia.<sup>142</sup>

### *3.3.2.2 Anaesthesia*

Careful assessment of a patient's comorbidity status should be made and their comorbidities optimised prior to surgery. Obese patients have higher anaesthetic risk than non-obese patients due to an increased burden of disease and the physiological impairment associated with obesity. Multiple aspects of the anaesthetic process should be considered in patients undergoing bariatric surgery. A summary of anaesthetic considerations in patients undergoing bariatric surgery is given in *Table 3.2*.

### 3.3.2.3 On-table positioning

Correct on-table positioning is vital for safe anaesthesia. This may require beds customized for bariatric patients and particular attention should be paid to pressure areas due to the increased incidence of pressure ulcers and neural injuries in these patients.<sup>143</sup> Padding of all pressure areas is also suggested in the literature to enhance prevention of rhabdomyolysis.<sup>144</sup>

*Table 3.2.* Summary of anaesthetic considerations in patients undergoing bariatric surgery

Bariatric Anaesthesia
On table positioning is vital for safe anaesthesia in obese patients with particular attention to be paid to pressure areas
Hypothermia can occur commonly in open and laparoscopic surgery and lead to impaired host immune defence
Positive End Expiratory Pressure at 10cm/H <sub>2</sub> O can be considered in order to help prevent atelectasis and improve oxygenation in obese patients
Anaesthetic agents whose distributions are less affected by lipophilicity (e.g. remifentanyl, propofol) may be favoured as they can be dosed according to lean body mass
Obese patients have an approximately 13% higher incidence of difficult intubation due to increased neck circumference

### 3.3.2.4 Warming

Preoperative warming must be considered in obese patients. Hypothermia occurs commonly in open surgery, due to wound and organ exposure to the ambient environment, and in laparoscopic procedures due to insufflation of cold, dry carbon dioxide (CO<sub>2</sub>) gas. In major abdominal surgery, including bariatric surgery, this has

been shown to lead to impaired host immune defence resulting in wound complications and prolonged recovery.<sup>145-147</sup> Nguyen et al compared the change in core body temperature in patients who underwent laparoscopic gastric bypass to patients who underwent open gastric bypass. They demonstrated a significant drop in intraoperative core body temperature, with up to 46% of the open group and 41% of the laparoscopic group becoming hypothermic at some stage during the operation.<sup>146</sup>

### *3.3.2.5 Respiratory function and positive end expiratory pressure*

The respiratory function of morbidly obese patients is characterised by a restrictive pattern of pulmonary impairment, hypoxia, hypoxaemia and ventilation-perfusion mismatch which is particularly evident in the supine position.<sup>148</sup> Anaesthesia drops functional residual capacity by 50% in obese patients which, combined with loss of diaphragmatic tone, leads to an increased incidence of atelectasis.<sup>148-150</sup> Recent literature suggests that positive end expiratory pressure (PEEP) at 10cm/H<sub>2</sub>O prevents the formation of atelectasis and improves oxygenation.<sup>151-153</sup>

### *3.3.2.6 Pharmacology*

Remifentanil is often used at induction of bariatric surgery due to its distribution not being affected by lipophilicity, allowing it to be dosed according to lean body mass.<sup>143</sup> Non-depolarising muscular agents and propofol are also dosed in this manner.<sup>143, 152</sup> Desflurane is the most commonly used inhaled induction agent for patients undergoing bariatric surgery due to its rapid and consistent recovery profile.<sup>143</sup> Dual administration of dexamethasone and ondansetron intraoperatively

has been shown to significantly decrease postoperative nausea and vomiting in laparoscopic gastroplasty.<sup>154</sup>

#### *3.3.2.7 Airway management*

Obese patients have been reported to have an approximately 13% higher incidence of difficult intubation compared to non-obese patients and this is largely due to a larger neck circumference.<sup>143, 155</sup> There is evidence to suggest that awake fiberoptic intubation in the reverse Trendelenburg position may be safe and effective in morbidly obese patients. In an RCT, the use of video laryngoscopy in bariatric surgery has also been shown to reduce time and attempts for intubation and prevent significant desaturation.<sup>156</sup> Currently, the use of video laryngoscopy is not routine but is advocated for by Pelosi et al as part of a suggested method of perioperative ventilation management.<sup>148</sup>

#### *3.3.2.8 Laparoscopy*

Both open and laparoscopic procedures are effective in treating morbid obesity with each therapy offering contrasting yet often complementary advantages and disadvantages. While open surgery allows for tactile dissection and more freely facilitates one's ability to perform ancillary procedures, laparoscopic bariatric surgery is associated with a lower incidence of postoperative complications, decreased LOS, decreased postoperative pain and greater cosmesis without increasing the procedure time.<sup>92, 106, 157, 158</sup>



Weller et al reported on the outcomes of 19,156 patients having either laparoscopic or open gastric bypass for the treatment of morbid obesity and found that despite being more expensive, laparoscopic surgery was associated with less postoperative complications and a shorter LOS.<sup>159</sup> Currently, the majority of bariatric procedures are performed laparoscopically.<sup>160</sup> However, super obesity ( $\text{BMI} \geq 50 \text{ kg/m}^2$ ) is associated with an increased risk of adverse surgical events with Kakarla et al showing an increased incidence of postoperative complications for super-obese patients when compared to non super-obese patients with a laparoscopic approach.<sup>85</sup>

It has been suggested that the benefits of laparoscopic surgery are usually achieved when performed by a surgeon experienced with laparoscopic techniques with Kelles et al showing an inverse relationship between surgeon experience and the incidence of postoperative complication and LOS in laparoscopic bariatric surgery.<sup>161</sup> However, Marsk et al suggested that morbidity and short-term results were acceptable even during the early stages of their learning curve.<sup>162</sup> The effect of pneumoperitoneum on postoperative recovery has been investigated by El-Dawlalty et al who found that though pneumoperitoneum had significant effects on haemodynamics, there was only a marginal impact on recovery.<sup>163</sup> In centres where laparoscopy is unavailable or financially unviable, bariatric surgery performed through mini-laparotomy has been shown in one study to be a safe and effective alternative though more data are required to clarify this.<sup>164</sup>

### *3.3.2.9 Warming and humidification of insufflation carbon dioxide (CO<sub>2</sub>)*

The current evidence is unclear as to whether there is significant benefit in warming and humidification of insufflation CO<sub>2</sub> in laparoscopic surgery. A recent meta-analysis looking at warming and humidification of insufflation CO<sub>2</sub> in laparoscopic surgery, which included three papers in the setting of gastric bypass, found some benefit to postoperative recovery.<sup>165</sup> However, its effectiveness specifically in LRYGB has been previously investigated and was not found to confer any benefit to postoperative recovery.<sup>166, 167</sup>

### *3.3.2.10 Fluids*

It was initially believed that obese patients required excessive levels of intravenous fluid (IVF) to maintain euvolaemia and electrolyte homeostasis and prevent rhabdomyolysis.<sup>143, 168</sup> However, recent literature by Kehlet et al, mostly in colorectal surgery, suggests that intraoperative IVF administration should be based upon haemodynamic parameters.<sup>169</sup> This has been termed goal directed fluid therapy (GDFT) and it has been shown to improve recovery in other types of surgery.<sup>169, 170</sup>

These benefits have also been demonstrated in obese patients and those undergoing bariatric surgery with Jain et al showing that IVF administration guided by stroke volume variation resulted in similar levels of IVF being given to obese patients and non-obese patients with non significant variations in haemodynamic parameters when compared to baseline and no effect seen on renal or metabolic indices.<sup>171</sup>

Wool et al were also able to demonstrate that there was no difference in the incidence of rhabdomyolysis between patients who received liberal or conservative IVF treatment.<sup>172</sup>

#### *3.3.2.11 Prophylactic drainage*

Prophylactic drainage is commonly used in bariatric surgery as this has been thought to aid with early detection of anastomotic leak, facilitate non-operative management of anastomotic leak and prevent wound infection in patients as had been shown in the setting of LRYGB.<sup>173, 174</sup> However, Salagado et al demonstrated that drainage in the setting of LRYGB for morbid obesity increased peritoneal inflammation, as indicated by increased levels of tumour necrosis factor and interleukin one in drainage fluid even in patients who had no complications, though this was in the context of drains left for seven days postoperatively.<sup>175</sup> Earlier work by Shaffer et al demonstrated that drains made no difference in the incidence of wound infection.<sup>174</sup> Although the evidence is limited in bariatric surgery, the use of prophylactic drainage may be unnecessary, as has been shown in other types of major abdominal surgery.

#### *3.3.2.12 Prophylactic nasogastric tube (NGT)*

The routine placement of a prophylactic NGT was popularised by the clinical benefits demonstrated in patients with small bowel obstruction.<sup>176</sup> However, recent work suggests that prophylactic NGT placement in bariatric surgery is unnecessary with Huerta et al finding no difference in complications in patients with or without NGT.<sup>177</sup> In patients undergoing gastrectomy for cancer it was shown to make no difference in the rate of anastomotic leak as well as significantly delay passage of flatus, early oral intake and day of discharge.<sup>178, 179</sup>

### *3.3.2.13 Analgesia*

Optimising the analgesic effect is vital to enhancing recovery in bariatric patients. Analgesia regimens should be proactive with implementation beginning intraoperatively. It is important not only for patient comfort but also for prompting early mobilisation. This helps to decrease the incidence of venous thromboembolism (VTE) and prevent respiratory complications such as atelectasis.<sup>180</sup>

### *3.3.2.14 Intra-peritoneal local anaesthetic*

Laparoscopic surgery requires minimal incisions for visceral access. However, dissection and resection lead to visceral nociception which is characterised by painful and non-painful sensations manifesting as illness behaviour.<sup>181</sup> Administration of intraperitoneal local anaesthetic (IPLA) has been theorised to decrease visceral pain by blocking visceral afferent pathways, thereby decreasing the downstream illness response. A recent systematic review looking at the use of IPLA in laparoscopic gastric surgery found that IPLA was effective at decreasing abdominal pain intensity.<sup>181</sup> The proposed mechanism of action is the blockade of afferent visceral nociceptive pathways. For this reason, the recommendation is to administer IPLA prior to visceral dissection. There are various methods of administration. Alkhamesi et al. used an aerosolised device to administer IPLA and Sherwinter et al used an infusion catheter.<sup>182, 183</sup> Both studies administered IPLA after visceral dissection. When given pre-visceral dissection, administration onto the surgical bed under direct vision is preferred.<sup>184, 185</sup> The choice of local anaesthetic is dependent on surgeon and anaesthetist preference.

### 3.3.3 Postoperative

#### 3.3.3.1 Multimodal postoperative analgesia

A multimodal approach to analgesia is the most effective method as it minimises opiate consumption which can enhance obstructive apnoea and lead to severe respiratory depression.<sup>180, 186</sup> Regional anaesthesia should be employed whenever possible to help decrease opiate use.<sup>187</sup> This includes administering local anaesthetic at the formation of port sites in laparoscopic surgery and the use of IPLA as previously described. Non-steroidal anti-inflammatory drugs have also been shown to be effective opioid-sparing agents in obese patients and, along with regular paracetamol, should form the basis of a patient's analgesic regimen.<sup>188</sup> Thoracic epidural analgesia has been shown to improve postoperative lung function in obese patients though its role in bariatric surgery is yet to be fully defined.<sup>189</sup> A potential multimodal regime is detailed in *Table 3.3*.

*Table 3.3.* A potential multimodal analgesia regime for bariatric surgery patients

Multimodal Analgesia
Intraoperative
Regional Anaesthesia
Intraperitoneal local anaesthetic
Local anaesthetic at formation of port sites
Postoperative
Regular Acetaminophen
Non-Steroidal Anti-Inflammatory medications / COX-2 Inhibitors
Judicious use of opiates

#### *3.3.3.2 Postoperative supplemental oxygen*

Obesity is a risk factor for impaired postoperative oxygenation.<sup>190</sup> This leads to an increased risk of tissue hypoperfusion and may help to explain the increased incidence of wound infection in obese patients. Greif et al demonstrated that postoperative supplemental oxygen following colorectal surgery increases subcutaneous tissue oxygen tension. They also demonstrated that patients receiving 80% oxygen had a significantly lower wound infection rate than those receiving 30% oxygen.<sup>191</sup> Other literature suggests that the amount of oxygen received does affect the incidence of wound infection.<sup>192, 193</sup>

#### *3.3.3.3 Oral intake*

Recent literature suggests that the initiation of early oral feeding improves postoperative recovery.<sup>170, 194</sup> Though this has shown to be the case in other types of abdominal surgery, there are comparatively less data in the setting of bariatric surgery. It is generally suggested that bariatric patients have clear oral fluids or full oral fluids for one to two days after surgery. Patients are then progressed onto pureed food and a gradual increase in food consistency over a period of weeks to months.<sup>106, 195</sup>

#### *3.3.3.4 Mobilisation*

There is a BMI dependent decrease in perioperative respiratory function which is associated with atelectasis and critical respiratory events in the recovery room. One method to avoid such events is to encourage early postoperative mobilisation which, along with chest physiotherapy, has been shown to improve lung volumes.<sup>196</sup> Early

postoperative mobilisation also has the added benefit of decreasing the incidence of VTE especially when used as a part of a multimodal approach to thromboprophylaxis.<sup>197, 198</sup> It is also thought to decrease the incidence of pressure ulcers, pain and pneumonia.<sup>199</sup> For these reasons, early mobilisation is essential for patients after bariatric surgery.

### *3.3.3.5 Thromboprophylaxis*

Bariatric patients are at increased risk of VTE due to their elevated BMI.<sup>200, 201</sup> Pulmonary embolism (PE) is estimated to account for 50% of the mortality associated with bariatric surgery.<sup>202</sup> Primary prevention of VTE should be standard practice. Chemical thromboprophylaxis with low molecular weight heparin (LMWH) is most commonly used followed by mechanical prophylaxis with pneumatic stockings.<sup>200</sup> LMWH is usually continued until day of discharge. However, there is evidence to suggest that it may be more effective in bariatric patients as an extended course lasting over one to three weeks.<sup>203</sup> More recent research suggests that targeted inferior vena cava (IVC) filter placement may be more effective at reducing the occurrence of PE in high risk patients.<sup>202</sup> However, there is contrasting evidence on IVC filters provided by Birkmeyer et al who demonstrated that they do not decrease the incidence of PE and are associated with additional complications.<sup>204</sup> Dobesh et al reviewed the current evidence on thromboprophylaxis in bariatric patients and found that a multimodal approach was most effective in preventing VTE. This includes 40mg subcutaneous enoxaparin, pneumatic stockings, thromboembolic deterrent stockings and early mobilisation.<sup>197</sup>

### **3.4 Conclusion**

This chapter details a variety of evidence-based perioperative care interventions which are currently used to facilitate enhanced postoperative recovery after a variety of operations. It shows that it is possible to formulate a bariatric-specific ERAS programme using perioperative interventions such as those described above. Though the interventions are discussed individually, it is important to recognise that the true value of an ERAS programme is the standardized manner in which the interventions are delivered. This helps to minimise heterogeneity of perioperative care which promotes greater validity of surgical outcomes. The following chapter will present data from a randomised controlled trial evaluating the safety and efficacy of an ERAS programme in patients undergoing LSG at our institution.



## Chapter 4

### **RANDOMISED CLINICAL TRIAL OF ENHANCED RECOVERY VERSUS STANDARD CARE AFTER LAPAROSCOPIC SLEEVE GASTRECTOMY**

## 4.1 Introduction

The previous chapter described a review of the current literature performed to identify evidence-based perioperative care interventions which could be used to formulate a bariatric specific ERAS programme. This chapter details a randomised controlled trial which evaluates a bariatric-specific ERAS programme formulated from the perioperative care interventions identified in Chapter 3.

Though the efficacy of ERAS protocols are well established in the setting of other types of major abdominal surgery, their effectiveness in the setting of bariatric surgery is less well defined. In a prospective study investigating the utility of an accelerated recovery programme in elective primary laparoscopic gastric resection, Grantcharov et al demonstrated that a number of the principles of an ERAS protocol, such as avoidance of prophylactic NGTs and abdominal drains, early postoperative feeding, and utilisation of multimodal analgesia could successfully be applied in this clinical setting without increasing postoperative morbidity.<sup>107</sup> However, this did not involve gastric resection as a primary bariatric procedure. McCarty and colleagues reported 84% of patients being discharged within 23 hours of LRYGB which was partly attributed to the cumulative effect of a number of independent components of perioperative care.<sup>108</sup>

Bambagade et al reported on their four year experience with ERAS in laparoscopic gastric bypass and were able to demonstrate a reduction in LOS from two days to one in the latter two years after overcoming the learning curve requirement of an ERAS protocol.<sup>109</sup> However, the current literature is restricted to non-randomised

studies and retrospective reviews which are not compared to a suitable control and have limited detail describing the ERAS or fast-track protocol.

We therefore conducted a randomised controlled trial with the aim of evaluating the efficacy of a bariatric specific ERAS protocol for improving recovery after elective LSG. We hypothesised that patients having LSG within an ERAS protocol would have superior recovery manifesting as a reduction in postoperative convalescence without an increase in perioperative morbidity. We also hypothesised that it would be more cost-effective.

## **4.2 Method**

This study was a randomised controlled trial which was approved by the Northern X Regional Ethics Committee of New Zealand and registered with clinicaltrials.gov (NCT01303809).

### **4.2.1 Participants**

All patients undergoing LSG as a definitive, stand-alone bariatric procedure between August 2011 and May 2012 were recruited. The only inclusion criterion was that patients had to have their operation at the elective surgery hospital Manukau Surgery Centre (CMDHB, Auckland, New Zealand), by a consenting surgeon. Exclusion criteria were patients not having surgery at Manukau Surgery Centre and those patients having LSG as a revision bariatric procedure. The surgical technique is standardised and has been described in previous chapters.

Randomisation was performed by an independent researcher not involved in patient recruitment or outcome assessment using a computerised random number generator. Group allocations were placed in sequentially numbered opaque sealed envelopes. Patient recruitment was performed following the collection of baseline data. Neither the patients nor the recruiting investigator were aware of the allocation sequence prior to recruitment. Allocation can therefore be described as concealed. Patients were randomly allocated to the exposure group (EG) or the control group (CG).

#### **4.2.2 Exposure Group**

Patients in the EG underwent LSG whilst having their perioperative care managed according to a bariatric specific ERAS protocol. The protocol directed care beginning in the preoperative period through to 30 days postoperatively. This protocol was developed by performing an extensive review of the current literature investigating evidence-based perioperative care interventions and ERAS protocols used in the settings of bariatric surgery and major abdominal surgery and is presented in Chapter 3. Multidisciplinary input was sought from bariatric surgeons, anaesthetists, bariatric outpatient clinic staff, as well as theatre and nursing staff at the study location site. Once the protocol was written, it was reviewed by all contributors and users of the protocol prior to its implementation in order to gain consensus agreement with regards to the protocol components. *Table 4.1* details the ERAS protocol used to direct the perioperative management of patients randomised to the EG.

Table 4.1. Bariatric ERAS protocol versus standard care

Stage of Perioperative Care	ERAS	Standard Care
Preoperative	Formal standardised preoperative education  Formal goal setting session  Tour of the ward	Advice as per the bariatric surgeon
Morning of surgery	COF up to 2 hours prior to surgery  2 x carbohydrate drinks	Care as per the anaesthetist and bariatric surgeon
Intraoperative	8mg of intravenous dexamethasone at anaesthetic induction  Standardised anaesthesia  Intraperitoneal local anaesthetic  Avoidance of prophylactic NGT and abdominal drains	Care as per the anaesthetist and bariatric surgeon
Postoperative	Early instigation of oral intake  Mobilisation 2 hours after return to ward  Standardised multimodal analgesia and antiemesis  Standardised multimodal thromboprophylaxis	Care as per the postoperative instructions given by the bariatric surgeon
Post discharge	2 week follow-up in clinic  Phone call day 1 and week 1 post discharge	2 week follow-up in clinic

The postoperative ward at Manukau Surgery Centre is split into an 'A' wing and a 'B' wing. Though it was not possible to adequately blind study participants and

personnel, we were able to exploit the ward set up in order to minimise the risk of cross-over by placing EG patients in the 'A' wing exclusively while placing CG patients in the 'B' wing.

#### **4.2.3 Control Group**

In contrast to the EG, patients allocated to the control arm underwent LSG whilst receiving standard bariatric perioperative care. The care provided was according to the individual surgeons and anaesthetists as well routine postoperative protocols used to dictate time to mobilise and time to instigate oral intake following the patient returning to the ward (*Table 4.1*).

#### **4.2.4 Historic Control Group (HCG)**

In addition to the study CG, an historic control group (HCG) was also generated in order to assess the effect of potential cross-over between the study CG and EG. This risk of cross-over was anticipated as a consequence of the limited ability to adequately blind participants and personnel. The HCG was formed from select patients who had LSG as part of the initial cohort of 400 patients between 2007 and 2010 using the propensity score analysis matching method. This was performed by generating a propensity score for each patient in the cohort of 400 and each patient recruited prospectively using potential confounding variables. The propensity score was then used to select matched patients in the initial cohort of 400 to create the HCG.

#### **4.2.5 Outcomes**

Demographic data were collected to determine whether both groups were matched at baseline. This included recording and analysing age, gender, and ethnicity. Preoperative weight characteristics recorded were total weight (kg), BMI ( $\text{kg}/\text{m}^2$ ), and total excess weight (kilograms). Preoperative comorbidity status was assessed by the American Society of Anaesthesiologists' (ASA) score and the incidence of T2DM, HTN, hyperchol and OSA.

The primary outcome of this study was median LOS. The LOS is a standard primary endpoint used in other randomised controlled trials which have investigated the efficacy of ERAS protocols used in other surgical settings.<sup>96</sup> As described in Chapter 2, the median LOS following LSG at our institution was 3 days. Using a two tailed Mann-Whitney U test, our study was powered to detect a reduction in the LOS from 3 days to 1 day. This required a sample size of 76 patients with 38 randomly allocated to each arm ( $\alpha=0.05$ ;  $\beta=0.8$ ).

Both study groups were discharged once they had fulfilled predetermined, standardised discharge criteria (*Table 4.2*). In all cases, the decision for discharge was made by the responsible medical staff at the study hospital. The decision for discharge was made independently of the researchers involved in the study.

Table 4.2. Standardised discharge criteria for LSG at CMDHB

Adequate pain relief with oral non-opioid analgesia (paracetamol and arcoxia)
No evidence of wound dehiscence or wound infection
No postoperative complications
Pulse rate <90, Temperature ≤37.6°C, Respiratory Rate <20
Uneventful technical procedure
Patient is ambulatory
Completed 1L of water within 24 hours
Tolerating free oral fluids (e.g. milk)

There were multiple secondary outcomes recorded and analysed in this study. Thirty day readmission rates were recorded and analysed. Thirty day postoperative complications were prospectively recorded and graded according the Clavien-Dindo Classification system.<sup>101, 102</sup> The incidence of major complications (classified as Clavien-Dindo grade 3 or higher including complications requiring radiological or surgical intervention, admission into the intensive care unit or death) was specifically recorded and analysed. Postoperative fatigue was assessed using the surgical recovery scale (SRS)<sup>205, 206</sup> at baseline and days 1, 7 and 14 postoperatively. Compliance to the ERAS protocol was also prospectively recorded and analysed. An acceptable compliance rate of 80% or higher was determined *a priori*. Postoperative fatigue and protocol compliance were assessed in the EG and CG only. The total cost incurred per patient was calculated by adding costs incurred during the index admission to costs incurred during subsequent readmissions. Comparative analysis was then performed to determine the cost-effectiveness of LSG performed within an ERAS protocol.



#### 4.2.6 Statistical Analysis

Statistical analysis was performed using SPSS (SPSS V13 Inc, Irvine CA). Continuous variable parametricity was tested using the Shapiro-Wilk test. Propensity scores, used to match patients as part of the HCG, were generated using a binary logistic regression model where the dependent variable was LSG within an ERAS intervention. The covariates used in this model are detailed in *Table 4.3*. The groups were compared using the chi squared test for categorical variables and one-way ANOVA test for continuous parametric variables. Subsequent post-hoc analysis after ANOVA was performed using the Tukey test. The Kruskal-Wallis test was used to assess continuous non-parametric variables with post-hoc analysis performed using the Mann-Whitney U test. Statistical significance was identified as  $p \leq 0.05$ . All data were analysed on an intention to treat basis.

*Table 4.3.* Logistic regression model used to generate propensity scores

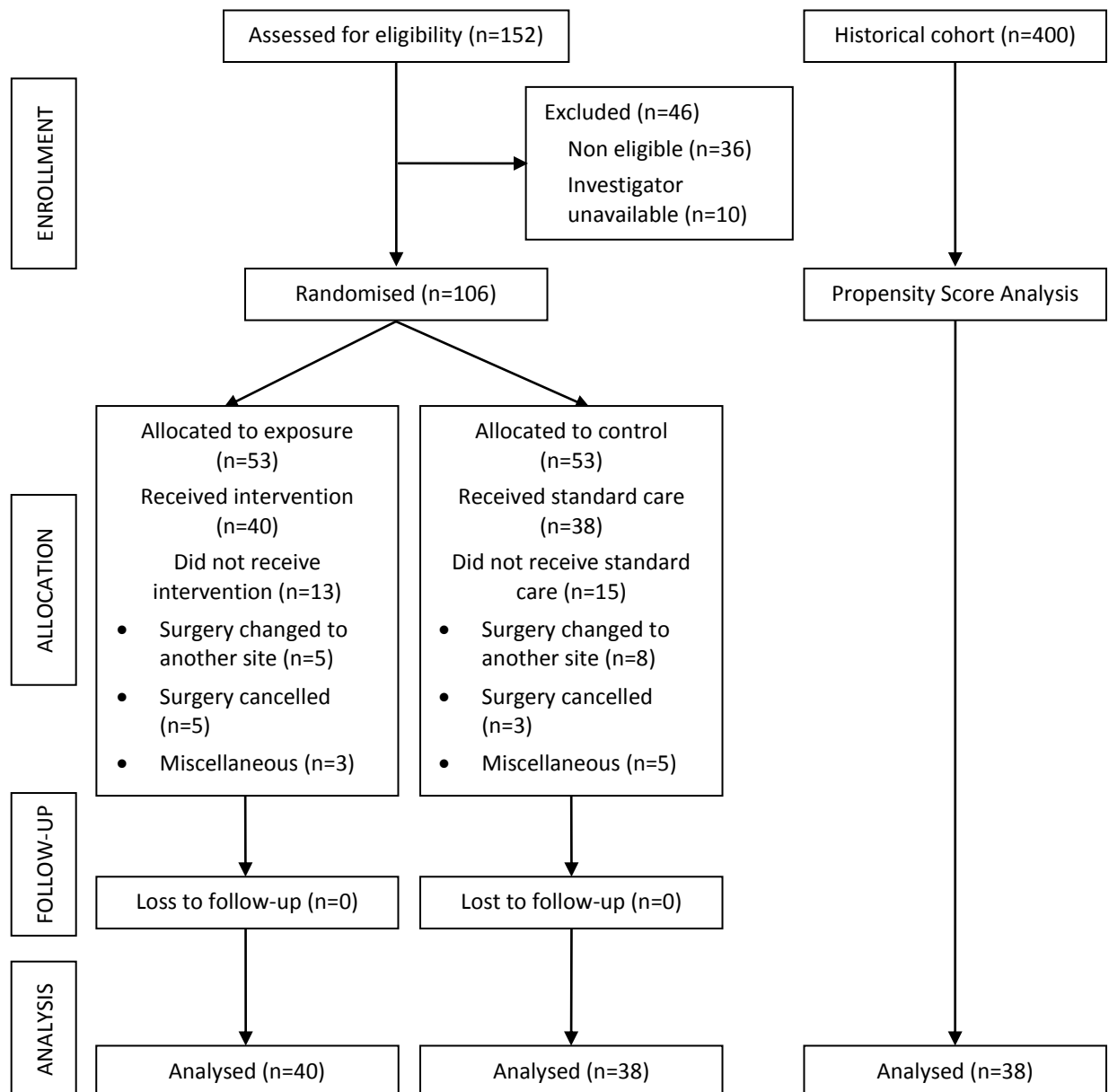
Variable	Odds Ratio	<i>p</i> value
Age	1.01	0.714
Female Gender	2.05	0.265
Ethnicity	1.22	0.280
Preoperative Weight	1.45	0.184
Preoperative BMI	1.09	0.051
Preoperative Excess Weight	1.44	0.186
T2DM	4.76	<0.001
HTN	1.62	0.151
Hyperchol	2.62	0.005
OSA	0.64	0.212

The primary predictor variable used as the dependent variable was inclusion in the trial.

### 4.3 Results

Figure 4.1 depicts the CONSORT flow diagram detailing the progress of patients through the trial.<sup>207</sup>

Figure 4.1. CONSORT flow diagram



In all, 106 patients were randomised to either the EG or the CG of which 78 were included in the final analysis following post randomisation exclusions. There were 38 patients matched using propensity scores from our historical cohort and included in the final analysis as the HCG. In all 116, patients were included in our final analysis of which 40 were in the EG, 38 in the CG and 38 in the HCG.

#### **4.3.1 Baseline Characteristics**

The baseline characteristics of are described in *Table 4.4*. There were no differences between the three groups for any variable. This confirmed both the adequacy of our randomisation and accuracy of the regression model to generate propensity scores.

Comparative analysis revealed a significant difference between the three groups during the index admission (*Table 4.5*). Post-hoc analysis revealed the index LOS to be significantly reduced in the EG when compared to both the study CG (EG: 1 day; CG: 2 days;  $p<0.001$ ) and the HCG (EG: 1 day; CG: 3 days;  $p<0.001$ ). Post-hoc analysis also revealed a significant reduction in index LOS in the CG when compared to the HCG (CG: 2 days; HCG: 3 days;  $p<0.001$ ).

Comparative analysis revealed a significant difference between the three groups during the index admission (*Table 4.5*). Post-hoc analysis revealed the index LOS to be significantly reduced in the EG when compared to both the study CG (EG: 1 day; CG: 2 days;  $p<0.001$ ) and the HCG (EG: 1 day; CG: 3 days;  $p<0.001$ ). Post-hoc analysis also revealed a significant reduction in index LOS in the CG when compared to the HCG (CG: 2 days; HCG: 3 days;  $p<0.001$ ).

Table 4.4. Baseline characteristics

Variable	Exposure Group (n=40)	Control Group (n=38)	Historical Control Group (n=38)	p value
Mean age (SD)	44 (7)	44 (6)	44 (7)	0.907 <sup>†</sup>
Female Gender (%)	27 (68)	28 (74)	30 (79)	0.520 <sup>‡</sup>
Ethnicity (%)				0.612 <sup>‡</sup>
European	20 (50)	17 (44.7)	19 (50)	
Maori	11 (27.5)	11 (28.9)	11 (28.9)	
Pacific	4 (10)	8 (21.1)	6 (15.8)	
Indian/Asian	3 (7.5)	0	2 (5.3)	
Other	2 (5)	2 (5.3)	0	
ASA (%)				0.833 <sup>‡</sup>
I	1 (0.4)	0	1 (2.6)	
II	23 (57.5)	25 (65.8)	22 (57.9)	
III	16 (42.1)	13 (34.2)	15 (39.5)	
Preoperative Weight Characteristics				
Mean Weight (kg, SD)	133.5 (22.5)	134.1 (22.1)	132.7 (22.1)	0.959 <sup>†</sup>
Mean BMI (kg/m <sup>2</sup> , SD)	46.2 (6)	46.1 (6)	45.9 (6.6)	0.980 <sup>†</sup>
Mean Excess Weight (kg, SD)	67.5 (19.3)	67.6 (20)	66.1 (18.5)	0.925 <sup>†</sup>
Preoperative Comorbidity Status				
T2DM (%)	24 (60)	23 (60.5)	26 (68.4)	0.693 <sup>‡</sup>
HTN (%)	22 (55)	21 (55.3)	21 (55.3)	1.000 <sup>‡</sup>
Hyperchol (%)	23 (57.5)	15 (39.5)	20 (52.6)	0.980 <sup>‡</sup>
OSA (%)	9 (22.5)	8 (21.1)	4 (10.5)	0.925 <sup>‡</sup>

SD=standard deviation; kg=kilograms; BMI=body mass index; T2DM=type 2 diabetes mellitus; HTN=hypertension; Hyperchol=hypercholesterolaemia; OSA=obstructive sleep apnoea

Comparative analysis revealed a significant difference between the three groups during the index admission (Table 4.5). Post-hoc analysis revealed the index LOS to

be significantly reduced in the EG when compared to both the study CG (EG: 1 day; CG: 2 days;  $p<0.001$ ) and the HCG (EG: 1 day; CG: 3 days;  $p<0.001$ ). Post-hoc analysis also revealed a significant reduction in index LOS in the CG when compared to the HCG (CG: 2 days; HCG: 3 days;  $p<0.001$ ).

There were eight readmissions in each group. Of these, ten patients were readmitted with major complications; four staple line leaks (two in the HCG and one each in the EG and CG), three staple line bleeds (one in each group) and three sleeve strictures requiring a gastric stent (one in each group). The median length of readmission was 6 days with no difference between the three groups ( $p=0.758$ ).

The total LOS was calculated by adding the LOS during any subsequent readmissions to the index LOS. Comparative analysis revealed a significant difference between the three groups (*Table 4.5*). Post-hoc analysis demonstrated total LOS of stay to be significantly reduced in the EG when compared to the CG (EG: 1 day; CG: 2 days;  $p<0.001$ ) and HCG (EG: 1 day; HCG: 3 days;  $p<0.001$ ). Total LOS was also found to be significantly reduced in the CG when compared to the HCG (CG: 2 days; HCG: 3 days;  $p=0.01$ ). The reduction in LOS in the CG when compared to the HCG confirm the occurrence of cross-over between the EG and CG.

There were no differences between the three groups with respect to total, major or technical complications (*Table 4.5*).

Table 4.5. Median LOS and postoperative complications

	Exposure Group (n=40)	Control Group (n=38)	Historical Control Group (n=38)	p value
Length of Index Admission (IQR)	1 day (1-2) <sup>a</sup>	2 days (0) <sup>b</sup>	3 days (2-4)	<0.001 <sup>†</sup>
Readmission Rate (%)	8 (20)	8 (21.1)	8 (21.1)	0.991 <sup>‡</sup>
Total LOS (IQR)	1 day (1-3) <sup>a</sup>	2 days (2-3) <sup>b</sup>	3 days (2-4)	<0.001 <sup>†</sup>
Total Complications	10	8	15	0.172 <sup>‡</sup>
Major Complications	5	5	6	0.906 <sup>‡</sup>
Staple-Line Leaks	2	2	2	0.998 <sup>‡</sup>
Staple-Line Bleeds	2	2	2	0.998 <sup>‡</sup>

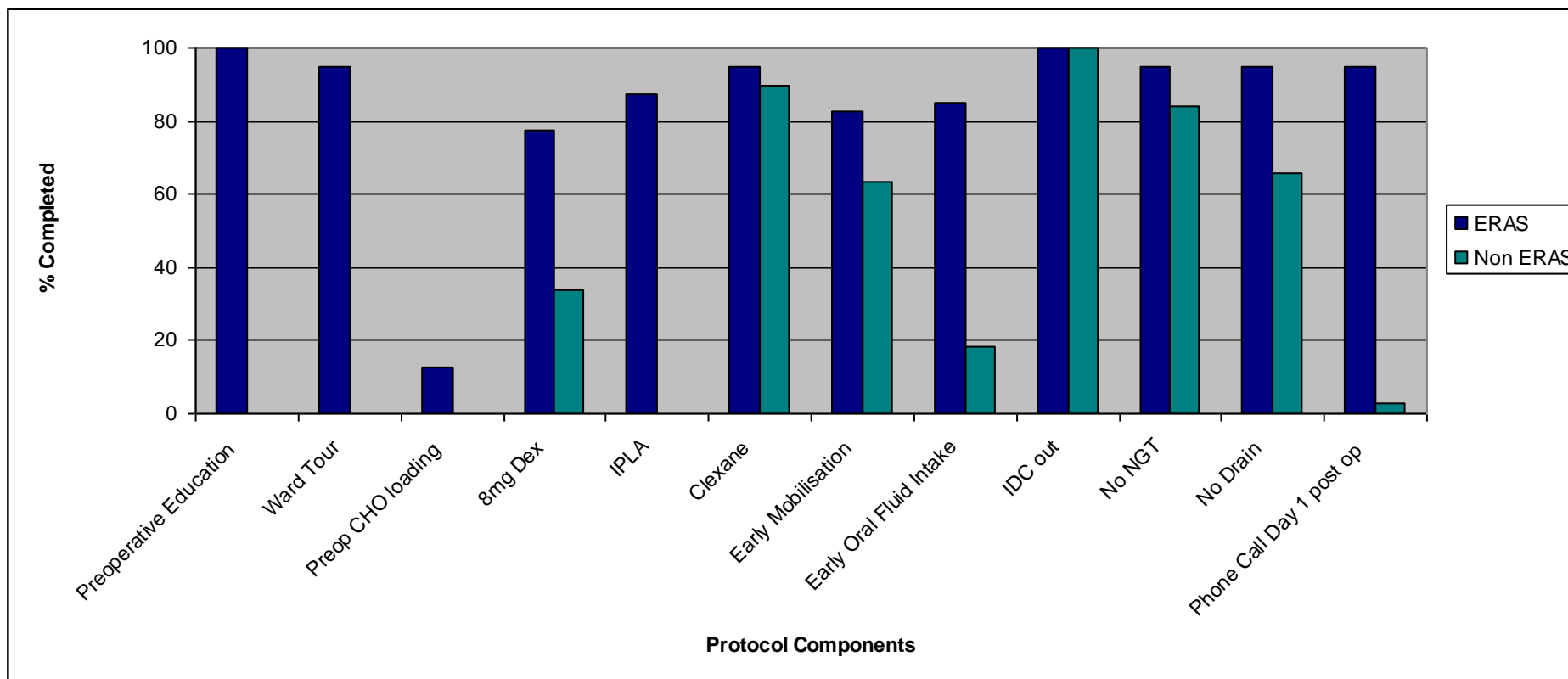
<sup>†</sup>Kruskal-Wallis Test. <sup>‡</sup>Chi squared Test. Post-hoc analysis performed using the Mann-Whitney U test. <sup>a</sup>Significant reduction in the Exposure Group compared to both the Control Group ( $p<0.001$ ) and the Historical Control Group ( $p<0.001$ ). <sup>b</sup>Significant reduction in Control Group when compared to the Historical Control Group ( $p=0.010$ ). LOS=Length of Stay; IQR=Interquartile range

The baseline SRS was completed by all participants. The completion rate of the postoperative SRS was 90%, 80% and 70% at postoperative days 1, 7 and 14 respectively. The mean SRS at baseline was 78.5% (SD, 15.9) in the EG and 76.1% (SD, 8.4) in the CG. The lowest mean SRS for both groups was on postoperative day 1 with 60% (SD, 12.0) in the EG and 62.3% (SD, 12.5) in the CG. The mean SRS of both groups increased on postoperative day 7 to 73.6% (SD, 11.9) and 72% (SD, 11.1) in the EG and CG respectively, and postoperative day 14 to 80.5% (SD, 10.2) and 80.1% (SD, 10.1) in the EG and CG respectively. There was no difference between the two groups at any time point.

Twelve components of the ERAS protocol were used to prospectively evaluate compliance. *Figure 4.2* illustrates the percentage of patients who had the individual

component completed as per protocol. When these components were compiled to give total protocol compliance, the EG was found to have 85% compliance. Whether these components were completed as per protocol in the CG was also recorded to assess the extent of cross-over between the two groups. These components were found to be completed as per protocol in 29% of the CG patients. This would suggest mild to moderate cross-over between the two groups.

Figure 4.2. Compliance to the (ERAS) Protocol



Overall protocol compliance within the exposure group was 85%. The rate of cross-over between the exposure group and control group was 29%. Preop CHO=Preoperative Carbohydrate Loading; Dex=Dexamethasone; IPLA=Intraperitoneal Local Anaesthetic; IDC=Indwelling Catheter; NGT=Nasogastric Tube; Postop=Postoperatively



Comparative analysis revealed a significant difference between the three groups for mean total costs per patient (*Table 4.6*). Post-hoc analysis revealed that the mean costs were significantly higher in the HCG when compared to both the EG ( $p=0.010$ ) and CG ( $p=0.018$ ). There was no difference between the EG and CG.

*Table 4.6.* Summary of costs

	Exposure Group (n=40)	Control Group (n=38)	Historical Control Group (n=38)	<i>p</i>
Total cost (NZD) per patient (SD)	\$14,836.13 <sup>a</sup> (13,092)	\$15,566.06 <sup>b</sup> (14,290)	\$27,700.08 (26,976)	0.005 <sup>†</sup>

\$1 NZD=0.633 EUR at the time of calculation (July 2012). <sup>†</sup>One Way ANOVA. Post-hoc analysis performed using the Tukey's Test. <sup>a</sup>Significant reduction in the Exposure Group when compared to the Historical Control Group ( $p=0.010$ ). <sup>b</sup>Significant reduction in the Control Group when compared to the Historical Control Group ( $p=0.018$ ). Total Cost is calculated by adding the cost incurred during the index admission to the cost of subsequent readmissions. NZD=New Zealand Dollars; SD=Standard Deviation

#### 4.4 Discussion

This study has shown that patients having LSG within an ERAS protocol have a significantly reduced length of postoperative hospital stay compared to those not within an ERAS protocol. The reduction in LOS did not come at the expense of increased postoperative morbidity. There was no difference in postoperative fatigue. There were costs savings of \$729.93 per patient undergoing LSG within an ERAS protocol which supports the concept that these protocols are also cost-effective. When compared to the HCG to account for potential cross-over between the study CG and EG, the LOS was still seen to be significantly reduced with a trend towards decreased postoperative morbidity and a significant reduction in cost per patients of

\$12,163.95 This study was unable to quantify the effect of the individual components of the ERAS protocol on this reduction of LOS due to the variations in care between the groups across the entire perioperative period.

This study has confirmed that bariatric surgery is expensive and that improving perioperative care produces significant cost savings. To our knowledge, this study is the first randomised controlled trial investigating the efficacy of an ERAS intervention used in bariatric surgery. Within the current literature, the few non-randomised studies which have evaluated ERAS protocols in bariatric surgery have demonstrated similar reductions in postoperative LOS without increases in perioperative morbidity.<sup>109, 152</sup> However, though the cost saving benefits of ERAS has been demonstrated in other types of surgery<sup>208-212</sup>, there are very few data investigating the cost-effectiveness of an ERAS intervention in bariatric surgery. However, existing literature does suggest that ERAS is associated with reduced perioperative costs. A recent systematic review demonstrated reduced perioperative costs in patients undergoing colorectal surgery within an ERAS programme.<sup>97</sup> In their review of 2000 patients undergoing LRYGB within an established bariatric programme, Jacobsen and colleagues found the utilisation of fast-track principles to be associated with an overall reduction in costs without comprising patient safety.<sup>213</sup>

The primary outcome of this current study was LOS following LSG performed within an ERAS protocol. Change in postoperative LOS has previously been used to assess the efficacy of an ERAS protocol in other surgical settings.<sup>214-216</sup> The current study has demonstrated similar results with a significant reduction in LOS in the EG of

1 day when compared to the CG using standardised discharge criteria and 2 days when compared to HCG. This reduction in LOS occurred without increasing postoperative morbidity. The utility of LOS as an outcome lies in its ability to function as a sensitive marker of how well an ERAS protocol is designed and run. Postoperative LOS may also have utility in helping to identify patients who may re-present to hospital or who may go on to develop perioperative morbidity. This may initially be signalled by failure to reach discharge criteria on the goal day set at the formal preoperative goal planning sessions.

The current study had insufficient statistical power to identify a difference in perioperative morbidity between the study EG and study CG. However, there was a trend towards a reduced morbidity during the study period when compared to patients included in the historical control. This strengthened the assumption that cross-over would occur due to lack of blinding which may have at least partly contributed to there being no difference between the study EG and CG with respect to complication rates. This result serves to reiterate that although LOS does act as an effective proxy of recovery after surgery, the true value of ERAS lies in its association with reduction in perioperative morbidity.<sup>215</sup> Future ERAS protocols implemented within established bariatric centres should pursue a reduction in morbidity as their primary aim.<sup>217</sup>

As has been mentioned previously, one of the main limitations of this study is the lack of blinding and subsequent risk of performance bias. This limitation has been encountered by all previous randomised controlled trials investigating ERAS.<sup>95</sup> The

issue of blinding is unavoidable with ERAS because patients and staff must be made aware of what is expected of them in order to meet their outcome goals. Though useful in generating hypotheses, purely observational studies evaluating ERAS are limited in their ability to make sound conclusions due to the inability to accurately account for known confounders.

A unique feature of this study was the utilisation of propensity score analysis which was used to assess for the risk of performance bias by accounting for intergroup cross-over. Propensity score analysis is a useful technique in surgical studies where randomisation is often difficult due to challenges with adequate blinding (as demonstrated in this current study) and where important outcomes, such as mortality and disease recurrence, are rare.<sup>218</sup> It works by generating a propensity score which represents the probability that a patient would receive an intervention based upon known potential confounders, and then using this propensity score to match patients who have received the intervention to those patients within a historical cohort.<sup>219</sup> The effect of this is the reconstruction of a scenario akin to randomisation by focusing on the relationship between baseline characteristics and the intervention in question, as opposed to the relationship between baseline characteristics and outcomes as is seen with multivariable analysis.<sup>220</sup> Future studies investigating the efficacy of ERAS interventions may choose to utilise this study method in order to avoid the inevitable bias associated with non-blinding seen in randomised trials evaluating ERAS.

In conclusion, an ERAS protocol can be safely utilised in patients undergoing bariatric surgery to facilitate earlier recovery from surgery. This creates a standardised perioperative milieu which acts as a platform for clinical evaluation of perioperative care interventions that may further promote optimal surgical recovery.



# Chapter 5

## **LONG-TERM FOLLOW UP DATA ON LSG**

## **5.1 Introduction**

As mentioned in previous chapters, whilst the early to mid-term efficacy of LSG is well established, there are comparatively less data detailing long-term efficacy at five years or more. The weight loss data in the current published literature evaluating long-term results are highly variable as are the means by which they have been reported.<sup>74, 75, 221-226</sup> These studies are largely retrospective and have high attrition rates at five years. Evaluation of comorbidity has been even less reliable with inconsistent reporting and variability in the obesity-related conditions selected for evaluation, as well as how resolution is evaluated.<sup>221, 223, 225-229</sup>

This chapter presents a prospective study which evaluates the long-term outcomes of patients who have had LSG as a stand-alone bariatric procedure at our institution. The aim of this study is to determine whether short and mid-term weight loss outcomes and comorbidity resolution are sustained out to five years.

## **5.2 Methods**

### ***5.2.1 Study Design***

This study was a prospective observational cohort study approved by The University of Auckland Human Participants Ethics Committee (Ref. No. 9061). The results of this study are reported in accordance with guidelines outlined in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.<sup>230</sup>

### **5.2.2 Participants**

The study was conducted at CMDHB, between June 2013 and August 2013.

All patients who had LSG performed at CMDHB and were five or more years following surgery were eligible for inclusion in the study. These patients were identified using a pre-existing, prospectively maintained database of all patients who had LSG at CMDHB. Those patients who were less than five years from the time of their surgery and those who were unable to be contacted by telephone despite numerous attempts were excluded. For those patients who agreed, an appointment time was arranged to meet with the researcher at CMDHB. For patients who agreed to participate but were not able to travel to CMDHB due to having moved to another city, permission was obtained to send the study questionnaire in the post and to contact the current general practitioner (GP) for information pertinent to the study. During the appointment, informed consent was obtained prior to the acquisition of study measurements. For patients not able to travel, consent was obtained via telephone.

### **5.2.3 Variables and Measurement**

#### *5.2.3.1 Baseline perioperative characteristics*

Baseline demographic data (age, gender, ethnicity and date of operation), preoperative weight characteristics (total weight [kg], body mass index [BMI, kg/m<sup>2</sup>] and excess weight [kg]), were recorded from computerised patient records. The surgical technique has been described previously.<sup>58, 78</sup>



#### *5.2.3.2 Weight loss*

For each participant, yearly weight data were collected from computerised patient records. A current weight was also measured at the study follow-up appointment using an electronic scale. The yearly absolute weight loss was then calculated as were the current BMI and %EWL. The %EWL was calculated using the formula previously described by Deitel et al.<sup>42</sup>

#### *5.2.3.3 Comorbidity resolution*

Preoperative comorbidity status and medical treatment for these conditions were recorded from computerised clinical records. The comorbidities of interest were type T2DM, HTN and OSA.

Participants were asked to identify their current treatment status in one of four categories: (1) no longer on treatment; (2) reduced treatment; (3) same treatment; (4) increased treatment. Those participants who answered 'no' to any preoperative comorbidity prior to surgery but had since developed the comorbidity during the five-year follow up period were recorded as a 'new diagnosis'. The treatment status was then confirmed through the computerised clinical records and, when required, by contacting the participants GP.

Preoperative and postoperative (five years after surgery) serum haemoglobin A1c (HbA<sub>1c</sub>) were recorded from computerised patient records. The results of each patient's fasting preoperative and postoperative serum lipid profile were also recorded and analysed. The tests included in this study were total cholesterol (TC),

triglyceride, low-density lipoprotein (LDL), high-density lipoprotein (HDL) and TC:HDL ratio. Those participants who did not have a recent HbA<sub>1c</sub> or serum lipid profile were provided with a blood test form for which these fasting tests were requested.

Resolution of T2DM was defined as cessation of medical therapy and HbA<sub>1c</sub> < 6% (or less than 42.1mmol/mol).<sup>24</sup> Resolution of HTN and OSA was defined as cessation of medical therapy. Comorbidity improvement was defined as reduction in medical therapy.

#### *5.2.3.4 Assessment of surgery outcome*

Participants were asked to answer 'yes' or 'no' as to whether they considered their surgery successful. They were then asked to complete the Bariatric Analysis Reporting Outcome System (BAROS) questionnaire. This is a validated tool used to assess outcomes following bariatric surgery. It does so by using five weighted outcome measures: weight loss, comorbidity status, development of complications, need for reoperation and changes in quality of life. The BAROS outcome group scoring key has been described previously.<sup>231</sup> Comparative analysis was then performed to determine whether the participants' initial response as to whether their surgery was successful or not correlated with the BAROS score.

#### *5.2.3.5 Super-Obese*

A sub-group analysis was performed with patients stratified by whether they were super-obese (BMI ≥ 50 kg/m<sup>2</sup>) or non super-obese preoperatively. Comparative analysis was performed between the two groups for all outcomes described above.

#### *5.2.3.6 Bias*

The effect of selection bias and attrition bias are minimised as much as possible by the study being prospective and inviting all eligible patients to participate. To minimise the potential for coercion, eligible patients were sent correspondence via post from the bariatric nurse specialist at CMDHB which included a participant information sheet detailing the study aims and objectives. Patients were then contacted by phone, two to four weeks after the correspondence being sent, where they were formally invited to participate in the study.

#### *5.2.3.7 Statistics*

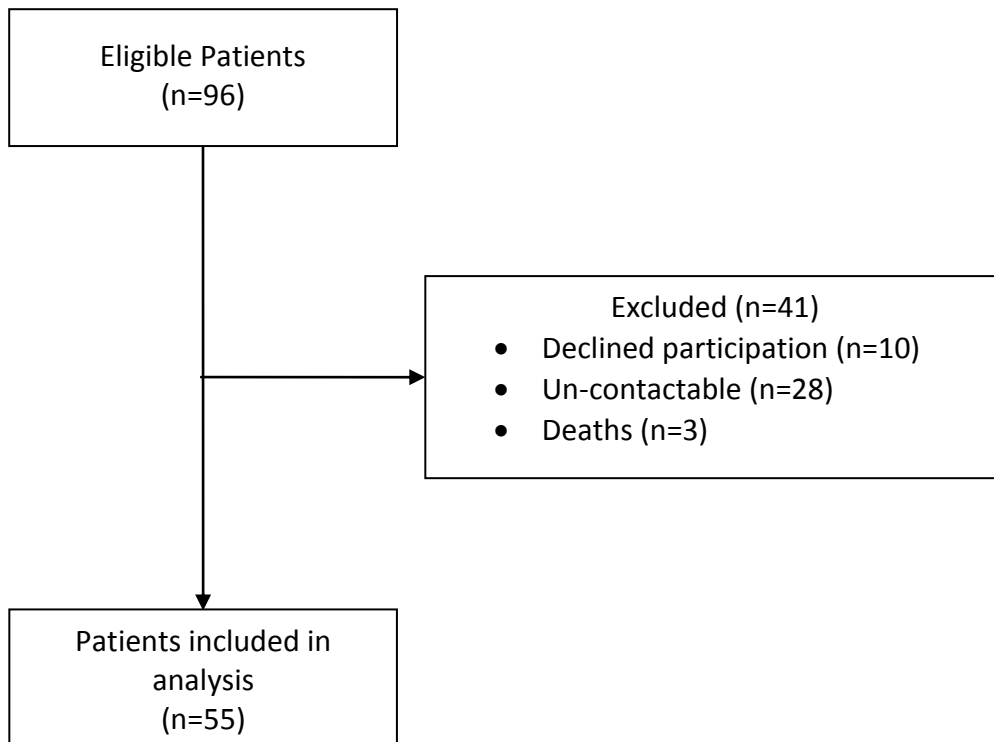
Statistical analysis was performed using SPSS (SPSS V19 Inc, Irvine CA). Continuous variable parametricity was tested using the Shapiro-Wilk test. Parametric results are presented as mean values with 95% confidence intervals (CI), while non-parametric results are presented as median values with interquartile range (IQR). For continuous variables, comparative analysis was performed using the Student's t-Test for parametric variables and Mann Whitney U test for non-parametric variables. Comparative analysis of categorical variables was performed using the Chi Square test. All data from patients lost to follow up were excluded from the analysis. Statistical significance was identified as  $p \leq 0.05$ .

### **5.3 Results**

*Figure 5.1* depicts the flow of patients through the study. All operations were performed between March 2007 and July 2008. Participants were contacted from

June 2013 to August 2013. In all, 96 patients were eligible for the study of which 55 were included in the analysis.

*Figure 5.1.* Flow of patients through the study



The mean time from surgery was 5.7 years (range, 5.1 to 6.3 years). Preoperative baseline demographic and weight characteristics are described in *Table 5.1*. There were three recorded deaths within the group of eligible patients. The causes of death were metastatic oesophageal cancer at six years postoperatively, metastatic colon cancer at five years postoperatively, and suicide at five years postoperatively. The results of these patients were not included within the comparative analysis.

*Table 5.1. Preoperative baseline demographic and weight characteristics*

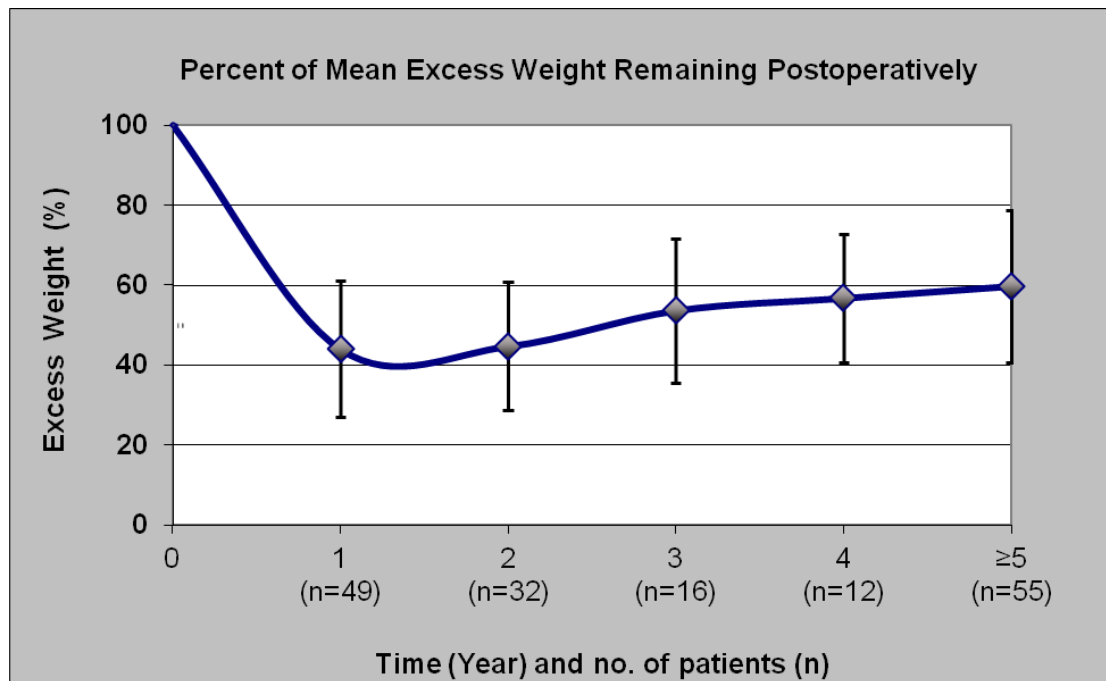
n=55	
Mean Age (CI)	46.9 (47.5, 52.3)
Female Gender (%)	45 (81.8)
Ethnicity (%)	
European	37 (67.3)
Maori	10 (18.2)
Pacific	6 (10.9)
Other	2 (3.6)
Preoperative Weight Characteristics	
Mean Weight (kg, CI)	141.3 (135.6, 146.9)
Mean BMI (kg/m <sup>2</sup> , CI)	50.7 (49.0, 52.4)
Mean Excess Weight (kg, CI)	77.2 (72.3, 82.2)

CI=95% confidence interval; kg=kilograms; m=metres; BMI=body mass index

### **5.3.1 Weight Loss**

Yearly mean %EWL is summarised in *Figure 5.2*. At five or more year follow up, %EWL ranged from 1.8% to 84.4%. Sixteen participants (29.1%) maintained %EWL of 50% or more. Only one participant had less than 10% EWL. No participant had a follow-up weight greater than their preoperative weight. The mean BMI at 5 year follow-up was 39.8kg/m<sup>2</sup> (CI, 37.8, 41.7). Twenty-four participants (43.6%) maintained a BMI greater than 40kg/m<sup>2</sup>, of which 5 (9.1%) maintained a BMI greater 50kg/m<sup>2</sup>.

Figure 5.2. Remaining %EWL



### 5.3.2 Comorbidity Resolution

Data on comorbidity status and biochemical markers are summarised in *Table 5.2* and *Table 5.3*. The majority of participants with a preoperative diagnosis of T2DM, HTN, or OSA had either resolution of their comorbidity or had a reduction in their treatment requirement at long-term follow up.

Mean HbA<sub>1c</sub> was significantly reduced for all participants. When analysed exclusively in participants with a preoperative diagnosis of diabetes, the mean HbA<sub>1c</sub> was also significantly reduced. Analysis of lipid profile demonstrated significant improvement in HDL and TC:HDL ratio.

*Table 5.2. Comorbidity status*

Co-morbidity	Preoperative Diagnoses (%)	Resolved (%)	Improved (%)	Same Treatment (%)	Increased Treatment (%)	New Diagnoses
T2DM	14 (25.5)	6 (42.9)	5 (35.7)	2 (14.3)	1 (7.1)	0
HTN	31 (56.4)	13 (41.9)	6 (19.4)	7 (22.6)	5 (16.1)	0
OSA	15 (27.3)	11 (73.3)	0	4 (26.7)	0	0

T2DM=Type 2 Diabetes Mellitus; HTN=hypertension; OSA=Obstructive Sleep Apnoea

*Table 5.3. Serum HbA<sub>1c</sub> and lipid profile*

Serum Marker	Preoperative	≥ 5 Years Postoperative	<i>p</i>
Mean HbA <sub>1c</sub> (mmol/mol, CI)			
All Participants <sup>†</sup>	46.5 (42.5, 50.5)	38.9 (36.0, 41.7)	0.011
Preoperative Diabetes	53.8 (47.4, 60.1)	47.4 (41.5, 53.3)	0.042
Lipid Profile <sup>‡</sup>			
Mean Total Chol (mmol/L, CI)	4.4 (4.1, 4.8)	4.8 (4.4, 5.1)	0.166
Mean Triglyceride (mmol/L, CI)	1.5 (1.3, 1.8)	1.6 (1.3, 1.9)	0.878
Mean HDL (mmol/L, CI)	1.1 (1.0, 1.2)	1.4 (1.3, 1.5)	0.001
Mean LDL (mmol/L, CI)	2.5 (2.2, 2.8)	2.7 (2.5, 3.0)	0.113
Ratio (Total Chol/HDL, CI)	3.9 (3.6, 4.2)	3.5 (3.1, 3.8)	0.045

Paired Samples t-test.

<sup>†</sup>Preoperative and postoperative HbA<sub>1c</sub> data was available for 31 and 44 participants respectively. Preoperative values converted from percentage of haemoglobin to mmol/mol

<sup>‡</sup>Preoperative and postoperative Serum lipid profile data was available for 51 and 41 participants respectively.

HbA<sub>1c</sub>=Haemoglobin A<sub>1c</sub>; CI=95% confidence interval; Chol=Cholesterol; HDL=High-Density Lipoprotein; LDL=Low-Density Lipoprotein

### **5.3.3 Assessment of Surgery Outcome**

A total of 49 participants completed the completed the assessment of surgery outcome questions of which 69.4% of participants stated their surgery was successful. Forty-seven participants then completed the BAROS questionnaire. The

mean BAROS score was 3.13 (CI: 2.4, 3.9; range, -2.75 to 8.00) which indicates a 'Good' outcome following surgery. The mean BAROS score of participants who considered their surgery successful was significantly greater than those who did not (4.28 vs. 0.68;  $p<0.001$ ).

#### 5.3.4 Super-Obese

There were 27 participants classified as super-obese preoperatively. *Table 5.4* and *Table 5* detail the results of the comparative analysis of weight loss in outcomes in super-obese to non super-obese. While %EWL in year 1 postoperatively was significantly higher in non super-obese than super-obese participants, there remained no difference in %EWL at any other time point. Despite this, the postoperative BMI at 5 year follow-up remained significantly higher in the super-obese participants compared to non super-obese. There were also significantly more super-obese participants who had a BMI at 5 year follow-up  $\geq 40\text{kg/m}^2$  and  $\geq 50\text{kg/m}^2$ . There were no differences in comorbidity resolution status or BAROS score.

*Table 5.4.* Super-obese vs. non super-obese – percentage excess weight loss

Follow Up Year	Super-Obese (n=25)	Non Super-Obese (n=27)	<i>p</i>
Postoperative Year 1 (CI)	50.8 (45.0, 56.6)	61.3 (53.4, 69.2)	0.031
Postoperative Year 2 (CI)	50.7 (41.8, 59.6)	59.1 (50.8, 67.3)	0.154
Postoperative Year 3 (CI)	41.3 (29.7, 52.8)	51.3 (34.2, 66.8)	0.270
Postoperative Year 4 (CI)	44.3 (31.7, 57.0)	41.2 (17.1, 66.2)	0.787
$\geq$ Postoperative Year 5 (CI)	36.8 (30.3, 43.3)	43.4 (35.1, 51.7)	0.207

Student's t-test. CI=95% confidence interval



## 5.4 Discussion

This study evaluated the long-term outcomes of patients who had LSG as a stand-alone bariatric procedure at our institution five or more years ago. While it has shown that weight regain occurs out to five years, there is maintenance of clinical benefits with respect to improvement and resolution of comorbidity status.

The %EWL at the five year follow-up point in the current study was 40.2%, which is less than other published series, with a tendency towards weight regain over time. The reported weight loss at long-term follow-up in the current literature is highly variable with %EWL ranging between 55% and 86%, though most also demonstrate a similar trend with respect to weight regain.<sup>74, 75, 223-226, 228, 229, 232</sup> Some of the difference in weight loss between the current study and other published series may be due to study design with the vast majority of previous studies being entirely retrospective introducing a significant possibility of a selection bias. Further, the other published series have had noticeably smaller sample sizes than the current study.<sup>74, 75, 224-226, 232</sup>

As mentioned previously, the current study demonstrates weight regain over time. This is consistent with other reported series. The LSG was initially used as a staging procedure prior to the biliopancreatic diversion with or without duodenal switch and gained popularity as stand-alone procedure after observers noted excellent weight loss results at early to mid-term follow-up.<sup>87, 233</sup> However, this study indicates that the maintenance of these results is less reliable and adds further evidence to

the notion that surgeons need to consider second-stage procedures for select patients at long-term follow-up.

Recent studies have attempted to identify factors which can help predict outcomes of bariatric surgery.<sup>134, 234-236</sup> However, while finding statistically significant factors, such as baseline weight and BMI, insulin resistance and age, it appears that the clinical impact of these factors on surgical recovery is less important when compared to the overall advantages of surgery in these patients. Interestingly, what is not well described is whether preoperative behaviour, such as exercise activity, correlates with surgical outcomes. It is possible that increased preoperative exercise may improve physiological reserve which could hasten surgical recovery. This could lead to an earlier return to preoperative activity levels facilitating optimisation of behavioural factors which influence weight outcomes. This in turn may help reduce long-term weight regain and subsequently optimise outcomes after LSG.

Super-obese patients had lesser weight loss outcomes after bariatric surgery when compared to non super-obese participants. The mean follow-up BMI for super-obese participants was 43.7kg/m<sup>2</sup> with over 66% of these participants having a follow-up BMI>40kg/m<sup>2</sup>. A study reporting early outcomes at our institution found LSG to be a safe and effective in super-obese patients with %EWL of 58.9% at a mean 1 year follow-up.<sup>237</sup> However, the current study shows maintenance of weight loss in super-obese patients has been less satisfactory. The results of this study in the super-obese would suggest that second stage procedures could be considered in these patients.

The success of LSG as the first stage in a 2-stage procedure has been described previously.<sup>50, 67, 238</sup>

The current study showed that 78.6% of participants with a preoperative diagnosis of T2DM either had improvement or resolution of their T2DM. It also showed that there was a significant improvement in HbA<sub>1c</sub> from 53.8 mmol/mol at baseline to 47.4 mmol/mol which, in accordance with established guidelines, correlates with exceptional diabetic control.<sup>239</sup> Previous studies have shown that LSG is effective at improving and resolving T2DM at early to mid-term follow-up.<sup>240-242</sup> The results of the current study provide further support to the comparatively smaller volume of data which suggests that improvement and resolution are effectively maintained long-term.<sup>223, 225-229, 243</sup> However, it is important to consider these results in conjunction with the heterogeneous definitions of improvement and resolution which make it difficult to compare results across studies.

This study has some limitations. The absolute sample size of the current study is limited, though it is comparably larger than other studies reporting long-term outcomes. Similarly, the attrition rate is high though this is reported sparsely in other series. The moderate attrition rate reported in the current study is aided by the prospective nature of the study and, as reported above, is comparable to those studies in which it is reported. Serum lipid profile was used as a proxy measure of cardiovascular risk. However it is difficult to interpret these results in isolation. This is due to patients being started on lipid-lowering medications for overall cardiovascular risk which is assessed in conjunction with other cardiac risk factors. It is important to

measure overall cardiovascular risk because while all-cause mortality is significantly reduced in morbidly obese patients who undergo bariatric surgery, myocardial infarction remains the most common cause of death in these patients.<sup>22</sup>

In conclusion, LSG was associated with modest weight loss results at five year follow-up with a tendency towards weight regain. Improvement in comorbidity status was maintained. Weight loss results were less favourable in the super-obese. Given these disappointing long-term results it is hypothesised that improving exercise behaviour preoperatively will improve outcomes. In order to do this, the issue of low adherence to exercise advice in obese patients must first be addressed. As mentioned previously, text-messaging may be an effective method of improving adherence to exercise preoperatively, and perhaps more importantly in the postoperatively. The following chapter will now present a systematic review of the current literature evaluating text-messaging as a way of improving physical activity.

# Chapter 6

## **A REVIEW OF THE LITERATURE EVALUATING TEXT-MESSAGING AS A MEANS TO IMPROVE LIFESTYLE INTERVENTIONS**

## 6.1 Introduction

The preceeding chapters have helped characterise and describe surgical recovery, early surgical outcomes and long-term surgical outcomes after LSG at CMDHB. What they show is that despite standardising and optimising perioperative care with an ERAS programme, there is little improvement in either recovery or outcomes. Whilst clinical procedures and care are important, a large part of the success of bariatric surgery is dependent on patient behaviour and motivation. One type of behaviour mentioned in previous chapters, for which is there little literature, is exercise activity, particularly during the perioperative period.

Preoperative exercise activity has been evaluated as a means of improving surgical recovery in various types of surgery. It is hypothesised to improve a patient's baseline physiological and functional reserve allowing them to cope better with the physiological stress of surgery. This in turn facilitates earlier surgical recovery. More interestingly, it has also been hypothesised that the improvements in baseline capacity are maintained postoperatively which may also facilitate improved surgical outcomes.<sup>113</sup>

A very significant problem with exercise advice is low adherence to the exercise prescription. Further, the current literature shows that adherence is poorly reported and that in those which do it is either highly variable or low.<sup>244</sup> Therefore, it is critical that any evaluation of preoperative exercise must attempt to optimise adherence.

A novel method for improving adherence to behavioural modification interventions such as exercise is mHealth. In recent times, mHealth, has been increasingly utilised for health promotion and disease prevention. Various mobile phone technologies have been utilised, the most widely adopted and least expensive of which is text-messaging.<sup>245</sup> Text-messaging has several advantages over other forms of mHealth technology including increased availability and general usage, low cost, ease of use, convenience and continuity of utility among resource poor populations.<sup>245</sup> It has been hypothesised to work by bridging the gap between intention and behaviour by enhancing the accessibility to one's goals and planned environmental cues<sup>246, 247</sup> and has been shown to be effective at improving adherence to long-term medication therapy, improving dietary intake, and contributing to improved rates of smoking cessation.<sup>248, 249</sup>

When compared to other types of mobile intervention, text-messaging is favoured due to its low cost and widespread availability.<sup>245, 250</sup> Furthermore, there appears to be no apparent discrepancy in the use of text-messaging with respect to gender, ethnicity and socioeconomic status, and this makes it particularly appealing when compared to other interventions, such as internet based programmes, where access is often variable.<sup>245, 251, 252</sup> Therefore, this chapter presents a systematic review of the literature evaluating the efficacy of text-message interventions for improving physical activity levels. The hypothesis is that text-messaging improves physical activity.

## 6.2 Methods

### 6.2.1 Search Strategy

A comprehensive review of the literature was performed in concordance with the methods outlined in the PRISMA statement.<sup>253</sup> The following databases were used from time of inception through to March 2012: MEDLINE, PUBMED, EMBASE, PsycINFO and Cochrane Central Register of Controlled Trials. *Table 6.1* details the combination of search terms used. References lists of recovered articles were also manually scrutinised to identify any further articles.

*Table 6.1.* Search terms

Hits Per Database	Search Terms
MEDLINE: 637	(Telemedicine or text messaging or text messag\$ or text message or txt or text or short message service or SMS or telehealth\$ or consumer health or mobile phone or cell phone or electronic intervention or electronic health or mobile health or mHealth).mp.
EMBASE: 862	
PsycInfo: 135	
Pubmed: 1107	
CENTRAL <sup>†</sup> : 149	
	AND
	(Exercise OR Exercise therapy OR physical activity).mp.
	AND
	(Randomised controlled trial or randomized controlled trial or RCT or random\$ study or random\$ trial or random\$).mp.

<sup>†</sup>CENTRAL=Cochrane Central Register of Controlled Trials

### 6.2.2. Study Selection

Studies were considered for review if they were randomised controlled trials investigating the efficacy of a text-message intervention for improving physical



activity which is defined by the World Health Organisation (WHO) as movement produced by skeletal muscle requiring energy expenditure. A text-message was defined as a written message sent through a short messaging service to appear on the viewing screen of a mobile phone. Exclusion criteria were as follows: the study was available only in abstract form, the text-message was not received by a mobile phone device, the message was in voice or picture form or the reception of the text-message intervention was optional. The decisions on article inclusion were made in consensus with the project supervisors.

### ***6.2.3 Assessment of Validity***

The author was masked to the journal and article title and study authors. An initial quality assessment of the included studies was performed using the Jadad Criteria.<sup>254</sup> The risk of bias was further assessed using the Cochrane Collaboration tool for assessing risk of bias and displayed using a summary figure generated by RevMan 5.1 (Review Manager Version 5.1, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011).

### ***6.2.4 Data Extraction***

Data extraction was carried out using predesigned electronic tables. The primary outcome of interest was assessment of change in levels of physical activity. We were specifically interested in changes in frequency and quantity. For this review, frequency was considered to be any measure of the incidence of activity per unit of time, while quantity was any measure of the amount of activity per unit of time. There were no limits on how these outcomes were assessed. It was also noted when

studies specifically measured exercise activity. Exercise activity is a sub-category of physical activity and is defined by the WHO as planned, structured and repetitive physical activity performed with the conscious purpose of improving one or more components of physical fitness. The content of the message received by participants in each study receiving the intervention was recorded.

#### **6.2.5 Data Analysis**

Though the papers included in the final review included measures of physical activity in their outcome, the method of measuring physical activity was inconsistent between each study. Variations in the text-message content, the duration of the intervention and the study cohorts made synthesis of the data vulnerable to innate heterogeneity. Calculation of standardised mean differences was attempted using RevMan 5.1. However, due to a lack of necessary data, this could not be performed. The data are therefore presented as a qualitative review.

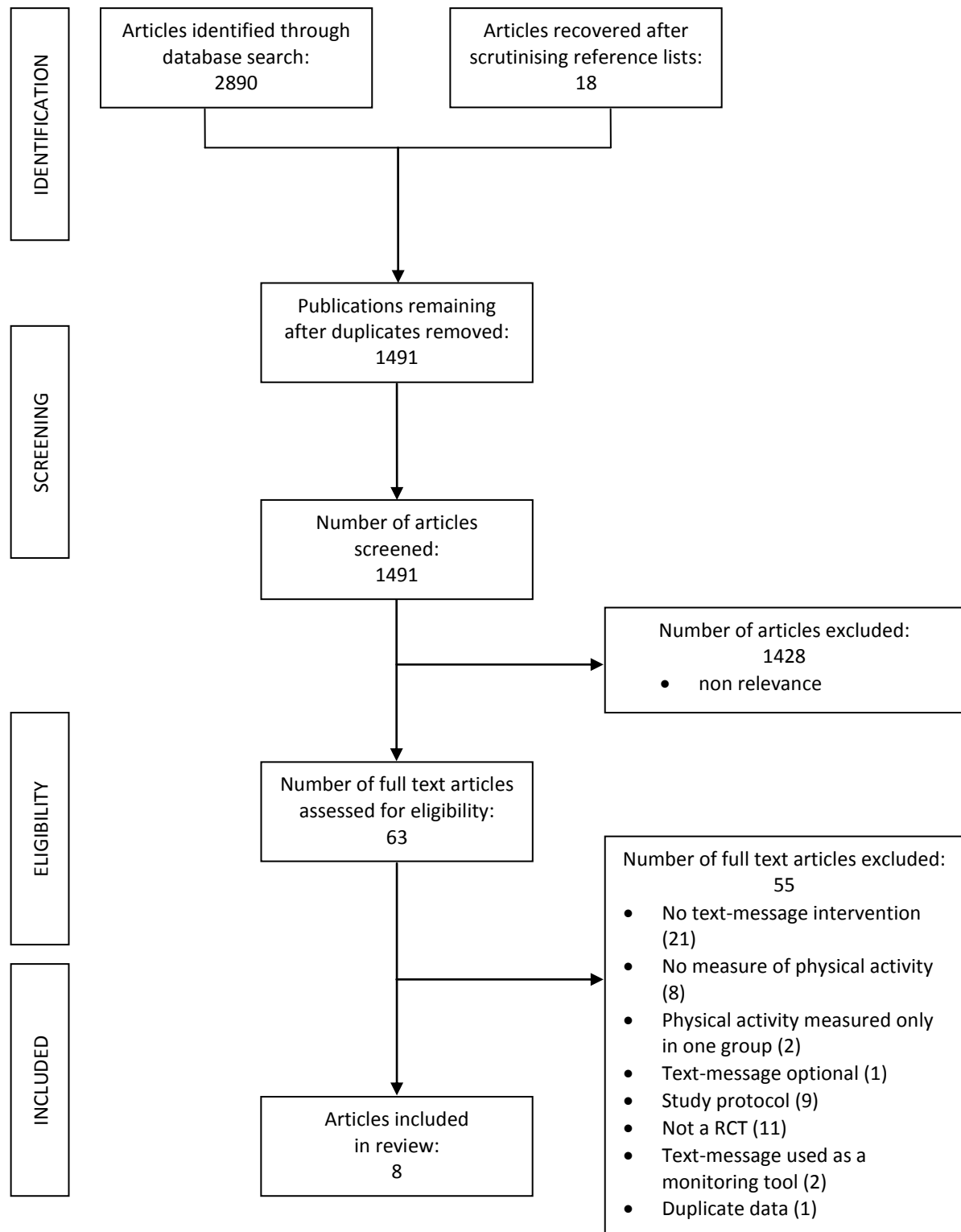
#### **6.3 Results**

There were eight studies included in this review.<sup>246, 247, 255-260</sup> Of these, one was conducted within the clinical setting of type 1 diabetes<sup>257</sup>, one was conducted in early postpartum mothers<sup>255</sup>, one was conducted in elderly African Americans<sup>256</sup>, two were conducted in school aged children<sup>259, 260</sup> and three were conducted in university students.<sup>246, 247, 258</sup> Five studies specifically assessed levels of exercise activity.

### 6.3.1. Study Characteristics

The PRISMA flow diagram for systematic reviews is presented in *Figure 6.1*.

*Figure 6.1.* PRISMA flow diagram showing study selection



This systematic review included 718 participants. Of these, 394 were randomised to a text-message intervention and 324 to a control group. The study characteristics of the included studies are described in *Table 6.2*.

### **6.3.2 Validity Assessment**

All the included studies were of poor to medium quality (Jadad Score 0 to 3). The risk of assessment bias is presented in *Figure 6.2*.

#### **6.3.2.1 Selection bias**

There was a moderate risk of selection bias. Two of the eight included studies did not adequately describe the randomisation technique.<sup>257, 258</sup> One study described randomisation performed by flipping a coin and with imbalanced allocation of two to one favouring the intervention group to amplify the intervention effects.<sup>256</sup> Five studies did not adequately describe allocation concealment.<sup>246, 256-259</sup>

#### **6.3.2.2 Performance bias**

The overall risk of performance bias was high. Only two studies adequately described blinding research personnel.<sup>247, 260</sup> No study was able to adequately blind study participants to their intervention for the duration of the study. Both studies conducted by Prestwich and colleagues and the study conducted by Sirriyeh et al attempted to minimise contamination by instructing participants to not talk to anyone about the study.<sup>246, 247, 260</sup> Sirriyeh et al also sent neutral text-messages to the control group in order to control for the independent effect of receiving a

text-message on physical activity.<sup>260</sup> The frequency of these messages was lower than those sent to participants in the intervention group.

#### *6.3.2.3 Detection bias*

Blinding of the outcome assessment was adequately described in three of the eight included studies.<sup>247, 257, 260</sup> Fjeldsoe et al described outcome assessment being conducted by a trained research assistant, yet it is unclear whether this assistant was independent of the research group.<sup>255</sup> It is unclear in the study conducted by Prestwich et al who conducted the outcome assessment.<sup>246</sup>

#### *6.3.2.4 Attrition bias and reporting bias*

The risk of attrition bias in six of the eight included studies was low.<sup>246, 247, 256, 257, 259, 260</sup> Fjeldsoe et al describe 77% and 69% retention rate at 6 week and 13 weeks follow-up respectively.<sup>255</sup> Schwerdtfeger et al provided inadequate information to determine the risk of attrition bias.<sup>258</sup> Reporting bias was present in the study by Kim et al which did not provide any results of a between-group comparative analysis.<sup>256</sup>

#### *6.3.2.5 Other sources of bias*

There were four studies which provided financial incentives or course credit to participants in the study.<sup>246, 247, 256, 258</sup> The 2009 study by Prestwich et al provided participants with £19 and gift vouchers<sup>246</sup>, while in the 2010 Prestwich study, participants were given £15 and course credit. These were given at the completion of the study.<sup>247</sup> Kim et al provided participants with US\$20 gift cards at baseline

assessment and follow-up whilst also providing US\$20 for additional texts in the intervention group.<sup>256</sup> Participants in the study by Schwerdtfeger et al were offered course credit where applicable.<sup>258</sup>


Table 6.2. Summary of study characteristics


Author (year)	Jadad Score <sup>254</sup>	Population (n)	Age	Physical Activity Outcomes	Method of Assessment	Assessment Times	Results
Fjeldsoe (2010) <sup>255</sup>	2	Early postpartum mothers (88)	Mean of 29.5yrs	Frequency (days exercising) Quantity (min exercising)	Study specific self-reported questionnaire	Baseline, 6 weeks, 13 weeks	↑ Frequency ND Quantity
Kim (2013) <sup>256</sup>	1	Elderly African American volunteers (36)	Range of 60-85yrs	Quantity (step count and Leisure Time Exercise)	Self-reported walking log and Leisure Time Exercise Questionnaire (LTEQ)	Baseline, 6 weeks	↑ Quantity
Newton (2009) <sup>257</sup>	1	Type 1 diabetic adolescents (78)	Range of 11-18yrs	Quantity (steps count and min of moderate and vigorous physical activity)	Closed pedometer and self-reported New Zealand Physical Activity Questionnaire (NZPAQ)	Baseline, 12 weeks	ND Quantity
Prestwich (2009) <sup>246</sup>	3	Healthy volunteer university students (154)	Range of 18-40yrs	Frequency (exercise sessions)	Study specific self-reported questionnaire	2 weeks pre-intervention and 4 weeks post-intervention	↑ Frequency
Prestwich (2010) <sup>247</sup>	3	Healthy volunteer university students (149)	Mean of 23.4yrs	Frequency (exercise sessions) Quantity (time performing PA)	Self Report Walking and Exercise Table (SWET)	Baseline, 4 weeks	↑ Frequency ↑ Quantity
Schwerdtfeger (2012) <sup>258</sup>	0	Healthy volunteer university students (62)	Mean of 23.7yrs	Quantity (activity counts per min using an accelerometer)	Uniaxial accelerometer (Actigraph GT1M)	1 week pre-intervention and 1 week post-intervention	ND Quantity
Shapiro (2008) <sup>259</sup>	3	Healthy volunteer families with a child aged 5-13yrs (31)	Mean of 8.7yrs	Quantity (steps per day and min of exercise per day)	Daily self-monitoring and self-recall	Baseline, 8 weeks	ND Quantity
Sirriyeh (2010) <sup>260</sup>	3	High school children (120)	Mean of 17.3yrs	Quantity (MET min)	Self-reported International Physical Activity Questionnaire (IPAQ)	Baseline, 2 weeks	↑ Quantity only if previously inactive

↑=Improved/increased; ND=No difference; min=minutes; MET=Metabolic Equivalent Task

Figure 6.2. Cochrane risk of bias tool

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Fjeldsoe 2010	+	+	-		-	+	+
Kim 2013	-		-		+	-	-
Newton 2009			-	+	+	+	+
Prestwich 2009	+		-		+	+	-
Prestwich 2010	+	+	-	+	+	+	-
Schwerdtfeger 2012			-			+	-
Shapiro 2008	+		-		+	+	+
Sirriyeh 2010	+	+	-	+	+	+	+

 =low risk

 =high risk

Clear squares=unclear risk



### **6.3.3 Description of the Intervention Groups**

Six of the included studies described text-message intervention groups with text-messages used in conjunction with an additional intervention.<sup>246, 247, 255, 257-259</sup>

Fjeldsoe et al used multiple additional interventions in parallel with the text-message intervention including formal physical activity goal setting sessions, a fridge magnet exercise planner, and a service where reminder messages were sent to a nominated support person.<sup>255</sup> Newton et al utilised open pedometers in both groups in conjunction with the text-message intervention as a motivating factor to exercise.<sup>257</sup> Schwerdtfeger et al included an education session for the text-message intervention group.<sup>258</sup>

In the 2010 study by Prestwich et al, all of the participants receiving the text-message intervention were also required to form an implementation intention prior to the intervention period. Forming an implementation intention required participants to deal directly with intention-behaviour discrepancies by writing down in advance of the exercise where they would exercise and what exercise activity they would partake in.<sup>247</sup> In contrast, the 2009 study conducted by Prestwich et al had patients randomised to either a text-message intervention group where patients received a text-message only, or a text-message intervention group where they received a text-message in conjunction with their implementation intention.<sup>246</sup>

The text-message intervention group in Shapiro et al received three education sessions over the course of the study which was also the case for the control group and an additional intervention group which utilised paper diaries to monitor physical

activity.<sup>259</sup> The text-message intervention group would then send two text-messages per day for eight days and receive corresponding replies to these outgoing messages. The text-message intervention groups in the studies by Kim et al and Sirriyeh et al received text-messages only.<sup>256, 260</sup>

#### **6.3.4 Text-Message Content**

There was considerable variation in the composition of the text-message intervention used in each study (*Table 6.3*).

Fjeldsoe et al based their messages on five constructs of social cognitive theory.<sup>255</sup> Differential timing was applied to sending the messages so that some constructs were targeted more than others at different times of the intervention period, whereas other messages were sent consistently.

In the study conducted by Sirriyeh et al, participants randomised to the text-message intervention groups received either purely instrumental text-messages focusing on reminding patients of their plan to exercise, affective text-messages focusing on the anticipated outcome of exercise as a means of motivation, or a combination of the two.<sup>260</sup> In contrast, Newton et al and Schwerdtfeger et al sent instrumental reminder messages to all participants reminding them to exercise and, in Newton et al, to wear their pedometer.<sup>257, 258</sup>

Table 6.3. Summary of text-message content

Author	Text-Message Content	Duration of Texts	Control Group
Fjeldsoe <sup>255</sup>	Individually tailored messages of which the content targeted 5 constructs of social cognitive theory	12 weeks	No text
Kim <sup>256</sup>	One-way direct motivational messages with the option to reply with comment or question or comment	6 weeks	No text
Newton <sup>257</sup>	'Motivational' reminder to message to exercise and wear the pedometer	12 weeks	No text
Prestwich <sup>246</sup>	Messages to remind them to exercise. The content of the message was specifically chosen by each participant	4 weeks	No text
Prestwich <sup>247</sup>	1 of 2 messages: (1) messages reminding the participants of their plan to exercise (2) messages reminding participants of the goal of their exercise	4 weeks	No text
Schwerdtfeger <sup>258</sup>	Messages to remind participants of their activity plan	1 week	2 CG's with one receiving education alone
Shapiro <sup>259</sup>	Instructed to send 2 messages daily. They would receive automated feedback	8 weeks	2 CG's with one using a paper diary for activity monitoring
Sirriyeh <sup>260</sup>	1 of 3 messages: (1) instrumental messages reminding participants of their plan to exercise (2) affective messages designed to motivate patients to want to exercise (3) combination of instrumental and affective	2 weeks	2 dummy texts (1 per week) with neutral content

In their 2009 study, Prestwich et al individualised the content of the text-message by asking participants what they would like the message to say, how many times they would like it to be sent and when they would prefer the message to be sent.<sup>246</sup> Despite this apparent freedom, they were encouraged to choose content which acted as a reminder to exercise. In their 2010 study, Prestwich et al standardised the message content sent to participants but randomised the participants to receive text-messages reminding them of their plan to exercise or reminding them of the final goals they wished to achieve from their exercise.<sup>247</sup>

Shapiro et al used the text-message intervention primarily in a monitoring capacity for physical activity, dietary and television-watching behaviour.<sup>259</sup> Participants would report on their self monitored behaviour through the text-message intervention and receive immediate automated responses which provided feedback as to whether or not they were on track with their behaviour goals. While Kim et al also included an optional outgoing text-message component for their text-message intervention, the intervention was primarily incoming motivational text-messages.<sup>256</sup>

### **6.3.5 Physical Activity (Frequency)**

Three of the eight included studies measured changes in physical activity frequency.<sup>246, 247, 255</sup> All three found text-messages to have a positive effect on exercise frequency.

Fjeldsoe et al defined frequency as the number of days participants engaged in physical activity per week.<sup>255</sup> Their study found that participants receiving text-

messages had a significantly greater increase in the frequency of moderate to vigorous physical activity when compared to the control group when measured at 6 weeks (text group: 1.32 days; control: 0.25 days;  $p=0.003$ ), and 13 weeks (text group: 1.82 days; control group: 0.24 days;  $p=0.001$ ).<sup>255</sup> This was also found when assessing the frequency of walking for exercise at 6 weeks (text group: 1.65 days; control group: 0.28 days;  $p=0.05$ ), but not at 13 weeks (text group: 1.08 days; control group: 0.73;  $p>0.05$ ).<sup>255</sup>

Using a self-reported questionnaire in their 2009 study, Prestwich et al found that participants receiving text-messages significantly increased the mean number of completed exercise sessions per participant at the end of the intervention period (0.62 sessions of physical activity increased to 1.50 sessions;  $p=0.03$ ).<sup>246</sup> However, this occurred only in participants who had created implementation intentions. In their 2010 study, Prestwich et al found participants receiving a text-message significantly increased the number of days they spent exercising by at least two days when compared to the control group.<sup>247</sup>

### **6.3.6 Physical Activity (Quantity)**

Seven of the eight included studies measured changes in physical activity quantity. Of these, only three found that text-messages had a positive effect.<sup>247, 256, 260</sup>

In their 2010 study, Prestwich et al found that the total amount of exercise physical activity undertaken was significantly higher in participants receiving text-messages when compared to the control group.<sup>247</sup> However, this effect was only apparent if

the content of the message was a reminder of a participants plan to exercise rather than a reminder of the goal of their exercise ( $p=0.03$ ).

Sirriyeh et al found that the quantity of moderate intensity physical activity (metabolic equivalent task [MET] of 4) increased over the entire two week study period on average by 31.5 minutes per participant.<sup>260</sup> However, post-hoc analysis lacked sufficient power to identify differences between the various groups. When stratified by baseline level of physical activity into 'active' and 'inactive', Sirriyeh et al found that the increase in moderate physical activity was only in participants classified as 'inactive' and in particular in those patients receiving affective text-messages.

Kim et al found that only participants in the text-message intervention group significantly increased the quantity of physical activity as evidenced by an increased mean daily step count (5452 steps increased to 6530 steps;  $p=0.05$ ).<sup>256</sup> All participants increased their exercise physical activity levels over the six week intervention period as measured by the activity MET values using leisure time exercise questionnaire.

Newton et al assessed quantity of physical activity by comparing daily step counts using a closed pedometer.<sup>257</sup> They also compared the total number of minutes of moderate to vigorous physical activity per week. They found no difference between the groups at 12 week follow-up in either daily step count (between group difference of 819 steps;  $p=0.4$ ) or weekly activity minutes (between group difference

of 9.9 minutes;  $p=0.9$ ).<sup>257</sup> Shapiro et al also measured daily step counts and minutes of exercise and found no difference over time or between the study groups.<sup>259</sup>

Schwerdtfeger et al used a uniaxial accelerometer to measure activity counts per minute and found no difference in physical activity between the text-message intervention group and education group or control group.<sup>258</sup> They also found that, while the control group significantly reduced their mean activity count over the time of the intervention period, no such reduction was seen in the text-message intervention group or the education group. Fjeldsoe et al assessed quantity of physical activity by comparing the amount of time each participant spent partaking in moderate to vigorous physical activity and walking for exercise. They found no difference between the two groups for either outcome.<sup>255</sup>

### **6.3.7 Exercise Activity**

Five studies specifically assessed exercise activity of which four found text-messages to improve exercise behaviour.<sup>246, 247, 255, 256, 260</sup> The improvements were predominantly in exercise frequency while Kim et al demonstrated improvement in exercise quantity.<sup>256</sup> Sirriyeh et al found no difference.<sup>260</sup> These results are summarised in *Table 6.2*.

## **6.4 Discussion**

This qualitative systematic review includes eight randomised controlled trials investigating the efficacy of a text-message intervention at improving physical activity levels. It has shown that the current literature reports largely mixed results

which are likely to be influenced by the low methodological quality of included studies.

One of the encouraging results of the systematic review was that four out of five studies specifically assessing exercise activity found text-messages to be associated with improved exercise frequency.<sup>246, 247, 255, 256</sup> While the WHO defines exercise as planned, structured, repetitive and purposeful physical activity with the goal of improving or maintaining one or more components of physical fitness, no such definition was provided or alluded to by the included studies. It is also important to recognise that all the studies used subjective means of assessment such as self-reported questionnaires and recall which varied from study to study. There were also very few data which provided a convincing objective assessment of physiological outcomes of the exercise activity. This likely reflects the difficulty in choosing an appropriate physiological measure as well as a lack of knowledge relating to the optimal intervention duration.

Text-message interventions were found to improve the frequency of physical activity, though it appeared to have less of an effect on the quantity of physical activity. A potential reason for this is a limitation in the text-message content. While the majority of studies described content to remind and encourage physical activity, only a select few studies described sending instructional messages describing what exercise to perform. This is in some part due to a lack of consensus around the optimal exercise prescription so that while it is easy to tell people to be more active based on the current literature it is far more difficult to advise what activity to do.



Another likely reason is a lack of adequate power to detect a significant difference though again, due to limitations in the current knowledge around optimal exercise prescription, it is difficult to know what would constitute a clinically significant improvement in activity quantity. Interestingly, two of the studies which did detect an improvement in activity quantity did so only after post-hoc subgroup analysis.<sup>247, 260</sup> Of these, Sirriyeh et al found that quantity improved only in patients who were physically inactive to begin with. This may help with the design of future studies which may choose to stratify patients by activity level *a priori*.

Though there is evidence of text-messages improving other lifestyle behaviours, there are comparatively less data to specifically demonstrate its effectiveness at improving physical activity. In a previous systematic review on the use of cell phones in healthcare, Krishna et al found cell phones and text-messages enhanced standard healthcare processes and outcomes.<sup>248</sup> However, of the 25 studies included, only seven used a text-message intervention as the sole electronic intervention and only one study included physical activity as an outcome.<sup>248</sup> Williams et al also reviewed the current literature investigating text-messaging as a health promotion tool to aid adherence to daily physical activity and concluded that it was effective at doing so.<sup>261</sup> However, the method of the review was not well described and was unable to convincingly answer the original research question.

The current literature evaluating text-message interventions compares the efficacy of text-messages to a control. However there are few data evaluating its effectiveness in comparison to other electronic or mobile health innovations. The

use of internet and web-based interventions have gained wide spread popularity with the volume of current literature describing its efficacy continuing to grow. In a recent systematic review evaluating the contribution of electronic health interventions to improving physical activity, of the 31 included studies, 22 evaluated internet or web-based applications.<sup>249</sup> Though the majority of literature showed no difference, these studies were also limited by their methodological quality.

This review has some limitations. Firstly, as with other reviews investigating the efficacy of electronic interventions in modifying health behaviour, the findings of this review are to be interpreted with caution due to the limited quality of the included studies. The studies were particularly prone to performance bias due to inadequate blinding of participants and personnel. In their review of electronic weight interventions, Nguyen et al reported on the inadequacy of randomisation, allocation and blinding procedures. They also reported on the limitations of the conclusions due to innate heterogeneity of the included studies.<sup>252</sup> This is a feature of all systematic reviews evaluating the efficacy of text-message intervention as a behaviour modifying intervention, including this current review, which has meant that no quantitative analysis of the current data has been reported.<sup>245, 248, 249, 251, 261</sup>

An unconventional solution to the problem of blinding is to use randomised consent or Zelen's design which randomises patients to exposure or control prior to consent.<sup>262</sup> This way, participants can give fully informed consent to receive either experimental care or standard care without knowing which form of care is the exposure and which is the control. By having independent investigators consent

participants, this can facilitate double-blinded study design. An example of this type of study design is Fisher et al which compared lumpectomy to mastectomy in the treatment of breast cancer.<sup>263</sup> Furthermore, the numbers of participants in this review are small which reduces its generalisability.<sup>248</sup>

Another limitation of this review was that the evaluation of physical activity was not standardised across the included studies. There are various self-reported questionnaires available which can be used to assess physical activity such as the internationally validated IPAQ.<sup>264</sup> The studies provide few objective measures of physical activity which should be considered in future studies. This may involve greater use of objective methods, such as closed pedometers for walking, to evaluate physical activity. It may also involve better evaluation of the clinical and health consequences of the physical activity such as weight loss, changes in biochemical markers or changes in body composition. Lastly, the results of the current review were unable to delineate the optimal duration for a text intervention. The duration of texts ranged from 2 weeks to 12 weeks but this appeared to have little effect on the cumulative results.

In conclusion, whilst the current literature is largely mixed, a number of studies do show that text-messages improve physical activity, particularly exercise. However, given the small volume of the literature and the low methodological quality of the studies, the null-hypothesis can neither be accepted nor rejected. With a design based on the results of the current and previous chapters, the following chapter

presents the results of a randomised controlled trial evaluating a text-message intervention to improve adherence to preoperative exercise advice.

# Chapter 7

**A RANDOMISED CONTROLLED  
TRIAL EVALUATING  
WHETHER TEXT-MESSAGING  
IMPROVES ADHERENCE TO  
PREOPERATIVE EXERCISE ADVICE**

## 7.1 Introduction

As demonstrated in Chapter 5, the long-term efficacy of LSG is underwhelming with modest weight loss and weight regain out to five years. This potentially could be related to limited change in lifestyle behaviour, particularly exercise behaviour. As shown in Chapter 6, text-messaging could improve preoperative exercise and this could lead to an improvement in postoperative exercise activity.

Text-message interventions are an increasingly popular means of improving adherence to other lifestyle interventions. Text-messaging has several advantages over other forms of mHealth including increased availability and general usage, low cost, ease of use, convenience and continuity of utility amongst resource-poor populations. Text-messaging has been shown to improve both health behaviour and clinical outcomes, and has been shown to be most effective at improving smoking cessation rates with studies from New Zealand reporting close to 30% improvement.<sup>245, 265, 266</sup> It has also been shown to be effective in promoting significant weight loss and decreased waist circumference in overweight and obese patients as well as in improving dietary habits. However, its effect in improving levels of physical activity is unknown.

We hypothesised that bariatric surgery patients receiving text-messages would have superior adherence to preoperative exercise advice which would continue in the postoperative period, and that improved exercise levels would correlate with improved surgical recovery.

## **7.2 Methods**

This study was a parallel design 1:1 ratio randomised controlled trial, approved by the Northern X Regional Ethics Committee of New Zealand and registered with clinicaltrials.gov (NCT01607177). The study is reported in accordance with the CONSORT statement.<sup>230</sup>

### **7.2.1 Participants**

All patients undergoing LSG as a stand-alone bariatric procedure within an established ERAS protocol were eligible for the trial. The ERAS protocol was established at CMDHB at the elective hospital Manukau Surgery Centre and, during the course of the trial, at Middlemore Hospital.<sup>267</sup> The surgical technique is standardised and has been described in Chapter 1.<sup>58</sup> Patients who did not have access to a cell-phone which could receive text-messages, did not have their surgery at either ERAS facility, were less than four weeks before their date of surgery at the time of recruitment or did not undergo LSG were excluded.

Eligible patients were identified from preoperative planning databases, maintained by administration staff at CMDHB. They were contacted and invited to participate. After the collection of baseline data, patients were recruited. Participants were further encouraged to aim to complete 30 minutes of light to moderate exercise a day, five days each week, as per the standard advice given by the bariatric surgeons and bariatric nurse specialist. They were also given a standardised exercise advice sheet. Once recruited, participants were randomly allocated to either the EG or CG.

### **7.2.2 Interventions**

Participants allocated to the EG received daily text-messages for four to six weeks leading up to surgery. These were a mixture of messages designed to remind or encourage patients to persevere with exercise as part of their prehabilitation prior to bariatric surgery. The template and format of the messages were modeled on text-messages used in another study after obtaining permission from the principal investigator.<sup>268</sup> The messages were uploaded to and sent from a web-based New Zealand Short Message Service provider (©One Way SMS, Dunedin, NZ). Whilst participants were able to receive the text-messages, they were made aware that there was no capacity to reply. The maximum intervention period was six weeks. The maximum number of texts-messages one participant could receive was 43 messages. An acceptable rate of message failure was set at <5% *a priori*.

In comparison, participants allocated to the CG did not receive daily text-messages. The potential number of text-messages was recorded for all participants to determine if there was a difference in the length of the intervention period. The total number of successfully sent text-messages was recorded once treatment allocation was revealed.

### **7.2.3 Outcomes**

Demographic data, including age, gender and ethnicity, were collected. Preoperative weight characteristics recorded were total weight (kg), BMI ( $\text{kg/m}^2$ ), and total excess weight (kg). Preoperative comorbidity status was assessed by the ASA score and the incidence of T2DM, HTN, hyperchol and OSA from computerised clinical records.



The primary outcome of this study was adherence to preoperative exercise advice. During preoperative visits, all patients were advised to partake in a minimum of 30 minutes of light to moderate exercise per day for five days a week. This equates to a minimum of 150 minutes of light exercise per week and is in accordance with recommendations for exercise activity outlined by the American College of Sports Medicine (ACSM).<sup>269</sup> A MET is a standardised unit of measurement used to estimate the physiological energy cost of a given physical activity. For reference, 1 MET is the energy cost of a body at rest. A standardised system for the assignment of MET value to exercise activity intensity was developed *a priori* where light exercise activity was assigned 3 METs, moderate exercise activity assigned 4 METs, and vigorous exercise activity assigned 6 METs. The MET value was then multiplied by the number of minutes the exercise activity was performed over a week to give MET minutes ( $\text{METmin}^{-1}$ ). The  $\text{METmin}^{-1}$  for each recorded exercise activity was then added together to give total weekly  $\text{METmin}^{-1}$ . Where the exercise intensity of an activity was unclear, the 2011 compendium of physical activity was used to convert an activity to METs.<sup>270</sup> Adherence to exercise advice was defined as a participant partaking in a minimum of  $450 \text{ METmin}^{-1}$  per week.

Exercise activity was assessed using the validated International Physical Activity Questionnaire (IPAQ).<sup>271</sup> The IPAQ is a questionnaire which is used to obtain comparable measurements of physical activity across five domains of activity over a period of seven days. For the purposes of this study, the domain of interest was 'recreation, sport and leisure time physical activity', which was utilized as the measure of exercise activity.

There were multiple secondary outcomes. They included mean number of minutes and days spent exercising per week and mean percentage excess weight loss (%EWL) after the intervention period preoperatively. Due to practical difficulties in attaining accurate measurements of physiological fitness with maximal and sub-maximal exercise tests in morbidly obese patients, functionality was evaluated as a surrogate measure of overall fitness.<sup>269</sup> This was assessed using the change in the distance walked during the 6 minute walk test (6MWT) at the end of the intervention period. The 6MWT was conducted in accordance with standardised guidelines.<sup>272</sup>

Median LOS during index admission and readmission rates were recorded and analysed. LOS during readmission was added to index LOS to give total LOS which was also analysed. Postoperative complications were prospectively recorded and graded according to the Clavien-Dindo classification system.<sup>101, 102</sup>

#### **7.2.4 Follow up**

The IPAQ was completed at baseline, at the conclusion of the intervention period preoperatively and six weeks postoperatively. The number of minutes and days spent exercising per week were also recorded at these times. The 6MWT was completed at baseline and at the conclusion of the intervention period preoperatively only. The %EWL was calculated and recorded at the conclusion of the intervention period preoperatively. Readmissions and postoperative complications were recorded up to 30 days postoperatively with readmissions defined as a subsequent hospital stay more than 24 hours.

### **7.2.5 Sample Size**

In a sample of patients awaiting bariatric surgery at our institution, only 20% were adherent to preoperative exercise advice, which was similar to the adherence reported in the study by Carli et al.<sup>118</sup> As reported earlier, text-messages intervention have been shown to improve adherence to other lifestyle interventions by up to 30%.<sup>10-12</sup> With the study also aiming to evaluate the effect of preoperative exercise on surgical recovery, it was felt that a 30% difference in adherence between the EG and CG would provide adequate power to evaluate this. Therefore the study was powered to detect a 30% increase in the proportion of patients partaking in the prescribed minimum of 450 METmins<sup>-1</sup> of exercise activity per week preoperatively. This required a sample size of 88 participants with 44 randomly allocated to each arm ( $\alpha=0.05$ ;  $\beta=0.8$ ).

### **7.2.6 Randomisation Sequence Generation and Allocation Concealment**

Randomisation was performed by an independent researcher not involved in patient recruitment or outcome assessment using a computerised random number generator. Group allocations were placed in sequentially numbered opaque sealed envelopes in blocks of ten thereby ensuring concealment of allocation.

### **7.2.7 Blinding**

The study was single-blinded with participants unblinded as to their treatment allocation. Two investigators were responsible for inputting data regarding text-group allocation. Other staff remained blinded to allocation. In order to maintain blinded staff, all participants were informed at the time of recruitment not to

disclose whether or not they received text-messages. Data analysis at the end of the study was also blinded with patient allocation concealed as 'Group 1' and 'Group 2'. Treatment allocation was only revealed once data analysis was completed.

All recruited participants were scheduled for surgery. Participants who did not proceed to surgical intervention were subsequently excluded from the comparative analysis (*Figure 7.1*). Participants who had surgery postponed to a later date or brought forward to an earlier date during the intervention period were included in the comparative analysis and analysed on an intention-to-treat basis.

### **7.2.8 Statistics**

Statistical analysis was performed using SPSS (SPSS V19 Inc, Irvine CA). Continuous variable parametricity was tested using the Shapiro-Wilk test. Categorical variables were analysed using McNemar's test and the Chi squared test for within-group and between-group comparisons respectively. Continuous parametric variables were analysed using the paired t-test and student t-test for within-group and between-group comparisons respectively. Continuous non-parametric variables were analysed using the Wilcoxon Signed Rank test and Mann Whitney U test for within-group and between-group comparisons respectively. Continuous parametric variables are presented as means with standard deviation, whilst continuous non-parametric variables are presented as medians with inter-quartile range. Missing data were excluded from the comparative analysis. Statistical significance was identified as  $p \leq 0.050$ . All data were analysed on an intention-to-treat basis.

### 7.3 Results

*Figure 7.1* depicts the CONSORT diagram detailing the progress of patients through the trial. In all, 137 patients were assessed for eligibility between August 2012 and September 2013. Of these, 102 participants were randomised to either the EG or CG of which 88 were included in the final analysis (44 in each arm).

The baseline characteristics of the two groups are described in *Table 7.1* and *Table 7.2*. Overall, 97% of text-messages were sent successfully. Within-group analysis showed that the EG had a significant increase in mean weekly METmin<sup>-1</sup>, median number of days per week during which exercise was performed, mean number of weekly exercise minutes, and adherence to exercise advice over the intervention period (*Table 7.2*). In comparison, no such changes were observed in the CG. Both groups significantly increased their results in the 6MWT.

*Table 7.2* summarises the post-intervention exercise outcomes of the two groups. Adherence to exercise advice was significantly higher in the EG than the CG. The median number of days participants partook in exercise activity was also significantly higher in the EG than the CG. There was no difference in median weekly METmin<sup>-1</sup>, exercise minutes or the 6MWT.

*Table 7.2* and *Table 7.3* summarise the results of the analysis comparing clinical measures of surgical recovery and exercise activity measured at 6 week postoperative follow-up. There was no difference between the two groups for any outcome.

Figure 7.1 CONSORT flow diagram

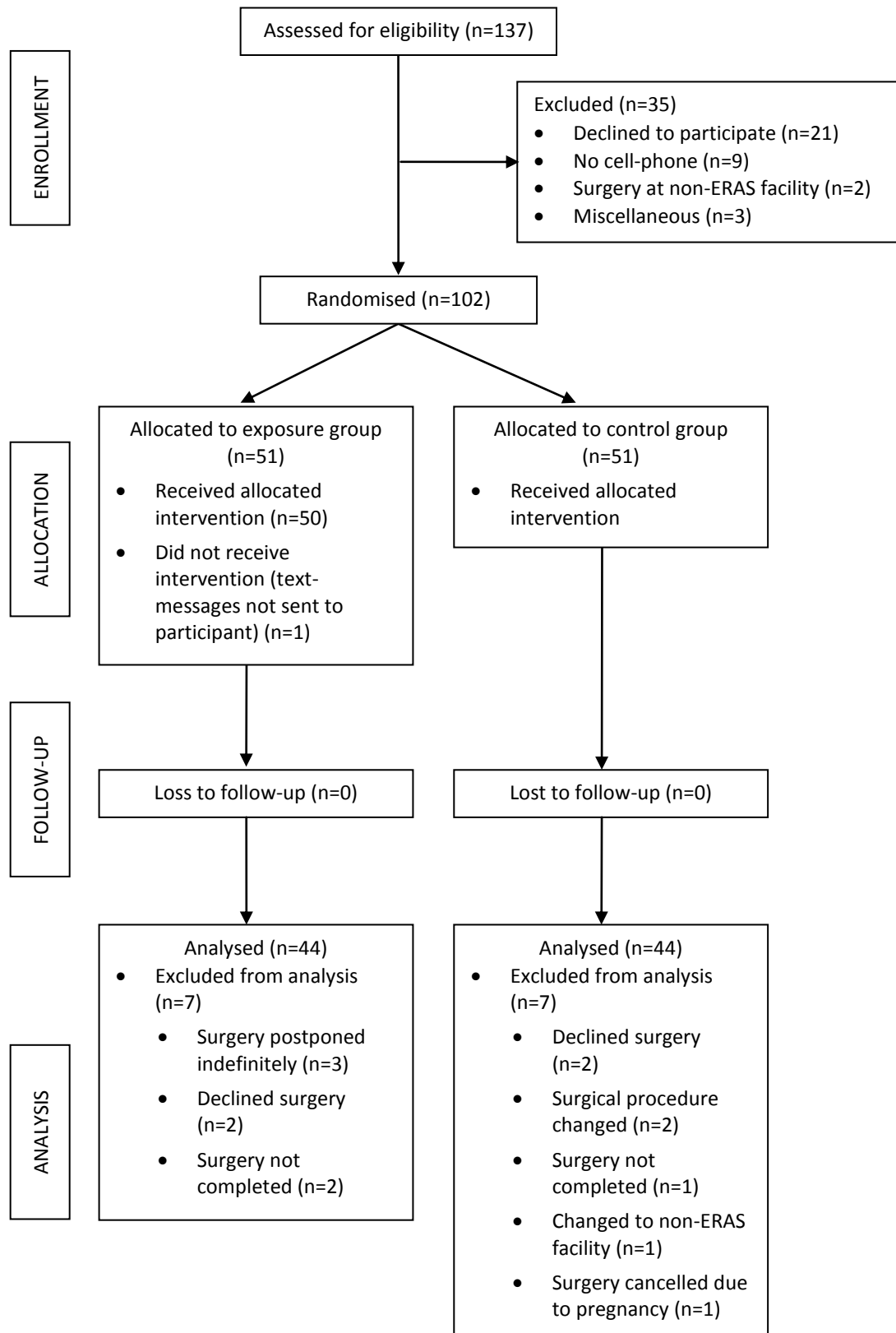


Table 7.1. Baseline Characteristics of the Study Population

Variable	EG (n=44)	CG (n=44)
Mean age (SD)	43.9 (6.9)	43.7 (8.8)
Female Gender (%)	32 (72.7)	29 (65.9)
Ethnicity (%)		
European	17 (38.6)	21 (47.7)
Maori	16 (36.4)	12 (27.3)
Pacific	4 (9.1)	5 (11.4)
Indian/Asian	2 (4.5)	1 (2.3)
Other	5 (11.4)	5 (11.4)
ASA Score(%)		
I	1 (2.3)	0 (0)
II	28 (63.6)	33 (75.0)
III	15 (34.1)	11 (25.0)
Preoperative Weight Characteristics		
Mean Weight (kg, SD)	125.9 (26.2)	128.7 (22.8)
Mean BMI (kg/m <sup>2</sup> , SD)	45.0 (6.5)	44.3 (7.3)
Mean Excess Weight (kg, SD)	62.0 (22.0)	62.0 (20.8)
Preoperative Comorbidity Status		
T2DM (%)	29 (65.9)	22 (50.0)
HTN (%)	25 (56.8)	22 (50.0)
Hyperchol (%)	19 (43.2)	21 (47.7)
OSA (%)	13 (29.5)	18 (40.9)
Median length of intervention period (number of text-messages, range)	33 (20-43)	36 (18-43)

EG=exposure group; CG=control group; SD=standard deviation; ASA=American Society of Anesthesiologists; kg=kilograms; BMI=body mass index; m=metres; T2DM=type 2 diabetes mellitus; HTN=hypertension; Hyperchol=hypercholesterolaemia; OSA=obstructive sleep apnoea

Table 7.2. Analysis of Exercise Activity

Variable	EG (n=44)	CG (n=44)	p value
<i>Baseline Exercise Activity</i>			
Mean Weekly METmins <sup>-1</sup> (SD)	745·8 (1265·3)	684·0 (748·1)	
Median days of exercise per week (IQR)	3 (4, 0)	4 (5, 0)	
Mean minutes of exercise per week (SD)	188·9 (299·1)	196·6 (213·2)	
Adherence to prehabilitation (%)	21 (47·7)	24 (54·5)	
Mean 6MWT (metres, SD)	462·0 (70·3)	496·4 (60·6)	
<i>Post-intervention Exercise Activity</i>			
Mean Weekly METmins <sup>-1</sup> (SD)	1196·9 (1662·4) <sup>a</sup>	871·4 (991·8)	0·268 <sup>§</sup>
Median days of exercise per week (IQR)	5 (4, 6) <sup>a</sup>	3 (2, 6)	0·046 <sup>†</sup>
Mean minutes of exercise per week (SD)	279·9 (283·7) <sup>a</sup>	254·1 (261·0)	0·658 <sup>§</sup>
Adherence to prehabilitation (%)	34 (77·3) <sup>a</sup>	25 (56·8)	0·041 <sup>‡</sup>
Mean 6MWT (metres, SD)	501·5 (66·9) <sup>a</sup>	513·6 (64·0) <sup>a</sup>	0·444 <sup>§</sup>
<i>Postoperative (6 week follow-up)<sup>b</sup></i>			
Mean Weekly METmins <sup>-1</sup> (SD)	469·2 (728·5)	428·5 (579·5)	0·789 <sup>§</sup>
Median days of exercise per week (IQR)	2·5 (0, 4)	2 (0, 4)	0·811 <sup>†</sup>
Mean minutes of exercise per week (SD)	136·3 (215·7)	126·3 (149·3)	0·815 <sup>§</sup>
Adherence to prehabilitation (%)	11 (30·6)	17 (43·6)	0·244 <sup>‡</sup>

<sup>§</sup>Students t-Test

<sup>†</sup>Mann Whitney U Test

<sup>‡</sup>Chi-Square Test

<sup>a</sup> Within-group comparative analysis shows a significant increase in the exercise activity variable post-intervention from baseline ( $p < 0.050$ )

<sup>b</sup> Data available for 36 and 39 participants in the EG and CG respectively

EG=exposure group; CG=control group; METmins<sup>-1</sup>=metabolic equivalent task minutes; IQR=interquartile range; 6MWT=6 minute walk test; SD=standard deviation



Table 7.3. Analysis of Surgical Recovery

Variable	EG (n=44)	CG (n=44)	p value
Median index LOS (days, IQR)	2 (1, 2)	2 (1, 2)	0.340 <sup>†</sup>
Readmissions	7	5	0.534 <sup>‡</sup>
Median total LOS (days, IQR)	2 (1, 3)	2 (1, 2)	0.709 <sup>†</sup>
Total complications	10	7	0.418 <sup>‡</sup>

<sup>†</sup>Mann Whitney U Test

<sup>‡</sup>Chi-Square Test

LOS=length of hospital stay; IQR=interquartile range

## 7.4 Discussion

This study shows that a daily text-message intervention improves adherence to preoperative exercise advice in patients awaiting LSG. The improvement in preoperative exercise activity did not improve fitness, was not associated with improved surgical recovery and was not sustained at postoperative follow-up.

To our knowledge, this is the first RCT to evaluate text-messaging in the setting of surgery. Previous RCTs have shown that text-message interventions have limited efficacy in improving physical activity.<sup>255, 256</sup> However, the current study has demonstrated more positive results. This may be influenced by the unique clinical environment within which the study was conducted where patients have already gone through a selection process to have surgery. The selection criteria for bariatric surgery and the tangible goal of the surgery itself may indeed select patients who have a greater degree of motivation and commitment towards lifestyle modification which may increase the susceptibility of these participants to the intervention.

The improvement seen in the uptake of preoperative exercise advice in the EG did not correlate with an improvement in surgical recovery and this is consistent with the current literature.<sup>244</sup> Little is known in regards to what the optimal preoperative exercise prescription should be. The prescription used in the current study was based on minimum recommendations from the ACSM which are not specific for morbidly obese patients.<sup>269</sup> This prescription was used because many of the patients were inactive at baseline. Also, morbid obesity is associated with physical and physiological limitations which inhibit exercise capacity and tolerance.<sup>273</sup> Lower intensity exercise may improve adherence, but the improvement in physiological function may be too small to affect clinical outcomes.


The optimal intervention period remains unclear. Four weeks has been suggested as the minimum exercise period preoperatively for patients to gain benefit. However, the optimal period to increase the chance of obtaining benefit in morbidly obese patients may be much longer. Recent studies have also shown that the majority of obese patients are metabolically more morbid and unfit than non-obese patients.<sup>274</sup> Therefore, regardless of the magnitude of improvement in physiological function, the physiological reserve may be too low to allow the improvements to affect clinical outcomes.

By improving baseline physiological and functional capacity, increased exercise activity preoperatively was hypothesised to facilitate increased postoperative exercise activity. However, at six weeks postoperative follow-up, activity levels in both groups had reduced to less than baseline. While the follow-up period may have

potentially been too short to allow full recovery from the postoperative fatigue<sup>140</sup>, fatigue levels have been shown to return to baseline two weeks after LSG.<sup>267</sup> Adherence to postoperative exercise prescription after bariatric surgery has previously been shown to be low<sup>275</sup>, and it is therefore possible that once the incentive of surgery is gone, motivation to exercise diminishes.

This study has some limitations. Participants in this study were unblinded due to the nature of the intervention. This may have led to contamination and a subsequent increase in exercise activity in the CG which could underestimate the true effect of the intervention. There was no true objective measure of physiological fitness. Maximal and sub-maximal measures of physiological fitness are difficult to perform in morbidly obese patients. Whilst the 6MWT was used as a proxy of fitness, it largely assesses functional capacity. The study was powered for adherence to preoperative exercise advice and lacked the statistical power to assess the secondary outcomes measured during the study.

In conclusion, although the text-message intervention improved adherence to preoperative exercise advice, this did not improve physical fitness or surgical recovery in patients undergoing bariatric surgery. Postoperatively, exercise levels returned to baseline in all participants suggesting that text-messaging in this group of patients does not have a long-term effect on exercise behaviour.



# Chapter 8

## DISCUSSION

## **8.1 Summary of Results**

This thesis had the following two aims: 1. to determine whether optimised perioperative care improved outcomes and decreased costs associated with surgery; 2. to determine whether improved exercise behaviour improved early outcomes after bariatric surgery.

As discussed in Chapter 1, the obesity epidemic is a challenging health problem. Currently bariatric surgery remains the only evidence-based method of treating severe obesity. At CMDHB, LSG is offered as a stand-alone bariatric procedure but, as shown in Chapter 2, the established benefits may come at the expense of significant morbidity, prolonged convalescence and impaired surgical recovery. Modifying and optimising perioperative care was hypothesised to improve surgical recovery and outcomes.

Chapters 3 and 4 detailed the design and successful implementation of a bariatric specific ERAS programme used to standardise perioperative care. The ERAS programme was shown to reduce postoperative LOS, despite crossover between the EG and CG, and be cost-effective when compared to a propensity score matched HCG. However, it did not lead to an improvement in clinical outcomes.

Chapter 5 described the long-term outcomes of patients having LSG at CMDHB and found that the early results described in Chapter 2 were not maintained at five year follow-up. Lifestyle factors had been identified in Chapter 3 as a potential limiting factor to achieving satisfactory surgical outcomes. In particular, preoperative

exercise behaviour had yet to be optimised which was hypothesised to be in large due to reduced adherence to exercise advice. Text-messaging interventions had previously been identified as a way to improve adherence to lifestyle interventions and the systematic review in Chapter 6 suggested that they may also be effective at improving exercise activity.

Finally, Chapter 7 evaluated whether preoperative exercise behaviour, optimised by a text-message intervention, improved surgical recovery and outcomes and found no difference between the EG and CG.

## **8.2. Future Studies**

This thesis has generated several interesting research questions which as yet remain unanswered.

A recent systematic review has shown that perioperative costs are reduced in patients having surgery within an ERAS programme compared to standard perioperative care. However, the data demonstrating cost-effectiveness of ERAS in bariatric surgery is very limited. Whilst Chapter 4 has shown a reduction in costs, the study was not powered to evaluate perioperative costs. Future studies are required to determine the true cost-effectiveness of ERAS within the setting of bariatric surgery as well identifying optimal methods of measuring cost-effectiveness which can be standardised and utilised in other studies.

Although optimising adherence, the thesis did not address optimisation of the exercise prescription. As demonstrated above, preoperative exercise did not affect fitness or surgical recovery. A potential reason for this may be that the exercise prescribed was too light. High-intensity exercise activity has been shown to significantly improve physiological fitness in obese patients.<sup>276</sup> Therefore, by prescribing higher-intensity exercise, it may be possible to elicit a large enough improvement in fitness to affect clinical outcomes.

Shah et al have previously shown there to be high rates of attrition and poor adherence to high-volume exercise programmes in obese patients following bariatric surgery.<sup>275</sup> It is possible that the incentive of surgery in conjunction with a text-message intervention may increase extrinsic motivation enough to minimise non-adherence.

As well as being unable to determine the optimal exercise intensity, it is impossible to tell from the results of the thesis what the optimal timing is for the exercise intervention. As mentioned in Chapter 3, the optimal timeframe for preoperative exercise ranges from as little as four weeks through to three months. It is possible that the six week intervention period was too short and did not allow enough time for the established benefits of exercise to accumulate to the point that it would be enough to affect clinical outcomes. Jakicic et al previously showed in an RCT that stratifying patients by exercise intensity and duration did not result in a significant difference in the improvement seen in cardiorespiratory fitness.<sup>277</sup> However, this study was not conducted in morbidly obese patients.

Further to optimising the exercise prescription, while the thesis provided advice and suggestions for exercise, it did not attempt to formalise the exercise activity by providing explicit exercise instructions or by supervising the exercise activity. Further studies are required to identify the components of an optimal exercise programme for patients awaiting bariatric surgery. This would require identifying areas of fitness that need to be targeted in order to provide the best chance of affecting clinical outcomes, whether the best fitness results are achieved when exercising in groups or alone, whether exercise programmes need to be tailored specifically to the individual, and whether there is a difference in the fitness results of patients who undergo either supervised or unsupervised exercise activity.

Preoperative exercise has consistently been shown to be ineffective at improving surgical recovery. However, it is still unknown whether there is an improvement in surgical outcomes after the surgery, such as postoperative weight loss and comorbidity resolution. Observational studies have previously shown weight loss after bariatric surgery to correlate with preoperative exercise levels<sup>278</sup>, but currently there is no level one or two evidence to support this finding.

This thesis has also shown that improved preoperative exercise activity or text-messaging did not improve postoperative exercise activity. It is widely acknowledged that while early surgical outcomes are largely attributable to the surgery, the long-term maintenance of weight loss and comorbidity resolution are primarily due to behavioural modification. Unpublished outcomes from a recent prospective study at our institution have shown disappointing weight loss results at five year follow-up



which may indicate a lack of long-term behavioural change. Therefore, it may also be useful to determine whether extending the exercise prescription and text-message intervention postoperatively would lead to improved outcomes in the long-term.

### **8.3. Conclusion**

From the sum of the studies presented above, the following conclusions can be drawn.

Standardising and optimising perioperative care reduces LOS and perioperative costs after LSG but does not improve clinical outcomes.

Text-messages are an effective method for improving adherence to prehabilitation in patients awaiting bariatric surgery but do not change exercise habits in the immediate term. Improving adherence levels did not correlate with improved preoperative fitness, surgical recovery or postoperative exercise activity. Therefore, prehabilitation is not an ineffective method of improving surgical recovery after bariatric surgery within an established ERAS programme.

The decision to proceed to bariatric surgery can be made independent of a patient's preoperative exercise activity level.



# Appendix A

## CHAPTER 4

### PATIENT INFORMATION SHEET

## Participant Information Sheet

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Principal Investigator: Associate Professor Andrew Hill, Department of Surgery, Middlemore Hospital- Phone 09-276 0044 ext 8424 ahill@middlemore.co.nz

---

### Introduction

You are invited to take part in a clinical research study. Your participation is entirely voluntary (your choice). You do not have to take part in this study and if you choose not to take part this will not affect any future care or treatment.

---

### About the study

A successful outcome from surgery is dependent on many factors. Most doctors agree that successful surgery is a combination of excellent care before, during and after surgery. As knowledge about the human body increases, we have developed many strategies to enhance a patient's recovery.

One way to improve recovery after surgery is to provide the best possible care around the actual operation and to ensure that this is done for every patient with no elements missed out. This can be achieved using protocols and checklists that care-givers can follow. We and other doctors internationally have trialled this for other operations such as operations for colorectal cancer with great success. We have now designed such a checklist to be used for patients having a Laparoscopic Sleeve Gastrectomy weight loss operation.

We are inviting you to participate in our study. We wish to investigate whether implementing this care pathway for Laparoscopic Sleeve Gastrectomy decreases complications, increases energy levels after surgery and increases the speed of recovery.

We are planning to invite 110 patients who are going to have a laparoscopic sleeve gastrectomy to take part in this study. If you agree to participate, you will be randomly chosen to receive care according to this care pathway or through the current care pathway. Your participation in this trial will not affect the standard of care you receive in any way. Participation in this study will not prevent you from having healthcare in the future.

During your stay in hospital, we will record data from the patient notes regarding how long you stay in hospital, whether you experience any complications.

---

## **Risks**

You may notice that many of the interventions are not vastly different from those already provided. However, it is their coordinated delivery which we think may make a difference over many patients. We do not anticipate any risk from this *intervention* in addition to the risks already posed by the operation and perioperative care.

---

## **Participation**

Your participation is entirely voluntary (your choice). You do not have to take part in this study. This will not affect your treatment in any way. If you do agree to take part you are free to withdraw from the study at any time, without having to give a reason and this will in no way affect your continuing health care.

---

## **General**

Further information regarding this study can be obtained from Dr Daniel Lemanu, Department of Surgery (Tel 276 0044 ext 2100 or 021 063 6264)

An interpreter will be provided if you would like one. You may have a friend, family, or whanau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

There will be no costs or payments to you in order to participate in this study.

---

## **Advocacy**

If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act:

Telephone (NZ wide): 0800 555 050

Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

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## **Confidentiality**

No material which could personally identify you will be used in any reports on this study. Your hospital records are confidential. Your name or any other personally identifying information will not be used in reports or publications resulting from this study. The information about your medical history and medications required to interpret the research results will be identified using a code to ensure your confidentiality.

---

## **Compensation**

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention, Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no

cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

---

### **Results**

The final results of the research will not be known until May 2012. At the conclusion of the study, results will be made available by mail to those who have requested this on the consent form. However, if you are not sure about whether you have requested the study results, you can contact Dr Daniel Lemanu, Research Fellow, Middlemore Hospital (ph 09 2760044 ext 2100).

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**Statement of Ethical Approval:** This study has received ethical approval from the Northern X Regional Ethics Committee.



# Appendix B

## **CHAPTER 4**

### **CONSENT FORM**

## ERAS in LSG study- CONSENT FORM

English	I wish to have an interpreter.	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.	Ae	Kao
Cook Island	Ka inangaro au i tetai tangata uri reo.	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.	E	Nakai
Samoaan	Ou te mana'o ia i ai se fa'amatala upu.	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea.	Io	Ikai
Deaf	I wish to have a sign language interpreter.	Yes	No
	Other languages to be added following consultation with relevant communities.		

I have read and I understand the information sheet dated 29/04/11 for volunteers taking part in the study designed to assess **whether a care pathway improves outcomes following laparoscopic sleeve gastrectomy**. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

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

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my future health care/continuing health care.

I have had this project explained to me by \_\_\_\_\_.

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

I understand that the treatment, or investigation, will be stopped if it should appear harmful to me.

I understand the compensation provisions for this study.

I have had time to consider whether to take part.

I know who to contact if I have any side effects to the study.

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

I agree to an approved auditor appointed by either the ethics committee, or the regulatory authority or their approved representative, and approved by the Northern X Ethics committee reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I wish to receive a copy of the results YES/NO

Alternatively “I would like the researcher to discuss the outcomes of the study with me”.  
YES/NO

4.11 I agree to my GP or other current provider being informed of my participation in this study/the results of my participation in this study YES/NO

5. I \_\_\_\_\_ (full name) hereby consent to take part in this study.

**Date**

**Signature**

**Contact Phone Number for researcher:**

Dr Lemanu 021 063 6264 Daniel.Lemanu@middlemore.co.nz

**Project explained by**

**Project role**

**Signature**

**Date**



# Appendix C

## **COUNTIES MANUKAU DISTRICT HEALTH BOARD ENHANCED RECOVERY AFTER SURGERY PROTOCOL**

## **FAST-TRACK CARE PATHWAY FOR PATIENTS UNDERGOING LSG**

### *Preoperative components*

1. Assessment of nutritional status
  - a. Preoperative weight loss
  - b. Dietician input
  - c. 2-4 weeks of optifast
2. Optimisation of pre-existing co-morbidities
3. Identifying social factors impacting on postoperative course
  - a. Social work services made available in high need cases
4. Education
  - a. including formal goal-setting and tour of ward
  - b. explanation of pathway
5. Glycaemic control
6. Prehabilitation
  - a.  $\geq 40$  minutes aerobic exercise 5-6 days per week until time of surgery

*Peri- and intraoperative components*

1. Pre-op carbohydrate loading
  - a. 2 drinks 2 hours before surgery
2. Pre-medication
  - a. Omeprazole at induction, 40mg IVI and to continue for 6 weeks
3. Analgesia
  - a. IV Paracetamol (first dose), Parecoxib 40mg
  - b. Fentanyl/morphine as per anaesthetist
4. Antiemetics
  - a. Dexamethasone 8mg IV at induction
  - b. Ondansetron, Droperidol and Scopaderm patch
5. Thromboprophylaxis
  - a. No chemoprophylaxis preoperatively
  - b. TEDS
  - c. Foot pumps
6. Fluid management
  - a. Fluid restriction
7. Method of anaesthesia
  - a. Propofol for induction in conjunction with fentanyl and non-depolarising neuromuscular agents.
  - b. After induction, propofol replaced by desflurane.
  - c. Medication dosed as per ideal body weight
  - d. PEEP at 10cm H<sub>2</sub>O intraoperatively
8. Local anaesthetic
  - a. Total of 40ml 0.5% bupivacaine with adrenaline administered prior to placement of all laparoscopic port sites
  - b. Intraperitoneal LA (10ml 0.75% ropivacaine diluted to 50ml with 0.9% normal saline solution) administered prior to dissection of stomach around site of operation
9. Antibiotic cover
10. Active warming preoperatively
  - a. Warmed blanket in the preoperative area

### *Postoperative components*

1. Analgesia
  - a. Rescue PCA if and as required
  - b. Sevredol 10mg and tramadol for rescue pain
  - c. Parecoxib at 24 hours post op
2. Antiemetics
  - a. Scopaderm patch and regular ondansetron
  - b. Cyclizine and droperidol as required
3. Thromboprophylaxis
  - a. Clexane daily 40mg from morning of day 1 post op
4. E&D/supplementation
  - a. Maintenance IV fluids
    - 60ml/hr plasmalyte to be stopped 0800 day 1 post op
    - Clear oral fluids (COFs) within 2 hours post op
      1. Aim to complete 1L of COF's 24hours from time of RTW
    - Bariatric free oral fluids once completed 1L of COF's
  - b. Supervise fluid intake
5. Post operative oxygenation
  - a. Supplemented O<sub>2</sub> to keep sats > 90%
6. Other
  - a. Incentive spirometry
  - b. All drains (e.g. IDC, NGT) to be removed in recovery
  - c. Early ambulation
    - Mobilise to chair 2 hours post op
    - Mobilise 20m 3-4 hours post op
    - Full mobilisation 4-8 hours post op
  - d. Discharge criteria (aim 24 hours post op)
    - Adequate pain relief with oral non-opioid analgesic (paracetamol and arcoxia)
    - Wound satisfactory
    - No postoperative complications
    - P <90, T ≤ 37.6, RR ≤ 20
    - Uneventful technical procedure
    - Ambulatory
    - Oral intake 1-1.5L per 24 hours (should include 1L of Clear Oral Fluids and additional Free Oral Fluids)
7. Early Follow up
  - a. Phone call day 1 and week 1 post discharge
  - b. 2 week follow up
  - c. Phone numbers to call 24 hours for advice (research fellow roster)



# Appendix D

## **SURGICAL RECOVER SCALE QUESTIONNAIRE**

## BEFORE THE OPERATION

# Investigating recovery after weight loss surgery

Some things to be aware of while you complete this questionnaire:

- There are **no right or wrong answers** to the questions
- It is best not to spend too long thinking about any one answer; normally the first response is best
- Some questions may seem very similar, but for measurement purposes it is often important to ask a question in slightly different ways. We would appreciate your patience and willingness to answer all of the questions.
- Please remember your answers to this questionnaire are **completely confidential**

*Thank you for taking the time to fill out this questionnaire*

Please think about the **last two days** and tick the box that applies best to you

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time
<b><i>During the last two days:</i></b>						
01. I have been feeling energetic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02. I have been feeling worn out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
03. I have been feeling vigorous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
04. I have achieved very little with the day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
05. I have been feeling fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
06. Physically, I have felt tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
07. I have had to restrict how much I try to do in a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
08. I have been feeling lively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



The following questions ask how much fatigue interferes with the things you can do.

For activities you aren't doing, for reasons other than fatigue, tick the box labelled "N/A" (not applicable).

Examples of why you might tick the "N/A" box include:

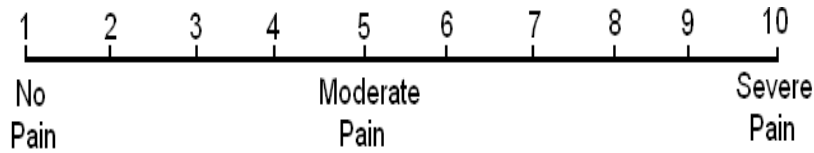
- You are still in hospital and are not required to do things like run errands.
- You are not the person who usually cooks in your household.
- Or, you have a wound that is vacuum-sealed and you are not able to do household chores because of this.

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time	N/A
<b><i>During the last two days I have had enough energy to:</i></b>							
09. Read a newspaper/book or watch TV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Dress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Visit or socialise with family & friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Engage in leisure or recreational activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Shop or do errands	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

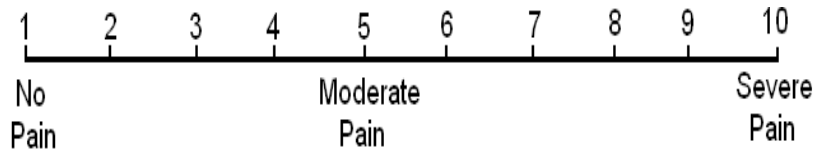
**Preop: Please fill this out before your operation**

Circle the appropriate answer or write in the space provided

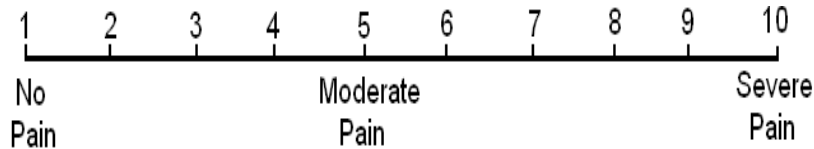
1. How would you describe your pain level at the present time, **while in bed?**



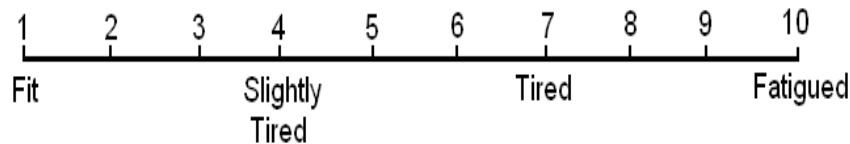
2. How would you describe your pain level at the present time, **when you move?**



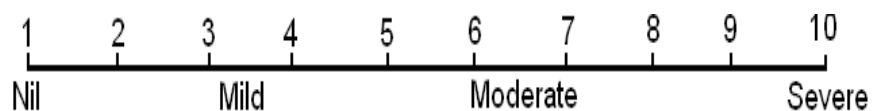
3. How would you describe your pain level at the present time, **when you cough?**



4. How would you describe your energy levels at the present time?



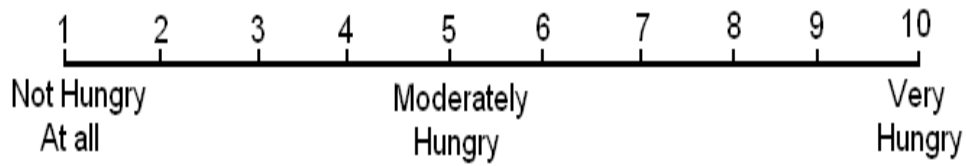
5. How would you describe your level of nausea at the present time?



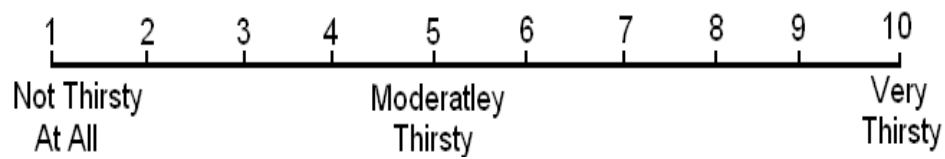
6. Have you vomited in the past 6 hours?

- a. No
- b. Yes, only once
- c. Yes, 2-3 times
- d. Yes, more than 3 times

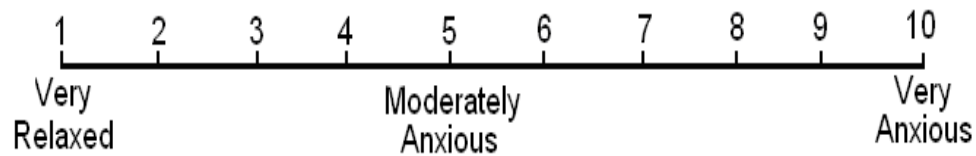
7. At the present time, do you feel:  
Hungry?



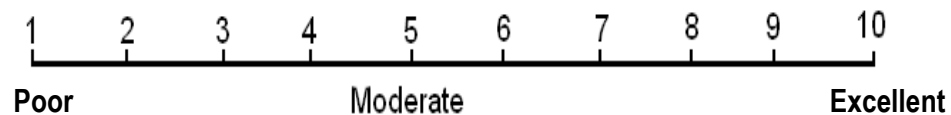
Thirsty?



8. How would you describe your anxiety level at the present time?



9. How would you rate the quality of care you have received thus far?



## AFTER THE OPERATION

## MORNING OF DAY 1

Please think about the **last two days** and tick the box that applies best to you

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time
<b><i>During the last two days:</i></b>						
01. I have been feeling energetic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02. I have been feeling worn out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
03. I have been feeling vigorous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
04. I have achieved very little with the day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
05. I have been feeling fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
06. Physically, I have felt tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
07. I have had to restrict how much I try to do in a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
08. I have been feeling lively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask how much **fatigue** interferes with the things you can do.

For activities you aren't doing, for reasons other than fatigue, tick the box labelled "N/A" (not applicable).

Examples of why you might tick the "N/A" box include:

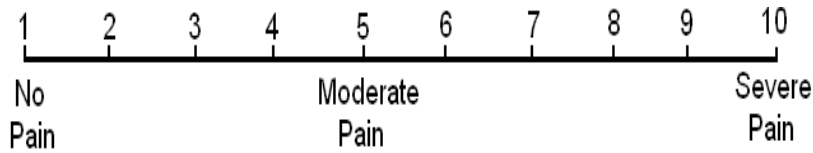
- You are still in hospital and are not required to do things like run errands.
- You are not the person who usually cooks in your household.
- Or, you have a wound that is vacuum-sealed and you are not able to do household chores because of this.

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time	N/A
<b><i>During the last two days I have had enough energy to:</i></b>							
09. Read a newspaper/book or watch TV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Dress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Visit or socialise with family & friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Engage in leisure or recreational activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Shop or do errands	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

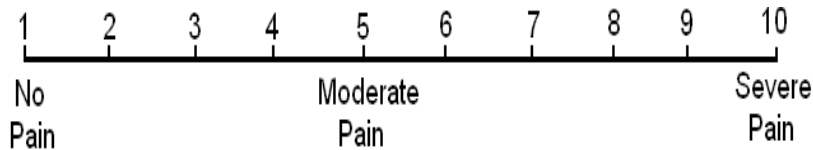
**Please fill this out on the morning of day 1 following your operation**

Circle the appropriate answer or write in the space provided

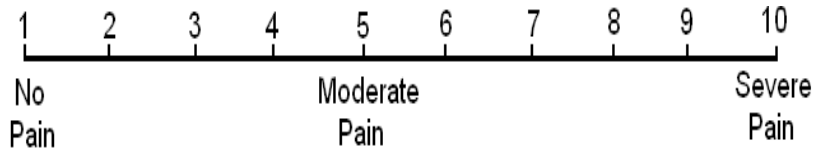
1. How would you describe your pain level at the present time, **while in bed?**



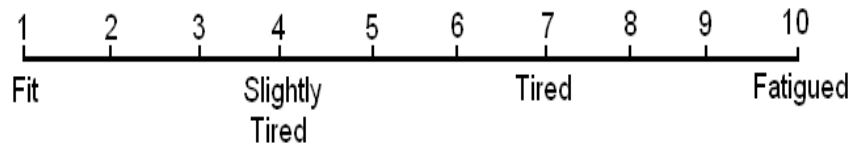
2. How would you describe your pain level at the present time, **when you move?**



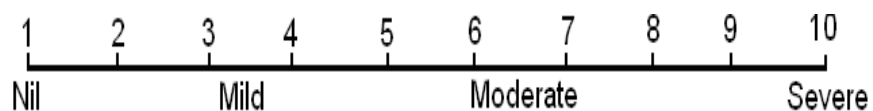
3. How would you describe your pain level at the present time, **when you cough?**



4. How would you describe your energy levels at the present time?



5. How would you describe your level of nausea at the present time?

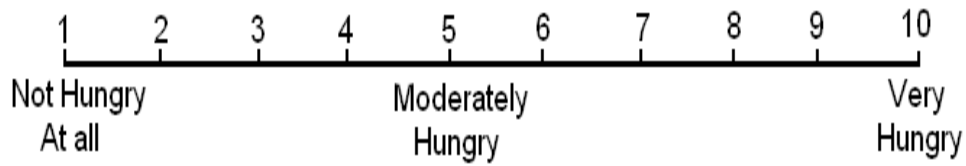


6. Have you vomited in the past 6 hours?

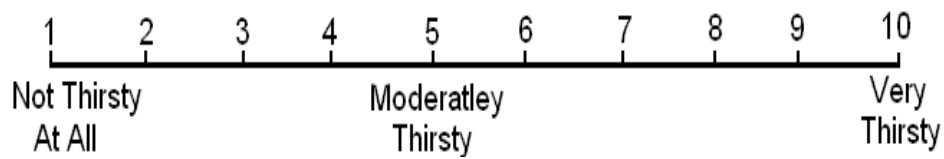
- a. No
- b. Yes, only once
- c. Yes, 2-3 times
- d. Yes, more than 3 times



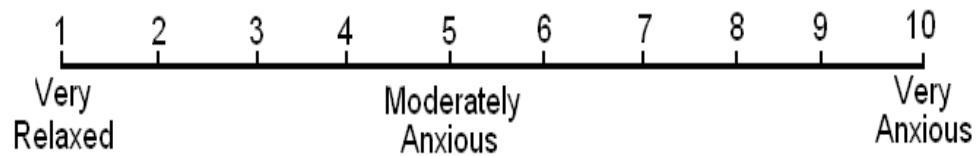
7. At the present time, do you feel:  
Hungry?



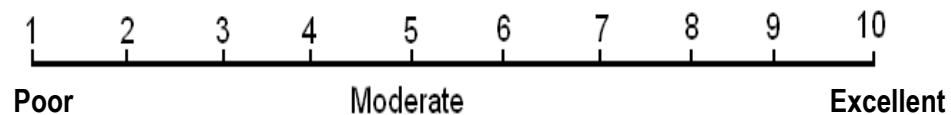
Thirsty?



8. How would you describe your anxiety level at the present time?



9. How would you rate the quality of care you have received thus far?



## MORNING OF DAY 7

Please think about the **last two days** and tick the box that applies best to you

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time
<b><i>During the last two days:</i></b>						
01. I have been feeling energetic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02. I have been feeling worn out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
03. I have been feeling vigorous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
04. I have achieved very little with the day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
05. I have been feeling fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
06. Physically, I have felt tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
07. I have had to restrict how much I try to do in a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
08. I have been feeling lively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask how much **fatigue** interferes with the things you can do.

For activities you aren't doing, for reasons other than fatigue, tick the box labelled "N/A" (not applicable).

Examples of why you might tick the "N/A" box include:

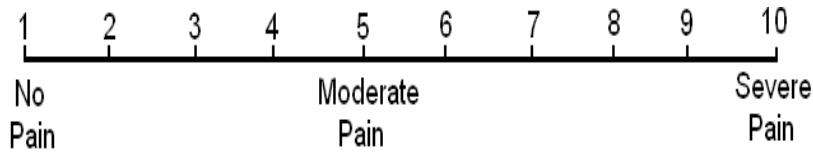
- You are still in hospital and are not required to do things like run errands.
- You are not the person who usually cooks in your household.
- Or, you have a wound that is vacuum-sealed and you are not able to do household chores because of this.

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time	N/A
<b><i>During the last two days I have had enough energy to:</i></b>							
09. Read a newspaper/book or watch TV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Dress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Visit or socialise with family & friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Engage in leisure or recreational activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Shop or do errands	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

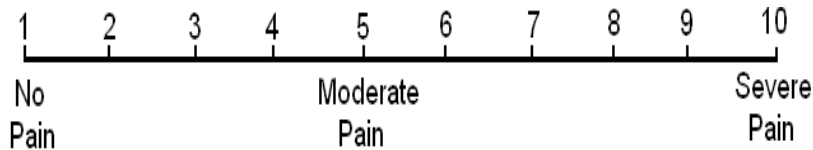
**Please fill this out on the morning of day 7 following your operation**

Circle the appropriate answer or write in the space provided

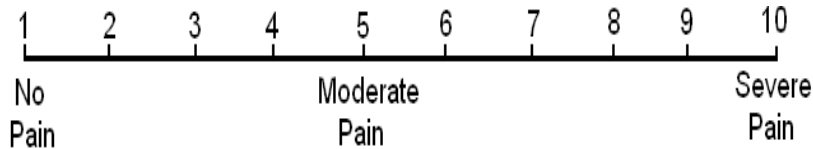
1. How would you describe your pain level at the present time, **while in bed?**



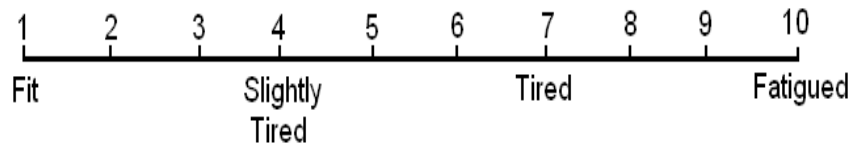
2. How would you describe your pain level at the present time, **when you move?**



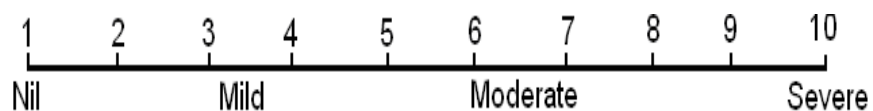
3. How would you describe your pain level at the present time, **when you cough?**



4. How would you describe your energy levels at the present time?



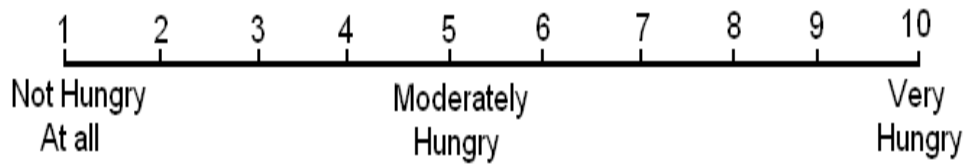
5. How would you describe your level of nausea at the present time?



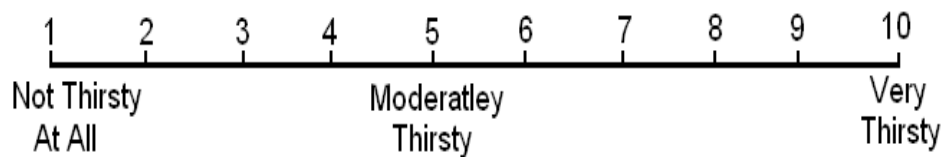
6. Have you vomited in the past 6 hours?

- a. No
- b. Yes, only once
- c. Yes, 2-3 times
- d. Yes, more than 3 times

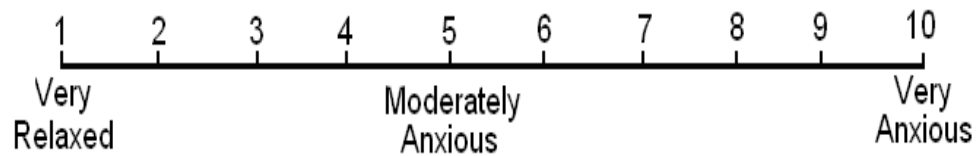
7. At the present time, do you feel:  
Hungry?



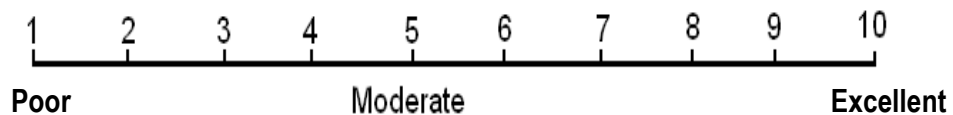
Thirsty?



8. How would you describe your anxiety level at the present time?



9. How would you rate the quality of care you have received thus far?



## MORNING OF DAY 14

Please think about the **last two days** and tick the box that applies best to you

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time
<b><i>During the last two days:</i></b>						
01. I have been feeling energetic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02. I have been feeling worn out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
03. I have been feeling vigorous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
04. I have achieved very little with the day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
05. I have been feeling fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
06. Physically, I have felt tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
07. I have had to restrict how much I try to do in a day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
08. I have been feeling lively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



The following questions ask how much **fatigue** interferes with the things you can do.

For activities you aren't doing, for reasons other than fatigue, tick the box labelled "N/A" (not applicable).

Examples of why you might tick the "N/A" box include:

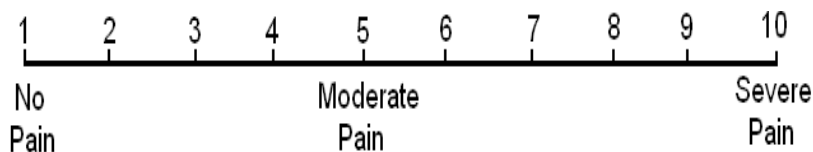
- You are still in hospital and are not required to do things like run errands.
- You are not the person who usually cooks in your household.
- Or, you have a wound that is vacuum-sealed and you are not able to do household chores because of this.

	Not at all	Almost never	Some of the time	Fairly often	Very often	All of the time	N/A
<b><i>During the last two days I have had enough energy to:</i></b>							
09. Read a newspaper/book or watch TV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Dress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Visit or socialise with family & friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Engage in leisure or recreational activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Shop or do errands	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

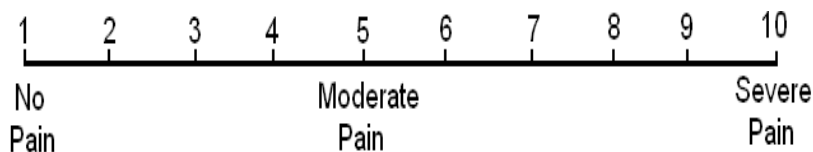
**Please fill this out on the morning of day 14 following your operation**

Circle the appropriate answer or write in the space provided

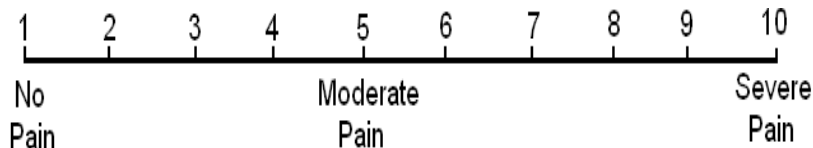
1. How would you describe your pain level at the present time, **while in bed?**



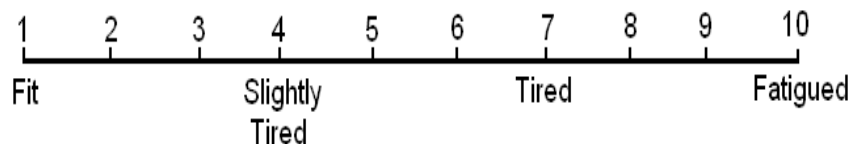
2. How would you describe your pain level at the present time, **when you move?**



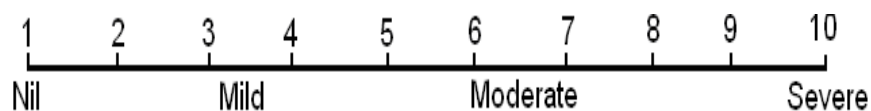
3. How would you describe your pain level at the present time, **when you cough?**



4. How would you describe your energy levels at the present time?



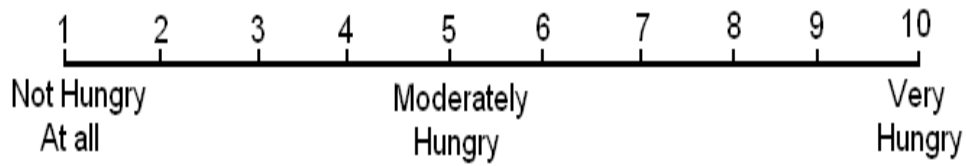
5. How would you describe your level of nausea at the present time?



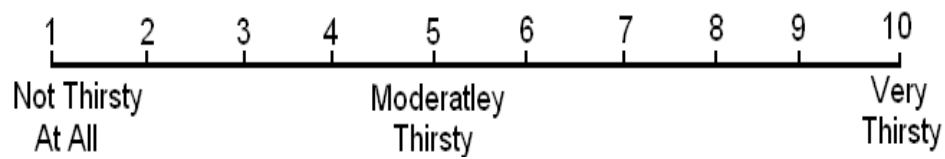
6. Have you vomited in the past 6 hours?

- a. No
- b. Yes, only once
- c. Yes, 2-3 times
- d. Yes, more than 3 times

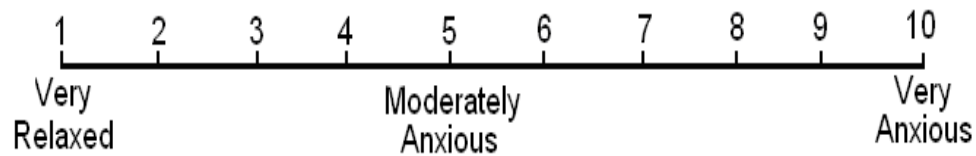
7. At the present time, do you feel:  
Hungry?



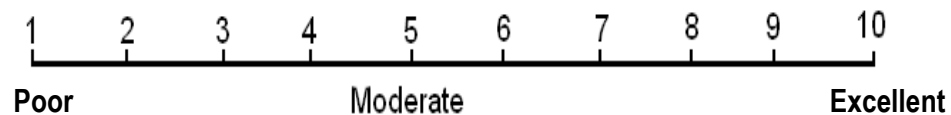
Thirsty?



8. How would you describe your anxiety level at the present time?



9. How would you rate the quality of care you have received thus far?





# Appendix E

## **CHAPTER 5 PATIENT INFORMATION SHEET**

## Participant Information Sheet

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—  
Principal Investigator: Professor Andrew Hill, Department of Surgery, Middlemore Hospital- Phone 09-276 0044 ext 8424 Andrew.Hill@middlemore.co.nz

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### Introduction

You are invited to take part in a clinical research study. Your participation is entirely voluntary (your choice). You do not have to take part in this study and if you choose not to take part this will not affect any future care or treatment.

---

### About the study

The surgical treatment of obesity (known as bariatric surgery) remains the only evidence-based method of treating severe obesity and curing conditions related to severe obesity, such as type 2 diabetes mellitus, high blood pressure, high cholesterol and obstructive sleep apnoea.

There are a variety of bariatric operations used throughout the world, one of which is the laparoscopic sleeve gastrectomy (LSG). The LSG has becoming increasingly popular among surgeons with more and more research showing excellent weight loss results and remission of conditions related to severe obesity. These results have been compared to other bariatric operations and have been shown to be as good as, and sometimes even better than, these other operations.

The current research shows that the LSG produces excellent results in the short term (mostly up to 3 years after surgery). However, because the LSG is a relatively new procedure, there is very little research describing the long term results of LSG. We are therefore carrying out a study to investigate this.

We are inviting you to participate in our study. We wish to investigate whether people who have LSG and are able to maintain their weight loss results and remain free of conditions related to severe obesity in the long term.

---

### Procedures

We are planning to invite all patients who had LSG at Counties Manukau District Health Board and who are now more than 5 years after their surgery to take part in this study. If you agree to participate, we will obtain your current weight, ask you to fill out a questionnaire to check your level of satisfaction with the results of your surgery, and take blood samples to measure your blood sugar and cholesterol levels. We may also contact your general practitioner (GP) to help confirm your weight and whether you have type 2 diabetes mellitus, high blood pressure, high cholesterol or

obstructive sleep apnoea and any changes to the medications you take (or took) for these conditions after your surgery. Your participation in this trial will not affect the standard of care you receive from you GP or from the hospital in any way.

We will invite those patients living in Auckland to meet with us in person at the Manukau Surgery Centre for approximately 30 minutes. For those no longer living in Auckland, we will obtain information over the telephone, provide you with blood forms in the post and, with your permission, may confirm the data provided with your GP.

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### **Data Storage and Retention**

Written and electronic data will be safeguarded in locked cupboards and computerised password protected files. The data will be kept for up to 10 years.

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### **Participation**

Your participation is entirely voluntary (your choice). You do not have to take part in this study. This will not affect your ongoing treatment for any conditions relating to your previous surgery in any way. If you do agree to take part you are free to withdraw your participation up until to the study's closing date on the 26<sup>th</sup> August 2013, without having to give a reason and this will in no way affect your continuing health care.

---

### **General**

Further information regarding this study can be obtained from Dr Daniel Lemanu, Department of Surgery (Tel 276 0044 ext 2219 or 021 063 6264). An interpreter will be provided if you would like one. You may have a friend, family, or whanau support to help you understand the risks and/or benefits of this study and any other explanation you may require. There will be no costs or payments to you in order to participate in this study. For any queries regarding ethical concerns, you may contact the Chair of The University of Auckland Human Ethics Committee at:

The University of Auckland  
Office of the Vice Chancellor  
Private Bag 92019, Auckland 1142  
Telephone: (09) 3737599 ext 93711

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### **Advocacy**

If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act:

Telephone (NZ wide): 0800 555 050  
Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)  
Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

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### **Confidentiality**

No material which could personally identify you will be used in any reports on this study. Your hospital records are confidential. Your name or any other personally

identifying information will not be used in reports or publications resulting from this study. The information about your medical history and medications required to interpret the research results will be identified using a code to ensure your confidentiality.

---

### **Compensation**

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention, Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

---

### **Results**

The final results of the research will not be known until November 2013 at which point they will be prepared as scientific article to be published in the current medical literature. All the data within this article will be de-identified in order to maintain the anonymity of all the participants in our study. At the conclusion of the study, results will be made available by mail to those who have requested this on the consent form. However, if you are not sure about whether you have requested the study results, you can contact Dr Daniel Lemanu, Research Fellow, Middlemore Hospital (ph 09 2760044 ext 2219).

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### **Statement of Ethical Approval**

This study has been approved by The University of Auckland Human Participants Ethics Committee on 25<sup>th</sup> FEBRUARY 2013 for (3) years (Reference Number 9061).



# Appendix F

## **CHAPTER 5 CONSENT FORM**



## 5 year outcome study- CONSENT FORM

English	I wish to have an interpreter.	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.	Ae	Kao
Cook Island	Ka inangaro au i tetai tangata uri reo.	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.	E	Nakai
Samoaan	Ou te mana'o ia i ai se fa'amatala upu.	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea.	Io	Ikai
Deaf	I wish to have a sign language interpreter.	Yes	No
	Other languages to be added following consultation with relevant communities.		

I have read and I understand the information sheet dated 28/05/12 for volunteers taking part in the study designed to assess **whether laparoscopic sleeve gastrectomy produce efficacious weight loss and comorbidity resolution at 5 year follow up**. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

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

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from my participation up until to the study's closing date on the 26<sup>th</sup> August 2013. This will in no way affect my future health care/continuing health care.

I have had this project explained to me by \_\_\_\_\_.

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

I understand that my general practitioner may be contacted for further information regarding my weight loss and the state of other conditions I may have relating to obesity such as diabetes, high blood pressure, high cholesterol and obstructive sleep apnoea.

I understand that the treatment, or investigation, will be stopped if it should appear harmful to me.

I understand the compensation provisions for this study.

I have had time to consider whether to take part.

I know who to contact if I have any side effects to the study.

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

I agree to an approved auditor appointed by either the ethics committee, or the regulatory authority or their approved representative, and approved by the relevant ethics committee reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I wish to receive a copy of the results YES/NO

Alternatively “I would like the researcher to discuss the outcomes of the study with me”.  
YES/NO

4.11 I agree to my GP or other current provider being informed of my participation in this study/the results of my participation in this study YES/NO

5. I \_\_\_\_\_ (full name) hereby consent to take part in this study.

**Date**

**Signature**

**Contact Phone Number for researcher:**

Dr Lemanu 021 063 6264

Email: [Daniel.Lemanu@middlemore.co.nz](mailto:Daniel.Lemanu@middlemore.co.nz)

**Project explained by**

**Project role**

**Signature**


























**Date**

**Statement of Ethical Approval**

This study has been approved by The University of Auckland Human Participants Ethics Committee on 25<sup>th</sup> FEBRUARY 2013 for (3) years (Reference Number 9061).

# Appendix G

## **CHAPTER 5 BARIATRIC ANALYSIS REPORTING OUTCOME SYSTEM QUESTIONNAIRE**

WEIGHT LOSS % OF EXCESS (points)	MEDICAL CONDITIONS (points)	QUALITY OF LIFE QUESTIONNAIRE
Weight gain (-1)	Aggravated (-1)	1. SELF ESTEEM  -1.0  -.50  0  +.50  +1.0
0 - 24 (0)	Unchanged (0)	2. PHYSICAL  -.50  -.25  0  +.25  +.50
25 - 49 (1)	Improved (1)	3. SOCIAL  -.50  -.25  0  +.25  +.50
50 - 74 (2)	One major resolved Others improved (2)	4. LABOR  -.50  -.25  0  +.25  +.50
75 - 100 (3)	All major resolved Others improved (3)	5. SEXUAL  -.50  -.25  0  +.25  +.50
Subtotal:	Subtotal:	Subtotal:

#### COMPLICATIONS

Minor: Deduct 0.2 point

Major: Deduct 1 point

#### REOPERATION

Deduct 1 point

#### TOTAL SCORE

#### OUTCOME GROUPS

##### SCORING KEY

FAILURE	1 point or less
FAIR	> 1 to 3 points
GOOD	> 3 to 5 points
VERY GOOD	> 5 to 7 points
EXCELLENT	> 7 to 9 points



# Appendix H

## **CHAPTER 7**

## **PATIENT INFORMATION SHEET**

## Participant Information Sheet

---

Principal Investigator: Professor Andrew Hill, Department of Surgery, Middlemore Hospital- Phone 09-276 0044 ext 8424 Andrew.Hill@middlemore.co.nz

---

### Introduction

You are invited to take part in a clinical research study. Your participation is entirely voluntary (your choice). You do not have to take part in this study and if you choose not to take part this will not affect any future care or treatment.

---

### About the study

A successful outcome from surgery depends on many things. One factor is making sure that patients are in good physical condition prior to their operation.

Health care providers encourage patients who are having surgery to do regular exercise before their scheduled operation. Studies show that this helps to improve their recovery and outcomes after surgery. In weight loss surgery, patients who do more exercise before surgery are more likely to exercise after surgery, and this is linked to improved weight loss.

However, for various reasons, advice to exercise before surgery is often not applied well enough. There are several suggested ways to improve exercise levels before surgery, one of which is sending regular text message reminders to encourage patients to exercise. This has been trialled both locally and internationally in other clinical settings to improve diet, smoking and weight loss behaviours. We have developed a series of text messages for patients having weight loss surgery to encourage them to exercise prior to surgery.

We are inviting you to participate in our study. We wish to investigate whether text message reminders to patients awaiting Laparoscopic Sleeve Gastrectomy improves exercise levels. We then wish to see whether this leads to faster recovery time, less complications and better weight loss results.

We are planning to invite 100 patients who are going to have laparoscopic sleeve gastrectomy to take part in this study. If you agree to participate, you will be randomly chosen to receive daily text message reminders for 6 weeks prior to your scheduled date of surgery or no text messages reminders. Your participation in this trial will not affect the standard of care you receive in any way. Participation in this study will not prevent you from having your scheduled surgery or prevent you from receiving healthcare in the future.

You will be seen by our research team at 3 time points – 6 weeks before surgery, 1 week before surgery and 6 weeks after surgery. Each of these appointments will take approximately 20 minute, 2 of which are routine clinical appointments. You will be

required to fill in internationally validated questionnaires which describe the amount of exercise you are doing as well as an assessment of your walking. The results of the questionnaire and walking assessment will in no way affect your intended treatment. During your stay in hospital, we will record data from the patient notes regarding how long you stay in hospital and whether you experience any complications.

---

### **Risks**

We do not anticipate any risk from this *intervention* in addition to the risks already posed by the operation and perioperative care.

---

### **Participation**

Your participation is entirely voluntary (your choice). You do not have to take part in this study. This will not affect your treatment in any way. If you do agree to take part you are free to withdraw from the study at any time, without having to give a reason and this will in no way affect your continuing health care.

---

### **General**

Further information regarding this study can be obtained from Dr Daniel Lemanu, Department of Surgery (Tel 276 0044 ext 2219 or 021 063 6264)

An interpreter will be provided if you would like one. You may have a friend, family, or whanau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

There will be no costs or payments to you in order to participate in this study.

---

### **Advocacy**

If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act:

Telephone (NZ wide): 0800 555 050

Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

---

### **Confidentiality**

No material which could personally identify you will be used in any reports on this study. Your hospital records are confidential. Your name or any other personally identifying information will not be used in reports or publications resulting from this study. The information about your medical history and medications required to interpret the research results will be identified using a code to ensure your confidentiality.

---

### **Compensation**

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention, Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no

cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

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### **Results**

The final results of the research will not be known until August 2013. At the conclusion of the study, results will be made available by mail to those who have requested this on the consent form. However, if you are not sure about whether you have requested the study results, you can contact Dr Daniel Lemanu, Research Fellow, Middlemore Hospital (ph 09 2760044 ext 2219).

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**Statement of Ethical Approval:** This study has received ethical approval from the Northern X Regional Ethics Committee.





# Appendix I

## **CHAPTER 7 CONSENT FORM**

## PREHAB Text Message Reminders study- CONSENT FORM

English	I wish to have an interpreter.	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.	Ae	Kao
Cook Island	Ka inangaro au i tetai tangata uri reo.	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.	E	Nakai
Samoaan	Ou te mana'o ia i ai se fa'amatala upu.	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea.	Io	Ikai
Deaf	I wish to have a sign language interpreter.	Yes	No
	Other languages to be added following consultation with relevant communities.		

I have read and I understand the information sheet dated 28/05/12 for volunteers taking part in the study designed to assess **whether text message reminders help people exercise prior to laparoscopic sleeve gastrectomy**. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

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

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my future health care/continuing health care.

I have had this project explained to me by \_\_\_\_\_.

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

I understand that the treatment, or investigation, will be stopped if it should appear harmful to me.

I understand the compensation provisions for this study.

I have had time to consider whether to take part.

I know who to contact if I have any side effects to the study.

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

I agree to an approved auditor appointed by either the ethics committee, or the regulatory authority or their approved representative, and approved by the Northern X Ethics committee reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I wish to receive a copy of the results YES/NO

Alternatively “I would like the researcher to discuss the outcomes of the study with me”.  
YES/NO

4.11 I agree to my GP or other current provider being informed of my participation in this study/the results of my participation in this study YES/NO

5. I \_\_\_\_\_ (full name) hereby consent to take part in this study.

**Date**

**Signature**

**Full names of Researchers:**

Professor Andrew G. Hill  
Mr Andrew MacCormick  
Professor Bruce Arroll  
Associate Professor Ralph Maddison  
Mr Richard Babor  
Dr Daniel Lemanu  
Dr Parry Singh  
Ms Kate Berridge

**Contact Phone Number for researchers:**

Dr Lemanu 021 063 6264 Daniel.Lemanu@middlemore.co.nz

**Project explained by**

**Project role**

**Signature**

**Date**



# Appendix J

## **STANDARDISED PATIENT EXERCISE ADVICE SHEET**

## Exercise Information Sheet

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### Introduction

Regular exercise before surgery is important because it helps to make sure that patients are best prepared for their upcoming operation. This may help with improving recovery after surgery as well as help provide better outcomes after your operation. This sheet will provide some advice on how to approach your exercise over the next 6 weeks.

### Getting started

Often, the hardest part of exercise is getting started. Remind yourself that exercise is an important part of preparing for your surgery. Then it simply becomes a matter of getting your shoes on and standing at the front door before you put one foot in front of the other. Though it may seem difficult to find time to exercise, try to look at it differently. Rather than fitting exercise into your day, fit your day around exercise. Make exercise a habit and give your body the fit and healthy lifestyle it deserves.

### Types of activity

It is always important to remember that when it comes to exercise, anything is always better than nothing. **Walking** is an excellent form of exercise and is an activity which is able to be done with friends or family. **Swimming**, or any other form of water based activity, is also an excellent form of exercise because it reduces the impact placed on joints. The same can also be said for **cycling**. At the end of the day, it is about finding an activity which you enjoy and are able to do comfortably. **Involving family/whanau** can also help to keep you motivated and make exercise fun.

### Intensity and timing of exercise

Our current guidelines for exercise suggest that the minimum recommended amount of exercise is **30 minutes per day of light to moderate intensity exercise for 5 days a week (150 minutes per week)**. Light to moderate intensity exercise should leave you breathing hard and feeling tired at the end of the 30 minutes. Examples of such activities include walking and stationary cycling.

Rather than start at 30 minutes per day for 5 days a week at the beginning, it may be more helpful to build up to this level of exercise over the 6 week period. Start by doing 10 minutes of exercise 3 times a week and build up slowly so that by the end of 6 weeks you are doing the recommended amount of exercise.

### **Warm up and cool down**

It is important to spend 5 minutes before and after exercise warming down to help avoid injury. Warm up and cool down exercises are simply easier versions of the activities you are about to do. Also get into the habit of stretching your muscles, particularly before to exercise, to help reduce muscle stiffness.

### **Tips and tricks**

The more you do, the easier it becomes. Try to make exercise a priority in your day. Some simple things to help improve the amount of exercise you do include:

- Setting yourself a set of realistic and achievable exercise goals. These can be both short and long term goals.
- Reinforcing your personal motivation for exercise by setting yourself a timeframe from the date of your surgery. By the time you have surgery, you should be doing the recommended level of exercise as suggested previously.
- Planning walking or cycling routes in advance. Ensure that wherever you exercise is safe, convenient and well maintained.
- Exercising with friends, family or as part of an exercise group. This keeps exercise fun and sociable and allows everybody to draw energy from the group.
- Keeping an exercise log book or diary. This keeps a record of your activity so you can continue to monitor the progress that you are making.
- Utilising alarm messages on mobile phones, calendars or post it notes to help remind you of your commitment to exercise.
- Scheduling exercise into your daily diary. Make it the first thing you put in your schedule so that you fit things around exercise.
- Keeping exercise fun by changing between different walking and cycling routes and exercise activities.
- Knowing your limitations. Do not push yourself too hard, especially when starting off, as this can often lead to injury and decreased motivation to exercise.

### **Safety**

Remember, if you start to feel overly short of breath or develop chest pain, stop and seek medical attention. If you hurt yourself during exercise, rather than make it worse, see your doctor to assess your injury.

### **Questions and concerns**

Remember, we are here to help. If at any stage you are unsure about the type of exercise that you are doing, please feel free to contact Dr. Daniel Lemanu by email at [Daniel.Lemanu@middlemore.co.nz](mailto:Daniel.Lemanu@middlemore.co.nz) or by telephone on 021 0636264. We wish you the best of luck and look forward to seeing you again in 6 weeks time.



# Appendix K

## **INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE**

# INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (October 2002)

## LONG LAST 7 DAYS SELF-ADMINISTERED FORMAT

### FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health-related physical activity.

#### ***Background on IPAQ***

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

#### ***Using IPAQ***

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

#### ***Translation from English and Cultural Adaptation***

Translation from English is encouraged to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at [www.ipaq.ki.se](http://www.ipaq.ki.se). If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

#### ***Further Developments of IPAQ***

International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

#### ***More Information***

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at [www.ipaq.ki.se](http://www.ipaq.ki.se) and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.



## INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

### **PART 1: JOB-RELATED PHYSICAL ACTIVITY**

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

☐

Yes

☐

No



**Skip to PART 2: TRANSPORTATION**

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

\_\_\_\_\_ **days per week**

☐

No vigorous job-related physical activity



**Skip to question 4**

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

\_\_\_\_\_ **days per week**

☐

No moderate job-related physical activity



**Skip to question 6**

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

\_\_\_\_\_ **days per week**

☐

No job-related walking



***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

## ***PART 2: TRANSPORTATION PHYSICAL ACTIVITY***

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

\_\_\_\_\_ **days per week**

☐

No traveling in a motor vehicle



***Skip to question 10***

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

\_\_\_\_\_ **days per week**

☐

No bicycling from place to place



***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?
- \_\_\_\_\_ **hours per day**  
 \_\_\_\_\_ **minutes per day**
12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?
- \_\_\_\_\_ **days per week**
- ☐ No walking from place to place → **Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY**
13. How much time did you usually spend on one of those days **walking** from place to place?
- \_\_\_\_\_ **hours per day**  
 \_\_\_\_\_ **minutes per day**

### **PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY**

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?
- \_\_\_\_\_ **days per week**
- ☐ No vigorous activity in garden or yard → **Skip to question 16**
15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?
- \_\_\_\_\_ **hours per day**  
 \_\_\_\_\_ **minutes per day**
16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?
- \_\_\_\_\_ **days per week**
- ☐ No moderate activity in garden or yard → **Skip to question 18**

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

\_\_\_\_\_ **days per week**

☐

No moderate activity inside home



***Skip to PART 4: RECREATION,  
SPORT AND LEISURE-TIME  
PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

#### ***PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY***

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

\_\_\_\_\_ **days per week**

☐

No walking in leisure time



***Skip to question 22***

21. How much time did you usually spend on one of those days **walking** in your leisure time?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

\_\_\_\_\_ **days per week**

☐

No vigorous activity in leisure time



***Skip to question 24***

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

\_\_\_\_\_ **days per week**

☐

No moderate activity in leisure time



**Skip to PART 5: TIME SPENT SITTING**

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

#### **PART 5: TIME SPENT SITTING**

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

**This is the end of the questionnaire, thank you for participating.**

# Appendix L

## CHAPTER 7

### TEXT-MESSAGE TEMPLATE SHEET

Week	Day	Message
1	1	Hi there! Thanks for joining the study. You will receive regular text messages for the next 6 weeks to help you exercise.
	1	This weeks programme is 10 minutes of walking at light intensity which should get you breathing harder and feeling tired. Try this 3 times this week
	2	Starting exercise can be difficult. However, if you stick at it you will notice the positive benefits so lets get started! Start with a 5 min warm up and then walk for 10 mins. Finish with a 5 min cool down.
	3	Its good day to have a rest day. Try to walk the next day. Go for 10 mins but don't forget 5 mins of warm up and cool down
	4	When you first start exercising you may get a bit short of breath, your heart rate will increase and you will sweat. These are all normal! It will get easier
	5	Its good day to have a rest day. Try to walk the next day. Go for 10 mins but don't forget to warm up and cool down
	6	After a day of rest its time to walk again. Walk for 10 mins at light intensity and remember to warm up and cool down
	7	Well done, you have finished the 1st week! Exercise is important for people awaiting surgery. If you don't like walking, try cycling, swimming or any other exercise activity you enjoy! Next week, lets go from 10 mins to 15 mins
2	1	Great stuff, we are at week 2! This weeks programme is 15 mins of walking 3 times this week. Remember to warm up and cool down for 5 mins at the beginning and end of each session
	2	Its good to have a rest day. Try to walk the next day. Go for 15 mins but don't forget to warm up and cool down
	3	Don't like walking? Then try something else you enjoy for 15 mins. Maybe swimming, cycling or golf
	4	Its good to have a rest day. Try to walk the next day. Go for 15 mins but don't forget to warm up and cool down
	5	By exercising, you set a great example to family and friends. Encourage them to get involved!
	6	Its good to have a rest day. Try to walk the next day. Go for 15 mins but done forget to warm up and cool down
	7	That's 2 weeks down, great work! Keep a track of your exercise with a journal. This will help you monitor your progress. Next week, lets aim for 20 mins
3	1	Lets start week 3 by increasing the walking to 20 mins for 3 days this week. Remember to warm up and cool down for 5 mins at the beginning and end of each session
	2	Look at things differently - instead of fitting exercise into your day, try fit your day around exercise!
	3	Ready to walk? Put your shoes on and head out the door for your 20 min walk
	4	Some people like to exercise in the morning and some in the evening. Pick a time that suits you and make exercise a habit
	5	Ready to walk? Put your shoes on and head out the door for your 20 min walk
	6	Sometimes it is hard to exercise when it is raining. Try an indoor activity or wrap up and enjoy the rain!
	7	We are 3 weeks in with 3 to go. Identify any obstables you may have faced and ways you can overcome them. Lets take another step forward next week and go from 3 days to 5 days

Week	Day	Message
4	1	Its week 4. Lets go for 20 mins of walking or another exercise you enjoy for 5 days this week. Remember to warm up and cool down
	2	It is important to warm up and cool down at the beginning and end of each session to help keep injury free. So lets get your shoes on and hit the pavement for your 20 min walk
	3	Great progress! Start with a 5 minute warm up and walk for 20 mins at a light pace. Don't forget to warm down
	4	Its good to have a rest day. Try to walk the next day. Go for 20 mins but don't forget to warm up and cool down
	5	Ready to walk? Put your shoes on and head out the door for your 20 min walk
	6	Getting started is the hardest part. The first step is to put your shoes on and stand at the door. Then put one foot in front of the other
	7	The end of week 4. Can you believe how far you have come since the beginning? Well done! Next week lets take it from 20 mins to 30 mins
5	1	Its week 5 and you are getting fitter! Lets aim this week for 30 mins of walking or another exercise you enjoy for 5 days this week. Don't forget to warm up and cool down for 5 mins at the beginning and end of each session
	2	You are worth it! Your body is entitled to a fit and healthy lifestyle. Give it a chance and get your shoes on!
	3	Great progress! Start with a 5 minute warm up and walk for 30 mins at a light pace. Don't forget to warm down
	4	Its good to have a rest day. Try to walk the next day. Go for 30 mins but don't forget to warm up and cool down
	5	Exercise has a positive effect on you mood and boosts your energy. If your feeling tired or stressed, going for your walk is good way of waking yourself up and melting away your tension. So get your shoes on
	6	Ready to walk? Put your shoes on and head out the door for your 30 min walk
	7	5 weeks down, 1 week to go. Let keep up the pace next week and continue with 30 mins of walking or another exercise you enjoy for 5 days
6	1	Its week 6! This week is 30 minutes of walking or another exercise you enjoy for at least 5 days this week. Don't forget to warm up and cool down!
	2	When life gets busy, exercise is often the first thing to go. Make it a priority as it will help you feel better. Lets get walking!
	3	Great progress! Start with a 5 minute warm up and walk for 30 mins at a light pace. Don't forget to warm down
	4	Its good to have a rest day. Try to walk the next day. Go for 30 mins but don't forget to warm up and cool down
	5	Are you feeling active? If you are exercising 5 days a week then you most certainly are. Keep it up and get walking!
	6	Ready to walk? Put your shoes on and head out the door for your 30 min walk
	7	Well done! You have made it to the end of the 6 weeks. Remember to make exercise a habit and I will see you next week to go through the questionnaire



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