Diet and eating behaviour following laparoscopic adjustable gastric banding: Informing dietary management practices

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A thesis submitted for the degree of PhD (Nutrition and Dietetics)

August 2013
Statement of Originality

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University’s Digital Repository, subject to the provisions of the Copyright Act 1968.

..............................................................

Alison A Fielding
Acknowledgement of Authorship

I hereby certify that this thesis is in the form of a series of published/submitted papers of which I am the first author. The co-authors of the papers were supervisors of the thesis and provided due input and guidance for each publication. I have included as part of my thesis a written statement from each co-author, endorsed by the Faculty Assistant Dean (Research Training), attesting to my contribution to each publication.

Alison A Fielding
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study; and my son, Jay, for all the joy you have brought into my life, and for always
being a reminder of what really matters. I would finally like to dedicate this thesis to
my Mum, Frances Dodsworth. Although Alzheimer’s disease prevented you from
sharing this journey, I’m sure you would have been proud of my achievements if
circumstances had have been different.
Conflict of Interest

The protein supplement that was used as part of the protein-enriched dietary intervention undertaken as part of this thesis was donated by Top Nutrition© (Newcastle, Australia). All elements of the study were conducted independent of Top Nutrition©, including the conception and design of the study, data analysis, interpretation of findings and preparation of the manuscript relevant to the intervention study.
Thesis Publications and Presentations

*Manuscripts in peer-reviewed journals: Published*


*Manuscripts in peer-reviewed journals: In press*


*Manuscripts in peer-reviewed journals: Submitted*


*Peer reviewed conference publications*


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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACTRN</td>
<td>Australian New Zealand Clinical Trials Registry</td>
</tr>
<tr>
<td>ADAEAL</td>
<td>American Dietetic Association Evidence Analysis Library</td>
</tr>
<tr>
<td>AI</td>
<td>Adequate Intake</td>
</tr>
<tr>
<td>AMDR</td>
<td>Acceptable macronutrient distribution range</td>
</tr>
<tr>
<td>ANCOVA</td>
<td>Analysis of covariance</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
</tr>
<tr>
<td>APL</td>
<td>AP large</td>
</tr>
<tr>
<td>APS</td>
<td>AP small</td>
</tr>
<tr>
<td>ASGB</td>
<td>Adjustable silicone gastric banding</td>
</tr>
<tr>
<td>BED</td>
<td>Binge eating disorder</td>
</tr>
<tr>
<td>BEE</td>
<td>Binge eating episodes</td>
</tr>
<tr>
<td>BIA</td>
<td>Bioelectrical impedance analysis</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>BPD</td>
<td>Biliopancreatic diversion</td>
</tr>
<tr>
<td>BPD-DS</td>
<td>Biliopancreatic diversion with duodenal switch</td>
</tr>
<tr>
<td>BSQ</td>
<td>Binge Scale Questionnaire</td>
</tr>
<tr>
<td>CHO</td>
<td>Carbohydrate</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CORE</td>
<td>The Centre for Obesity Research and Education</td>
</tr>
<tr>
<td>CV</td>
<td>Coefficients of variation</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>DSM-IV</td>
<td>Diagnostic and statistics manual of mental disorders, 4th edition</td>
</tr>
<tr>
<td>DXA</td>
<td>Dual x-ray absorptiometry</td>
</tr>
<tr>
<td>EAR</td>
<td>Estimated Average Requirements</td>
</tr>
<tr>
<td>EB</td>
<td>Eating behaviour</td>
</tr>
<tr>
<td>EDI-BU</td>
<td>Eating Disorders Inventory-2-Bulimia subscale</td>
</tr>
<tr>
<td>EWL</td>
<td>Excess weight loss</td>
</tr>
<tr>
<td>FFM</td>
<td>Fat free mass</td>
</tr>
<tr>
<td>FFQ</td>
<td>Food frequency questionnaire</td>
</tr>
<tr>
<td>g</td>
<td>Grams</td>
</tr>
<tr>
<td>GI</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>HAGA</td>
<td>Heliogast advanced band</td>
</tr>
<tr>
<td>HAGE</td>
<td>Heliogast evolution band</td>
</tr>
<tr>
<td>HC</td>
<td>High carbohydrate</td>
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<tr>
<td>HP</td>
<td>High protein</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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</tr>
<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>JIB</td>
<td>Jejunoileal bypass</td>
</tr>
<tr>
<td>Kg</td>
<td>Kilogram</td>
</tr>
<tr>
<td>kJ</td>
<td>Kilojoule</td>
</tr>
<tr>
<td>LAGB</td>
<td>Laparoscopic adjustable gastric banding</td>
</tr>
<tr>
<td>LMM</td>
<td>Linear mixed models</td>
</tr>
<tr>
<td>m</td>
<td>Month/s</td>
</tr>
<tr>
<td>MCS</td>
<td>Mental component summary</td>
</tr>
<tr>
<td>MJ</td>
<td>Mega joule</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable</td>
</tr>
<tr>
<td>NES</td>
<td>Night eating syndrome</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NR</td>
<td>Not reported</td>
</tr>
<tr>
<td>NRV</td>
<td>Nutrient Reference Value</td>
</tr>
<tr>
<td>NSD</td>
<td>No significant differences</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
</tr>
<tr>
<td>PCS</td>
<td>Physical component summary</td>
</tr>
<tr>
<td>PS</td>
<td>Pre-surgery</td>
</tr>
<tr>
<td>QCCPR</td>
<td>Quality Criteria Checklist for Primary Research</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised control trial</td>
</tr>
<tr>
<td>RDI</td>
<td>Recommended daily intake</td>
</tr>
<tr>
<td>REE</td>
<td>Resting energy expenditure</td>
</tr>
<tr>
<td>RR</td>
<td>Relative risk</td>
</tr>
<tr>
<td>RYGB</td>
<td>Roux-en-Y gastric bypass</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>SDT</td>
<td>Suggested Dietary Target</td>
</tr>
<tr>
<td>SG</td>
<td>Sleeve gastrectomy</td>
</tr>
<tr>
<td>TEF</td>
<td>Thermic effect of food</td>
</tr>
<tr>
<td>TFEQ</td>
<td>Three Factor Eating Questionnaire</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>VBG</td>
<td>Vertical banded gastroplasty</td>
</tr>
<tr>
<td>VLED</td>
<td>Very low energy diet</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>WL</td>
<td>Weight loss</td>
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<td>y</td>
<td>Year/s</td>
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Abstract

Obesity remains a pervasive health issue in the developed world. Surgery is the most efficacious treatment option available for obese individuals at present, with laparoscopic adjustable gastric banding (LAGB) representing one of the most popular surgical obesity treatments worldwide. Despite the relative efficacy of LAGB, successful weight loss is not guaranteed. Ongoing dietary follow-up is recognised as a crucial element in determining the success of LAGB; yet the evidence base guiding best-practice dietary management for the optimisation of weight loss and other diet-related outcomes is currently limited.

The overarching aim of this thesis is to contribute to the evidence base guiding the dietary management of individuals who have had LAGB, with focus on weight loss, dietary intake and eating behaviour outcomes. Three components of research were undertaken to meet this aim.

Systematic reviews of dietary intake and eating behaviour after LAGB examined the existing evidence base for these outcomes including their relationship with weight loss outcomes. These reviews highlight the paucity of evidence currently available to guide the best-practice dietary management of individuals who have had LAGB; and emphasise the need for well-designed interventions to better establish evidence-based strategies for optimising weight loss after surgery. Enhanced protein intake was identified as a dietary strategy of potential value in this context.

A pilot dietary intervention (n=47, 38 females and 9 males) was undertaken to examine the feasibility of a protein-enriched diet in the first six months after LAGB for the optimisation of weight loss and body composition outcomes. Compliance with the diet was problematic; indicating that adherence difficulties may negate the feasibility and potential benefits of a protein-enriched diet in the early months after surgery.

The relationship between eating behaviour and weight loss, dietary intake, food tolerance and quality of life in the first 12 months after surgery was also examined from pilot intervention data. Higher post-operative disinhibition scores were
significantly associated with lower percentage weight loss, supporting the wider literature indicating that uncontrolled eating behaviours can negatively impact on weight loss after surgery.

A broad ranging cross-sectional survey (n=67, 55 females and 12 males) examining dietary intake, eating behaviour, food tolerance, weight loss and quality of life within the first two years after LAGB was also conducted. This study suggested that disinhibited eating may remain significantly higher in individuals who have had LAGB than the general community. No postoperative dietary or eating behaviour-related variables were strongly associated with reported weight loss or quality of life after surgery.

Overall, the findings of this thesis support that poor compliance with dietary modification and uncontrolled eating behaviour represent important targets for dietary and behavioural interventions aimed at optimising weight loss and other outcomes after LAGB. There remains a critical need for such interventional research in this area, particularly for individuals identified as ‘at risk’ of poorer outcomes. The findings of this thesis have important implications for future research into the best-practice dietary management of individuals who have LAGB; and will be of value to a diversity of health professionals involved in the follow-up care of LAGB patients, including dietitians, psychologists, nurses and surgeons.
Chapter 1  Introduction

1.1 Thesis overview

The overarching aim of this thesis is to contribute to the evidence base informing dietary management practices for the optimisation of weight loss and other diet-related outcomes following LAGB surgery for obesity. Centralised around this aim, three components of investigation were undertaken:

i) Systematic reviews of the literature examining dietary intake and eating behaviours after LAGB

ii) A pilot dietary intervention investigating the feasibility and potential utility of a protein-enriched diet after surgery. This component of research includes a sub-analysis of eating behaviour as a secondary outcome of the intervention study.

iii) A cross-sectional survey of eating behaviour, food tolerance, dietary intake, weight loss and health and wellbeing after LAGB.

The systematic review component of research was undertaken given that the evidence base for dietary intake and eating behaviour after LAGB had not previously been systematically evaluated, which represents a critical step in informing dietary management practices and targets for future research.

The findings from the systematic reviews contributed to the rationale for undertaking the protein-enriched dietary intervention, with dietary intervention strategies for optimising weight loss and protein intake recommendations following LAGB identified as key gaps in the evidence base informing the dietary management of LAGB patients. The assessment of eating behaviour as a secondary outcome of the dietary intervention was also informed by the systematic review component of research; and provides further evidence relating to changes in behaviour after LAGB, including an exploration of the relationship between eating behaviours and weight loss, quality of life, dietary intake and food tolerance after LAGB.
The cross-sectional study was undertaken as the final component of investigation for the thesis, providing a comprehensive exploration of eating behaviour, food tolerance and dietary intake after LAGB, including an examination of how these factors relate with weight loss and quality of life after surgery. This study expands from the narrow focus of the protein-enriched dietary intervention and was informed by the findings from both the systematic reviews and the intervention study, which supported that a wider examination of diet-related factors may provide further insight and direction for the future development of best-practice dietary management strategies for individuals who have had LAGB.

1.2 Thesis structure and outline

The thesis is primarily presented as a series of published and submitted research papers. Accordingly, the specific background, methods, results and discussion of findings for each component of research undertaken is embedded within each chapter. General methodology for the thesis is provided as an additional unpublished chapter (Chapter 3) and an overall discussion and summary of the whole body of research is presented in Chapter 7. A detailed outline of the thesis is provided below.

Chapter 1: This introductory chapter provides the contextual background and rationale for the research undertaken. This is followed by the aims, research questions, scope and significance of the thesis.

Chapter 2: This chapter provides a review of the literature, and is presented as two embedded papers encompassing a systematic literature review of dietary intake and eating behaviour after LAGB. These reviews also represent the first component of investigation for the thesis. This chapter also includes an unpublished section reviewing higher protein diets and weight loss, providing further background and justification for the protein-enriched dietary intervention component of research that was undertaken.
Chapter 3: This chapter details the overall methodology for the original components of research undertaken as part of this thesis, including the pilot dietary intervention and cross-sectional study.

Chapters 4-6 are presented as a series of published/submitted papers:

Chapter 4: This chapter details findings from the pilot dietary intervention examining the feasibility of a protein-enriched diet following LAGB, representing the second component of investigation for the thesis.

Chapter 5: This chapter explores the relationship between eating behaviour and weight loss, quality of life, dietary intake and food tolerance after LAGB as a secondary outcome from the pilot dietary intervention.

Chapter 6: This chapter details results from the third component of research undertaken as part of the thesis, namely the cross-sectional survey of nutrition, health and wellbeing outcomes after LAGB.

Chapter 7: This chapter contains an integrated discussion of the research undertaken in the context of the existing body of knowledge in this field. This final chapter includes a discussion of the key findings and significance of this research, implications for practice, implications for future research and final conclusions of the thesis.
1.3 Background

1.3.1 Prevalence and consequences of obesity

Obesity, a condition defined by an excess of fat mass, has become a global epidemic associated with serious morbidity and mortality. The international standard for defining obesity is Body Mass Index (BMI), which measures weight (kg) divided by height (meters) squared (Table 1.1) and is highly correlated with fat mass in the general population [1]. Using this BMI classification system, it is estimated that over 502 million adults are obese worldwide [2]. In Australia, approximately 28% of men and women are defined as obese [3] which is comparable with other western nations including North America and the United Kingdom [4]. The prevalence of obesity in Australian adults has been increasing steadily in recent years and has more than doubled since the 1980’s [5, 6].

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
<th>Risk of co-morbidities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.5</td>
<td>Low (but risk of other clinical problems increased)</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.5 - 24.9</td>
<td>Average</td>
</tr>
<tr>
<td>Overweight</td>
<td>&gt; 25.0</td>
<td>Increased</td>
</tr>
<tr>
<td>Pre-obese</td>
<td>25 - 29.9</td>
<td>Increased</td>
</tr>
<tr>
<td>Obese Class I</td>
<td>30.0 - 34.9</td>
<td>Moderate</td>
</tr>
<tr>
<td>Obese Class II</td>
<td>35.0 - 39.9</td>
<td>Severe</td>
</tr>
<tr>
<td>Obese Class III</td>
<td>&gt; 40.0</td>
<td>Very severe</td>
</tr>
</tbody>
</table>

Obesity is strongly associated with numerous chronic conditions including cardiovascular disease (CVD) (coronary heart disease, stroke and hypertension), type II diabetes, kidney disease/renal failure, some cancers, osteoarthritis and depression [7]. Obesity is also associated with reduced quality of life [8]. The risk of poor health increases with degree of obesity: individuals who have a BMI greater than 35kg/m² are classified to be at severe risk of co-morbidities and this risk increases to very severe for individuals whose BMI’s are ≥ 40 kg/m² [1].

The economic impact of obesity is extensive, encompassing the costs of healthcare, disability and lost productivity [7]. In 2008, the overall economic cost of obesity in
Australia was estimated to be $58.2 billion [9]. The direct financial costs of obesity were estimated to be $8.3 billion, including $3.6 billion in lost productivity, $2 billion in direct health system costs and $1.9 billion in carer costs [9]. These costs are predicted to increase exponentially with the increasing prevalence of obesity [7].

1.3.2 Overview of treatment strategies for obesity

Weight loss is the fundamental strategy for improving health risks and health outcomes in obese individuals. Current treatment options include lifestyle modification, pharmacological intervention or surgery.

**Lifestyle modification**, which aims to achieve weight reduction via diet, physical activity and behaviour change, is the first line treatment for obesity and underpins all treatment modalities [10, 11]. Although many dietary strategies are utilised for weight reduction (including general portion-controlled healthy eating, manipulation of nutrients/food groups and meal replacements), generally it is accepted that caloric restriction is the principle dietary modification required for weight loss [12]. The role of physical activity in the absence of caloric restriction remains disputed; however overall it has been demonstrated that the most successful lifestyle interventions incorporate changes in both diet and exercise habits [13]. Although lifestyle modification strategies commonly result in short term weight loss, longer term outcomes are typically poor with maintenance of weight loss highly problematic [14-17].

**Pharmacological interventions**, which are generally considered as an adjunctive therapy for lifestyle modification, can be grouped into three major functional categories [10]. These include: medications that reduce food intake, for example appetite suppressants; medications that alter metabolism, for example drugs that prevent fat absorption in the intestines; and agents that increase energy expenditure, for example thyroid hormone [10]. Most of the presently available pharmacological therapies are limited by their significant potential for adverse effects, including for example hypertension, arrhythmias, palpitations, chest pain and gastrointestinal problems such as nausea, vomiting, diarrhoea, constipation and fecal urgency [10].
Furthermore, most of the evidence supporting their efficacy is limited to short-term studies only [10, 18].

The relative ineffectiveness of lifestyle and pharmacological weight loss strategies has led to increasing interest in **surgical weight loss approaches** for obesity in recent decades [15-17]. Although surgery is usually only indicated for an individual after they have failed to lose weight using conventional approaches [17], surgical weight loss strategies have proven the most successful in achieving long-term weight loss and subsequent decreases in co-morbidities and obesity-related disease risk factors [14, 17, 19, 20]. This is especially true for individuals considered to be at greatest risk of obesity-related poor health (ie individuals with a BMI >35kg/m²) [17].

### 1.3.3 Obesity surgery

Obesity surgery is generally considered as a potential weight loss therapy for individuals who meet the following criteria developed by the National Institute of Health in 1991: BMI>40kg/m² or BMI >35kg/m² with obesity-related comorbidities (including for example cardiopulmonary disorders, type II diabetes or physical dysfunction interfering with activities of daily living); previous failed attempts at weight loss using lifestyle modification approaches; motivated and able to understand consequences of surgery; and considered to be of an acceptable operative risk [21]. In recent years, individuals with a BMI of 30-35kg/m² and comorbidities are also being increasingly considered as potential candidates for obesity surgery given the relative inefficacy of non-surgical weight loss therapies in achieving sustained weight loss and subsequent improvements in health [22].

Surgical treatments for obesity have been available for approximately 50 years [23] and can broadly be classified as restrictive, malabsorptive or combined (restrictive/malabsorptive) procedures [24]. Malabsorptive procedures alter the functionality of the small intestines to reduce food/nutrient absorption; whereas restrictive procedures primarily reduce gastric capacity and/or induce early satiety in order to reduce food intake [25].
Different techniques have been developed and refined over this time in response to various failures of surgery, including health complications and poor weight loss outcomes in the medium-long term [26]. Technological innovations such as laparoscopy (key-hole surgery) have also influenced the evolution of surgical procedures [26]. Historical procedures include jejunoileal bypass (JIB), loop gastric bypass, horizontal gastroplasty and vertical banded gastroplasty (Table 1.2 and Figure 1.1). Currently performed procedures include: biliopancreatic diversion (BPD) with or without duodenal switch, sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB) and LAGB [27] (Table 1.3 and Figure 1.2). The two most commonly performed procedures worldwide are RYGB and LAGB, followed by SG [28].
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Classification</th>
<th>Era</th>
<th>Description</th>
<th>Reason for discontinuation / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jejunoileal bypass</td>
<td>Malabsorptive</td>
<td>1950’s – early 1960’s</td>
<td>Involves almost complete bypass of the small intestines, where the upper section of the small intestine is attached to the lowest section of small intestine [26]. This leaves approximately 35-45cm of continuous intestine for nutrient absorption [26](normal intestinal length is approximately 500-700cm [29].)</td>
<td>Achieved highly significant weight loss due to malabsorption of nutrients and reduced caloric intake as a consequence of symptom-related food aversion (frequent loose bowel motions) [26]. It also however caused severe adverse effects leading to its discontinuation. This included: liver failure, metabolic abnormalities, dehydration, bacterial overgrowth in disused portion of intestine, lactic acidosis and renal stones. Multiple severe nutrient deficiencies (including protein, vitamin D and calcium) also lead to bone loss, peripheral oedema, hair loss and night blindness [26, 30].</td>
</tr>
<tr>
<td>Loop gastric bypass</td>
<td>Combined malabsorptive and restrictive</td>
<td>Late 1960’s – early 1970’s</td>
<td>Involves the creation of a small upper gastric pouch (detached from the larger portion of stomach). The pouch is then attached to the intestinal tract, with a small portion of upper intestine bypassed [26].</td>
<td>Achieved successful weight outcomes but frequently caused alkaline reflux gastritis and oesophagitis due to backward bile flow into the stomach [26]. Modifications to the surgical technique largely resolved this issue. As such the loop bypass has been replaced with the Roux-en-Y gastric bypass (RYGB) [26].</td>
</tr>
<tr>
<td>Horizontal gastroplasty</td>
<td>Restrictive</td>
<td>1970’s</td>
<td>Involves the creation of a horizontal staple line across the stomach, with a channel formed between the upper and lower parts of the stomach to allow for passage of food and fluids [17].</td>
<td>Discontinued due to a high rate of weight regain and complications in the medium-longer term [17, 26].</td>
</tr>
<tr>
<td>Vertical banded gastroplasty (VBG)</td>
<td>Restrictive</td>
<td>1980’s – early 1990’s</td>
<td>VBG evolved from horizontal gastroplasty. It involves the creation of a small gastric pouch at the top of the stomach [26]. An opening to the larger portion of the stomach is created and restricted by a non-stretch synthetic band [26].</td>
<td>Generally considered to be outdated procedure due to high rate of complications and questionable longer-term weight loss outcomes [31]. In most countries, VBG has been superseded by LAGB, which is technically easier to perform and has lower complication rates whilst achieving the same or better weight loss outcomes [26]. VBG is still performed in some countries [32-34].</td>
</tr>
</tbody>
</table>
Table 1.3 Description of current surgical procedures for obesity

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Classification</th>
<th>Description</th>
<th>Advantages / Disadvantages</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biliopancreatic diversion (BPD)</td>
<td>Combined malabsorptive and restrictive</td>
<td>Two stage procedure. The first involves a partial gastrectomy, with horizontal partitioning of the stomach, creating a small, gastric pouch (250-500ml capacity) [30]. The second stage involves connection of the lower small intestine to the gastric pouch, leaving approximately 50-100cm of intestine for nutrient absorption. The bypassed portion of small intestine (which continues to receive bile and pancreatic secretions) is reconnected to the remaining intestinal tract, which prevents stasis and bacterial overgrowth in the bypassed intestinal section [26].</td>
<td>Achieves highest level of sustained weight loss of all current procedures [35] / Non reversible, high complication rates, can cause major nutritional deficiencies, can cause gastrointestinal (GI) side effects including dumping syndrome and diarrhoea [26, 36].</td>
<td>BPD is the only predominantly malabsorptive procedure that is still currently performed (in a limited number of centres only) [27]. Due to its high complexity and greatest potential for adverse health and nutritional outcomes, it is generally only undertaken in extremely obese individuals (BMI greater than 60kg/m^2); or used as a last resort in the case of failure of other procedures [27].</td>
</tr>
<tr>
<td>BPD with duodenal switch (BPD-DS)</td>
<td>Combined malabsorptive and restrictive</td>
<td>A variation of BPD which includes a different type of gastrectomy and a longer common intestinal channel. The gastrectomy involves the creation of a sleeve-like gastric pouch (150-200ml capacity), which preserves the gastric pylorus and proximal duodenum (beginning of the intestinal tract). The end of the proximal duodenum is attached to remaining intestinal tract [26].</td>
<td>Achieve high level of sustained weight loss [26] / Non reversible, high complexity increasing risk of complications, can cause nutritional deficiencies [26, 36].</td>
<td>This procedure with the longer common channel was designed in response to protein-energy malnutrition observed with ordinary BPD [26].</td>
</tr>
<tr>
<td>Sleeve gastrectomy</td>
<td>Restrictive</td>
<td>Involves creation of a small gastric sleeve as per the first stage of BPD with duodenal switch.</td>
<td>Requires less follow up than LAGB, less likely to cause GI side effects than BPD/BPD-DS [26] / Non reversible, little known regarding long-term weight loss and complication outcomes [26].</td>
<td>This is an emerging procedure with limited data available on long term weight and health outcomes, including complications [37].</td>
</tr>
<tr>
<td>Procedure</td>
<td>Classification</td>
<td>Description</td>
<td>Advantages / Disadvantages</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------</td>
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<tr>
<td>Roux-en-Y gastric bypass (RYGB) RYGB cont.</td>
<td>Primarily restrictive</td>
<td>Involves the creation of a small gastric pouch (15-30ml capacity), which is usually completely detached from the remaining larger portion of stomach. The intestinal tract is then divided, with one part (jejunum) surgically connected to the gastric pouch (called the Roux limb). The other part of the intestine (duodenum) remains joined to the disused portion of stomach, and is reconnected to the Roux limb at approximately 75-150cm down the tract. [26].</td>
<td>Achieves significant long term weight loss Lower rate of complications and adverse nutritional effects than BPD [26]/ Non reversible, higher rate of complications than LAGB, can cause GI side effects including dumping syndrome and diarrhoea, can cause nutritional deficiencies [26, 36].</td>
<td>RYGB may include an element of malabsorption given that a portion of the upper intestines is bypassed [38]. The malabsorptive potential of gastric bypass depends on the length of intestine bypassed, whereby shorter bypasses (most common) are less likely to involve significant malabsorption [26]. Considered 'gold standard' procedure for comparison and evaluation of outcomes [26].</td>
</tr>
<tr>
<td>Laparoscopic adjustable gastric banding (LAGB)</td>
<td>Restrictive</td>
<td>An adjustable silicone band is fixed around upper portion of stomach. A port attached to the band is placed underneath the skin in the abdomen, which can be used to adjust restriction level of the band with saline [26].</td>
<td>Achieves significant weight loss, minimally invasive, low risk profile, adjustable, reversible; unlikely to cause diarrhoea/ dumping or nutrient deficiencies [26, 36]/ Less weight loss when compared with BPD and RYGB, requires more intensive follow-up (dietary counselling and band adjustments), can cause vomiting and regurgitation [26, 36].</td>
<td>Evolved from VBG [26].</td>
</tr>
</tbody>
</table>
Figure 1.1 Historical surgical procedures for obesity

(A) Jejunoileal bypass. (B) Loop gastric bypass. (C) Horizontal gastroplasty. (D) Vertical banded gastroplasty. Figures adapted from Current Problems in Surgery, 45(2), Tessier, D. and Eagon, C., Surgical Management of Morbid Obesity, Pages 68-37, Copyright (2088), with permission from Elsevier [26].

Figure 1.2 Current surgical procedures for obesity

(A) Biliopancreatic diversion. (B) Biliopancreatic diversion with duodenal switch. (C) Sleeve gastrectomy (D) Roux en Y gastric bypass. (E) Laparoscopic gastric banding. Figures adapted from Current Problems in Surgery, 45(2), Tessier, D. and Eagon, C., Surgical Management of Morbid Obesity, Pages 68-37, Copyright (2088), with permission from Elsevier [26].
1.3.4 Laparoscopic adjustable gastric banding

Laparoscopic adjustable gastric banding involves fixing an adjustable silicone band around the upper portion of stomach and a port attached to the band is placed underneath the skin in the abdomen [26]. The port can be used to adjust the level of restriction within the band via the addition or removal of saline using a syringe at the port site [26] (Figure 1.3). The specific mechanisms of LAGB remain unclear; however it is believed that the pressure exerted by the band on the stomach acts to induce physiological signals of reduced hunger and early satiety, thereby facilitating reductions in overall food intake and subsequent weight loss [39].

![Figure 1.3 Laparoscopic adjustable gastric banding](image)

Figure 1.3 Laparoscopic adjustable gastric banding

Figure adapted from Current Problems in Surgery, 45(2), Tessier, D. and Eagon, C., Surgical Management of Morbid Obesity, Pages 68-37, Copyright (2088), with permission from Elsevier [26]

Worldwide, LAGB accounts for approximately 40% of obesity surgery procedures [28] and it is the most popular form of obesity surgery in Australia, accounting for up to 95% of obesity surgeries performed [40, 41] (Figure 1.4). The popularity of LAGB can be attributed to its favourable risk profile and minimal invasiveness when compared with other techniques [36]. It is also less likely to cause nutritional deficiencies given that integrity of the gastrointestinal tract is maintained [42]. Furthermore, LAGB is the only completely reversible surgical option with proven weight loss efficacy [16, 42-44]. As such, LAGB is predicted to remain at the forefront of obesity treatment well into the future [16, 45, 46].
1.4 Health outcomes following laparoscopic adjustable gastric banding

1.4.1 Weight loss and reductions in comorbidities

On average, individuals who undergo LAGB lose approximately 50% of their excess body weight by two years post-surgery [23, 31, 47]. This equates to an average weight loss range of approximately 20-40kg or 20-30% of initial body weight [15, 47-56]. The most rapid period of weight loss occurs during the first six months after surgery, with a more gradual loss occurring over the next six months to two years [15, 53, 57-62]. Although there is limited published data available for longer-term weight loss outcomes following LAGB, there is some evidence to suggest that maximal weight loss is achieved at this two year time point [20, 23]. The best evidence for long-term weight loss is from a large Swedish case-control study that compared weight loss after bariatric surgery (n=2010) with lifestyle modification (n=2037) over a ten year period.
Average weight loss after LAGB (n=237) was 14% (of baseline weight) compared with a weight change of ±2% in the control group (n=886) [20].

Weight loss achieved following LAGB is associated with significant improvements in obesity related conditions including CVD, type II diabetes, depression, hypertension, hyperlipidemias and impaired glucose metabolism [15, 16, 20, 53, 61, 63]. Individuals also report significant improvements in health-related quality of life following surgery [64] [65]. Despite the weight and health improvements that are achievable following LAGB, one of the primary reported failings is the potential for inadequate weight loss and weight regain following surgery [66-72]. Individuals who do not achieve significant weight loss or regain weight following LAGB remain at severe risk of developing obesity-related comorbidities. This key limitation must be addressed to ensure that LAGB is available as a safe and effective weight loss strategy for obese individuals who are most vulnerable to obesity-related poor health.

### 1.4.2 Changes in body composition

Weight loss following LAGB is predominantly from loss of fat mass [15, 50, 51, 53, 54, 56, 73-76] however some loss of fat free mass (FFM) also occurs. Components of FFM include muscle, bone, organs, connective tissue and body water [77]. A systematic review investigating changes in FFM during significant weight loss found that the median loss of FFM as a percentage of total weight loss between 6 and 24 months after LAGB is 17.5% [78]. The authors highlighted that there was limited high quality data available (n=7 studies) for the review and that further research is required to examine such changes in body composition [78].

In absolute terms, FFM loss reported in observational studies averages at approximately 4kg at six months [15, 50, 53, 73, 74] and 5kg at 12 months post-surgery [15, 51, 53, 56, 75, 76]. Most studies have reported these changes as statistically significant [15, 20, 50, 51, 53, 56, 73-76]. Although there have been few body composition outcomes reported in the literature beyond 12 months, there is evidence
from some studies that significant losses of FFM continue into the second postoperative year [15, 49].

The consequences of FFM loss following LAGB remain unclear; and not all studies support that the observed level of loss is problematic [51, 73, 78]. One difficulty in evaluating this is that there is no well-defined level of FFM loss that is associated with negative health effects [78]. Given that FFM is a major regulator of resting energy expenditure, body temperature, skeletal strength and integrity and also helps to maintain functional capacity and quality of life during aging [77], it can be argued that any attenuation of FFM loss may contribute to optimising weight loss and health outcomes for individuals who have LAGB.

1.5 Diet and nutrition after laparoscopic adjustable gastric banding

1.5.1 Nutritional status

Several studies have assessed the nutritional status of individuals who have had LAGB based on biochemical nutrient parameters [15, 42, 53, 79]. These studies, although limited by small sample sizes and relatively short follow-up periods, have consistently demonstrated that LAGB is unlikely to result in any major clinical nutrient deficiencies [15, 42, 53, 79]. Given that individuals who undergo LAGB remain theoretically vulnerable to suboptimal nutrition as a consequence of significantly reduced food intake, ongoing multivitamin supplementation is generally recommended [80]. Although the need for micronutrient supplements has not been proven unequivocally [53, 79], multivitamin supplementation is considered as a safe and viable measure to help prevent the development of deficiencies following LAGB [15].

1.5.2 Dietary management of individuals who had had LAGB

Given that LAGB does not alter biological digestive or absorptive capacity, it is generally recognised that its success as a weight loss procedure is dependent on the successful adoption of new eating behaviours in order to achieve reduced daily energy
intakes. As such the role of diet, eating behaviour and dietary follow-up is considered critical to the success of LAGB [81-84]. Despite this, the evidence base guiding dietary and nutritional management of individuals who have LAGB is limited (Chapter 2). Although based on limited evidence, current dietary management principles for individuals who have had LAGB can be divided into three phases: i) pre-operative preparation, ii) convalescence from surgery in the immediate post-operative period and iii) longer-term dietary management. Table 1.4 outlines the key elements of each phase.

### Table 1.4 Current dietary management principles for LAGB

<table>
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<tr>
<th>Phase</th>
<th>Key elements</th>
<th>Rationale</th>
</tr>
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</table>
| Pre-operative period         | Very low energy diet (meal replacement program) for 2-6 weeks prior to surgery [85, 86]                                                                                                                     | - To reduce liver size/volume to assist surgeon with ease of operation [85-87]  
- To prepare individuals for liquid phase in immediate post-operative period and dramatic dietary intake changes post-surgery                                    |
| Immediate post-operative period | Fluid diet for first 1-2 weeks [88-90].  
- Include protein-rich fluids e.g. milk, protein supplements [89].  
Transition phase for following 2-4 weeks [88][90]:  
- Puree foods for 1-2 weeks [89, 90]  
- Graduate to soft foods for further 1-2 weeks [88-90]  
- Graduate to regular solid foods by 4-6 post surgery [88-90]  
- Daily energy intake goal: ~3300-5000kJ (800-1200kcal)[88] | To allow convalescence from surgery:  
- Allow site of band to heal (membrane forms around band)[88]  
- Allow band to settle into appropriate position (i.e. ensure band is not dislodged)[88]  
- Aim is to prevent vomiting and excessive pressure on band during the band-settling period to help prevent gastric prolapse complications [88] |
| Longer-term dietary management | Ongoing once regular solid diet has been introduced:  
- Eat 3-6 small meals per day [80, 88, 90]  
- Eat healthy, balanced diet with focus on adequate protein, fruit, vegetables and wholegrains [80]  
- Protein intake goal: 60-120g/day [80, 89]  
- Daily energy intake goal ~3300-5000kJ (800-1200kcal)[88]  
- Eat slowly [60, 88] and chew foods well [88]  
- Stop eating when comfortably full [88]  
- Avoid fluids with meals [60, 88]  
- Consume non-caloric fluids only [88]  
- Limit intake of extras foods (e.g. sweets, cakes, ice-cream, chips) [90]  
- Daily multivitamin supplementation [80] | - Prevent food lodgement/vomiting/regurgitation [88, 90]  
- Help maximise satiating effect of band [88]  
- Help maximise nutrient intake [89]  
- Minimise intake of high energy foods to assist with weight loss [60, 88, 90] |

Despite the intuitive nature of existing dietary management principles for individuals who have had LAGB, the majority are based on professional opinion and anecdotal evidence rather than empirically proven strategies [80, 81, 88-90]. Furthermore, existing guidelines have also tended to focus on the prevention of clinical nutrient deficiencies and overt post-surgery difficulties with food ingestion rather than optimisation of weight loss and other diet-related outcomes [80, 89]; or provide only general
suggestions for weight loss (for example, minimising energy and fat intake [88, 90]), with management of eating behaviours largely overlooked. Currently available practice guidelines are also further limited by their generic nature, covering multiple types of surgical procedures for obesity rather than focused on issues specific for LAGB [80, 89].

In summary, there remains a broad scope for research to contribute to the evidence base for the best-practice dietary management of individuals who have undergone LAGB. This underpins the overall rationale for the body of research undertaken for this thesis.

1.6 Research aims

The overarching aim of this thesis is to contribute to the evidence base informing the dietary management of individuals who have had LAGB surgery; with focus on the optimisation of weight loss after surgery. Specific aims of this research according to component of investigation are:

i) Systematic reviews of the literature examining dietary intake and eating behaviours after LAGB:

1. To systematically review the current evidence base for dietary intake outcomes after LAGB.
2. To systematically review the current evidence base for eating behaviour outcomes after LAGB.

ii) Pilot intervention study investigating the feasibility and potential utility of a protein-enriched diet after surgery:

3. To evaluate the feasibility of implementing a protein-enriched diet after LAGB.
4. To assess the relationship between protein intake and weight loss and body composition outcomes after LAGB.
5. To examine whether eating behaviours are related to weight loss, quality of life, dietary intake and food tolerance outcomes after LAGB
iii) Cross-sectional survey of eating behaviour, food tolerance, dietary intake, weight loss and wellbeing within the first two years after LAGB:

6. Describe eating behaviours, food tolerance, and dietary intake in individuals who have undergone LAGB.
7. Explore associations between eating behaviour, food tolerance and dietary intake variables.
8. Examine the relationship between eating behaviour, food tolerance, dietary intake and percentage weight loss.
9. Examine the relationship between eating behaviour and food tolerance and quality of life.

1.7 Research questions

The subsequent research questions for each research aim are:

i) Systematic review of the literature examining dietary intake and eating behaviours after LAGB:

1. What are the dietary intake outcomes of LAGB, as indicated by previous published studies in this field?
2. Is there any evidence for the relationship between postoperative dietary intake and weight loss following LAGB?
3. What are the eating behaviour outcomes of LAGB, as indicated by previous published studies in this field?
4. Is there any evidence for the relationship between postoperative eating behaviours and weight loss following LAGB?

ii) Pilot intervention study investigating the feasibility and potential utility of a protein-enriched diet after surgery:

5. Is the implementation of a protein-enriched diet feasible after LAGB?
6. Is protein intake related to weight loss and/or body composition outcomes after LAGB?
7. Is eating behaviour related to percentage weight loss after LAGB?
8. Is eating behaviour related to quality of life after LAGB
9. Is eating behaviour related to energy and macronutrient intake after LAGB?
10. Is eating behaviour related to food tolerance after LAGB?

iii) Cross-sectional survey of eating behaviour, food tolerance and dietary intake after LAGB:

11. What are the eating behaviours of individuals who undergo LAGB and how do they compare with reference/community norms?
12. What are the food tolerance outcomes of individuals who undergo LAGB?
13. What are the dietary intakes of individuals who undergo LAGB and how do these compare with recommended intakes?
14. Are eating behaviour, food tolerance and dietary intake outcomes after LAGB interrelated?
15. What eating behaviour, food tolerance and dietary intake variables are related to percentage weight loss after LAGB?
16. What eating behaviour, food tolerance and dietary intake variables are related to functional health and wellbeing after LAGB?

The research aims and associated research questions are addressed within the respective research papers/chapters of this thesis, as outlined in Table 1.5.

| Table 1.5 Chapter reference for each research aim and associated research questions |
|--------------------------------|----------------|----------------|
| Research aim | Question | Chapter |
| To systematically review the current evidence base for dietary intake outcomes after LAGB. | 1, 2 | 2 (Section 2.2) |
| To systematically review the current evidence base for eating behaviour outcomes after LAGB. | 3, 4 | 2 (Section 2.3) |
| To evaluate the feasibility of implementing a protein-enriched diet after LAGB. | 5 | 4 |
| To assess the relationship between protein intake and weight loss and body composition outcomes after LAGB. | 6 | 4 |
| To examine whether eating behaviours are related to weight loss, quality of life, dietary intake and food tolerance outcomes after LAGB | 7-10 | 5 |
| Describe eating behaviours, food tolerance, and dietary intake in individuals who have undergone LAGB. | 11-13 | 6 |
| Explore associations between eating behaviour, food tolerance and dietary intake variables. | 14 | 6 |
| Examine the relationship between eating behaviour, food tolerance, dietary intake and percentage weight loss. | 15 | 6 |
| Examine the relationship between eating behaviour and food tolerance and quality of life. | 16 | 6 |
1.8 Scope of research

Excluding the systematic review component of the thesis, this research was limited to the study of individuals who had undergone LAGB between 2008 and 2009 in the greater Newcastle/Lake Macquarie region of NSW, Australia; reflecting geographic accessibility for undertaking the research. This specifically involved the two Newcastle/Lake Macquarie-based private surgical practices that offered LAGB services at the time the research was undertaken; with the private healthcare setting reflecting the predominantly privately funded nature of LAGB in Australia [91].

The research for this thesis was undertaken within the typical timeframe and funding limitations of three year full-time doctoral studies. Thus it was not possible to assess longer-term outcomes or conduct longer-term follow-up of participants, despite the importance of and need for longer-term data in this field of research. Additionally, it was necessary for the research undertaken to be unobtrusive to usual systems of care within the private practices involved in the studies undertaken, which imposed some flexibility limitations regarding the nature of research undertaken.

1.9 Significance

Obesity surgery has proven to be the most efficacious treatment presently available for obesity, with LAGB representing the second most popular surgical procedure in the world and the most popular procedure in Australia [28]. Despite the potential advantages of LAGB, there is growing evidence that suboptimal weight loss and/or weight regain can be problematic for a significant number of individuals who undergo the procedure [66-71]. Although ongoing dietary follow-up of individuals is considered integral to the success of LAGB, very little evidence exists to guide best-practice dietary management of individuals who have had LAGB. This thesis seeks to contribute to knowledge in this field, with view to better inform strategies that may help to optimise weight loss, body composition, dietary, behavioural and wellbeing outcomes of individuals who have LAGB.
This body of research includes the first known dietary intervention conducted in the LAGB population, providing an original contribution to the body of evidence regarding potential dietary intervention strategies for the optimisation of weight loss and other diet-related health outcomes after LAGB. This thesis also contributes detailed data to the existing evidence base for eating behaviour, food tolerance and dietary intake after LAGB, providing potential guidance and insights for practice and future research into the optimal dietary management of individuals who undergo LAGB.

Overall, this thesis will help inform the continuing development of best-practice dietary management guidelines for LAGB patients, making an important contribution to dietary management practices in this emerging field.
Chapter 2   Literature review

2.1 Overview

This chapter begins with two published systematic review papers examining the existing evidence base for dietary intake and eating behaviour outcomes following LAGB, representing the first component of investigation for the body of research undertaken for this thesis. The final section of the literature review provides a detailed review of protein intake and weight loss, including proposed advantages of higher protein intakes and an analysis of the evidence from surgical and lifestyle weight loss interventions regarding the influence of higher protein diets on weight loss, body composition and metabolic markers of health. This final section of the literature review provides further justification of the underlying rationale for the protein-enriched dietary intervention component of research.
2.2 A systematic review of dietary intake after laparoscopic adjustable gastric banding

This section has been published:


The work presented in the manuscript was completed in collaboration with the co-authors (Appendix 1). Permission to reproduce the text and figures from the manuscript has been granted by the publishers.

2.2.1 Abstract

Background: Laparoscopic adjustable gastric banding (LAGB) is currently one of the most popular surgical obesity treatments worldwide. Although dietary modification is recognised as a key factor in determining weight loss and health outcomes post-surgery, existing evidence regarding changes in dietary intake after LAGB has not been systematically evaluated. This is essential for developing best-practice dietetic guidelines for the management of LAGB patients. The aim of this systematic review was to evaluate the current evidence base regarding changes in dietary intake after LAGB.

Methods: A literature search of Medline, EMBASE, Scopus, Cinahl and the Cochrane Library from 1990 to February 2010 was conducted to identify original studies that assessed dietary intake in adults who have undergone LAGB.

Results: Only 11 articles (10 separate studies) met inclusion criteria. Although the strength of the evidence base is limited by the small number of studies, observational study designs and methodological weaknesses, the results indicate that short-term positive changes occur post-surgery, including reduced caloric intake, contributed to by reductions in fat, carbohydrate and protein intake. Issues including optimal macronutrient intake, diet quality and longer-term sustainability of reduced food
intake remain largely unexplored. Because no dietary intervention studies were identified, evidence-based dietary strategies that may help optimise weight loss outcomes and other health outcomes remain unknown.

Conclusions: There is a paucity of high-quality evidence regarding changes in dietary intake after LAGB. Further well-designed, dietary-based intervention research will be beneficial to better establish dietetic management guidelines for optimising outcomes for individuals who have LAGB.

2.2.2 Introduction

Bariatric surgery is increasingly gaining recognition as the most efficacious treatment strategy for obesity compared to traditional lifestyle and pharmacological approaches [43]. Laparoscopic adjustable gastric banding (LAGB) is currently the most popular form of obesity surgery in the UK, Europe and Australia [92], and is the second most popular procedure in the USA [93]. LAGB is a purely restrictive procedure, facilitating weight loss by acting as a tool to reduce food intake rather than altering digestive and/or absorptive processes [43].

Average weight loss following LAGB is 20–30% of initial body weight by 2 years post-surgery [15, 94], with longer-term weight loss maintained at approximately 14% of initial weight [94]. Although LAGB generally achieves smaller weight losses compared to more invasive procedures such as roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy [43], this is offset by its favourable risk profile and complete reversibility, with integrity of the gastrointestinal tract maintained [36]. As such, LAGB is likely to remain as a preferred surgical option for obesity in the foreseeable future, despite criticism that it may lead to inadequate weight loss and/or weight regain over the longer term [67, 71].

Given the intrinsic link between an individual’s ability to modify food intake behaviours and weight loss following LAGB, compliance with dietary advice and ongoing dietary follow-up are often cited as key factors in determining weight loss and health outcomes post-surgery [44, 83, 95]. Despite this, there has been limited
evaluation of the evidence regarding post-operative dietary intake in the context of weight loss and health optimisation after LAGB. Previous reviews and practice guidelines have generally focused on clinical nutritional deficiencies [25, 38, 68, 80, 89, 96], where it is generally accepted that prophylactic supplementation with a multivitamin post-surgery is sufficient to prevent overt deficiencies from occurring [15, 89].

Evaluation of the current evidence base is an important step for identifying dietary strategies that may help optimise weight loss and health outcomes for individuals who have had LAGB. This will assist in the development of best practice dietetic guidelines for the management of LAGB in the context of weight loss and health optimisation post-surgery. Therefore, the present study aims to systematically review the current evidence regarding changes in dietary intake following LAGB, with a view to inform further development of dietetic management guidelines in the future.

2.2.3 Materials and methods

This present study reports on dietary intake outcomes identified as part of a broader systematic review of dietary intake and eating behaviours after LAGB. Results of the eating behaviour component of the review will be published separately.

2.2.3.1 Review inclusion criteria

Any original published study that reported dietary intake outcomes for adults (aged >18 years) who had undergone LAGB was considered for inclusion. Children/adolescent studies were not included given that LAGB is traditionally performed in adults, and children/adolescents represent a distinct needs group that is not directly comparable with the adult population. Studies were not limited to randomised control trials (RCTs) because based on preliminary literature searches, the authors anticipated a scarcity of RCTs in the area. Cross-sectional studies were considered only if they included a post-operative LAGB group and a preoperative comparison group. Because it was anticipated that there would be a paucity of studies
available for inclusion in the review, the minimum length of follow-up post-surgery was not set as an inclusion criterion.

The following types of articles were excluded: narrative reviews, conference abstracts, case reports, editorials, letters, comments and any other articles that were not original research papers. Studies that did not clearly specify the surgical procedure undertaken or that combined results of LAGB with other surgical procedures were also excluded. Studies that only reported preoperative dietary variables or that did not report specific results for which data could be extracted were also deemed ineligible for inclusion.

2.2.3.2 Search strategy

To identify relevant articles, the following electronic databases were searched: Medline (Ovid SP), EMBASE, Scopus, Cinahl and the Cochrane Library. Combinations of the following search terms were used: ‘gastric banding’ OR ‘LAGB’ OR ‘gastroplasty’ AND ‘dietary’ OR ‘nutrition’ OR ‘food’ OR ‘eating’ OR ‘feeding’ OR ‘calori*’. The search strategy was modified for each database as required, with limits set for humans, English language, adult population and publication date after 1990. A publication date limit was set given that LAGB was not an established procedure prior to this time. Reference lists of all retrieved papers were also manually searched to identify any additional articles not identified by the electronic search. The search included articles published up to February 2010. Unpublished studies were not included in the search strategy.

2.2.3.3 Study selection

To identify studies that met review criteria, two reviewers independently assessed information provided in the title, abstract and keywords aiming to make a decision about the article’s suitability for inclusion. In the case that there was insufficient information in the title and abstract to determine suitability for inclusion, the full paper was retrieved and reviewed so that a determination could be made.
2.2.3.4 Critical appraisal

Methodological quality of included studies was assessed independently by two reviewers using the Quality Assessment Tool for Quantitative Studies [97]. This tool has established content and construct validity [98] and has been deemed appropriate for assessing study quality in systematic reviews, with the advantage of covering multiple types of study design including controlled and uncontrolled studies [99]. The tool was modified to include an additional question for assessment of confounders relevant to observational study designs, as adapted from the American Dietetic Association Evidence Analysis Library: Quality Criteria Checklist for Primary Research (ADAEAL: QCCPR) [100]. A copy of the modified tool is provided in Appendix 2.

Detailed instructions as provided by the Quality Assessment Tool for Quantitative Studies developers were used as a basis to determine the overall quality rating for each study [101]. In summary, this involved rating each component within the tool as ‘strong’, ‘moderate’ or weak’, based on question specific criteria provided in the guidelines [101]. A global rating was then assigned using the following criteria: strong (at least four strong component ratings with no weak ratings); moderate (less than four strong ratings and one weak rating); and weak (two or more weak ratings) [97]. Because the quality checklist tool did not include an assessment of potential funding bias, this was assessed using a question from the ADAEAL: QCCPR, ‘Is bias due to study’s funding or sponsorship unlikely?’, determined by the sub-questions: ‘Were sources of funding and investigators’ affiliations described?’ and ‘was there no apparent conflict of interest? The overall response options were: Yes/No/Unclear or N/A, with critical reasoning skills required to make an overall determination [100].

Studies were also graded according to Australia’s National Health and Medical Research Council (NHMRC) level of evidence guidelines to further assess the degree to which bias has been eliminated by study design [102]. Level I reflects the highest level evidence (systematic reviews of RCTs) and level IV reflects the lowest (case series and cross-sectional studies) [103].
2.2.3.5 Data extraction and synthesis

Data relating to study characteristics, study design, methodology and dietary intake outcomes were extracted by the first reviewer using standardised, self-developed data extraction forms. Specific data extracted included: length of follow-up, number of participants, retention rate, study setting, subject characteristics (gender, age, preoperative weight, body mass index), mean weight loss post-surgery, dietary intake assessment methodology and all dietary intake results for which post-operative data were reported. These dietary intake results included: pre-operative and post-operative energy, nutrient and food group intakes (including changes in intake); dietary-related comparisons between non-operative controls and/or subjects with different types of gastric band; relationships between dietary intake variables; and relationships between dietary intake variables and weight loss outcomes where available.

In the case that a study compared LAGB with another surgical procedure/weight loss intervention, only data relevant to the LAGB arm of the study were extracted because it was not an aim of the present review to compare outcomes of LAGB with other procedures. Data extraction was verified by the second reviewer. Results for dietary intake outcomes were tabulated and described using narrative summary. A meta-analysis was not attempted as a result of variability in the outcomes assessed and methodological differences between studies.

2.2.4 Results

2.2.4.1 Description and critical appraisal of included studies

Of the 815 articles identified from the search strategy, 85 articles were retrieved with 11 articles (10 separate studies) identified for inclusion in the dietary intake component of the review (Figure 2.1). All studies were observational with respect to dietary intake outcomes, with one study classified as level III-2 evidence [14], one as level III-3 [104] and eight studies (nine articles) as level IV evidence [52, 60, 79, 82, 105-109] according to NHMRC guidelines. Although all studies were classified as observational, most did include some reference to post-operative dietary advice provided [52, 60, 79, 82, 104,
Details regarding the nature and frequency of this follow up care were variable, however, and no study directly evaluated the impact that this advice may have had on dietary intake outcomes.

The follow-up period of included studies was in the range 3 months to 10 years; however, the majority of studies were in the range 6 months and 2 years. Sample size was in the range 20–946 subjects, although most studies (n = 7) had <100 participants. Females predominated in every study, although six studies did include a small proportion of males. Average baseline body mass index of participants was generally >40 kg/m² and all studies were from Europe or Australia. Summary characteristics of included studies are provided in Table 2.1.

Figure 2.1 Flow diagram of included and excluded studies for review

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*Results published in a separate review article (Section 2.2)*

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106-109]
No articles met the criteria for a strong quality study. Eight articles were classified as moderate quality [14, 60, 82, 104-107, 109] and three articles were classified as weak [52, 79, 108]. Key limitations included: a nonrandomised study design (all studies), potential for selection bias [52, 106-108], poor or unknown validity and reliability of data collection methods [52, 79, 108, 109], and limited consideration of confounding factors [52, 79, 108]. Only three studies reported the funding source [14, 52, 108], for which potential funding bias was deemed as unlikely. Potential funding bias for the remaining eight studies was deemed as unclear. Based on author affiliations, however, there were no apparent conflicts of interest for any of the included studies.
<table>
<thead>
<tr>
<th>Study (first author)</th>
<th>Study design</th>
<th>Level of evidence¹</th>
<th>Follow-up</th>
<th>n</th>
<th>Retention²</th>
<th>Setting</th>
<th>Female:Male</th>
<th>Age±SD (years)³</th>
<th>Weight±SD (kg)</th>
<th>BMI±SD (kg/m²)</th>
<th>Mean weight loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Busetto 1996 [60])</td>
<td>Prospective case series</td>
<td>IV</td>
<td>1 year</td>
<td>80</td>
<td>100% (80/80)</td>
<td>Italy</td>
<td>57.23</td>
<td>36.0±11.0</td>
<td>133.4±26.7</td>
<td>48.0±7.5</td>
<td>34.4±14.9 kg</td>
</tr>
<tr>
<td>Busetto 1997 [104]</td>
<td>Comparative case series with historical control: ASGB (matched controls from [60] (a) versus Lap-band (b))</td>
<td>III-3</td>
<td>1 year</td>
<td>60 (a/b) 30/30</td>
<td>100% (60/60)</td>
<td>Italy</td>
<td>60.0</td>
<td>(a) 34.1±10.1 (b) 37.4±10.6</td>
<td>(a) 117.4±10.8 (b) 111.2±13.7</td>
<td>(a) 44.2±3.3 (b) 43.1±5.1</td>
<td>(a) 30.0±11.4 kg (b) 25.4±9.7 kg</td>
</tr>
<tr>
<td>Colles 2008 (a) [82] &amp; Colles 2008 (b) [109]</td>
<td>Prospective case series</td>
<td>IV</td>
<td>1 year</td>
<td>129</td>
<td>75% (129/173)</td>
<td>Australia</td>
<td>103:26</td>
<td>45.2±11.5</td>
<td>122.2±20.5</td>
<td>44.3±6.8</td>
<td>4 m: 16.5 kg 12 m: 25.7 kg</td>
</tr>
<tr>
<td>Coupaye 2009 [79]</td>
<td>Comparative case series (LAGB versus RYBG)</td>
<td>IV</td>
<td>1 year</td>
<td>21</td>
<td>Unclear</td>
<td>France</td>
<td>18.3</td>
<td>35±10</td>
<td>116±12</td>
<td>43±3</td>
<td>16±8 kg</td>
</tr>
<tr>
<td>Ernst 2009 [52]</td>
<td>Cross-sectional comparison (LAGB, RYGB and non-obese and obese controls)</td>
<td>IV</td>
<td>Time since LAGB: 78.9±3.2 months</td>
<td>73</td>
<td>NR</td>
<td>Switzerland</td>
<td>59:14</td>
<td>44.0±1.2</td>
<td>NR</td>
<td>44.6±0.5</td>
<td>Mean % EWL: 48.1±2.6</td>
</tr>
<tr>
<td>Guida 2005 [106]</td>
<td>Prospective case series</td>
<td>IV</td>
<td>2 years</td>
<td>20</td>
<td>100% (20/20)</td>
<td>Italy</td>
<td>20.0</td>
<td>36±6</td>
<td>120.2±16.4</td>
<td>46.1±6.8</td>
<td>6 m: 18.5±5.9 kg 2 y: 34 kg</td>
</tr>
<tr>
<td>Study (first author)</td>
<td>Study design</td>
<td>Level of evidence</td>
<td>Follow-up</td>
<td>n</td>
<td>Retention</td>
<td>Setting</td>
<td>Female:Male</td>
<td>Age±SD (years)</td>
<td>Weight±SD (kg)</td>
<td>BMI±SD (kg/m²)</td>
<td>Mean weight loss</td>
</tr>
<tr>
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</tr>
<tr>
<td>Larsen 2004 [105]</td>
<td>Cross-sectional comparison [3 groups: PS (a), 8-24m PO (b), 25-68m PO (c)]</td>
<td>IV</td>
<td>Time since LAGB (months): (a) NA (b) 16 (8-24) (c) 42 (25-68)</td>
<td>(a) 89 (b) 48 (c) 109</td>
<td>(a) 75.6% (b/c) 81.6%</td>
<td>Netherlands</td>
<td>(a) 77.16 (b) 42.6 (c) 102:7</td>
<td>(a) 39 (22-59) (b) 40 (24-61) (c) 41 (22-55)</td>
<td>NR</td>
<td>(a) 46.5 (37-67) (b) 45.5 (37-72) (c) 45.4 (36-63)</td>
<td></td>
</tr>
<tr>
<td>Savastano 2005 [107]</td>
<td>Prospective case series</td>
<td>IV</td>
<td>2 years</td>
<td>30</td>
<td>100% (30/30)</td>
<td>Italy</td>
<td>30:0</td>
<td>36.7±6.4</td>
<td>126.3±17.3</td>
<td>48.4±7.1</td>
<td>Mean % WL: 12 m: 25.1±5.2 (~33 kg) 24 m: 27.7±6.4 (~36 kg)</td>
</tr>
<tr>
<td>Sjostrom 2004 [14]</td>
<td>Prospective cohort with matched controls [Surgical group: LAGB, VBG, RYBG (a) versus nonsurgical controls]</td>
<td>III-2</td>
<td>10 years</td>
<td>(a) 641 (LAGB: 156)</td>
<td>Unclear: Overall for (a) 75.3%</td>
<td>Sweden</td>
<td>Unclear: Overall for (a) 445:196</td>
<td>Unclear: Overall for (a) 47.0±5.6</td>
<td>Unclear: Overall for (a) 120.0±16.4</td>
<td>Unclear: Overall for (a) 41.9±4.2</td>
<td>Mean % WL: LAGB 1 y: 21±10 10 y: 13.2±13</td>
</tr>
<tr>
<td>Wahlroos 2007 [108]</td>
<td>Pre-post comparative study (LAGB versus VLED)</td>
<td>IV</td>
<td>3 months</td>
<td>25</td>
<td>NR</td>
<td>Australia</td>
<td>25:0</td>
<td>20-62</td>
<td>104.5±12.2</td>
<td>38±5</td>
<td>Mean % WL: 9.0±4.3</td>
</tr>
</tbody>
</table>

**Abbreviations:** SD, standard deviation; BMI, body mass index; ASGB, adjustable silicone gastric banding; m, months; LAGB, laparoscopic adjustable gastric banding; RYGB, roux en Y gastric bypass; NR, not reported; EWL, excess weight loss; y, years; NA, not applicable; PS, pre-surgery; PO, postoperative; WL, weight loss; VBG, vertical banded gastroplasty; VLED, very low energy diet.

*Source: NHMRC levels of evidence and grades for recommendations for developers of guidelines [103]*

*For cross-sectional studies response rate is reported*

*Data reported as the mean ± SD for all studies except Larsen et al. [105] which is reported as the mean (range)*
2.2.4.2 Changes in dietary intake after LAGB

Detailed findings for the ten studies that assessed dietary intake outcomes are presented in Table 2.2. The method of dietary assessment was variable; however, all but one study [108] used a retrospective approach. This included different food frequency questionnaires [52, 82, 106, 107, 109], specifically developed dietary intake questionnaires [14], dietitian administered 24-h recalls [60, 104] and non-specified dietitian assessment [79]. Additionally, one study used the Dutch Fat Consumption Questionnaire to assess the level of fat intake only [105].

Despite methodological variability, eight studies reported outcomes for energy intake [14, 60, 79, 82, 104, 106-108]. Significant reductions in energy intake were consistently reported for the immediate 3–6 months post-surgery, with energy intake reductions in the range 45–73% [60, 82, 106-108]. Studies with longitudinal measures suggest this reduction was generally maintained over the first 1–2 post-operative years [60, 82, 104, 106, 107]; however, there was a non-statistically significant trend for energy intake to increase gradually over time in three of these studies [60, 104, 106].

The reduction in energy intake reported by Coupaye et al. [79] who only measured energy intake at baseline and 1 year, was more modest than other studies, equating to a reduction of approximately 30%. The one longer-term study by Sjöström et al. (Swedish Obese Subjects cohort) [14] reported energy intakes of approximately 7.7 MJ (approximately 1840 kcal) at 10 years after LAGB. In their study, the lowest energy intakes occurred at 6 months post-surgery, with gradual increases recorded between this point and 4 years, before a relative plateau occurring between 4 and 10 years post-surgery [14].
**Table 2.2 Summary of dietary intake findings**

<table>
<thead>
<tr>
<th>Study (first author)</th>
<th>Assessment Method</th>
<th>Variable/s</th>
<th>Result$^{ab}$</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Busetto 1996 [60]</strong></td>
<td>Dietitian administered 24-hour recall</td>
<td>Time point</td>
<td>PS</td>
<td>3 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Energy intake (MJ/day)</td>
<td>11.9±6</td>
<td>3.2±1.2*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Macronutrient intakes as % daily energy intake:</td>
<td>Fat</td>
<td>36±10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carbohydrate</td>
<td>45±11</td>
<td>40±11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein</td>
<td>17±5</td>
<td>22±7*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Food consistency as % daily energy intake:</td>
<td>Liquid foods</td>
<td>15±13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Soft foods</td>
<td>13±12</td>
<td>18±22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Solid foods</td>
<td>72±15</td>
<td>56±26*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of food contacts (meals and snacks) per day</td>
<td>4.3±1</td>
<td>3.4±0.5*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Correlation between energy intake and WL</td>
<td>NA</td>
<td>$r=-0.28$</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Busetto 1997 [104]</strong></th>
<th>Dietitian administered 24-hour recall</th>
<th>Time point</th>
<th>(a) ASGB (controls)</th>
<th>(b) LAP-BAND Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Energy intake (MJ/day)</td>
<td>3.2±9.1</td>
<td>3.5±1.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Macronutrient intakes as % daily energy intake:</td>
<td>Fat</td>
<td>37±11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carbohydrate</td>
<td>42±13</td>
<td>42±13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein</td>
<td>21±6</td>
<td>19±8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Food consistency as % daily energy intake:</td>
<td>Liquid foods</td>
<td>29±20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Soft foods</td>
<td>18±21</td>
<td>16±16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Solid foods</td>
<td>53±24</td>
<td>52±27</td>
</tr>
<tr>
<td>Study (first author)</td>
<td>Assessment Method</td>
<td>Variable/s</td>
<td>Result&lt;sup&gt;a,b&lt;/sup&gt;</td>
<td>Significance</td>
</tr>
<tr>
<td>---------------------</td>
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<td>-----------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Colles 2008 (a)</td>
<td>74 item validated FFQ</td>
<td>Time point</td>
<td>PS</td>
<td>4 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Energy intake (MJ/day)</td>
<td>10.0±4.0</td>
<td>4.0±1.5*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Macronutrient intake as % daily energy intake:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fat</td>
<td>37±5</td>
<td>30±6*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carbohydrate</td>
<td>38±6</td>
<td>40±7**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein</td>
<td>20±3</td>
<td>23±4*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fat intake (g/d)</td>
<td>98.5±42.6</td>
<td>34.1±15.9*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carbohydrate intake (g/d)</td>
<td>233.0±93.4</td>
<td>100.4±39.4*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein intake (g/d)</td>
<td>113.8±40.6</td>
<td>54.0±19.7*</td>
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<tr>
<td></td>
<td></td>
<td>Food consistency as % daily energy intake:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Liquid foods</td>
<td>31±13</td>
<td>43±14*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Soft foods</td>
<td>13±6</td>
<td>13±7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Solids</td>
<td>57±12</td>
<td>45±12*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of eating episodes per day</td>
<td>5±3</td>
<td>4±3*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Correlations between dietary variables:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 m E intake and % E from fat</td>
<td>r=−0.19</td>
<td>P=0.035</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 m E intake and % E from protein</td>
<td>r=−0.25</td>
<td>P=0.006</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 m E intake and % E from carbohydrate</td>
<td>r=−0.08</td>
<td>P=0.37</td>
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<td>Relationship between dietary variables and WL:</td>
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<td></td>
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<td>Total E intake and % WL</td>
<td>r=−0.23</td>
<td>P=0.009</td>
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<td></td>
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<td>Magnitude of change in E and % WL</td>
<td>r=−0.22</td>
<td>P=0.020</td>
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<tr>
<td></td>
<td></td>
<td>Consumption of soft foods and WL</td>
<td>r=−0.16</td>
<td>P=0.075</td>
</tr>
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<td></td>
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<td>Poorer weight loss in highest energy intake quartile (5.9±1 MJ/day) versus lowest quartile (2.3±0.3MJ/day)&lt;sup&gt;f&lt;/sup&gt;</td>
<td></td>
<td>P=0.041</td>
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<td></td>
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<td>Poorer weight loss in highest fat intake quartile (&gt;41.1g/day) versus lowest quartile (&lt;22.9g/day)&lt;sup&gt;f&lt;/sup&gt;</td>
<td></td>
<td>P=0.029</td>
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<td></td>
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<td>Total energy intake independent predictor of %WL: β=−0.182; explaining 29.6% of variance&lt;sup&gt;g,h&lt;/sup&gt;</td>
<td></td>
<td>P=0.075</td>
</tr>
<tr>
<td>Coupaye 2009 [79]</td>
<td>Dietitian assessment (unspecified)</td>
<td>Energy intake (MJ/day)</td>
<td>PS: 9.6±2.7</td>
<td>12 m: 6.5±1.8</td>
</tr>
<tr>
<td>Study (first author)</td>
<td>Assessment Method</td>
<td>Variable/s</td>
<td>Resulta,b</td>
<td>Significance</td>
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<tr>
<td>Ernst 2009 [52]</td>
<td>24 food category FFQ. Frequency categories: 1, almost every day; 2, several times weekly; 3, once/week; 4, several times monthly; 5, once/month or less; 6, never</td>
<td>Food item/group intake: Obese control group</td>
<td>LAGB group (78.9±3.2 m PO)</td>
<td>P=0.002</td>
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<tr>
<td></td>
<td></td>
<td>Poultry</td>
<td>2.9±0.1</td>
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<td></td>
<td></td>
<td>Fish</td>
<td>3.6±0.1</td>
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<td></td>
<td>Pasta</td>
<td>2.9±0.1</td>
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<td>Fresh fruit</td>
<td>2.5±0.2</td>
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<td></td>
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<td>White bread/toast</td>
<td>3.3±0.2</td>
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<td>Sausage products/ham</td>
<td>2.7±0.2</td>
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<td>Potatoes, cooked/raw vegetables, chocolate, cakes/biscuits, sweets, salted snacks, cereals, yogurt, cheese, eggs, milk, fruit juice/soft drinks, diet drinks between groups</td>
<td>No differences between groups (Figures NR)</td>
<td>NS</td>
</tr>
<tr>
<td>Guida 2005 [106]</td>
<td>130 item validated FFQ</td>
<td>Time point Energy intake (MJ/day)</td>
<td>PS 6 months 12 months 24 months 12.1±1.8 5.7±1.1* 6.0±1.0* 6.5±1.0*</td>
<td>P&lt;0.05 versus PS</td>
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<td></td>
<td></td>
<td>Macronutrient intake as % daily energy intake: Fat</td>
<td>35±10 27±5* 25±8* 26±5*</td>
<td>P&lt;0.05 versus PS</td>
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<td></td>
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<td>Carbohydrate</td>
<td>47±11 53±9 55±10 54±10</td>
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<td></td>
<td>Protein</td>
<td>18±5 20±7 20±6 20±7</td>
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<td>Fat intake (higher score reflects higher intake)</td>
<td>(a) PS group:  (b) &lt;2 y PO group:  (c) &gt; 2y PO group: 30.07±7.28 26.17±5.15* 26.91±5.54*</td>
<td>P=0.00 versus (a)</td>
</tr>
<tr>
<td>Larsen 2004 [105]</td>
<td>Dutch Fat Consumption Questionnaire (validated)</td>
<td>Time point Energy intake (MJ/day)</td>
<td>PS 6 months 12 months 24 months 13.3±1.9 5.6±0.9* 5.7±1.2* 5.6±1.2*</td>
<td>P&lt;0.05 versus PS</td>
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<tr>
<td></td>
<td></td>
<td>Macronutrient intake as % daily energy intake: Fat</td>
<td>38±8 29±3* 25±8* 25±6*</td>
<td>P&lt;0.05 versus PS</td>
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<tr>
<td></td>
<td></td>
<td>Carbohydrate</td>
<td>46±9 55±9* 56±8* 55±8*</td>
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<td>Protein</td>
<td>18±2 19±4 19±4 19±3</td>
<td></td>
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<tr>
<td>Savastano 2005 [107]</td>
<td>130 item validated FFQ</td>
<td>Time point Energy intake (MJ/day)</td>
<td>PS 6 months 12 months 24 months 9.5 (LAGB and RYGB subjects) 19.7% reduction in intake (LAGB subjects)</td>
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<tr>
<td>Sjostrom 2004 [14]</td>
<td>Swedish Obese Subjects Dietary Questionnaire (validated)</td>
<td>Time point Energy intake (MJ/day)</td>
<td>PS 6 months 12 months 24 months 9.5 (LAGB and RYGB subjects) 19.7% reduction in intake (LAGB subjects)</td>
<td></td>
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<tr>
<td>Study (first author)</td>
<td>Assessment Method</td>
<td>Variable/s</td>
<td>Result&lt;sup&gt;ab&lt;/sup&gt;</td>
<td>Significance</td>
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<tr>
<td>Wahlroos 2007 [108]</td>
<td>4-day weighed food diary ('informal diet analysis') (n=17)</td>
<td><strong>Time point</strong></td>
<td>PS</td>
<td>3 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Energy intake (MJ/day)</td>
<td>11.8±4.7</td>
<td>6.5±1.7*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% Energy from fat</td>
<td>39±4</td>
<td>36±7</td>
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<tr>
<td></td>
<td></td>
<td>Total fat intake (g)</td>
<td>123±58</td>
<td>61±20*</td>
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<td></td>
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<td>Saturated fat intake (g)</td>
<td>50±20</td>
<td>23±8*</td>
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<td></td>
<td></td>
<td>Carbohydrate intake (g)</td>
<td>279±101</td>
<td>145±40*</td>
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<tr>
<td></td>
<td></td>
<td>Protein intake (g)</td>
<td>126±65</td>
<td>80±29*</td>
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<tr>
<td></td>
<td></td>
<td>Alcohol intake (g)</td>
<td>8±9</td>
<td>11±13</td>
</tr>
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</table>

Abbreviations: PS, pre surgery; m, months; MJ mega joules; WL, weight loss; ASGB, adjustable silicone gastric banding; NSD, no significant difference; E, energy; FFQ, food frequency questionnaire; PO, post-operative; NR, not reported; y, years; RYGB, roux en Y gastric bypass. * **Asterisks indicate significant time points for longitudinal results, and correspond with P values in the significance column for each variable; <sup>a</sup> Results are presented as the mean ± SD unless otherwise specified; <sup>b</sup> Statistics not reported for 6 and 12 months versus presurgery (PS); <sup>c</sup> Longitudinal changes NR; <sup>d</sup> Statistics not reported for 12 months versus presurgery; <sup>e</sup> From Colles et al. [82]; <sup>f</sup> From Colles et al. [109]; <sup>g</sup> Other significant variables in model: Higher appearance dissatisfaction, β = −0.278, subjective hunger, β = −0.254, postsurgical grazing, β = −0.186, baseline BMI, β = 0.194.
Five studies assessed overall macronutrient composition of the diet [60, 82, 104, 106, 107]. Little change in overall macronutrient composition was observed in the studies of Busetto et al. [60, 104]; however, modest reductions in percentage energy from fat and concurrent increases in percentage energy from carbohydrate were found by Colles et al. [82], Guida et al. [106] and Savastano et al. [107]. The level of protein intake as a percentage of energy remained comparable with preoperative levels [60, 106, 107] or slightly higher than [82] preoperative levels.

Only Colles et al. [82] and Wahlroos et al. [108] reported an intake of macronutrients in absolute terms (grams/day), with fat, carbohydrate and protein intake all significantly reduced at 3–4 months post-surgery. Colles et al. [82] reported these reduced intakes were maintained at 1 year post-surgery, and a similar pattern of reduced macronutrient intakes can also be calculated from the studies that reported overall macronutrient composition of the diet [60, 104, 106, 107]. Based on this, protein intake was in the range of 40–80 grams per day at 3–6 months [60, 82, 104, 106-108] and 47–75 grams per day at 12 months post-surgery [60, 82, 104, 106, 107].

Two studies reported on changes in eating frequency, with both reporting decreased eating frequency in the first 12 months post-surgery [60, 82]. Neither study reported specific results for a relationship between eating episodes and weight loss; however, Colles et al. [82] stated that weight loss was ‘similar’ between subjects who reported eating one to three times per day versus those who reported eating four or more times per day.

Changes in the consistency of foods consumed were also assessed in the studies of Busetto et al. [60, 104] and Colles et al. [82, 109]. Both reported significant increases in intake of fluids as a percentage of daily energy intake, with a concomitant decrease in solids post-surgery. When Busetto et al. [104] compared patients who had undergone higher volume band adjustments sooner post-surgery with patients who received smaller, more gradual fills, the latter group was found to have a significantly higher intake of solid foods as a percentage of daily energy intake, with significantly less
calories contributed from liquids. There were no differences in weight loss according to adjustment protocol however.

Only one cross-sectional study reported dietary intake according to intake of different food groups [52]. In comparison with the obese pre-surgical control group, LAGB subjects reported more frequent intake of poultry, fish, sausage and ham products and less frequent intake of pasta, bread/toast and fresh fruit.

2.2.5 Discussion

This systematic review comprehensively assesses the evidence base for dietary intake after LAGB, providing a basis for further research and development of best practice management guidelines for LAGB patients. It is the first systematic review to exclusively assess LAGB dietary intake outcomes, thereby eliminating the potential confounding influence of data derived from other restrictive procedures such as vertical banded gastroplasty (VBG).

The review highlights that there is a paucity of high quality evidence for changes in dietary intake after LAGB. The existing evidence base is limited by vulnerability to bias, reflected by level III and IV study designs and weak to moderate quality ratings of included studies. Most studies involved small, selected population samples and there was a concentration of output from certain single research centres [60, 82, 104, 109]. This potentially limits the generalisability of findings to the wider LAGB population. Furthermore, there is a scarcity of studies assessing longer-term dietary intake and eating behaviours. Thus, the current evidence base provides limited insight into the sustainability of changes over the longer term.

Although most studies used a retrospective method of dietary assessment, the validity, reliability and comparability of the specific approaches used to assess dietary intake is also unclear. Accuracy of dietary intake data is problematic in all dietary research as a result of inherent difficulties in obtaining objective measurements, with key sources of potential error in retrospective approaches including recall bias of the subject, difficulties in estimating portion sizes, and interviewer skills if an interview approach
is used [110]. This may result in an under-reporting of intake, particularly in obese subject populations [111]. To support potential confounding of under-reporting in the current LAGB evidence base, both Colles et al. (2008) [82] and Busetto et al. (1996) [60] reported only weak correlations between post-surgery energy intakes and weight loss in their studies and, although Colles et al. [109] did find energy intake to be a significant independent predictor of weight loss, it remained a weak predictor only. Given that reduced food and energy intake is considered the primary weight loss mechanism of LAGB, this highlights the likely accuracy limitations in dietary intake data that form the current evidence base.

These limitations must be taken into account when interpreting and applying the findings of the review. As such, this review offers preliminary insight into dietary intake issues following LAGB, and primarily provides a basis for further research to establish stronger evidence for best-practice management guidelines in future.

Studies consistently reported significant reductions in energy intake in the first 1–2 years after LAGB, with most studies reporting 1–2 year energy intakes in the range of 4–6 MJ (approximately 960–1435 kcal) per day [60, 82, 104, 106, 107, 109]. This is generally consistent with weight loss outcomes over the same period [60, 82, 104, 106, 107, 109]. The only long-term data is provided by Sjostrom et al. [14]. Although this study suggests intake remains reduced at 10 years post-surgery, when compared with the shorter-term results of the other studies, energy intake is notably higher, equating to approximately 7.7 MJ (1840 kcal) per day [14] Although greater energy intakes may be required to facilitate weight maintenance rather than continued weight loss over the longer-term, the apparent trend for increasing energy intake over time also suggests that individuals have trouble maintaining longer-term caloric restriction. Notably, Sjostrom et al. [14] concurrently reported less percentage weight loss at 10 years versus 1 year post-LAGB (13.2% versus 21%, respectively).

This parallels growing evidence that difficulties with sustained weight loss and weight regain are significant problems in the LAGB population [67, 71]. Although this has led to suggestions for the abandonment of LAGB [67], it must be remembered that LAGB
consistently achieves greater and more clinically significant weight loss compared to conventional lifestyle interventions [43], and the longer-term safety and efficacy of other procedures versus LAGB versus remains unclear [43]. As such, an opportunity exists to identify long-term dietary and behavioural strategies that may assist individuals to maintain reduced energy intakes over time. This will be valuable for maximising the effectiveness of LAGB until other treatment strategies that are clearly proven as both efficacious and acceptable are better determined.

Despite the finding that protein intake when expressed as a percentage of daily intake does not decrease significantly after LAGB, three of five studies [60, 82, 104] suggested post-surgical protein intakes less than the commonly recommended minimum of 60 grams per day for bariatric surgery patients [89]. Despite the possible confounder of under-reporting, this may represent a sub-optimal dietary pattern, where there is evidence from nonsurgical interventions to suggest that increased protein intakes can positively influence weight loss, preserve lean mass and improve disease risk profile in overweight and obese individuals [112-115].

Although a level of optimal protein intake after bariatric surgery remains to be determined [89], a recent meta-regression suggested that a protein intake >1.05g/kg body weight is associated with greater preservation of fat free mass during weight loss compared to intakes of <1.05 g/kg [116]. Theoretically, the protein intakes reported by studies in the current review are well below this level. For example, based on the average protein intake and weight at 12 months reported in Colles et al. [82], protein intake equates to approximately 0.5g/kg. Even in studies suggesting higher protein intakes, such as that by Guida et al. [106], protein intake at 12 months equates to approximately 0.8g/kg. Given the potential for suboptimal protein intake in the early months post-surgery, appropriate targets for protein intake and dietary strategies to achieve this need to be better established for the LAGB population.

Previous research in VBG populations has suggested a link between the consumption of energy-dense soft foods and fluids and lower weight loss [117, 118]. The present review finds little evidence to support this for LAGB patients; however, only three
studies included consistency of food intake as an outcome [60, 82, 104] and two of these studies did not directly assess the relationship between food consistency and weight loss [60, 82, 104]. Colles et al. [82] did find a weak, non-significant correlation between poorer weight loss in subjects reporting a higher consumption of soft foods; however, this was not identified as an independent predictor of weight loss in multivariate analysis.

Busetto et al. [104] provides evidence to suggest that band adjustment protocol (timing and volume of fills) has a significant influence on food consistency, with a delayed and more gradual fill strategy promoting a more desirable pattern of intake (i.e. a greater intake of solids). There was no difference in 12-month excess weight loss between the groups receiving the two different adjustment protocols, however, despite the significant differences in the consistency of food intake. Further research examining the relationship between food consistency and weight loss outcomes will be valuable for better defining guidelines regarding optimal consistency of the LAGB diet. Beyond influence on weight loss, consistency of food may also have an important impact on diet quality, given that soft or liquid type foods can typically be nutrient-poor compared to solid, whole foods.

It is commonly advised that individuals who have LAGB should strictly eat only three meals per day [88]; however, there is little evidence available to support or refute this guideline, with only two studies assessing the number of eating occasions post-surgery. Furthermore, only Colles et al. [82] assessed the relationship with weight loss, failing to find any statistically or clinically significant relationship between eating frequency and weight loss outcome. The broader lifestyle weight loss literature has also failed to show that eating frequency (e.g. consuming three larger meals or six small meals per day) impacts on weight loss [119]. It is likely that overall caloric intake has a greater influence on weight loss rather than eating occasions per se; however, further research is required to determine more definite guidelines regarding optimal eating frequency after LAGB.
Diet quality is gaining increased recognition in the epidemiological literature as a potential determinant of chronic disease outcomes [120], which highlights that diet quality issues extend beyond the traditional bariatric surgery interest of avoiding overt nutritional deficiencies. There has been some speculation that LAGB may promote poor diet quality as a result of the potential for the gastric band to obstruct passage of ‘high-quality’ foods, such as vegetables, fruit, bread, seafood and lean meat/poultry, as has been suggested in VBG studies [33, 118, 121, 122].

Research conducted in the LAGB population has largely neglected assessment of diet quality outcomes, however, with only one study reporting food group intakes as a reflection of diet quality [52]. Unfortunately, Ernst and colleagues study is limited by its cross-sectional nature and the food frequency questionnaire used, which only captured consumption frequency of broad food groups without any detail regarding portion sizes. The results of Ernst et al. [52] do suggest that some aspects of diet quality may be compromised after LAGB (e.g. fruit intake); however, the cross-sectional study design precludes any causal inferences being made. Further prospective research is required to better investigate diet quality issues and potential influence on health outcomes following LAGB.

Given the diversity of issues related to diet and nutrition in the bariatric surgery field, it was considered beyond the scope of the present review to include all issues of relevance. One ongoing area of interest not included in the review is a comparison of dietary intake and nutritional status of individuals who have LAGB versus other surgical procedures. Few studies were identified from the search strategy that compared these outcomes. Of note, two studies that compared LAGB with RYGB did show some suggestion that RYGB may be more beneficial in terms of achieving better reductions in energy intake at 1 year post-surgery [79] and the promotion of better diet quality according to intake of different food groups [52]. Sjostrom et al. [14], however, did not find a significant difference in longer-term energy intakes between LAGB and RYGB. Dietary outcomes are essential considerations when assessing the merit of obesity surgery options, and further review of the existing evidence base exclusively
focused on a comparison of dietary and nutritional outcomes of different procedures may be warranted.

Additionally, food tolerance outcomes were not addressed in the present review because no papers that specifically assessed food tolerance outcomes met the review inclusion criteria. Furthermore, related issues such as vomiting and regurgitation were considered to be beyond the scope of the current research question, and thus were not included in the original search strategy. Given that food tolerance, vomiting and regurgitation have the potential to influence diet quality, quality of life and postsurgical complications such as pouch dilation [123], further evaluation of these issues will contribute to the development of a more comprehensive evidence base concerning diet and LAGB in the future.

In conclusion, despite the importance of diet after LAGB, there is a paucity of evidence currently available to help inform best practice management guidelines for optimising outcomes after LAGB. Although the current evidence base is limited by its observational nature and widespread methodological weakness, it does suggest that LAGB is effective in reducing overall caloric intake, including intake of fat, carbohydrate and protein. Maintaining reduced food intake over the longer-term, however, may be problematic. Other issues that may require attention include the optimal level of protein intake and diet quality, with further research required in these areas. There is a need for high-quality dietary-focused studies to better assess the influence of diet on weight loss and health outcomes and, furthermore, to determine optimal dietary interventions for individuals who have LAGB.
2.3 Changes in eating behavior after laparoscopic adjustable gastric banding: A systematic review of the literature

This section has been published:


The work presented in the manuscript was completed in collaboration with the co-authors (Appendix 1). Permission to reproduce the text and figures from the manuscript has been granted by the publishers.

2.3.1 Abstract

This systematic review evaluates the current evidence base for eating behaviour changes after laparoscopic adjustable gastric banding (LAGB). A literature search from 1990 to February 2010 was conducted to identify original studies that assessed eating behaviour in adults who have undergone LAGB. Sixteen articles (14 separate studies) met inclusion criteria. Although strength of the evidence base was limited by observational study designs and methodological weaknesses, results suggest that positive changes in eating behaviour occur after surgery, including reduced overeating in response to emotional and situational cues. There is some evidence to suggest that uncontrolled eating behaviours persist in some individuals, and that this may be problematic for weight loss after surgery. Few studies examined the relationship between changes in eating behaviour and weight loss; thus, optimal behavioural strategies for promoting positive weight outcomes remain unclear. Further interventional research addressing the inherent limitations of the current evidence base is required to guide development of evidence-based management guidelines for LAGB in future.
2.3.2 Introduction

Obesity has become a global epidemic associated with serious morbidity and mortality. It is estimated that over 400 million adults are obese worldwide [124] and based on current global trends, it is predicted that one in three adults will be obese by 2025 [7]. The relative ineffectiveness of lifestyle and pharmacological weight loss strategies has led to increasing interest in surgical weight loss approaches for obesity in recent decades [15-17]. Although surgery is usually only indicated for an individual after they have failed to lose weight using conventional approaches [17], it has proven more successful in achieving long-term weight loss with subsequent decreases in comorbidities and disease risk factors [17, 19, 20].

Laparoscopic adjustable gastric banding (LAGB) is currently the most popular form of obesity surgery in Europe and Australia and is gaining popularity in the USA [66, 93]. Attributing to the popularity of LAGB is its favourable risk profile, minimal invasiveness and complete reversibility when compared with other techniques [36, 66]. Although weight loss and subsequent health improvements are achievable following LAGB, one of the primary reported failings is the potential for inadequate weight loss and longer-term weight regain following surgery [66, 67, 69-71]. Considering that LAGB has distinct advantages over more invasive and irreversible surgical procedures, it is important to identify strategies that can help optimise the effectiveness of LAGB as a treatment option for obesity.

Given that LAGB does not alter anatomy or functionality of the gastro-intestinal tract, it is primarily regarded as a device that influences eating behaviour, by acting as a tool to reduce food intake. As such, LAGB is considered to be a form of ‘forced behaviour modification’ [125], and postoperative eating behaviour is likely to have an important impact on LAGB outcomes. Despite this, the existing evidence base for eating behaviour changes after LAGB has not been systematically evaluated, with existing reviews and practice guidelines giving little attention to eating behaviour after surgery [25, 38, 68, 80, 89, 96]. Previous systematic reviews that have examined eating
behaviour in the bariatric surgery setting have not been specific to the LAGB population, and have included only few LAGB studies [126, 127].

Evaluation of the current evidence base is essential for further development of best-practice guidelines for the management of individuals who have LAGB. Thus, the aim of this paper is to systematically review the current evidence regarding changes in eating behaviour following LAGB.

2.3.3 Methods

This paper reports on eating behaviour outcomes identified as part of a broader systematic review of dietary intake and eating behaviours after LAGB. Results of the dietary intake component of the review will be published as a separate review article.

2.3.3.1 Review Inclusion Criteria

Any original study that reported changes in dietary intake and/or eating behaviours after LAGB in adults (aged 18 years or older) were considered for inclusion. Child/adolescent studies were not included given that LAGB is traditionally performed in adults, and children/adolescents represent a distinct needs group not directly comparable with the adult population. Studies were not limited to randomized control trials (RCT) as based on preliminary literature searches the authors anticipated a paucity of RCTs in the area. Cross-sectional studies were considered only if they included a postoperative LAGB group and a pre-operative comparison group. The following types of articles were excluded: narrative reviews, conference abstracts, case reports, editorials, letters, comments, and any other articles that were not original research papers. Studies that did not clearly specify the surgical procedure undertaken or combined results of LAGB with other surgical procedures were also excluded. Studies that only reported pre-operative dietary and/or eating behaviour variables or that did not report specific results for which data could be extracted were also deemed ineligible for inclusion.
2.3.3.2 Search Strategy

To identify relevant articles, the following electronic databases were searched: Medline (Ovid SP), EMBASE, Scopus, Cinahl, and the Cochrane Library. Combinations of the following search terms were used: “gastric banding” or “LAGB” or “gastroplasty” and “dietary” or, “nutrition” or “food” or “eating” or “feeding” or “calori*”. The search strategy was modified for each database as required, with limits set for humans, English language, adult population, and publication date after 1990. Publication date limit was set given that LAGB was not an established procedure prior to this time. Reference lists of all retrieved papers were also manually searched to identify any additional articles not identified by the electronic search. The search included articles published to February 2010.

2.3.3.3 Study Selection

To identify studies that met review criteria, two reviewers (AD and SB) independently assessed information provided in the title, abstract, and keywords to make a decision about the article’s suitability for inclusion. In the case that there was insufficient information in the title and abstract to determine suitability for inclusion, the full paper was retrieved and reviewed in order for a determination to be made. Studies in disagreement between reviewers were discussed until consensus was reached.

2.3.3.4 Critical Appraisal

Methodological quality of included studies was assessed independently by two reviewers (AD and SB) using the Quality Assessment Tool for Quantitative Studies, developed by the Effective Public Health Practice Project, Canada [97]. This tool was selected as it has been deemed appropriate for assessing study quality in systematic reviews [99] and covers multiple types of study design, including controlled and uncontrolled studies. Domains assessed include selection bias, randomization, confounding factors, blinding, data collection methods, and attrition bias [97]. Content and construct validity of the tool have been established [98]. Studies were also graded according to Australia’s National Health and Medical Research Council (NHMRC)
level of evidence guidelines (Table 2.3) in order to further assess the degree to which bias has been eliminated by study design [102].

### Table 2.3 National Health and Medical Research Council (Australia) levels of evidence [102]

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly-designed randomised controlled trial.</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case series, either post-test or pretest/post-test.</td>
</tr>
</tbody>
</table>

#### 2.3.3.5 Data Extraction and Synthesis

Data relating to study characteristics, methodology, and dietary intake and/or eating behaviour outcomes was extracted by the first reviewer (AD) using standardized, self-developed data extraction forms. In the case that a study compared LAGB with another surgical procedure/weight loss intervention, only data relevant to the LAGB arm of the study was extracted, as it was not an aim of the current review to compare outcomes of LAGB with other procedures. Data extraction was verified by the second reviewer (SB). Results for dietary intake and eating behaviour outcomes were tabulated and described using narrative summary. Meta-analysis was not attempted due to variability in outcomes assessed and methodological differences between studies.

#### 2.3.4 Results

2.3.4.1 Description and critical appraisal of included studies

Of the 815 articles identified from the search strategy, 85 articles were retrieved with 14 studies (16 separate articles) identified for inclusion in the eating behaviour component of the review (Figure 2.2). Duration of included studies spanned from 6 months to 5 years; however, most studies ranged from 1 to 3 years follow-up. Sample size ranged
from 18 to 946 subjects, although most studies (n=10) had less than 100 participants, with only one study having more than 200 LAGB participants [128]. The predominant gender in all studies was female. Summary characteristics of included studies are provided in Table 2.4.

![Flow diagram of included and excluded studies for review](image)

**Figure 2.2 Flow diagram of included and excluded studies for review**

*a* Results published in a separate review (Section 2.2)
<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Level of Evidence</th>
<th>Follow up</th>
<th>N</th>
<th>Retention a</th>
<th>Setting</th>
<th>Female: Male</th>
<th>Age (years)</th>
<th>Weight (kg)</th>
<th>BMI (kg/m^2)</th>
<th>Mean weight loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bueter 2007 [129]</td>
<td>Retrospective case series</td>
<td>IV</td>
<td>27 (8-90)m</td>
<td>85</td>
<td>84% (71/85)</td>
<td>Germany</td>
<td>69:16</td>
<td>40 (18-64)</td>
<td>136 (68-202)</td>
<td>49 (37-73)</td>
<td>Median: 23 (~30 to 100) kg</td>
</tr>
<tr>
<td>Chevallier 2007 [128]</td>
<td>Prospective cohort</td>
<td>III-2</td>
<td>2 years</td>
<td>946</td>
<td>~82%</td>
<td>France</td>
<td>809:137</td>
<td>41 ± 10</td>
<td>117.7 ± 20</td>
<td>43.6 ± 5.9</td>
<td>27 kg</td>
</tr>
<tr>
<td>Colles 2008 (a) &amp; Colles 2008 (b) [109]</td>
<td>Prospective case-series</td>
<td>IV</td>
<td>1 year</td>
<td>129</td>
<td>75% (129/173)</td>
<td>Australia</td>
<td>103:26</td>
<td>45.2±11.5</td>
<td>122.2±20.5</td>
<td>44.3±6.8</td>
<td>4 m: 16.5 kg 12 m: 25.7 kg</td>
</tr>
<tr>
<td>De Panfilis 2007 [130]</td>
<td>Prospective case-series</td>
<td>IV</td>
<td>1 year</td>
<td>35</td>
<td>NR</td>
<td>Italy</td>
<td>31:4</td>
<td>41.2±8.3</td>
<td>121±18.1</td>
<td>45.5±4.8</td>
<td>Mean BMI reduction: 7.7±3.3 1 y: 14 (-5 to 38) kg 3 y: 17 (0 to 40) kg</td>
</tr>
<tr>
<td>Himpens 2006 [131]</td>
<td>Prospective “randomised” trial (LAGB vs SG)</td>
<td>III-2</td>
<td>3 years</td>
<td>40</td>
<td>NR</td>
<td>Belgium</td>
<td>33.7</td>
<td>36 (20-61)</td>
<td>NR</td>
<td>37 (30-47)</td>
<td></td>
</tr>
<tr>
<td>Horchner 2002 [132]</td>
<td>Cross-sectional comparison (LAGB vs PS waiting list subjects)</td>
<td>NA</td>
<td>Minimum time since LAGB: 2 years</td>
<td>31</td>
<td>31/35 (89%)</td>
<td>Netherlands</td>
<td>31.0</td>
<td>38 (20-58)</td>
<td>NR</td>
<td>41.9±6.1</td>
<td>NR</td>
</tr>
<tr>
<td>Hudson 2002 [133]</td>
<td>Retrospective case-series</td>
<td>IV</td>
<td>1-3 years</td>
<td>200</td>
<td>(100 with PO data)</td>
<td>Australia</td>
<td>163:37</td>
<td>41.5±9.9</td>
<td>NR</td>
<td>45.1±7.8</td>
<td>NR</td>
</tr>
<tr>
<td>Lang 2002 [134]</td>
<td>Prospective case series</td>
<td>IV</td>
<td>1 year</td>
<td>66</td>
<td>68% (66/97)</td>
<td>Switzerland</td>
<td>58:8</td>
<td>38.1±11.2</td>
<td>132.9±24.0</td>
<td>48.1±8.2</td>
<td>6 m: 19.7±9.3 12 m: 23.1±21.4</td>
</tr>
<tr>
<td>Larsen 2004 [105]</td>
<td>Cross-sectional comparison [3 groups: PS (a), 8-24m PO (b), 25-68m PO (c)]</td>
<td>NA</td>
<td>Time since LAGB (m): a) NA b)16 (8-24) c)42 (25-68)</td>
<td>89</td>
<td>a) 75.6%</td>
<td>Netherlands</td>
<td>a) 77:16</td>
<td>a) 39 (22-59)</td>
<td>a) 46.5 (37-67)</td>
<td>b) 45.5 (37-72) c) 45.4 (36-63)</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2.4 Summary of characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Level of Evidence</th>
<th>Follow up</th>
<th>N</th>
<th>Retention a</th>
<th>Setting</th>
<th>Female: Male</th>
<th>Age (years)</th>
<th>Weight (kg)</th>
<th>BMI (kg/m^2)</th>
<th>Mean weight loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>Study design</td>
<td>Level of Evidence</td>
<td>Follow up</td>
<td>N</td>
<td>Retention a</td>
<td>Setting</td>
<td>Female: Male</td>
<td>Age (years)</td>
<td>Weight (kg)</td>
<td>BMI (kg/m²)</td>
<td>Mean weight loss</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------------------------------------------------------------------</td>
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<td>-------------</td>
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</tr>
<tr>
<td>Nickel 2005 (a) [135]&amp; Nickel 2007 (b) [136]</td>
<td>Prospective comparative case-series (LAGB vs non-surgical group)</td>
<td>III-2</td>
<td>a) 3 years</td>
<td>21</td>
<td>(a) 95% (20/21) (b) 90% (19/21)</td>
<td>Germany</td>
<td>21:0</td>
<td>38.0±9.5</td>
<td>NR</td>
<td>47.4±7.8</td>
<td>BMI reduction: a) 13.6 b) ~17</td>
</tr>
<tr>
<td>Poole 2005 [137]</td>
<td>Retrospective case-control [LAGB “poor compliers” (a) vs LAGB compliers (b)]</td>
<td>III-3</td>
<td>Unclear</td>
<td>a) 9</td>
<td>NA</td>
<td>UK</td>
<td>a) 7:2</td>
<td>a) 44 (31-52)</td>
<td>b) 37 (25-54)</td>
<td>NA</td>
<td>NR</td>
</tr>
<tr>
<td>Schindler 2004 [138]</td>
<td>Prospective case-series</td>
<td>IV</td>
<td>6 months</td>
<td>23</td>
<td>NR</td>
<td>Austria</td>
<td>20:3</td>
<td>35.6±2.1</td>
<td>127.5±4.1</td>
<td>44.8±1.0</td>
<td>15.7±1.4kg</td>
</tr>
<tr>
<td>Scholtz 2007 [139]</td>
<td>Retrospective case-series</td>
<td>IV</td>
<td>5 years</td>
<td>37</td>
<td>29/37 (78%)</td>
<td>UK</td>
<td>28:1</td>
<td>39±9</td>
<td>45±7</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Zijlstra 2006 [140]</td>
<td>Prospective case-series</td>
<td>IV</td>
<td>1 year</td>
<td>77</td>
<td>60% response (77/129); 77/77 followed up (100%)</td>
<td>Netherlands</td>
<td>68:9</td>
<td>43±9</td>
<td>47±6 (6m pre-op)</td>
<td>Mean BMI reduction: 10±5</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** m=months; y=years; BMI=body mass index; LAGB=laparoscopic adjustable gastric banding; SG=sleeve gastrectomy; NR=not reported; NA=not applicable; PO=post-operative; PS=pre-surgery

*For cross sectional studies response rate is reported*
All studies were observational with respect to eating behaviour outcomes, with three studies (four articles) classified as level III-2 evidence [128, 131, 135, 136], one as level III-3 [137] and eight studies (nine articles) as level IV [82, 109, 129, 130, 133, 134, 138-140] according to NHMRC guidelines. Two cross-sectional studies [105, 132] did not qualify for an evidence rating based on current guidelines. Despite the observational nature of studies, most articles reported that subjects received routine follow-up care [82, 109, 129-131, 133-137, 139]; however, detail regarding nature and frequency of follow-up varied. Only Colles et al. [82] summarized postoperative counselling provided for eating behaviours, with other studies not providing any description of behavioural advice provided during follow-up care [105, 128-140].

No articles met the criteria for a strong quality study. Eight articles were classified as moderate quality [82, 105, 109, 128, 130, 134-136] and the remaining eight articles were classified as weak [129, 131-133, 137-140]. Key limitations included: non-randomized study design (all studies), potential for selection bias [129, 137, 138, 140], poor, or unknown validity and reliability of data collection methods [109, 128, 129, 131, 133, 137, 139] and limited consideration of confounding factors in analysis or discussion of findings [131-133, 137-140].

### 2.3.4.2 Eating behaviour after LAGB

Results for eating behaviour outcomes are presented in Table 2.5. A variety of eating behaviours were analysed by different studies, with substantial variation in study aims and assessment methodologies. Only seven studies included some analysis of relationship between specific eating behaviours and weight loss outcomes [82, 105, 109, 133, 134, 138-140].

Binge eating, including binge eating disorder (BED) as defined by the Diagnostic and Statistical Manual of Mental Disorders and/or other episodes of binge eating (not necessarily meeting BED diagnostic criteria) was assessed in six studies [105, 109, 130, 134, 137, 139]. The four case series that examined binge eating all reported a significant reduction in prevalence of binge eating behaviour at 12 months [109, 130, 134] and 5 years [139] after surgery. Not all subjects recovered from binge eating however, with
Colles et al., De Panfilis et al., Lang et al., and Scholtz et al. all reporting the continuance of binge eating-type behaviours in 11–33% of individuals [109, 130, 134, 139]. The cross-sectional study by Larsen et al. found that the prevalence of binge eating was significantly lower in the two LAGB groups when compared with the pre-surgical group; however, binge eating was still reported in 31.9% and 37.4% of subjects in the less than 2 years and the more than 2 years post-surgery groups respectively [105]. The case-control study by Poole et al. found that binge eating was higher in cases who were poor compliers with follow-up care; however, this was not statistically significant [137].

Four of the studies that assessed binge eating-type behaviours also examined relationship with weight loss outcome [105, 109, 134, 139] with some, but not all, suggesting a link between the two. Colles et al. found that ‘uncontrolled eaters’ (including four subjects diagnosed with postoperative BED) had lower percentage weight loss than the remainder of the cohort, although uncontrolled eating was not reported as an independent predictor of weight loss according to multivariate analysis [109]. Grazing-type behaviours were however identified as an independent predictor [109]. Scholtz et al. found that subjects who developed an eating disorder (including BED) postoperatively were more likely to have a “poor” outcome after surgery, defined as less than 40% excess weight loss (EWL) or a complication or patient request requiring band removal [139]. Larsen et al. also reported that within the post-operative cross-sectional groups, subjects with binge eating had significantly less BMI loss [105]. Lang et al. however reported no correlation between any eating behaviour, including binge eating, and weight loss outcome [134].

Restraint, disinhibition and hunger as measured by the Three Factor Eating Questionnaire (TFEQ) were measured in four studies [82, 109, 134-136, 138]. Restraint score, reflecting a conscious effort to restrict food/calorie intake [141] consistently increased in the first 6–12 months after surgery [82, 134, 135, 138], while disinhibition and hunger scores, reflecting a tendency to overeat in response to certain environmental, situational and social cues and susceptibility to subjective sensations of
hunger [141] were consistently lower [82, 134, 138]. In the cross-sectional studies by Horchner et al. [132] and Larsen et al. [105], higher restrained eating and lower emotional and external eating (Dutch Eating Behaviour Questionnaire) were also found in post-operative LAGB patients when compared with pre-operative patients. Only Nickel et al. [135, 136] assessed changes in TFEQ scores over a longer term, finding that hunger and disinhibition scores remained lower at 6 years; however, restraint scores showed a trend for a decrease towards baseline between 3 and 6 years after surgery [135, 136].

Only three studies assessed the relationship between restraint, disinhibition, subjective hunger, and weight outcome [82, 109, 134, 138] with some inconsistency in results. Lang et al. [134] found no correlation between any eating behaviour variable and weight loss whereas Schindler et al. [138] found a moderate correlation between reduced hunger score and weight loss, however no correlation for restraint or disinhibition score. Colles et al. however reported a weak positive correlation between restraint and weight loss and weak inverse associations between disinhibition and hunger and weight loss, although only lower hunger scores at 12 months post-surgery were found to be a significant independent predictor of greater weight loss [82, 109].

Colles et al. also assessed a range of other eating behaviours related to emotional triggers for eating/overeating and night eating syndrome, finding that individuals reporting these disordered behaviours achieved less weight loss according to t tests; however, none of these behaviours were reported to be significant predictors of poorer weight loss in multivariate analysis [82, 109].

Sweet eating was assessed in three studies; however, study aims and assessment methodology were not consistent [129, 131, 133]. Hudson et al. used a retrospective questionnaire to assess relationships between pre-operative and post-operative sweet eating and weight loss, finding that sweet eating at 3 years post-surgery was significantly reduced when compared with retrospectively reported preoperative sweet eating [133]. Bueter et al. assessed sweet eating prospectively as a potential behavioural predictor of success or failure after LAGB using general interview
administered questions [129]. Although Bueter et al. univariate analysis found that ‘sweet eating’ individuals were less likely to achieve successful weight loss, sweet eating was not a significant predictor in multivariate analysis. Furthermore, Bueter et al. [129] also reported that sweet eating was not a predictor of failure according to univariate or multivariate analysis [129]. Himpens et al. [131] prospectively assessed cravings for sweets using a self-developed questionnaire to compare individuals who had undergone LAGB with sleeve gastrectomy. It was found that 35% of LAGB patients lost their cravings for sweet foods at 12 months, however, this reduced to 2.9% at 3 years; however, the relationship between this and weight loss outcomes was not assessed [131].

Eating behaviour self-efficacy score, reflecting confidence in regulating eating behaviours was assessed in two studies [105, 140]. Larsen et al. [105] reported higher eating behaviour self-efficacy in the post-operative cross-sectional groups and self-efficacy was found to be significantly higher at 12 months post-surgery in Zijlstra et al. prospective case series [140]. Zijlstra also found a significant but weak inverse correlation between residual BMI loss and eating self-efficacy score, suggesting that higher self-efficacy is associated with greater weight loss after surgery [140].

Two studies examined overall post-operative eating behaviour change in the context of predicting either positive or negative weight loss outcomes, using unvalidated questionnaire items [128, 129]. Bueter et al. reported that “modification of eating behaviour” was a strong and significant predictor of success (defined as more than 50% EWL) [129] and similarly, the cohort study of Chevallier et al. found that subjects who reported not changing eating behaviour were at higher risk of not achieving successful weight loss (defined as less than 50% EWL) [128].
<table>
<thead>
<tr>
<th>Study</th>
<th>Behaviour/s</th>
<th>Assessment method</th>
<th>Outcome</th>
<th>Result</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buetet 2007 [129]</td>
<td>Sweet eating; stress eating</td>
<td>Standardised EB questionnaire (unvalidated) administered during pre and post-operative care.</td>
<td>Predictors of success (&gt;50% EWL) odds ratio (95% CI):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sweet eating</td>
<td>RR 0.2 (0.05-0.7)a</td>
<td>P=0.008</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Stress eating</td>
<td>RR 0.1 (0.02-0.5)a</td>
<td>P=0.003</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Modification of eating behaviour</td>
<td>RR 8.62 (1.75-42.4)b</td>
<td>P=0.008</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Predictors of failure (&lt;20% EWL or band removal) odds ratio (95% CI):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sweet eating</td>
<td>RR 0.6 (0.2-2.0)a</td>
<td>P=0.530</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Stress eating</td>
<td>RR 0.4 (0.1-1.2)a</td>
<td>P=0.121</td>
</tr>
<tr>
<td>Chevallier 2007 [128]</td>
<td>Overall change in EB post surgery</td>
<td>Questionnaire item (unvalidated)</td>
<td>Change in eating habits as a predictor of success (≥50% EWL)</td>
<td>Subjects who did not change eating habits had higher risk of no success: OR 2.2 (1.2-4.1)</td>
<td>P=0.009</td>
</tr>
<tr>
<td>Colles 2008 (a) [82] / Colles 2008 (b) [109]</td>
<td>Dietary restraint, disinhibition and hunger</td>
<td>Three Factor Eating Questionnaire</td>
<td>Restraint score</td>
<td>PS: 8.3±3.9</td>
<td>12m: 13.0±4.2*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Disinhibition score</td>
<td>PS: 11.5±3.4</td>
<td>12m: 6.2±3.9*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hunger score</td>
<td>PS: 9 (6-12)</td>
<td>12m: 2 (1-5)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Correlation between 12m TFEQ variables and 12m energy intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Restraint</td>
<td>r=-0.23</td>
<td>P=0.013</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Disinhibition</td>
<td>r=0.229</td>
<td>P=0.011</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hunger</td>
<td>r=0.029</td>
<td>P=0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Relationship between 12m TFEQ variables and 12m %WL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Restraint</td>
<td>r=0.22</td>
<td>P=0.014</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Magnitude ∆ restraint</td>
<td>r=0.2</td>
<td>P=0.025</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Disinhibition</td>
<td>r=-0.39</td>
<td>P=0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Magnitude ∆ disinhibition</td>
<td>r=-0.36</td>
<td>P=0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hunger</td>
<td>r=-0.43</td>
<td>P=0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Magnitude ∆ hunger</td>
<td>r=-0.3</td>
<td>P=0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lower 12m hunger score independent predictor of greater %WL: β=-0.275; explaining 33.7% of variance f</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>In Colles (b) [109]: higher hunger independent predictor of poorer %WL at 12m: β=-0.254; explaining 29.6% of variance f</td>
<td></td>
<td>P=0.006</td>
</tr>
<tr>
<td>Study</td>
<td>Behaviour/s</td>
<td>Assessment method</td>
<td>Outcome</td>
<td>Result</td>
<td></td>
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<tr>
<td>---</td>
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<tr>
<td>Colles 2008 (b) [109]</td>
<td>Subjective fullness, return of “old eating habits”, situations/emotions stimulating eating/overeating</td>
<td>“Series of questions” at 12m follow-up interview (unvalidated)</td>
<td>Relationship between EB variables and 12m energy intake</td>
<td>Higher energy intakes in subjects reporting: Eating in response to anxiety (Figures NR) Eating in response to fatigue (Figures NR) Recurrence of “old eating patterns” (n=35) consumed more energy than subjects reporting no difficulty maintaining changes</td>
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<td>Relationship between EB variables and 12m %WL</td>
<td>Inverse association for: Eating in response to anxiety (Figures NR) Frequent recurrence of “old patterns” (Figures NR) Eating despite feeling full upset (Figures NR) Eating when depressed/upset (Figures NR)</td>
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<td></td>
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<td>BED prevalence</td>
<td>PS: n=18 (14%) 12m n=4 (3.1%)</td>
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<td>Uncontrolled eating prevalence</td>
<td>PS: n=40 (31%) 12m n=29 (22.5%)</td>
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<td>Dietaty intake, EB and WL variables in uncontrolled eaters (including subjects with BED) v. remainder of cohort at 12m:</td>
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<td>Uncontrolled eaters</td>
<td>Remainder cohort</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Restraint</td>
<td>10.9±3.7 13.7±4.1</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Disinhibition</td>
<td>10.1±3.1 4.8±3.2</td>
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<td></td>
<td>Hunger:</td>
<td>6 (3-9) 2 (1-4)</td>
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<td></td>
<td></td>
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<td>Energy (MJ)</td>
<td>4.4±1.5 3.8±1.4</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>% Fat</td>
<td>34.3±5.6 30.3±6.4</td>
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<td>% Protein</td>
<td>21.3±3.3 22.8±4.5</td>
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<td></td>
<td>% Carbohydrate</td>
<td>39.1±5.6 39.3±7.4</td>
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<td></td>
<td>Eating episodes/day:</td>
<td>3.0 (3-4) 3.0 (2-4)</td>
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<td>%WL:</td>
<td>17.4±8.2 22±8.3</td>
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<td>Emotional triggers for eating</td>
<td>Uncontrolled eaters more likely to eat in response to: anxiety**, fatigue*, boredom*, stress*, anger*, depression* (Figures NR) **P&lt;0.001</td>
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<td>Other behaviours</td>
<td>Uncontrolled eaters more likely to: Continue to eat when full (Figures NR) Report return old eating patterns (Figures NR) Fear weight regain (Figures NR)</td>
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<td>Study</td>
<td>Behaviour/s</td>
<td>Assessment method</td>
<td>Outcome</td>
<td>Result</td>
<td>Sig.</td>
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<td>Colles 2008 (b) cont’d.</td>
<td>“Grazing” behaviour</td>
<td>Semi-structured clinic and phone interview questions (unvalidated)</td>
<td>Grazing prevalence PS: n=34 (26.4%)</td>
<td>12m: n=49 (38%)</td>
<td>NS</td>
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<td>Dietary intake, EB and weight loss variables in grazers v. remainder of cohort at 12m:</td>
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<td>P=0.031</td>
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<td></td>
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<td>Restraint Lower in grazers</td>
<td>(Figures NR)</td>
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<td></td>
<td>Disinhibition Greater in grazers</td>
<td>(Figures NR)</td>
<td>P&lt;0.001</td>
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<td>Hunger Greater in grazers</td>
<td>(Figures NR)</td>
<td>P&lt;0.001</td>
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<td>Daily eating episodes Higher in grazers</td>
<td>(Figures NR)</td>
<td>P=0.005</td>
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<td>%WL: Grazers: 17.3±7.6 Remainer cohort: 22.9±8.4</td>
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<td>P=0.001a</td>
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<td>Emotional triggers for eating Grazers more likely to eat in response to:</td>
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<td>Anxiety (Figures NR)</td>
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<td>P=0.012</td>
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<td>Stress (Figures NR)</td>
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<td>Other behaviours Grazers more likely to:</td>
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<td>Continue to eat when full</td>
<td>(Figures NR)</td>
<td>P=0.05</td>
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<td>Fear weight gain</td>
<td>(Figures NR)</td>
<td>P=0.004</td>
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<td>Grazing as a predictor of %WL: Higher postsurgical grazing independent predictor of poorer %WL: β=−0.186; explaining 29.6% of variance</td>
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<td>P=0.032</td>
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<td>NES prevalence PS: n=22 (17.1%)</td>
<td>12m: n=10 (7.8%)</td>
<td>P&lt;0.05</td>
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<td>Of 12m NES subjects: 4 reported PS NES; 6 developed NES after surgery</td>
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<td>Nocturnal snacking prevalence PS: n=10 (7.8%)</td>
<td>12m: n=4 (3.1%)</td>
<td>P=0.033</td>
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<td>EB and weight loss variables in NES v. remainder of cohort at 12m:</td>
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<td>P=0.042</td>
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<td>Restraint Lower in NES</td>
<td>(Figures NR)</td>
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<td>“Hard” (solid) food intake Lower in NES</td>
<td>(Figures NR)</td>
<td>P=0.032</td>
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<td>Protein intake Less in NES</td>
<td>(Figures NR)</td>
<td>P=0.05</td>
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<td>%WL NES: 16.9 Remainder cohort: 21.1</td>
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<td>Triggers for eating NES subjects more likely to eat:</td>
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<td>In response to fatigue (Figures NR)</td>
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<td>P=0.034</td>
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<td>When socialising</td>
<td>(Figures NR)</td>
<td>P=0.004</td>
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<td>Study</td>
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<td>Assessment method</td>
<td>Outcome</td>
<td>Result</td>
<td>Sig.</td>
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<td>De Panfilis 2007 [130]</td>
<td>BED</td>
<td>Structured Clinical Interview using DSM-IV criteria</td>
<td>BED prevalence</td>
<td>PS: n=13 (37.1%) 12m: n=4 (11.4%)</td>
<td>$P&lt;0.01$</td>
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<td>9 (25.7%) subjects recovered from BED post surgery</td>
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<td>Himpens 2006 [131]</td>
<td>Severity of bulimic symptoms</td>
<td>EDI-2 – BU bulimia subscale</td>
<td>EDI-BU Score</td>
<td>PS: 5.9±4.1 12m: 3.1±1.9</td>
<td>$P&lt;0.01$</td>
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<td>Feelings of hunger and craving for sweets</td>
<td>Self-developed questionnaire item (unvalidated)</td>
<td>% of LAGB patients reporting “loss of feeling of hunger”</td>
<td>12m: 42.5% 3yr: 2.9%</td>
<td>NR</td>
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<tr>
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<td>% of LAGB patients reporting “loss of craving for sweet eating”</td>
<td>12m: 35%; 3yr: 2.9%</td>
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<tr>
<td>Horchner 2002 [132]</td>
<td>Restrained, emotional and external eating</td>
<td>Dutch Eating Behaviour Questionnaire</td>
<td>PS group: Restrained eating</td>
<td>2.92±0.72 3.22±0.85 3.04±0.88</td>
<td>$P&lt;0.005$</td>
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<td>Emotional eating</td>
<td>2.32±0.85 2.56±0.87 2.5±0.62</td>
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<td>External eating</td>
<td>3.45±0.88</td>
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<td>Sweet eating score</td>
<td>45.3±14.4</td>
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<td>Hudson 2002 [133]</td>
<td>Sweet eating</td>
<td>Standardised questionnaire with retrospective recall of PS consumption (unvalidated)</td>
<td>Prevalence of subjects reporting BEE</td>
<td>PS: 63.6% reported BEE; PO: 39.4% ceased BEE; 24.2% cont’d. BEE; 4.5% reported new BEE (31.8% free of BEE PS &amp; PO)</td>
<td>$P&lt;0.001$</td>
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<tr>
<td>Lang 2002 [134]</td>
<td>Binge eating; Dietary restraint (including flexible and rigid control), disinhibition and hunger</td>
<td>Binge Scale Questionnaire; Three Factor Eating Questionnaire</td>
<td>Time point</td>
<td>PS 3m 6m 9m 12m</td>
<td>$***P&lt;0.001$</td>
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<td>BSQ Sum score</td>
<td>14.2±10.4 4.9±8.1*** 6.9±9.4* 6.2±8.9 6.2±9.3</td>
<td>$**P&lt;0.01$</td>
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<tr>
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<td>Restraint score</td>
<td>8.4±3.9 13.0±4.7*** 12.2±4.7** 11.7±4.7 11.5±4.9</td>
<td>$*P&lt;0.05$ (from previous time point)</td>
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<tr>
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<td>Disinhibition score</td>
<td>10.9±3.3 6.0±3.2*** 6.1±3.1 6.2±3.1 5.6±2.8*</td>
<td>$*P&lt;0.05$</td>
</tr>
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<td>Hunger score</td>
<td>7.7±3.4 3.7±3.4*** 3.3±3.0 3.0±2.9 2.9±3.2</td>
<td>$*P&lt;0.05$</td>
</tr>
<tr>
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<td>Flexible control</td>
<td>1.9±1.5 4.5±2.0*** 4.1±1.9* 3.9±1.9 4.0±2.2</td>
<td>$*P&lt;0.05$</td>
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<tr>
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<td>Rigid control</td>
<td>3.7±1.4 4.4±1.6*** 4.1±1.7 4.2±1.7 3.8±1.6*</td>
<td>$*P&lt;0.05$</td>
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<td>Correlation between EB and BMI</td>
<td>No correlation between any EB variable and BMI change</td>
<td>(Figures NR)</td>
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<td>Correlation between EBs</td>
<td>BSQ score &amp; disinhibition</td>
<td>(r=0.54)</td>
<td>$P&lt;0.05$</td>
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<td>BSQ score &amp; hunger</td>
<td>(r=0.36)</td>
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<td>Result</td>
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<td>Larsen 2004</td>
<td>Restrained, emotional and external eating</td>
<td>Dutch Eating Behaviour Questionnaire</td>
<td>PS group (a)</td>
<td>≤2y PO group (b)</td>
<td>≥2y PO group (c)</td>
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<td>Emotional eating</td>
<td>3.12±0.92</td>
<td>2.69±0.91*</td>
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<td>3.01±0.80</td>
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<td>Restrained eating</td>
<td>2.84±0.71</td>
<td>3.35±0.73*</td>
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<td>3.13±0.70*</td>
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<td>External eating</td>
<td>3.08±0.58</td>
<td>2.64±0.55*</td>
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<td>2.73±0.67*</td>
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<td>Eating behaviour self-efficacy</td>
<td>Obesity Psychological State Questionnaire-EB self-efficacy subscale</td>
<td>Self-efficacy score</td>
<td>2.45±0.83</td>
<td>3.51±1.02*</td>
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<td>3.21±1.00*</td>
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<td>Satiety</td>
<td>Self-developed Satiety Questionnaire (unvalidated)</td>
<td>Satiety score</td>
<td>6.32±2.19</td>
<td>7.70±1.98*</td>
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<td>6.97±2.59</td>
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<td>Binge eating</td>
<td>Binge Eating Scale</td>
<td>Binge eating prevalence</td>
<td>55.9%</td>
<td>31.9%*</td>
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<td>37.4%*</td>
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</table>

EB and fat intake in post-operative subjects with binge eating v. those without binge eating:

Fat intake
- Higher in binge eating (Figures NR)  
  - External eating: Higher
  - Emotional eating: Higher
  - Eating behaviour self-efficacy: Lower
  - Binge eating and BMI loss: Lower

External eating
- Higher in binge eating (Figures NR)  
  - Higher

Emotional eating
- Higher in binge eating (Figures NR)  
  - Higher

Disinhibition score
- Lower in binge eating (Figures NR)  
  - Lower

Hunger score
- Lower in binge eating (Figures NR)  
  - Lower

<table>
<thead>
<tr>
<th>Study</th>
<th>Behaviour/s</th>
<th>Assessment method</th>
<th>Outcome</th>
<th>Result</th>
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<tr>
<td>Nickel 2005</td>
<td>Dietary restraint, disinhibition and hunger</td>
<td>Three Factor Eating Questionnaire</td>
<td>Time Point</td>
<td>PS</td>
<td>3y</td>
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<td>Restraint score</td>
<td>8.1±4.3</td>
<td>10.7±4.9</td>
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<td>Disinhibition score</td>
<td>10.4±3.0</td>
<td>8.2±3.5</td>
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<td>Hunger score</td>
<td>9.0±3.5</td>
<td>6.1±3.0</td>
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<td>Poole 2005</td>
<td>Past or current disordered eating behaviour: bulimic episodes, grazing, purging, impulsivity, psychiatric disorder</td>
<td>Retrospective review of psychiatric and surgical case notes. Psychiatric disorders defined as per DSM-IV criteria.</td>
<td>Emotional eating prevalence</td>
<td>89%</td>
<td>22%</td>
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<td>Grazing prevalence</td>
<td>78%</td>
<td>22%</td>
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<td>BED Prevalence</td>
<td>44%</td>
<td>22%</td>
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<td>Bulimia Nervosa prevalence</td>
<td>22%</td>
<td>0%</td>
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<td>Behaviour/s</td>
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<td>Outcome</td>
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<td>Schindler 2004 [138]</td>
<td>Dietary restraint, disinhibition and hunger</td>
<td>Three Factor Eating Questionnaire</td>
<td>Restraint score</td>
<td>PS: 10.2±1.0</td>
<td>6m: 15.2±1.1</td>
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<td>Disinhibition score</td>
<td>PS: 11.1±0.8</td>
<td>6m: 7.1±0.6</td>
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<td>Hunger score</td>
<td>PS: 8.2±0.8</td>
<td>6m: 3.5±0.6</td>
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<td>Correlation between EB and weight / BMI</td>
<td>No correlation with any EB</td>
<td>(Figures NR)</td>
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<td>Correlation between EB and change in body weight</td>
<td>Change in weight &amp; decreased hunger</td>
<td>r=0.48</td>
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<td>Scholtz 2007 [139]</td>
<td>Past or current disordered eating behaviour</td>
<td>Retrospective review of medical notes. Eating Disorders Examination used to identify relevant behaviours. Psychiatric disorders defined as per DSM-IV criteria.</td>
<td>Binge eating prevalence</td>
<td>PS: n=12 (41%) reported history of BED; n=5 (17%) diagnosed with BED at time of surgery; n=4 (13%) reported BEE (not meeting BED criteria) at time of surgery</td>
<td>5y PO: n=5 (10.3%) diagnosed with BED; n=4 (10.8%) reported BEE (not meeting BED criteria); of subjects with history BED: resolution of BED in 66%, recurrence in 33%</td>
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<td>Outcome according to PO psychiatric/eating disorder</td>
<td>Subjects who developed PO disorders more likely to have poor outcome (failure to loss 40% EWL/complication requiring band removal/patient request band removal)</td>
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<td>Zijlstra 2006 [140]</td>
<td>Eating behaviour self-efficacy</td>
<td>Eating behaviour self-efficacy subscale of the Obesity Psychological State Questionnaire</td>
<td>Self-efficacy score</td>
<td>PS: 2.59±0.74</td>
<td>12m: 3.73±0.78</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Correlation between 12m EB self-efficacy and WL (residual BMI change)</td>
<td>Self-efficacy score</td>
<td>r=−0.26</td>
</tr>
</tbody>
</table>

Abbreviations: Sig.=significance; EB=eating behaviour; EWL=excess body weight loss; CI=confidence interval; RR=relative risk; OR=odds ratio; m=month/s; TFEO=three factor eating questionnaire; WL=weight loss; NR=not reported; BED=binge eating disorder; DSM-IV=Diagnostic and statistics manual of mental disorders, 4th edition; PS=pre-surgery; MJ=megajoule; CHO=carbohydrate; NES = night eating syndrome; EDI-BU=Eating Disorders Inventory-2-bulimia subscale; PO=post-operative; BEE=binge eating episodes; BSQ=Binge Scale Questionnaire; y=year/s

= univariate analysis
= multivariate analysis
= other significant variables in model: higher baseline BMI (β=0.241), higher physical function (β=0.309), higher leisure time physical activity (β=0.213)
= other significant variables in model: baseline BMI (β = 0.194), higher appearance dissatisfaction (β = −0.278), postsurgical grazing (β = −0.186) and total energy intake (β = −0.182)
= other significant variables in model: baseline BMI (β = 0.194), higher appearance dissatisfaction (β = −0.278), hunger (β = −0.254) and total energy intake (β = −0.182)
= group × time effect
2.3.5 Discussion

This systematic review comprehensively assesses the evidence base for eating behaviours after LAGB. It is the first systematic review to exclusively assess LAGB eating behaviour outcomes, thereby eliminating the potential confounding influence of data derived from other restrictive procedures such as vertical-banded gastroplasty (VBG). The review highlights that there is a paucity of high-quality evidence regarding changes in eating behaviours after LAGB. The existing evidence base is limited by vulnerability to bias, reflected by level III and IV study designs and weak to moderate quality ratings of included studies.

Variations in types of eating behaviours assessed, including differences in definition of behaviours, makes it difficult to identify clear and consistent trends in eating behaviour modification after LAGB. Subsequently, it is difficult to characterize behaviours that may be either beneficial or problematic following surgery. This may be partly attributable to the use of unvalidated interview questions and questionnaires [28, 29, 33–35, 38] and retrospective review of clinical records [32, 41]. This reflects a major limitation of the current evidence base for eating behaviours, and contributes to uncertainty regarding validity of study findings. Additionally, much of the evidence comes from a single Australian study [34, 35], this generalizability to the broader LAGB population may be questioned.

Although the strength and significance of the evidence base for eating behaviour outcomes after LAGB remains questionable, it does provide preliminary insight into eating behaviours after surgery. This may form a basis for further research and development of best-practice management guidelines in future.

2.3.5.1 Positive Eating Behaviours after LAGB

Despite methodological limitations and differences in study design and aims, there is an overall suggestion that a range of problematic eating behaviours improve after surgery. This includes reduced binge eating disorder, reduced eating in response to emotional and situational triggers, reduced feelings of subjective hunger, increased
dietary restraint, and improved feelings of eating self-efficacy [82, 109, 130, 134-136, 138-140]. This supports that LAGB is effective for promoting positive eating behaviour modification in many individuals who have surgery.

Few studies however examined the relationship between these changes in eating behaviour and weight loss outcomes. This is a critical gap in the evidence base, given that weight loss is the primary goal of eating behaviour modification. Of the studies that did assess the relationship between positive eating behaviour changes and weight loss, findings were inconsistent. Thus the link between ‘desirable’ changes in eating behaviour and weight loss is unclear, and it remains unknown which behaviour modifications promote best outcomes. This is an essential area for further research if strategies for optimising weight loss after LAGB are to be developed.

Adding to difficulty in assessing the link between eating behaviours and weight loss is variability in the way weight loss outcomes were classified by different studies. For example, Scholtz et al. [139] defined a poor outcome as less than 40% EWL or band removal, whereas Bueter et al. [129] defined failure as less than 20% EWL or band removal and Chevallier et al. [128] as less than 50% EWL. The use of standardized weight outcome classifications, based on clinically significant cut-points, may help to redress this difficulty and assist with synthesis of findings so that clearer relationships between eating behaviour and weight loss may be established in future.

A further gap in the evidence base is assessment of eating behaviour change and dietary intake, which represents a key link between eating behaviour and weight loss. Only one prospective study examined the relationship between these variables [82, 109]. This study provides some basic support for the concept that eating behaviour modification does facilitate changes in dietary intake, with a positive correlation found between dietary restraint and energy intake and negative correlations found for disinhibition and perceived hunger.

Despite the relatively weak evidence for specific eating behaviours and weight loss outcomes after LAGB, it is important to note that in all studies that reported weight changes, average weight loss was clinically significant [82, 109, 128-130, 134-138, 140].
This is in agreement with the broader evidence for the effectiveness of LAGB [43] and supports that at a more general level, LAGB is effective in promoting overall behavioural change for weight loss in most individuals. The results of Bueter et al. [129] and Chevallier et al. [128] strengthens the concept that overall eating behaviour modification is important after LAGB, with both of these studies finding that broad eating behaviour change increases chance of a successful outcome. Unfortunately, the crude nature of eating behaviour assessment in these studies does not provide any specific evidence to help inform practice guidelines regarding which behaviours to promote for successful weight loss.

The lack of consistent evidence for eating behaviour change and weight loss may also reflect the inherent complexity and difficulty that exists in obtaining valid, reliable, and clinically significant measurements of eating behaviour and eating behaviour change. Given that eating behaviour assessment is dependent on self-report measures, social desirability bias may have also influenced reported eating behaviour changes. Some subjects may have reported false positive changes in behaviour after surgery to reflect expectations of the researchers/clinicians, thus confounding evidence for positive behaviour changes and weight loss.

### 2.3.5.2 Negative Eating Behaviours after LAGB

Although positive changes in behaviour were reported in many studies, there is also evidence to suggest negative eating behaviours can persist or develop after surgery. Notably, multiple studies found that binge eating behaviours did not improve in a substantial number of individuals who had pre-operative binge eating [109, 130, 134, 139]. Furthermore, although binge eating per se may decline, Colles et al. [109] results suggest that uncontrolled eating can remain problematic, manifesting in behaviours such as frequent grazing. These grazing-type behaviours, which are more physically possible than binge episodes with the restrictive presence of the gastric band, may reflect a failure to modify disordered eating behaviours after surgery.

There is some preliminary evidence to suggest that such behaviours impact negatively on weight loss outcomes, with several studies suggesting less weight loss in subjects
with binge and/or uncontrolled eating and related behaviours such as grazing [105, 109, 139].

The explorative studies of Colles et al. [82, 109] also found that in conjunction with less weight loss, individuals with uncontrolled eating had significantly higher energy intakes, less dietary restraint and higher levels of disinhibition and hunger, reflecting a less desirable post-operative behaviour profile. Unfortunately this analysis did not account for the potential confounding effect of variables such as age, baseline BMI and gender, thus it is inconclusive if “uncontrolled eating” was the key determinant of these outcomes. Larsen et al. [105] supports the potential link between uncontrolled eating behaviour and less favourable dietary intake after surgery, finding that postoperative binge eaters had higher fat intakes when compared with non-binge eaters.

Disinhibition and perceived hunger, which have previously been linked with binge eating and uncontrolled eating behaviours [142] were also found to be inversely, albeit modestly, correlated with percentage weight loss by Colles et al. [82]. Furthermore, higher levels of perceived hunger were found to be small yet significant independent predictor of poorer weight loss [109]. Given that other studies did not find any relationship for disinhibition [134, 138] or hunger [134], and that much of the evidence is based on correlation analyses which cannot be used to indicate causation, the impact these behaviours have on weight outcomes remain inconclusive.

Evidently, further research is required to better ascertain the impact of binge eating and related eating behaviours on weight loss and other health outcomes after LAGB. Despite this, the current evidence suggests that LAGB may be ineffective in modifying eating behaviours associated with loss of control in some individuals, which may subsequently influence weight loss outcome. Unfortunately, it remains inherently difficult to predict pre-operatively which individuals are most at risk of this, given that LAGB is specifically designed to facilitate change in existing eating behaviours. As such, the evidence supports that individuals who have LAGB require ongoing monitoring for the continuance or development of negative eating behaviours.
Continued behavioural support for these patients may help to minimize the risk of such behaviours having a negative influence on weight loss and other outcomes after surgery. Further research specifically designed to evaluate the effect of different interventional support strategies is required to better determine optimal follow-up care protocols however.

2.3.5.3 Sweet Eating

An ongoing area of controversy in the wider bariatric surgery literature is that of ‘sweet eating’, where some studies have suggested a link between sweet eating behaviour and poorer weight loss outcomes following restrictive procedures [121, 143]. The current review does not support this, however only three studies [129, 131, 133] reported on sweet eating, and one of these did not assess relationship with weight loss [131]. Furthermore, sweet eating was defined and assessed differently between the two relevant studies and although both methodologies were standardized, they were not validated. Despite these limitations, neither study found post-operative sweet eating to be a predictor of poor weight loss [129, 133].

The conflict between these findings and the earlier studies suggesting a link between sweet eating and poorer weight loss may also be explained by the fact that earlier studies involved subjects who had undergone VBG rather than LAGB [121, 143]. It is possible that results from VBG studies may have been related to over-tight banding, a known problem of VBG [133]. This may have necessitated maladaptive intake of softer foods and fluids, many of which are energy dense and match the profile of sweet foods. Thus the so-called ‘soft-calorie’ syndrome may have been the cause of poorer weight loss rather than sweet eating per se. Future studies that prospectively assess overall dietary intake as well as sweet eating with consistent, validated methods will be valuable in providing further insight into the importance of this behaviour following LAGB.
2.3.5.4 Review Limitations

The diversity and scope of issues related to eating behaviour in the bariatric surgery field precluded consideration of all relevant issues in the current review. Other pertinent issues closely related to, but not included in the review include: the relationship between pre-operative eating behaviours and weight loss success; the impact of vomiting and regurgitation behaviours on post-operative outcomes, including both weight loss and complications; and comparison of postoperative eating behaviours between LAGB and other surgical procedures. Further evaluation of these issues will contribute to the development of a more comprehensive evidence base concerning eating behaviour after LAGB in the future.

Given that the current evidence base for eating behaviours consists predominantly of short medium-term studies, another limitation of the review is that it provides limited insight into the sustainability of eating behaviour changes in the longer term after LAGB, or how eating behaviours may influence longer-term weight loss and other health outcomes. Arguably, it is these outcomes that will be of ultimate importance for determining strategies that can promote durable weight loss after LAGB. Review of longer-term studies as they become available will also strengthen the evidence base in future.

2.3.6 Conclusion

Despite the importance of eating behaviour after LAGB, this review emphasizes that the existing evidence base is limited, consisting primarily of short-term observational studies with widespread methodological weakness. This limited evidence does support that positive changes in eating behaviour occur after LAGB, although over-eating may remain problematic in certain individuals. Appropriate and ongoing counselling after surgery are likely to be important for optimising outcomes; however, further intervention studies are required to evaluate this. There is an overall need for high-quality research to assess the influence of eating behaviour on weight loss and health outcomes after LAGB, and furthermore to determine optimal eating behaviour change interventions for individuals who have LAGB. Inherent limitations of the existing
evidence base need to be addressed with well-designed intervention studies to inform the development of best-practice management guidelines for optimising outcomes after LAGB.

2.4 Proposed advantages of high protein diets during weight loss

2.4.1 Preservation of resting energy expenditure

The potential metabolic and health advantages of high protein (HP) diets during weight loss have long been debated in the scientific literature, with preservation of resting energy expenditure (REE) suggested as a key potential benefit [144, 145]. High protein diets may help to preserve REE through a variety of mechanisms, with attenuation of FFM loss a primary area of interest given that REE is largely determined by FFM [146, 147]. During periods of energy restriction, breakdown of FFM can occur if dietary intake of protein is inadequate for protein synthesis requirements of the body, potentiating FFM-related declines in REE [148]. Higher protein intakes may therefore help to prevent the breakdown of FFM by helping to ensure adequate dietary substrate is available for protein synthesis [146]. Preservation of FFM may also have additional benefits during weight loss, given that is important for maintaining musculoskeletal integrity, functional capacity and quality of life during aging [77].

2.4.2 Increased thermogenesis

Independent of its effects on FFM and REE, higher protein intakes may also help to preserve total energy expenditure by increasing diet-related thermogenesis/thermic effect of food (TEF). This refers to the increase in energy expenditure above resting levels that occurs after food consumption; attributed to the extra energy required to digest, absorb and dispose of ingested food/nutrients [149]. It is generally reported that the TEF of protein is approximately 20-30% of energy consumed, compared to 5-15% for carbohydrate [150]. The TEF of fat is reported to be equivalent or lower than that of carbohydrate [149, 150].
Although short-term test meal studies support that higher protein intakes result in greater dietary thermogenesis (equating to an approximate increase in energy expenditure of 136-250kJ per day) [150, 151], the impact of this on longer-term energy balance and subsequent weight loss outcomes remains unclear [152]. Despite this, the relative inefficiency of protein consumption cannot be discounted as a potential beneficial mechanism for higher protein intakes during weight loss [144].

2.4.3 Enhanced satiety

Another potential key benefit of higher protein intakes for weight loss relates to the satiating effect of protein, which has generally been shown to induce greater levels of satiety than fats and carbohydrates [153]. This satiating effect of protein intake may assist individuals to reduce their total food intake, helping to maintain lower energy intakes over time in order to promote weight loss [153]. Although the influence of this on longer-term weight outcomes remains unclear, there is some evidence from lifestyle interventions to support a potential role for protein and enhanced satiety in promoting short-medium term weight loss [112, 154, 155].

2.5 Protein intake during weight loss: intervention studies

2.5.1 Surgical interventions

There has only been one published study involving manipulation of protein intake in a surgical patient group [156]. This pilot study by Swenson et al., conducted in individuals who had undergone RYGB, found no differences between weight loss or body composition outcomes between a high-protein, low-carbohydrate diet and a traditional low fat diet over a 12 month period after surgery [156]. Unfortunately it is difficult to appraise findings of this study, as few details were provided regarding the energy and macronutrient profile of the prescribed diets, and compliance with the diets was not reported. The small sample size (n=32) may have limited the power to detect differences between groups. Heterogeneity between groups may have also influenced
findings, where nearly 50% of the HP intervention group had type II diabetes (n=9), compared with only 23% of the control group (n=3). Although this difference was not statistically significant, it cannot be discounted that metabolic differences between subjects with and without diabetes may have been a confounding factor. Furthermore, the generalisability of Swenson et al. study to individuals who have had LAGB may be limited given the differences in GI functionality between RYGB and LAGB patients.

2.5.2 Lifestyle interventions

Unlike surgical interventions, numerous lifestyle weight loss studies examining the utility of high protein diets have been conducted in recent years. A key similarity between LAGB and lifestyle interventions is that both rely on decreasing food/energy intake to achieve weight loss, given that LAGB maintains integrity and absorptive capacity of the GI tract. Given that no interventional studies have previously been conducted in the LAGB population, an evaluation of these lifestyle interventions provides an evidence base to support a potential role for high protein diets after LAGB.

As there is a vast number of studies that have investigated the effects of macronutrient composition of the diet on weight loss and related health outcomes, this review focuses on studies that have specifically included a high protein diet to examine the influence of protein intake on weight loss and other relevant outcomes, rather than studies that have compared the effects of popular “low carbohydrate” diets (which by definition may include high protein and/or high fat intakes) with “high carbohydrate” diets.

The following section of the review is divided according to the following key outcomes of interest: weight loss and maintenance of weight loss, changes in body composition, resting energy expenditure, cardiovascular disease risk markers and type II diabetes/glucose metabolism. The safety of HP diets is also included within the following section of the review.
2.5.2.1 Weight loss and maintenance of weight loss

There is little consistency in the lifestyle weight loss literature regarding the utility of a high protein diet for weight loss and maintenance of weight loss in overweight and obese individuals. Some studies/researchers have found that a high protein intake may be of benefit for overall weight loss [112, 115, 154, 155, 157-162]; whereas others have failed to show any additional weight loss benefit of a HP diet when compared with a high carbohydrate (HC) diet [113, 152, 157, 160, 163-174].

Of note, most of the studies which failed to detect differential weight loss outcomes between HP and HC diets utilised isoenergetic study designs [113, 152, 157, 160, 164-167, 170, 171]. This strongly suggests that overall restriction in energy intake is the greatest determinant of weight loss rather than macronutrient composition of the diet. Although this may cast doubt on the potential metabolic weight loss advantages of HP diets, there may remain an independent role for protein intake to promote weight loss by assisting individuals to maintain lower voluntary energy intakes. This cannot be readily assessed by studies utilising isoenergetic study designs and may explain why such studies failed to detect any influences of diet composition on weight loss outcomes. In support of this, most studies that support a potential weight loss benefit of HP diets have utilised ad libitum energy intake study designs [112, 154, 158, 161, 175].

Evidence for the utility of a HP diet in promoting longer-term weight loss and maintenance of weight loss is also inconsistent. Some studies have refuted any benefit of higher protein diets when compared with higher carbohydrate diets for maintenance of weight loss [154, 157, 166, 174, 176] whereas others suggest that HP diets may actually have specific weight maintenance benefits [177-179]. Differences in study design may have a key role in explaining inconsistent findings, with studies that failed to show any benefit of a HP diet generally including an ad libitum follow-up phase after an intensive HP/HC weight loss intervention, with limited dietary guidance provided in the follow up period [154, 157, 166, 176]. The studies that have had more positive findings however have specifically focused on promoting protein intake after weight loss, with the inclusion of regular dietary counseling during the weight
maintenance phase [177-179]. This suggests that a key factor for a HP diet in achieving favourable weight outcomes is the provision of ongoing dietary support.

The three key studies to demonstrate a weight maintenance benefit of a HP diet utilised a similar study design, whereby subjects undertook a 4-6 week very low energy diet (VLED) (~2100kJ) and were then randomised to consume an ad libitum, energy balanced diet with or without an additional protein supplement (30-50g) for three months [177, 179] and six months [178]. The study by Claessens et al. also included an isoenergetic maltodextrin supplement in the control arm [179]. The former two studies by Westerterp-Plantenga et al. and Lejeune et al. found that weight regain was significantly lower in the protein-supplemented groups [177, 178] with regained weight consisting entirely of FFM, with some further decreases in fat mass also observed. The control groups however regained both FFM and fat mass. Although no differences in resting or total energy expenditure between groups were observed, the authors hypothesise that the increase FFM in the HP group may still have accounted for the slower weight regain due to the relative metabolic inefficiency of gaining FFM compared to fat mass, as facilitated by a higher protein intake [177, 178]. This suggests an alternate mechanism for the benefit of a HP diet in helping to improve weight maintenance outcomes.

The latter study by Claessens et al. also found that fat mass continued to decrease in the protein-supplemented arm, however small but significant increases in FFM were observed for both groups. Differences between these findings and the earlier studies of Westerterp-Plantenga and colleagues may be a consequence of differences in overall dietary intake and specific protein prescriptions of the studies, including the use of a HC supplement for the control group in the research of Claessen et al. It is difficult to ascertain the likely influence of overall diet composition between studies, as dietary intake was not recorded in the earlier studies [178]. Despite the specific differences in body composition outcomes between these studies, they do provide overall support for a potential weight maintenance benefit of higher protein intakes.
Although providing theoretically interesting results, a common limitation of these studies is the relatively short duration of the weight maintenance phase investigated. Thus the longer-term effects and sustainability of a protein-supplemented weight maintenance diet is unknown. Beyond these weight maintenance studies, short study duration is also a widespread limitation of most of the research conducted into the utility of a HP diet for weight loss overall, with few studies including weight loss outcomes beyond three to six months. Unfortunately therefore, the potential influences of higher protein intakes on weight loss and maintenance of weight loss in the longer-term remains unclear.

Of the studies that have reported longer-term outcomes, there is a general trend for poor compliance with dietary prescriptions, with a tendency for convergence in weight loss and/or weight regain over time, regardless of macronutrient composition of the diet [154, 157, 160, 166, 173, 174, 176, 180, 181]. Of note, attrition from many of these longer-term studies was also high [154, 160, 166, 173, 176, 181]. These findings are likely to be attributable to the general difficulties that individuals experience in complying with reduced-energy/energy-balanced diets over time, as reflected by the poor longer-term weight outcomes reported for lifestyle interventions in general. From a practical perspective therefore, it must be considered that compliance difficulties associated with following a HP diet may negate any potential weight loss benefits of such a diet in the longer term.

2.5.2.2 Changes in body composition

Despite the inconsistent evidence for an additional weight loss benefit of a HP diet compared with a HC diet, the literature provides stronger support that higher protein intakes may promote beneficial changes in the composition of weight loss; including greater loss of fat mass [112, 115, 158, 172, 182] and preservation of FFM [113, 114, 158, 163, 165, 170, 183]. These favourable changes in body composition have been reported in studies that did find an effect of protein intake on total weight loss [112, 158] as well as studies that did not find any additional weight loss benefit of a HP diet compared with a HC diet [113, 114, 163, 170, 172, 183]. Similarly, some studies have found that
Despite similar overall weight losses when compared with a higher carbohydrate diet, individuals with higher protein intakes achieved greater reductions in abdominal obesity [154, 167, 182]. Overall this suggests that although protein intake may not influence absolute weight loss, it can still promote more desirable changes in body composition.

Not all studies support that a HP diet has any additional benefit for body composition outcomes during weight loss when compared with a HC diet; with many reporting similar overall decreases in fat mass [152, 157, 164, 166-168, 175] and/or FFM [152, 164, 166-169, 172] regardless of macronutrient composition of the diet. Of note, not all studies observed significant decreases in FFM in either intervention arm [157, 169, 175].

It should be noted that although studies have been broadly grouped according to positive and neutral body composition outcomes for the purpose of this review, there is broad heterogeneity between studies in terms of sample population characteristics (including overall health status, degree of overweight/obesity, age, gender and menopausal status) and study design (including dietary protocol and degree of energy restriction utilised, study duration and the inclusion/exclusion of an exercise component within the study groups). All of these factors have the potential to influence body composition outcomes, which may account for differential findings between groups.

Another key issue to consider in interpreting study findings is the method used to define the “high protein” intervention. Some studies have defined this based on body weight whereas others have used protein as a percentage of daily energy intakes. In the context of an energy restricted diet, the latter method may result in an inadequate prescription of protein intake for beneficial effects to occur, given that protein requirements are determined by body size rather than energy intake [148, 183]. This may help to explain the lack of benefit of a high protein diet in some studies that have been conducted.

In support that protein requirements are best determined according to body weight in order to have beneficial effects on body composition, a recent meta-regression that
examined the effect of variations in protein intake on body composition during energy restriction [116], found that a protein intake of >1.05g/kg was associated with a 0.6kg additional FFM preservation in studies of less than 12 weeks duration; and an additional 1.21kg in studies greater than 12 weeks duration. This suggests that protein intake needs to be greater than 1.05g per kilogram of actual body weight to be of most benefit for preserving FFM [116].

Some studies that defined protein prescriptions based on a percentage of daily energy intakes did however provide a level of protein intake that is theoretically sufficient for preserving FFM without observing any beneficial effects when compared with a lower protein (HC) intervention arm. In explaining the lack of effect of higher protein intake in these studies, it is possible that the level of energy-restriction was not severe enough to cause substantial loss of FFM in any of the diet intervention groups.

Methodological differences in measuring body composition may also help to account for differential study findings; with methodologies including dual x-ray absorptiometry (DXA), bioelectrical impedance analysis (BIA) [159, 169, 175] and skinfold thickness [170]. Accuracy of body composition outcomes is variable between these different measures [184], which makes it difficult to compare results between studies.

### 2.5.2.3 Changes in resting energy expenditure

Despite preservation of REE being proposed as a primary potential benefit of a HP during weight loss, relatively little research has been conducted in this area. Some limited evidence to support that higher protein intakes may help to preserve REE during weight loss is provided by two small, short-term HP interventions [159, 185]. Baba et al. found that REE decreased more significantly in the HC group (-1600± 350kJ) when compared with the HP group (-550± 220kJ) after a four week hypo-energetic diet [159]. These differences remained significant after adjusting for weight loss. In an earlier seven day intervention, Whitehead et al. also found that declines in REE were also significantly less following a HP diet [185]. The small sample populations (n=13
and 8 respectively) and short-term nature of these studies limit the strength and quality of these findings however.

In contrast to theoretic expectations, other lifestyle weight loss studies that measured REE found no differences according to different dietary protocols, with statistically significant declines [152, 168, 169, 171], non-significant declines [175] or no change [169] reported after weight loss for all subjects. This may be explained by the fact that most of these studies also failed to detect any differences in preservation or loss of FFM between groups [152, 168, 171, 175]. Alternatively, it is also possible that these studies lacked power to detect small but clinically significant changes in REE between groups [152, 169, 175].

Unfortunately most of the lifestyle intervention studies that found a positive association between protein intake and preservation of FFM did not measure REE [113, 114, 158, 163, 165, 170, 183]. Thus it remains largely unknown whether the observed preservation of FFM or attenuation of FFM losses had any corresponding impact on REE.

2.5.2.4 Co-morbidity risk markers: Blood lipid profile and glucose/insulin metabolism

Overall there are few consistent trends in the literature regarding the specific effects of a high protein diet on blood lipid profile and glucose and insulin metabolism. When compared with a HC diet, the most consistent trend for blood lipid profile is that a HP diet may promote greater reductions in triglycerides [112, 113, 115, 158, 161, 162, 164, 165, 172, 173, 176]. In some studies, a HP intake has also been shown to better reduce LDL cholesterol [115, 167] and increase/preserve HDL [115, 158, 172-174, 176]. Other studies however have suggested that HP diets are less effective in reducing LDL cholesterol [115, 158, 161, 174, 186]; or produce similar changes in blood lipid profile when compared with a HC diet [113, 157, 159, 163, 166]. An important overall finding regarding co-morbidity risk outcomes is that very few studies have reported detrimental effects of a HP intake on the relevant disease risk markers when fat intake
is also controlled for. This helps to support the overall efficacy and safety of a HP diet for weight loss.

2.5.2.5 Safety of high protein dietary protocols

A recurring theme in the literature relates to the safety of high protein, low energy diets. Major concerns that have been raised include potential detrimental effects on renal function and bone turnover. These concerns however are not supported by evidence from lifestyle interventions examining higher protein intakes, with no negative effects reported on these parameters in either generally healthy overweight/obese sample populations or populations considered at greater risk of adverse effects, for example individuals with type II diabetes [112, 154, 164, 165, 169]. Furthermore in the case of bone health, there is some evidence to suggest that a HP diet may actually help to preserve skeletal integrity by helping to reduce overall bone resorption [144, 187].

From a theoretic perspective, maximal safe absolute protein intakes for individuals with normal renal function have been suggested as high as 285 grams per day [188], with leading researchers in the field suggesting that intakes of 2-3g/kg of protein intake per day remains safe [188]. It is important to highlight this level of protein intake is unfeasibly high in the context of an energy-restricted dietary intervention designed to facilitate weight loss via a nutritionally balanced diet.

The safety of HP diets in individuals with existing renal dysfunction is a separate consideration, given that there is strong evidence to show that high protein intakes can increase the progression of renal impairment [188]. Thus caution is required for individuals with existing renal dysfunction, for whom a HP diet may be contraindicated or considered inappropriate.

2.5.2.6 Overall evaluation of lifestyle-based evidence for HP diets and weight loss

Overall, little agreement exists in the lifestyle literature to support or refute the utility of a HP diet for improving weight loss, body composition and other nutrition-related
health outcomes including improvements in comorbidities or disease risk factors. This is a likely reflection of the heterogeneity between studies, with major differences existing in sample population characteristics, dietary protocol/s investigated and study duration. Key differences in sample population characteristics include: age, gender, degree of overweight/obesity and disease status of subjects. Key differences between study protocols include heterogeneous prescriptions of protein intake and differing degrees of prescribed energy restriction and rapidity of weight loss, which is likely to have influenced overall weight loss and body composition outcomes as well as changes in co-morbidity risk profile.

Despite the equivocal evidence for the utility of a HP in achieving additional weight loss, improvements in body composition and reductions in disease risk factors, one consistent theme from the literature is that HP diets are at least equally effective in achieving weight loss and improvements in body composition and health as other types of energy-restricted diets in the short-medium term. Furthermore, although there have been concerns raised regarding the safety of a HP diet, there is little evidence to support that a HP diet has detrimental effects on health during weight loss (with the exclusion of specific disease states such as chronic renal failure). This highlights that overall a HP diet may be considered as an effective and safe approach to weight loss as part of an energy-restricted diet.

The longer-term efficacy of a HP diet remains unclear, with issues relating to compliance an essential consideration in determining the overall utility of a HP diet for weight loss, improvements in body composition and other related health outcomes in the longer-term. Overall there is a need for further research to better elucidate the potential benefits of a HP diet for weight loss and weight maintenance; and also to determine if there is a best-practice approach that can be used to maximise longer-term compliance with such a diet if its benefits are further proven.
2.5.3 Application of current evidence for high protein diets to the LAGB population

Despite the overall similarity in gastrointestinal function between individuals who undertake lifestyle weight loss interventions without surgery and those who undergo LAGB, limitations remain in the generalisability of lifestyle intervention outcomes for the LAGB population. Differences in baseline body weight between these groups are a key consideration, with most lifestyle interventions selecting a sample population with lower BMI’s than are typical for individuals who have LAGB. Corresponding level of overall health must also be taken into account, where many lifestyle studies have excluded subjects with comorbidities or who were taking medications for hypertension, dyslipidemias and other metabolic abnormalities. The LAGB population however generally includes a larger proportion of individuals with existing comorbidities, including individuals who take medication for various obesity-related metabolic disturbances. It cannot be discounted that obese individuals who undergo LAGB may respond differently to a HP diet, given their increased likelihood of having various metabolic abnormalities [189].

Given that absolute weight loss and rapidity of weight loss is greater following LAGB when compared with conventional lifestyle therapies [20, 58] another key consideration is that protein intake may be more influential /important for some outcomes in the LAGB population and less influential for other outcomes. For example, given the potential for greater magnitudes of FFM losses and declines in REE following LAGB, arguably the potential for protein to help preserve of FFM and REE may be more important. For other outcomes such as changes in blood lipid profile and glucose metabolism, it is possible that any potential benefits of a higher protein intake may be overshadowed by overall weight loss achieved following LAGB, given that weight loss has a positive and independent effect on these parameters [190].

Also of note is that dietary intake patterns achieved in lifestyle interventions may not be achievable in the LAGB population, given that gastric banding can result in difficulties in consuming protein-rich foods such as meat [123, 191] and induces
restrictions in the overall volume of food that can be consumed. Thus it is possible that the acceptability and sustainability of a HP diet will be different for individuals who have LAGB.
Chapter 3  Overall methodology

3.1 Pilot dietary intervention study

3.1.1 Overview

This study aimed to examine the feasibility and potential utility of a protein-enriched diet for optimising weight loss, body composition and other diet related outcomes in the first six months after laparoscopic adjustable gastric banding (LAGB). Subjects were alternately allocated to follow either a protein-enriched or usual care diet for six months after surgery and were then followed-up for a further six months after the intervention period.

Originally the dietary intervention was intended to be undertaken as a full-scale study; however, practical difficulties with recruitment for the study, compliance with the intervention and compliance with completing study measures necessitated modification of the trial to a pilot study. Although the initial research aims and questions for this component of investigation (Appendix 3) could not be addressed as a consequence of this, results of the pilot study nevertheless present important implications for dietetic practice and further research in this field.

3.1.2 Study approvals

3.1.2.1 Ethics approval

The study proposal was submitted to the University of Newcastle’s Human Research Ethics Committee (HREC) using the National Ethics Applications Form on 30/09/2008 as a Level 3 application (potential for significant or unavoidable risk). Full approval was granted on 14/11/2008 (HREC Approval Number: H-2008-0345). Four variations were applied for and approved by the HREC since initial approval was granted. These variations reflected the need to modify the study design and data collection methods in response to practical issues that arose prior to and during the course of the study.
Copies of the final participant Information Statement and Consent Form (inclusive of approved variations) are provided in Appendices 4 and 5 respectively.

3.1.2.2 Safety approval
An application for safety approval was submitted to the University of Newcastle’s Health and Safety team and Chemical and Radiation Technical Committee on 6/11/2008 and safety clearance was granted on 27/02/2009 (Reference number: 333/2008).

3.1.2.3 Clinical trial registration
An application was submitted to register the study with the Australian New Zealand Clinical Trials Registry (ANZCTR) on 23/04/2009 and was granted registration on 13/05/2009 (Registration number: ACTRN12609000258257). Updates to the protocol reflecting changes in study design and methodology were approved on 09/06/2010. Trial details can be viewed at: http://www.anzctr.org.au/trial_view.aspx?ID=83363).

3.1.3 Study design
The overall structure of the study, including data collection time points is shown in Figure 3.1.

3.1.3.1 Participants and inclusion/exclusion criteria
Study participants were adult males and females with a body mass index (BMI) greater than 30kg/m², who were undergoing or who had undergone LAGB at either one of the two major private gastric banding practices in Newcastle, NSW, Australia [Dr Jon Gani’s Rooms (Lake Macquarie Specialist Medical Services, Gateshead) and Newcastle Obesity Surgery Centre, Lake Macquarie].

Specific inclusion criteria for the study were: undergoing or had undergone LAGB no earlier than two weeks prior to study entry; aged between 18-65 years; and BMI greater than 30kg/m². Exclusion criteria were: having an existing medical condition requiring a diet incompatible with the dietary intervention, surgeon did not approve participation based on pre-operative health status, pacemaker or other electronic implant
(contraindicated for body composition measurement using BIA), food allergy or intolerance that may affect health or compliance with the study, pregnant/lactating women or those unwilling or unable to understand or follow the study diet/materials.

3.1.3.2 Intervention diet

The protein-enriched diet was designed to provide 4000-6000kJ and 90-100g of protein per day, with an overall macronutrient distribution of ~35% protein, ~40% carbohydrate and ~25% fat. This is consistent with the definition of a relatively high protein diet with respect to overall macronutrient composition of the diet [144]; and also provides a higher level of protein intake than what might be expected from usual care, based on previous reports of protein intake following LAGB and existing nutritional management guidelines for bariatric surgery patients, which suggest protein intakes of approximately 50-60 grams per day following surgery [82, 89]
Of primary consideration when designing the intervention protocol was how to achieve protein intake targets suggested by the literature to preserve lean muscle mass (greater than 1.05g/kg actual body weight) [116] in the context of LAGB. It was decided that achieving this target was likely to be unrealistic for individuals who have LAGB, given that they generally experience dramatic food and drink volume restrictions after surgery. To illustrate this, based on an average gastric banding patient body weight of 120kg, a high protein intake (defined as greater than 1.05g/kg/body weight) [116] would require the participant to consume more than 126 grams of protein per day. This is more than double the current reported protein intakes that individuals achieve 4-12 months after surgery and also exceeds reported pre-surgery intakes [82]. Thus the protein-enriched diet was designed to provide a higher amount of protein than what might be expected when compared with usual care, whilst remaining practicable and nutritionally balanced within the context of expected post-operative dietary intakes.

The intervention diet utilised a whole-food approach with the addition of a powdered, neutral-flavoured, 100% whey protein isolate supplement (a commercially available product provided by Top Nutrition©, Newcastle, Australia). This supplement was incorporated into the protocol to enhance overall protein intake (intended to provide an additional ~15 grams of protein per day) without substantially increasing total energy intake or food volumes, in order to ensure that the intervention diet remained consistent with overall weight loss aims of LAGB. A whey-based protein supplement was utilised given that whey protein is of high biological value, representing a high quality protein source [192]. The overall nutrient composition of the protein supplement is provided in Table 3.1.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Quantity per 100g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (kJ)</td>
<td>1528</td>
</tr>
<tr>
<td>Protein (source: 100% whey protein isolate) (g)</td>
<td>90</td>
</tr>
<tr>
<td>Carbohydrate :</td>
<td></td>
</tr>
<tr>
<td>- Total (g)</td>
<td>4.7</td>
</tr>
<tr>
<td>- Sugars (g)</td>
<td>2.0</td>
</tr>
<tr>
<td>Fat (g)</td>
<td>1.3</td>
</tr>
<tr>
<td>Water content (g)</td>
<td>4.0</td>
</tr>
</tbody>
</table>
The intervention diet was designed to broadly accommodate participants with differing protein and energy intake requirements, whereby recommendations for serves of protein-rich and other food groups were determined using clinical judgement based on the initial body weight and gender of the participant. The overall dietary model for the intervention is summarised in Table 3.2.

<table>
<thead>
<tr>
<th>Food Group</th>
<th>Serves / Day</th>
<th>Protein (g)</th>
<th>CHO (g)</th>
<th>Fat (g)</th>
<th>Energy (kJ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat &amp; meat alternatives</td>
<td>4-5</td>
<td>40-50</td>
<td>negligible</td>
<td>8-10</td>
<td>1000-1300</td>
</tr>
<tr>
<td>Dairy</td>
<td>2-3</td>
<td>20-30</td>
<td>30-45</td>
<td>3-5</td>
<td>1000-1400</td>
</tr>
<tr>
<td>Breads, cereals &amp; starchy vegetables</td>
<td>3-4</td>
<td>7-10</td>
<td>44-60</td>
<td>3-4</td>
<td>960-1300</td>
</tr>
<tr>
<td>Fruit</td>
<td>1-2</td>
<td>1-2</td>
<td>16-32</td>
<td>0</td>
<td>300-600</td>
</tr>
<tr>
<td>Non-starchy vegetables</td>
<td>3</td>
<td>4</td>
<td>11</td>
<td>0</td>
<td>300</td>
</tr>
<tr>
<td>Extra fats</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>17</td>
<td>750</td>
</tr>
<tr>
<td>Protein Supplement</td>
<td>3 (Tb)</td>
<td>14.0</td>
<td>negligible</td>
<td>negligible</td>
<td>225</td>
</tr>
<tr>
<td>~Totals</td>
<td>90-110</td>
<td>110-150</td>
<td>30-35</td>
<td>4500-5800</td>
<td></td>
</tr>
</tbody>
</table>

The research student (A Fielding) as the research dietitian provided all participants in the intervention group with verbal and written instructions regarding the dietary protocol during the baseline interview/measurement session. Guidelines for the intake of protein-rich foods were provided using a food exchange system, which was based on protein exchanges of approximately 10 grams of protein per serve. Guidelines were also provided for the intake of other core foods including cereals, vegetables and fruit.

Participants were also instructed to take three tablespoons of the protein supplement per day, which could be added to ordinary foods and drinks according to individual participant preferences. Suggestions were provided regarding the most appropriate foods/fluids to add the supplement to in the context of texture/palatability, including for example yoghurt or milk-based liquids. Participants were provided with three months’ supply of the protein supplement at the baseline interview, with further supplies provided at the midway (three month) interview/data collection session. An example of the intervention resource provided to participants is provided in Appendix 6.
Participants in the intervention group also continued to attend regular follow-up with the usual care dietitian at their surgical practice, in accordance with routine follow-up care procedures within these surgical practices. Broadly, the usual care advice covered issues including: progression from fluids to solids after surgery, and eating techniques and dietary advice as appropriate for LAGB (e.g. chewing foods well, eating slowly, avoiding fluids with meals, selecting nutrient-dense foods and balancing dietary intake across food groups). The approximate frequency of this routine dietetic follow-up was every 2-4 weeks in the early postoperative months and approximately every 1-2 months thereafter.

The intervention was discussed and guidelines reinforced with participants via six weekly telephone calls and also during the three month interview/data collection sessions. Compliance with the intervention was assessed via reported dietary intake at three and six months, and self-reported data obtained during follow-up interviews regarding the average quantity of protein powder consumed per day/week, as well as the quantity of protein powder remaining from distributed supplies. Based on the latter information, compliance with the supplement was divided into four categories (full, partial, minimal and zero). Definitions for each category are provided in Table 3.3.

<table>
<thead>
<tr>
<th>Compliance category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full</td>
<td>Reported taking 3 tablespoons for at least 6 days per week; or had used entire quantity of supplement provided by the next follow-up point</td>
</tr>
<tr>
<td>Partial</td>
<td>Reported taking at least half of supplement dose (equivalent to &gt;10 tablespoons per week (eg 2T on 5 days); or had used at least half of supplies provided</td>
</tr>
<tr>
<td>Minimal</td>
<td>Reported taking &lt;1 tablespoon of supplement per day; or did not meet criteria for partial or zero compliance</td>
</tr>
<tr>
<td>Zero</td>
<td>Did not consume any supplement</td>
</tr>
</tbody>
</table>

### 3.1.3.3 Usual care diet

The usual care group followed the dietary recommendations provided by the usual care dietitians as per standard practice following gastric banding, with no specific dietary intervention provided as part of the study. It was anticipated that the energy and macronutrient intake of the usual care group would be reflective of intakes
reported in observational LAGB studies [82] [60, 79] and in line with general nutritional recommendations for bariatric surgery patients [193]. Therefore it was expected that the usual care diet would provide approximately 4000-6000kJ per day, consisting of ~20% protein (~60 g/day), ~50% carbohydrate (~150 g/day) and less than 30% fat (~40 g/day).

3.1.3.4 Recruitment
Recruitment for the study was undertaken between March and December in 2009. The primary method for recruiting participants was via the usual care dietitians at each of the surgical practices involved in the study. The usual care dietitians informed potential participants about the study and provided them with an Information Statement and Consent Form (Appendices 4 and 5) to take home to consider participation in the study. If an individual wished to participate they were asked to mail their signed consent form to the researchers (via reply paid envelopes provided). Due to the varying nature of the timeframe for usual care dietetic appointments prior to LAGB, it was not possible for all potential participants to be informed of the study and complete the informed consent process prior to undergoing LAGB. This practical difficulty explains why the inclusion criteria for the study included individuals who had undergone LAGB no earlier than two weeks prior to study entry.

Presentations were also conducted at gastric banding information seminars provided by the surgeons for people who are interested in having gastric banding. The presentation gave an overview of the study and provided potential gastric banding patients an opportunity to consider participating in the study if they choose to have the surgery. Recruitment posters were displayed at the surgeons’ waiting rooms to alert potential participants to the study (Appendix 7).

3.1.3.5 Eligibility screening
Upon return of the consent forms, the research student contacted the potential participant to complete an eligibility checklist (Appendix 8) in accordance with study inclusion/exclusion criteria.
3.1.3.6 Diet allocation method

It was originally intended for subjects to be allocated to either the intervention diet or usual care diet using a randomly generated number list. However, due to unforeseen difficulties in obtaining the protein supplement at the commencement of recruitment, the first six subjects were block allocated to usual care, with the following six subjects block allocated to the intervention diet. Thereafter, subjects were alternately allocated to follow usual care or the intervention diet for convenience/practical considerations. Allocation occurred upon confirmation of participation in the study (i.e. after informed consent was received and eligibility screening was completed successfully).

3.1.3.7 Primary outcome measures

Weight loss as a percentage of initial body weight

The best method to examine and report weight loss in the field of obesity and particularly obesity surgery has been an area of debate in recent years [194-200]. Weight loss as a percentage of initial body weight was selected as the key weight-related outcome for the study, consistent with the principal reporting strategy of the wider weight loss literature [200]. Advantages of reporting weight loss as a percentage of initial body weight include: it accounts for variability in baseline body weight between individuals; has definable links with health improvements/clinical outcomes associated with weight loss; and allows for outcomes to be compared with the broader weight loss literature [200]. Weight loss as a percentage of initial body weight was calculated as:

\[
\frac{(\text{baseline weight} - \text{postoperative weight})}{\text{baseline weight}} \times 100
\]

In the field of obesity surgery, percentage excess weight loss (%EWL) is the most commonly reported measure of weight loss [195]. This is based on the concept of excess weight, defined as the difference between actual body weight and ideal body weight (IBW), where IBW is derived from a standard benchmark, usually based on the Metropolitan Life Insurance Company (USA) Height and Weight Tables or weight
corresponding with a BMI of 25kg/m² [195]. Thus %EWL can thus be calculated as [195]:

\[
\frac{\text{(preoperative weight - postoperative weight)}}{\text{(preoperative weight - ideal weight)}} \times 100
\]

There is increased recognition in the literature that %EWL is not an accurate, objective measure of weight loss outcomes [195, 199, 200]. Problems with %EWL as a measure of weight loss include that: %EWL has been shown to vary according to initial BMI [199]; the definition of %EWL loss is arbitrary depending on how IBW is defined, and there is a lack of transparency regarding how %EWL is defined by different researchers/reports [194, 196]; and it is often based on dated “ideal body weight” data (1979 Metropolitan Life Insurance Height and Weight Tables) [195]. There is no current evidence clearly defining an IBW in relation to life expectancy and health outcomes, thus the concept of IBW, which is integral to the concept of %EWL, remains arbitrary rather than objective [194, 200]. Furthermore, there is no evidence-based threshold for %EWL clearly linked to clinical outcomes and health improvements following weight loss [194, 200]. Therefore %EWL was included as a secondary weight loss outcome in order to maintain comparability with previous studies that have used %EWL only to report outcomes.

BMI, defined as: weight (kg)/height (m²), was also calculated as a secondary measure of weight loss, consistent with standard reporting methodology for weight loss studies [194].

**Body composition: fat mass, fat free mass and percentage body fat**

A dual approach for measuring body composition was utilised. This included DXA and single frequency BIA. DXA is a precise and accurate method for measuring fat mass and fat free mass, and is often considered as a reference standard for estimating body composition in research [201]. In summary, DXA generates two X-ray beams at different energy levels, with the differential attenuation of the two energies due to the differing densities of body tissue (bone mineral and soft tissue (including fat and lean
mass)] used to estimate body composition via integrated computer software [202]. The radiation dose from DXA measurements is considered to be very low [202].

Key advantages of DXA include that it is highly precise, non-invasive and is not influenced by an individual’s hydration status [203]. DXA is also less burdensome to conduct when compared with other reference standards such as the four-compartment model, which requires multiple complex measures and highly specialised equipment [204].

DXA does have some limitations however, particularly in the context of obesity research. This includes weight limits of the equipment and relatively small scanning area dimensions, which many obese individuals do not fit within completely [205-207]. Furthermore, accuracy of soft tissue measurements decreases with the amount of tissue the x-rays have to pass through; thus accuracy of measures is typically lower for obese individuals [206]. Given its high precision however, DXA remains a highly useful method for assessing longitudinal changes in body composition [201, 203].

Due to weight limit restrictions for DXA, BIA was also used to measure body composition in order to ensure that data for this key outcome could be obtained for all participants, regardless of weight. It was considered important not to exclude participants with a weight greater than 136kg (reflecting the weight limit for DXA equipment utilised in the study) due to the limited pool of potential participants available for the study and in order to maximise generalisability of findings to the wider LAGB population.

In summary, BIA involves the passing of a small electrical current through the subject’s body, with resistance to the current (impedance) in being used to calculate body composition (including percentage body fat, fat mass, fat free mass and total body water) using specifically developed algorithms/prediction equations based on an individual’s height and weight [208]. Although BIA is not considered accurate enough to assess individual changes in body composition [209], it has been validated for assessing changes in group means [210].
**Dietary intake**

Mixed methodology was used to collect dietary intake data in response to practical difficulties associated with the timing and collection of dietary intake data. Baseline dietary intake was assessed using diet histories in order to capture habitual pre-operative dietary intake [211]. Within the context of systematic bias associated with all self-report dietary intake methodologies, diet histories have been shown to provide a valid estimate of mean intake at a group level [212, 213]. Given the time consuming nature of obtaining an adequate diet history and the participant burden associated with this [211], it was not practicable to collect diet histories at three, six and 12 month time points.

It was therefore originally planned to collect all follow-up dietary intake data using three day food records (with the inclusion of one weekend day) based on standard household measures. This form of three day food record was selected as it is less burdensome for individuals to complete and thus less likely to influence usual food habits when compared with four day, weighed records [211]. Although estimated food records do not necessarily reflect habitual intake and are less precise than weighed records [211], they may still provide valid mean nutrient intakes at a group level [213].

Due to poor return and completion of three day food records in the initial stages of six month data collection, dietary intake data at six and 12 months was collected using single 24 hour recalls, taken on the day of follow-up data collection to reflect the previous day’s intake. Although single 24 hour recalls are subject to recall bias and do not reflect habitual intake [211], they achieve a higher response rate than other dietary assessment methods [211] and have not been shown to have significantly higher levels of under-reporting of energy when compared with weighed or estimated food records [214].
3.1.3.8 Secondary outcome measures

*Waist circumference*

Waist circumference was measured as a marker of abdominal adiposity and associated cardiometabolic health risk (including hypertension, hyperlipidaemia, impaired glucose metabolism/diabetes, cardiovascular disease and all-cause mortality) [215]. There is no universally accepted waist circumference measurement protocol/site that most accurately reflects health risk [215], however a recent systematic review suggested that the site of measurement (including minimal waist, midpoint between ribs and iliac crest and umbilicus) does not substantially influence overall association with mortality, CVD or diabetes [216].

*Eating behaviour*

Eating behaviour was measured using the three factor eating questionnaire (TFEQ) (included within Appendix 9). The TFEQ measures three dimensions of eating behaviour: cognitive restraint, disinhibition and hunger [141]. Restraint reflects the intention to restrict food/energy intake in order to maintain or lose weight; disinhibition reflects a tendency to overeat in response to certain environmental, situational and social cues; and hunger reflects a susceptibility to subjective sensations of hunger [141]. The TFEQ has 51 questions in the format of 36 true/false and 15 likert-type scale responses. Twenty-one 21 questions are used to assess restraint, 16 questions are used to assess disinhibition and 14 questions are used to assess hunger. Scoring for each dimension is calculated on a continuous point scale, with higher scores indicating higher levels of restraint, disinhibition and hunger respectively [141].

The TFEQ was selected as it is considered to be a validated and standardised eating behaviour assessment tool [141]; and is the most commonly used questionnaire for the assessment of eating behaviour in obesity surgery studies [217] as well as being widely used in the broader obesity literature [218]. Therefore using the TFEQ enabled maximal comparability of findings with previous research.
**Food tolerance**

Food tolerance, broadly definable in the context of obesity surgery as the ability to ingest foods without adverse effects arising from gastrointestinal alterations related to surgery [219], was assessed using the food tolerance checklist [220] (included within Appendix 9). This tool was developed and partially validated by Suter et al. in 2007 as a brief, standardised measure of food tolerance after surgery [220], and represents one of the only standardised obesity surgery-specific measures of food tolerance available in this field of research. The food tolerance checklist is divided into four sections: 1) an overall qualitative assessment of the subject’s satisfaction with eating ability; 2) questions relating to the frequency/timing of meals and snacks 3) an assessment of the subject’s ability to eat certain types of food; and 4) an evaluation of frequency of vomiting and/or regurgitation symptoms after surgery [220]. In accordance with Suter et al. scoring guidelines, a quantitative score was derived from sections 1, 3 and 4 and added to provide an overall food tolerance score, ranging from: 1 (very poor food tolerance) to 27 (excellent food tolerance) [220]. Individual scores for sections 1, 3 and 4 were also reported, with higher scores reflecting greater satisfaction with eating ability, better ability to eat certain foods and lower vomiting and regurgitation frequency respectively.

**Quality of life/functional health and wellbeing**

Functional health and wellbeing was measured using the SF-36v2® Health Survey (Quality Metric, USA) (included within Appendix 9). The SF-36v2® is a standardised, validated survey used to measure health-related quality of life [221] and has been widely used in previous studies investigating quality of life after LAGB [82, 109, 123, 222-224]. The SF-36v2® includes eight health domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health [221]. Higher scores reflect higher levels of functioning for each domain [221]. The SF-36v2® also includes physical health and mental health component summary scores, which are based on aggregated scores from each domain. All SF-36v2® data was scored using scoring guidelines provided by Quality Metric. Component summary scores were used as overall measures of physical and mental
wellbeing/quality of life, and were calculated using Australian norm data [225] rather than the 1998 USA population data provided by the scoring manual [221]. Component summary scores are expressed as T-scores (population norm-based scores), with a population norm mean of 50 and SD of 10 in accordance with scoring guidelines [221].

### 3.1.3.9 Additional outcomes measures not reported in this thesis

Table 3.4 outlines outcomes for which data was collected as part of the study but not included within results of this thesis, and a brief rationale for omission of these outcomes.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Assessment method</th>
<th>Reason for omission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical activity</td>
<td>Data was collected using the International Physical Activity Questionnaire short format [226]. Additional questions adapted from the exercise component of the National Health Survey [227] were also included to further assess leisure time activity.</td>
<td>Quality of data was insufficient for meaningful analysis.</td>
</tr>
<tr>
<td>Blood lipid profile; inflammation (C-reactive protein); glucose and insulin profile</td>
<td>Blood samples were collected and analysed by Hunter Area Pathology Services using standard pathology laboratory practices/protocols. All blood tests were based on fasting samples.</td>
<td>Insufficient longitudinal data available due to suboptimal participant attendance for blood sample collection.</td>
</tr>
<tr>
<td>Resting energy expenditure (REE)</td>
<td>Indirect calorimetry using a ventilated hood system (Sensormedics Vmax Spectra 229D).</td>
<td>Insufficient data due to low participant attendance for REE measurements.</td>
</tr>
</tbody>
</table>

### 3.1.4 Data collection

Key data collection time points for the study were: baseline, three, six and 12 months after surgery. The average time of baseline data collection was 11±5 days since surgery, given that it was not logistically possible to recruit participants and complete required baseline data collection prior to surgery. The research student was responsible for collecting all data (with the exception of clinic information detailed in Section 3.1.4.5).

Data were collected using a combination of methodologies including: face-to-face interviews and measurement sessions, telephone calls and self-administered surveys. At baseline, each participant attended an individual face-to-face interview and measurement session, which included collection of demographic information, weight history, diet history and completion of physical measures including weight, height,
body composition (DXA and/or BIA) and waist circumference. Participants were also asked to complete a self-administered survey booklet (Appendix 9) at the baseline interview/measurement session, which included the following sections: medical information (self-developed item); SF-36v2©; TFEQ; physical activity; and the food tolerance checklist. The booklet was then checked for completeness and clarity with the participant during the data collection session.

3.1.4.1 Anthropometric measurements

Body weight was measured to the nearest 0.1kg using an electronic scale (Tanita, Model BF-310), with participants wearing light clothing and no shoes. Height was measured to the nearest 0.1cm using a stadiometer (Harpenden Portable, model SO 98.603). BMI was calculated from weight and height data as: weight (kg)/height (m²).

Waist was measured to the nearest 0.1cm by the same assessor (the research student) using a non-stretch tape (Seca 201 Circumference Measuring tape). As reproducibility of waist circumference measures is commonly problematic, especially in obese populations and following weight loss [228], the umbilicus was used as the measurement site for males and approximately one inch above the umbilicus was used for females, with anatomical features at the site of measurement recorded for each individual to enhance precision and reproducibility of measurements across study time points.

3.1.4.2 Body composition measurements

Dual-energy x-ray absorptiometry

Total body scans were performed by the research student using a Lunar Prodigy DXA scanner (GE Medical Systems, Madison, USA; software: enCORE version 9.30.044; X-ray energies of 55kVp and 80kVp) for those subjects (n=39) who met weight specifications for the DXA scanning bed (weight less than 136.1kg). DXA total body scans measure the density of soft tissue (including fat and lean mass) and bone tissue, with the integrated software providing estimates of percentage body fat, fat mass, lean
mass and bone mineral content, from which total fat free mass was calculated as: lean mass + bone mineral content.

Prior to study commencement, the research student attended and passed a Clinical Densitometry Training Course (Australian and New Zealand Bone and Mineral Society) for accreditation in use of DXA equipment. The research student also obtained and maintained a Radiation Licence (RL40697) from the NSW Department of Environment and Climate Change /Environmental Protection Agency for the use of DXA equipment.

Subjects were instructed to wear light clothing free of metallic components (for example zippers) and remove all unfixed metal objects (including for example jewellery and watches) and shoes prior to the scan given that these interfere with the accuracy of density readings. Subjects were positioned lying on their back centred on the scanning table, approximately 3cm below the top horizontal line of the scanning bed, with hips and shoulders squared and legs straight with toes pointed slightly inwards, in accordance with total body scan guidelines. Due to difficulties with fitting subjects within the outer dimensions of the scanner, subjects were instructed to hold their arms and hands next to their sides, thumb-side upwards for the duration of the scan.

Scans were conducted on the ‘thick’ scan setting for all subjects in accordance with manufacturer guidelines/defaults based on participant body weight. The duration of each scan on this setting was approximately 10 minutes, with the scanning arm moving over the top of the subject from the top of the scanning table to the bottom (i.e. from head to toe of the subject). An example of the digital image acquired and body composition output from a total body scan is provided in Figure 3.2.
Standard manufacture procedures for quality assurance and quality control were performed prior to every DXA measurement session to ensure scan precision and reliability. Coefficients of variation (CV) for DXA body composition measurements were: bone mineral density 0.08%, lean tissue 1.7% and fat tissue 0.06%.

**Bioelectrical impedance analysis**

Body composition was measured in all subjects using Tanita® TBF-300A single frequency BIA scales (Tanita, Model TBF-300A), involving a single frequency current passed from foot-to-foot. Estimated clothes weight, gender, age, height and build type data were first entered into the processing unit of the scales, as required for the manufacture’s pre-programmed algorithms for calculating body composition data. Subjects were instructed to stand bare-footed on the weighing platform of the scales, with feet placed in the appropriate zones of the weighing platform, with the impedance measurement taking approximately one minute to complete. A printout of body composition estimates was then automatically generated by the processing unit.
of the scales. The weighing platform of the scales was placed on a hard, flat surface for all assessments and subjects were instructed to wear light clothing for the measurements.

### 3.1.4.3 Dietary intake assessments

Diet histories were collected using face-to-face semi-structured interviews. A chronological approach from time of waking through the following 24 hours was used to determine usual foods consumed (including usual/typical variations of meals, snacks and drinks) to establish a typical week’s menu. A food group checklist discussing frequency of consumption of food/drink items and portion sizes and specific questions relating to variations on weekends and eating out/take away were included within the interview. Verbal discussion was used to quantify portion sizes, which were discussed based on standard household measures, packaging sizes (where appropriate) and estimates of physical dimensions if required. The template used as a basis for the diet history interview is included within Appendix 10. The duration of each diet history interview was approximately one hour, consistent with the suggested timeframe required for establishing an adequately detailed diet history [211].

The three day food records used to collected dietary intake data at three months is provided in Appendix 11. The 24 hour recalls conducted at six and 12 months were collected using a chronological approach, where subjects were asked to describe all foods and drinks consumed on the previous day from time of waking through the next 24 hours. Participants were asked for details of foods/drinks consumed, including portion sizes and specific food types as required throughout the recall process. All data was analysed by the research student using specialised dietary analysis software based on Australian food nutrient composition databases (Foodworks 2009 Professional, Version 6.0.2562, Xyris Software, Australia).

### 3.1.4.4 Follow-up data collection sessions

Follow-up data collection sections (three, six and 12 months) followed a similar format to the baseline sessions. Weight, waist circumference, dietary intake and BIA
measurements were collected at each study point; and DXA measurements were collected only at the major study time points, namely baseline, six and 12 months. Survey booklets (as per baseline) were mailed to participants to complete prior to attending follow-up measures and survey items were verified for completeness and clarity during follow-up interviews. The three-day food record was also sent with instructions prior to the three month follow-up sessions.

3.1.4.5 Additional clinical data collected

Data pertaining to pre-surgery weight history, number of dietetic follow-up visits with the usual care dietitian and band adjustments were collected during face-to-face follow-up interviews with study participants and recorded on a standardised data collection form (Appendix 10). Due to suboptimal participant recall of requested information, this information was also retrospectively collected from clinic records, for which an ethics variation was submitted and approved by the University of Newcastle’s HREC. The Information statement and consent form associated with this variation are provided in Appendix 12 and 13 respectively. This data was collected and recorded on an electronic spreadsheet by staff at each surgical practice and provided to the research student in order to maintain participant confidentiality.

3.2 Cross-sectional study

3.2.1 Overview

The cross-sectional study aimed to examine a broad range of diet-related factors following LAGB. The target population for the survey were individuals who had undergone LAGB at the same gastric banding practices involved in the dietary intervention study (Dr Jon Gani’s Rooms, Lake Macquarie Specialist Medical Services, Gateshead, NSW, Australia and Newcastle Obesity Surgery Centre, Lake Macquarie, NSW Australia) in 2008 or 2009, reflecting a post-surgery time-frame of approximately 1-2 years at the time of survey distribution (July 2010).
3.2.2 Ethics approval

Ethics approval was granted by the University of Newcastle’s Human Research ethics Committee as a variation of the pilot protein-enriched dietary intervention (HREC Approval Number: H-2008-0345). The variation application was submitted on 6/05/2010 and full approval was granted on 11/6/2011. A copy of the information statement for the study is provided in Appendix 14. Consent for participation in the study was assumed upon the return of completed surveys. Respondents were also asked if they would agree to consider participation in future follow-up surveys/research, and were provided with an optional consent form (Appendix 15) to complete and return with the survey package.

3.2.3 Survey items

The survey (Appendix 16) consisted of nine sections, covering the following broad areas: anthropometrics (current weight, height, weight prior to surgery, weight loss since surgery), demographics, current health conditions, quality of life/functional health and wellbeing, eating behaviour, food tolerance, physical activity, dietary practices and post-surgical follow-up. Dietary practices included intake of selected core foods (fruit, vegetables, dairy and meat/chicken/fish), use of meal replacements/food supplements and vitamin/mineral supplementation. Post-surgical follow-up included questions relating to number of band adjustments and frequency of dietetic and surgeon follow-up. There was also an open-ended section for respondents’ to provide any further comments/feedback if desired.

A combination of validated and/or standardised questionnaires, question items adapted from previous surveys and self-developed question items were used to assess these factors. Validated and standardised questionnaires included the SF-36v2® Health Survey (Quality Metric, USA) [221] for the assessment of quality of life and the TFEQ for the assessment of eating behaviour [141].

Standardised questionnaires included: the Physical Activity Questionnaire (IPAQ) (Short Last 7 Days Self-Administered Format) for the measurement of physical activity
The IPAQ has been validated for use in national and regional prevalence studies; however has less validity in small studies [229] and is subject to typical limitations in reliability and validity as all self-report methods for assessing physical activity [230]. Given that there are no well-validated surveys for the assessment of physical activity, the short version of the IPAQ was used for its feasibility to administer and for consistency with the protein-enriched dietary intervention. The food tolerance checklist has been partially validated [220] and represented one of the only standardised tools to assess food tolerance specifically in a bariatric surgery population at the time of survey development.

The sections of the survey pertaining to demographics and socioeconomic status (SES) were adapted from the Women’s Health Australia cohort study [231]; and the sections on anthropometrics, health, post-surgery follow-up and general dietary practices were self-developed. These non-standard/self-developed sections of the survey are provided in Appendix 16. The SF-36v2©, TFEQ, IPAQ and food tolerance checklist are included within Appendix 9 (survey booklet for the dietary intervention study).

### 3.2.3.1 Food frequency questionnaire

The Dietary Questionnaire for Epidemiological Studies Version 2 © (DQES) (Cancer Council Victoria) [232] (Appendix 17) was used to measure dietary intake as it has been previously validated [232] and is one of the most commonly used FFQs for the Australian population. Although the DQES has not been specifically validated for use in the obesity surgery population, it has been used to evaluate dietary intake in two previous Australian LAGB studies [109, 233]. The FFQ includes 74 foods items grouped into four categories: cereal foods, sweets and snacks; dairy products, meat and fish; fruit; and vegetables. There are 10 frequency response options (ranging from never to three or more times per day) and additional questions with photographs of scaled portions are included to calibrate portion sizes [232]. Nutrient analyses for the FFQs were performed by the Victorian Cancer Council according to a standardised and
calibrated protocol, with nutritional data derived from Australian nutrient composition of food databases [232].

3.2.3.2 Items included in final analysis

Given the wide ranges of factors assessed, not all of the items were included within the paper arising from this study (Chapter 6), which focuses on eating behaviour, food tolerance and dietary intake (including relationship with reported weight loss and overall quality of life) as key areas of interest for the thesis as a whole.

3.2.4 Survey distribution methods

Dissemination of the survey was facilitated by the two gastric banding practices involved in the study in order to protect patient confidentiality. Survey packs were provided to each of the practices, where a staff member searched practice databases to identify potential respondents based on type and date of surgery (2008 or 2009). The practice staff member then addressed the survey packs to individuals identified from the database search for mailing.

The survey pack contained: an information statement for the study; survey booklet; an optional consent form regarding completion of the DQES and potential participation in future research; and a self-addressed reply paid envelop for return of the survey/study documents. The DQES could not be included with the initial survey pack due to significant costs associated with its use ($14.95 per survey), with a distribution population of greater than 300 individuals. A hard copy of the DQES and reply paid envelope was mailed directly to survey respondents who indicated they would consider completing an FFQ upon return of the initial survey pack.

It was not possible to provide potential respondents with reminders or further incentive to complete the survey as there were insufficient financial resources available to pay the gastric banding practices to make further contact with subjects from their databases regarding the survey.
Chapter 4  Feasibility of a protein-enriched diet after laparoscopic adjustable gastric banding: results from a pilot intervention

This chapter has been published:


The work presented in the manuscript was completed in collaboration with the co-authors (Appendix 1). Permission to reproduce the text and figures from the manuscript has been granted by the publishers.

Supplementary results for dietary intake, anthropometric and body composition outcomes that are not included in the final version of the published paper are also provided in Appendix 18.

4.1 Abstract

**Background and aims:** Weight loss following laparoscopic adjustable gastric banding (LAGB) is variable. Increased protein intakes may promote optimal weight and body composition outcomes during weight loss. This study aimed to determine the feasibility of a protein-enriched diet after LAGB and to report pilot data findings.

**Methods:** LAGB patients (n=47) were allocated to follow a protein-enriched diet or usual care for six months after surgery. Weight, body composition and dietary intake were measured at baseline, three, six and 12 months.

**Results:** Compliance with the protein-enriched diet was problematic. No differences in protein intake, weight or body composition were observed between the intervention and usual care groups. Relative protein intake for the study sample as a whole was not a significant predictor of weight or body composition at any time point.
**Conclusions:** Feasibility of increasing protein intake from usual foods and a dietary supplement following LAGB was limited by compliance difficulties. This may negate any potential utility of a protein-enriched diet after LAGB. Further research is required to establish evidence-based guidelines for protein intake following LAGB and to determine methods to enhance compliance with dietary recommendations.

**Clinical trial registration number:** ACTRN 12609000258257.

### 4.2 Introduction

Obesity surgery is presently the most efficacious strategy available for the treatment of obesity [43]. Laparoscopic adjustable gastric banding (LAGB) is the most popular form of obesity surgery in Australia, Asia and Europe, and is increasing in popularity in the USA, accounting for approximately 40% of bariatric operations worldwide [28]. When compared with more invasive procedures such as Roux-en-Y gastric bypass (RYGB), LAGB is less likely to cause nutritional deficiencies and has the advantage of being completely reversible [16]. One of the primary reported failings of LAGB however is the potential for inadequate weight loss and weight regain following surgery [68]. This has gained increased recognition in recent years as a significant clinical issue associated with LAGB [234, 235]. Given that efficacious treatment options for obesity are presently limited, it is important to develop intervention strategies to better optimise weight loss for all individuals who undergo LAGB.

Despite the fundamental relationship between dietary intake and weight loss, no dietary interventions have been conducted in the LAGB population to determine if there is a dietary regimen that may promote optimal weight loss and changes in body composition in individuals who undergo LAGB. In recent years protein intake has received much attention in the non-surgical weight loss literature for promoting such outcomes, where there is evidence to suggest that higher protein intakes may promote greater weight loss, fat mass loss and preservation of fat free mass (FFM) [236].

Furthermore, optimal protein intake recommendations remain a key area of uncertainty following bariatric surgery [89]. At least 60g of protein per day is
commonly recommended as a target for post-surgery intake; however this is not evidence-based [89]. A meta-regression analysis of lifestyle interventions suggests that for optimisation of FFM retention during weight loss, protein intakes of at least one gram per kilogram of actual body weight are required [116]. The limited observational data on protein intake after LAGB suggests that post-operative intakes range from approximately 40-80 grams per day in the first 12 months after surgery [237], which is potentially below theoretical levels for optimisation of body composition outcomes.

It is presently unclear if a higher protein diet is a feasible dietary management option for individuals who have LAGB. Issues that may impede ability to consume a higher protein diet after surgery include substantially reduced food intake volumes, potential mechanical/textural difficulties with protein-rich foods and general difficulties/barriers in complying with post-operative dietary advice [89].

As there have not been any protein-based dietary intervention studies previously conducted in the LAGB population, this study aimed to assess the feasibility of implementing a protein-enriched diet for six months after LAGB in a real-world setting; and to determine if pilot data supports any favourable effects of a protein-enriched diet on weight loss and body composition after surgery.

4.3 Materials and Methods

4.3.1 Study design, subjects and settings

This study was a 12 month pilot pseudo-randomised control trial. Participants were alternately allocated to follow either a protein-enriched or usual care diet for six months after LAGB, with a further six month follow-up period. Participants were recruited from two private gastric banding practices (Newcastle, Australia) between March and November 2009.

The study included males and females aged between 18-65 years with a body mass index (BMI) greater than 30kg/m², who were undergoing or who had undergone LAGB no earlier than two weeks prior to study entry. Exclusion criteria were: existing
medical conditions requiring a diet incompatible with the dietary intervention, surgeon did not approve participation based on pre-operative health status, pacemaker or other electronic implant, food allergy or intolerance that may affect health or compliance with the study, pregnant/lactating women or those unable to understand or follow the study diet/ materials.

The study was approved by the University of Newcastle’s Human Research Ethics Committee, with all subjects providing written, informed consent prior to participation in the study. The study was also registered with the Australia New Zealand Clinical Trials Register (ACTRN 12609000258257).

4.3.1.1 Surgical procedure and routine follow-up care

Subjects underwent LAGB as performed by one of three experienced surgeons from two practices using the *pars flaccida* technique [238]. A variety of bands were used by surgeons in both practices involved in the study, including Allergan AP small (APS), Allergan AP large (APL), Heliogast evolution (HAGE), Heliogast advanced (HAGA) and Swedish VC bands. All subjects received regular post-operative care with the participating surgical practices as clinically required. This included follow-up and band adjustments with a general practitioner specialising in LAGB and/or surgeon, and regular dietary counselling with a dietitian specialising in bariatric treatments. Routine dietetic care included a very low energy diet (VLED) prescription for subjects prior to surgery, advice regarding progression from fluids to solids after surgery, and eating techniques and dietary advice as appropriate for LAGB (e.g. chewing foods well, eating slowly, avoiding fluids with meals, selecting nutrient-dense foods and balancing dietary intake across food groups). All subjects received routine follow-up (usual care) with the dietitian every 2-4 weeks in the early postoperative months and approximately every 1-2 months thereafter.

4.3.1.2 Intervention diet

The protein-enriched diet was designed to provide 4000-6000kJ (960-1400kcal) and 90-100g of protein per day, with an overall macronutrient distribution of ~35% protein, ~
40% carbohydrate and ~25% fat. To achieve this, a whole-food plus dietary supplement approach was used. Subjects were provided food exchange guidelines detailing daily serve targets for protein-rich foods (including meat, poultry, fish, eggs, dairy and legumes) as well as other core food groups (breads/cereals, fruit and vegetables). Subjects were also provided with 15g/day of 100% whey protein isolate (Top Nutrition, Newcastle, Australia). This was a neutral-flavoured powder which could be added to usual foods and drinks in order to enhance total protein intake. The research dietitian implemented all advice specific to the protein intervention and further reinforced these intervention guidelines via 4-6 weekly telephone calls and at the three month follow-up sessions for the study. The intervention group also continued to receive routine follow-up from the usual care dietitian; who advised subjects to follow the intervention guidelines as provided by the research dietitian in addition to the more general dietary advice provided during routine follow-up. The control arm was provided with usual dietetic care only, with no specific protein or food group intake recommendations provided as part of the study.

Compliance with the intervention was assessed via reported dietary intake and self-reported data obtained during follow-up interviews regarding the average quantity of protein powder consumed per day/week, as well as the quantity of protein powder remaining from distributed supplies.

4.3.1.3 Height, weight and body composition

Height was measured to the nearest 0.1cm using a stadiometer (Harpenden Portable, model SO 98.603). Body weight was measured to the nearest 0.1kg using an electronic scale (Tanita, Model BF-310) with participants wearing light clothing and no shoes. To supplement weight data collected at baseline (average time of baseline measurement was 11 days post-surgery), pre-operative weights and weight on the day of surgery were also collected from clinic records and self-report. Weight change results are expressed as percentage total weight loss (%TWL) from baseline. Percentage excess weight loss (%EWL) is also reported for comparability with other bariatric surgery studies. %EWL calculations were based on the 1983 Metropolitan Life Insurance
Company height and weight tables and the %EWL formula as reported by Deitel et al. [195]. BMI was calculated as weight (kg) divided by height in meters squared (kg/m²). Waist was measured to the nearest 0.1cm by the same assessor using a non-stretch tape (Seca 201 Circumference Measuring tape). Measurement site for each subject was recorded based on individual anatomical features to help maximise reproducibility of waist measurements.

Body composition was measured in all subjects using single frequency bioelectrical impedance analysis scales (BIA: Tanita, Model TBF-300A). Body composition was also measured using total body dual energy X-ray absorptiometry (DXA: Lunar Prodigy, software: enCORE version 9.30.044, GE Medical Systems, Madison, USA) for those subjects (n=39) who met weight specifications for the DXA scanning bed (<136.1kg). Standard manufacture procedures for quality assurance and quality control were performed prior to every DXA measurement session to ensure scan precision and reliability. Coefficients of variation (CV) for DXA body composition measurements were: bone mineral density 0.08%, lean tissue 1.7% and fat tissue 0.06%. All scans were measured and analysed by the same technician using standard manufacturer guidelines. As DXA results were generally reflective of those obtained via BIA, primary body composition results are reported for BIA to reflect the whole study sample. DXA findings are also reported where clinically significant differences in results were evident.

4.3.1.4 Dietary intake

Dietary intake was assessed at baseline using diet histories to reflect pre-operative, pre-VLED intake. Three day food records (based on common/household measures) were used to assess dietary intake at three months. Due to poor compliance with return of three day food records, dietary intake was assessed at six and 12 months using 24-hour recalls, conducted on the day of follow-up assessments to capture the previous day’s intake. All dietary intake data was collected by the same research dietitian using standard dietetic procedures. All data was analysed by this dietitian using specialised dietary analysis software (Foodworks 2009 Professional, Version 6.0.2562, Xyris
Protein intake was defined and assessed according to absolute intake (grams per day), intake relative to body weight (grams per kilogram of body/day) and as a percentage of daily energy intake.

The validity of baseline (pre-surgery, pre-VLED) dietary intake data was assessed using Goldberg cut-offs for energy intake as described by Black [239]. Goldberg cut-offs were applied in order to determine the overall likelihood of under-reporting bias in the study sample as a whole, as well to determine the distribution of likely under-reporters at the individual level. Because Goldberg cut-off methodology assumes weight stability [239], these cut-offs could not be applied for dietary data collected at three, six and 12 months given that the majority of subjects were not weight stable at these time points.

4.3.1.5 Statistical analysis

Statistical analyses were performed using PASW Statistics 18.0 software. Repeated measures linear mixed models (LMMs) were used to assess differences in weight and body composition outcomes between groups and within individuals over time. Gender and band type were included as fixed factors in all models. Other potential covariates including age, baseline BMI, number of band adjustments and routine dietetic follow-up appointments were not included in the LMMs as preliminary data analyses revealed no correlation between these factors and primary outcomes of interest. Given the small sample population and uneven distribution of subjects from the gastric banding practices involved in the study (n=41 and n=6 from the two practices respectively), no attempt was made to control for banding practice in analyses. An unstructured covariance matrix provided the best fit for the data and was used for all LMM analyses.

To further explore the relationship between protein intake and outcomes of interest, univariate analysis of co-variance (ANCOVA) controlling for baseline measurement, gender and band type was also conducted using a regression approach (forced-entry method). Separate ANCOVA analyses were conducted for absolute protein intake,
protein intake relative to body weight and protein intake as a percentage of daily energy intake.

Not all variables were normally distributed; however non-parametric data were not transformed in order to maximise interpretability of results. LMMs and ANCOVA are relatively robust in handling minor departures from normality [240] as seen in the variables of interest; and reasonable normality of residuals were verified in order to ensure key test parameters were not violated. Regression analyses were also checked for outliers, linearity, homoscedasticity and independence of residuals. Descriptive data for parametric variables are reported as mean ± standard deviation (SD) and median (interquartile range) for non-parametric variables unless otherwise specified.

### 4.4 Results

Forty-seven subjects (38 females, 9 males) provided informed consent to participate and completed baseline measurements for the study. The average age of subjects was 44.5±10.5 years, with a baseline BMI of 42.1±7.6kg/m$^2$. There were no differences in baseline characteristics between groups (Table 4.1). Males were significantly heavier and taller than females, with a greater waist circumference, higher levels of FFM and a significantly lower percentage body fat. Subjects with an APL band had a significantly greater waist circumference and FFM when compared with subjects with any other band type.

Participant retention was 96% (n=45) at three months, 87% (n=41) at six months and 70% (n=33) at 12 months (Figure 4.1). Baseline characteristics of completers and non-completers at 12 months were similar. Weight information was available for ten of the subjects who did not attend 12 month follow-up measures (obtained via self-report or clinic data). There were no differences in total weight loss at 12 months for these subjects when compared with study completers.
Table 4.1 Baseline characteristics according to diet allocation a, b

<table>
<thead>
<tr>
<th></th>
<th>Usual care</th>
<th>Protein-enriched</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (female/male)</td>
<td>23 (18/5)</td>
<td>24 (20/4)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>44.0 ± 10.0</td>
<td>44.9 ± 11.3</td>
</tr>
<tr>
<td>Band type:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APL</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>APS</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>HAGE</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>HAGA</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>SVC</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>167.9 ± 7.1</td>
<td>167.2 ± 9.1</td>
</tr>
<tr>
<td>Weight: Pre-VLED (kg) (n=43)</td>
<td>115.6 (108.8-135.0)</td>
<td>129.7 (112.6-139.5)</td>
</tr>
<tr>
<td>Weight: Day of surgery (kg) (n=45)</td>
<td>113.0 (104.5-131.5)</td>
<td>120.0 (106.0-130.5)</td>
</tr>
<tr>
<td>Weight: Baseline (kg)</td>
<td>110.5 (102.0-126.6)</td>
<td>118.5 (105.4-131.3)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>40.3 (36.9-44.4)</td>
<td>42.8 (36.7-46.7)</td>
</tr>
<tr>
<td>Waist (cm) (n=44)</td>
<td>119.2 ± 14.3</td>
<td>118.3 ± 12.9</td>
</tr>
<tr>
<td>Body fat (%) c</td>
<td>48.1 ± 6.3</td>
<td>49.1 ± 6.0</td>
</tr>
<tr>
<td>Fat mass (kg) c</td>
<td>50.4 (45.9-61.0)</td>
<td>55.7 (45.5-69.3)</td>
</tr>
<tr>
<td>Fat free mass (kg) c</td>
<td>56.6 (51.7-62.7)</td>
<td>56.9 (52.1-63.5)</td>
</tr>
</tbody>
</table>

a Normally distributed continuous variables presented as mean ± standard deviation, nonparametric continuous variables presented as median (interquartile range). Categorical variables presented as counts. n for each variable is 47 unless otherwise specified. b There were no significant differences between groups for any variable. c Measured by bioelectrical impedance analysis APL=AP large, APS=AP small, HAGE=Heliogast Evolution, HAGA=Heliogast Advanced, SVC=Swedish VC

Subjects had an average of 4±2 band adjustments over the 12 month study period, with five (2-9) routine dietetic follow-up appointments in the first six months after surgery and a further two (0-6) visits between six and 12 months. There were no differences in number of band adjustments or dietetic visits between the protein-enriched and usual care groups; and no relationship was found between number of adjustments or dietetic visits and weight outcome at any study time point. There were also no differences in outcomes of interest according to banding practice at any time point.
All subjects reported significantly reduced energy intakes after surgery, corresponding with significantly lower intakes of all macronutrients (Table 4.2). Compliance with the dietary intervention was poor; with no differences found in reported protein intake according to diet allocation at any study time point, regardless of how protein intake was defined (Appendix 18). Only 23% (n=5) and 30% (n=6) of subjects reported full compliance with the protein supplement at three and six months respectively, 55% (n=12) and 45% (n=9) reported partial compliance and approximately 25-30% of subjects reported zero or minimal compliance at either time point. Validity assessment of dietary intake suggested a moderate degree of likely under-reporting in the study sample as a whole, with 28% (n=13) of subjects identified as low-energy reporters at baseline. There were no differences in the distribution of under-reporters between the protein-enriched and usual care groups.
Table 4.2 Reported dietary intake at baseline, three, six and 12 months

<table>
<thead>
<tr>
<th></th>
<th>Baseline (n=47)</th>
<th>3 months (n=37)</th>
<th>6 months (n=38)</th>
<th>12 months (n=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (MJ/d)</td>
<td>11.4 (10.2-12.5)</td>
<td>5.7 (5.2-6.1)a</td>
<td>5.8 (5.2-6.3)a</td>
<td>6.3 (5.5-7.1)a,b</td>
</tr>
<tr>
<td>Protein (g/d)</td>
<td>123 (110-135)</td>
<td>73 (66-79)a</td>
<td>74 (64-84)b</td>
<td>67 (57-77)a</td>
</tr>
<tr>
<td>Carbohydrate (g/d)</td>
<td>294 (265-323)</td>
<td>145 (132-159)a</td>
<td>145 (130-160)b</td>
<td>160 (142-177)a</td>
</tr>
<tr>
<td>Fat (g/d)</td>
<td>106 (92-119)</td>
<td>45 (39-51)a</td>
<td>47 (40-54)b</td>
<td>57 (44-70)a,b</td>
</tr>
<tr>
<td>Protein (g/kg/body weight)</td>
<td>1.0 (0.9-1.1)</td>
<td>0.7 (0.6-0.7)a</td>
<td>0.7 (0.6-0.8)b</td>
<td>0.6 (0.5-0.7)a</td>
</tr>
<tr>
<td>% energy from protein</td>
<td>19 (18-20)</td>
<td>23 (21-24)a</td>
<td>22 (20-24)b</td>
<td>18 (17-20)c</td>
</tr>
<tr>
<td>% energy from carbohydrate</td>
<td>43 (40-45)</td>
<td>43 (40-45)</td>
<td>43 (40-45)</td>
<td>44 (40-48)</td>
</tr>
<tr>
<td>% energy from fat</td>
<td>33 (32-36)</td>
<td>29 (26-31)a</td>
<td>29 (27-33)b</td>
<td>31 (27-35)</td>
</tr>
</tbody>
</table>

Results are based on linear mixed models analysis and are reported as estimated marginal mean (95% confidence interval). There were no significant differences between the usual care and protein-enriched groups for any dietary variable at any time point. a P <0.05 vs. baseline; b P <0.05 vs. 3 months; c P <0.05 vs. 6 months

4.4.1.1 Weight and body composition outcomes

Average total weight loss for all subjects from baseline was 7.1±5.6% after the six month intervention period and 9.6±7.6% after 12 months, equivalent to 16±13.2% EWL and 22±17.7% EWL respectively. With the inclusion of weight loss prior to baseline, total weight loss was significantly higher (Figure 4.2).

Results presented as mean ± SEM. Median length of VLED was 14 (11-14) days. Average length of time between surgery and baseline was 11±5 days. Differences between weight loss from baseline, surgery and pre-surgery VLED at each time point were assessed using repeated-measures ANOVA. a P <0.001 vs. from pre-surgery VLED; b P <0.001 vs. from surgery.

Weight loss was statistically significant for the study sample as a whole, with no difference between the protein-enriched and usual care groups (Figure 4.3a). BMI, waist circumference, percentage body fat and fat mass also decreased significantly over the 12 month study period; with no differences between the usual care and protein-
enriched groups (Appendix 18). Minimal changes were observed in FFM, with 12 month FFM not significantly different from baseline and no differences in FFM outcomes based on diet allocation (Figure 4.3b). There was a significant time by band type interaction for FFM as measured by BIA (F=4.2, p=0.013), where subjects with APL bands gained more FFM in the first three months and generally maintained this gain until 12 months. This result, however, was not replicated in the sub-group measured by DXA (F=1.33, p=0.281).

**Figure 4.3** Changes in weight (A) and fat free mass (measured by BIA) (B) over the 12 month study period from study baseline according to diet allocation.

Usual care (■); protein-enriched (■). Results presented as estimated marginal mean ± SEM. Sample sizes for each time point: 0 (n=47), 3 (n=45), 6 (n=41) and 12 (n=33). Between-subjects effects for time × diet allocation: A. *P*<0.05 vs. baseline; B. *P*<0.05 vs. three months.

Given that compliance with the dietary intervention was poor, ANCOVA based on reported dietary intake rather than diet allocation was also conducted to determine if there were any relationships between protein intake and weight and body composition outcomes for the study sample as a whole.

After controlling for baseline measurements, gender and band type, absolute protein intake was not a significant independent predictor of any weight or body composition outcomes at three months. At six months, higher absolute protein intake was found to be a small but significant predictor of a higher weight, BMI, waist circumference and FFM as measured by BIA (Table 4.3).
Table 4.3 Absolute protein intake as a predictor of weight, BMI, waist circumference and fat free mass at six months post-surgery

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Adjusted R² for model</th>
<th>Significant predictor variables ¹</th>
<th>Standardised coefficient (β)</th>
<th>P value for β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>0.918 (P &lt;0.001)</td>
<td>Baseline weight 0.874</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein intake (g/day) 0.198</td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male gender -0.173</td>
<td>0.015</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>APL band ¹b 0.153</td>
<td>0.013</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>0.928 (P &lt;0.001)</td>
<td>Baseline BMI 0.897</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein intake (g/day) 0.164</td>
<td>0.012</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male gender -0.161</td>
<td>0.015</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>APL band ¹b 0.142</td>
<td>0.013</td>
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</tr>
<tr>
<td>Waist (cm)</td>
<td>0.882 (P &lt;0.001)</td>
<td>Baseline waist 0.864</td>
<td>&lt;0.001</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>APL band ¹b 0.224</td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male gender -0.221</td>
<td>0.028</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein intake (g/day) 0.168</td>
<td>0.049</td>
<td></td>
</tr>
<tr>
<td>FFM (kg)</td>
<td>0.933 (P &lt;0.001)</td>
<td>Baseline FFM 0.729</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>APL band ¹b 0.192</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein intake (g/day) 0.177</td>
<td>0.006</td>
<td></td>
</tr>
</tbody>
</table>

¹ Variables are presented in order of largest to smallest contributor to model
² Comparison category: all other band types (including AP Small, Heliogast Evolution, Heliogast Advanced and Swedish VC bands)

At 12 months, a higher absolute protein intake was a small independent predictor of a greater percentage body fat in the sub-group measured by DXA (β=0.205, p=0.028). Along with baseline percentage body fat (β=0.783, p<0.001) and gender (β=-0.296, p=0.016), this model predicted 88.3% of the variance in percentage body fat at 12 months (p<0.001). Absolute protein intake was not a significant predictor of any other weight or body composition variable at six or 12 months.

Protein intake relative to body weight was not a significant predictor of body weight, BMI, waist circumference, percentage body fat or fat mass at any study time point. A higher relative protein intake at 12 months was found to be a significant predictor of a lower FFM as measured by DXA at 12 months (β=-0.160, p=0.047) [adjusted R²=0.902, P <0.001; other significant variables in the model were: baseline FFM (β=0.713, P <0.001) and male gender (β=0.310, P=0.021)]. The significance of this relationship was not replicated with BIA, although the direction of the relationship was the same (β=-0.057, P=0.322). Protein intake as a percentage of daily energy was not a significant predictor of any outcome of interest at any time point.
4.5 Discussion

To our knowledge, this is the first interventional study to evaluate the feasibility of a protein-enriched diet in an LAGB population and to report pilot findings regarding the influence of protein intake on weight loss and body composition outcomes after surgery. Despite the pilot nature of this study, it was conducted in a real-world, practical setting. In this context, the principal finding of the study is that any potential utility of a higher-protein intake after surgery is likely to be negated by compliance issues, particularly over the longer term. This is a recurring theme from lifestyle interventions that have assessed high protein diets for weight loss in overweight and obese populations [242]. Furthermore, overall compliance with post-operative dietary regimens is commonly noted as problematic in bariatric surgery populations [243]. It is possible that the broad range of dietary issues requiring attention after LAGB may over-shadow the ability of individuals to focus on any specific dietary regimens, including the protein-enriched intervention of the present study.

Despite poor compliance with the protein-enriched intervention, results based on intakes of the study sample as a whole suggest that sub-optimal protein intake is not problematic for LAGB patients who receive regular follow-up care. Absolute protein intakes in the present study were higher than several previous studies [237] and were generally above the recommended minimum of 60g/day [89]. Relative protein intake also generally met the Australian estimated average requirement (0.6-0.7g/kg)[244] over the study period. Although relative protein intakes remained below theoretical targets for preservation of FFM [116], loss of FFM was not significant in the present study.

This is inconsistent with some previous reports, which have suggested significant FFM losses after LAGB [15, 51]. This may be attributable to disparities in weight loss between the present and previous studies, given that FFM loss is associated with extent of total weight loss and the rapidity at which weight loss occurs [78]. The surgical practices that participated in the present study place an emphasis on healthy, balanced eating for gradual weight loss. Bands are adjusted in stages accordingly; thus it is
possible that different band adjustment protocols and dietary education approaches may help to explain differences in weight and FFM loss between the present study and previous literature. For other LAGB centres that promote a similar graduated approach to band adjustments and weight loss, it is reasonable to expect that FFM loss will be similarly non-problematic.

Although relative protein intake was not found to be associated with favourable weight loss and changes in body composition, absolute protein intake was actually found to be a small but significant predictor of less favourable weight, BMI and waist circumference outcomes at six months post-surgery. This may have been attributable to a mediating effect of energy intake. Although the influence of energy intake was not assessed in the current report, preliminary data analysis did reveal a significant, moderate-strong positive correlations between protein intake and total energy intake at every study time point. It is possible that higher absolute protein intakes simply reflected higher overall energy intakes, which can be intuitively linked with a higher body weight and/or less weight change after surgery. Similarly, a mediating role of energy intake may also help to account for the significant relationship between higher absolute protein intake and higher percentage body fat as measured by DXA at 12 months.

Overall weight loss in the present study was smaller than previous reports of weight loss at 12 months following LAGB [245]. Although this may reflect the possibility that the sample population represented a patient group that was poorly compliant with postoperative instructions overall, this result supports growing evidence that weight loss outcomes are highly variable following LAGB and that not all individuals achieve sustained weight loss after surgery [71]. Despite the lower weight loss achieved in this study, it is notable however that weight loss outcomes at 12 months remained favourable when compared with lifestyle-based weight loss interventions [246].

It is also noteworthy that in the present study, weight loss at three, six and 12 months post-surgery was statistically and clinically more significant with the inclusion of pre-surgery VLED and immediate post-operative weight losses when compared with study
baseline. This suggests that pre-operative weight loss can make a significant
correction to overall weight loss following laparoscopic obesity surgery; supporting
the value of pre-surgery VLED protocols beyond that of reducing liver volume for
improved operability [87]. Few other LAGB studies have reported the contribution of
pre-surgery weight loss to overall outcomes. This would be an interesting outcome to
assess in future studies.

Results for the present study need to be interpreted with caution given the pilot nature
of the data presented and other limitations of the study. The small sample size limited
statistical power to detect significant differences in outcomes of interest, with post-hoc
power calculations indicating that the study had 34% power to detect a 1.5kg
difference in change in fat free mass between the intervention and control groups. Data
from this study suggest that in order to detect a 1.5kg difference in change in fat free
mass with 80% power at a type I error probability rate of 0.05, 68 subjects per group
would be required.

The small sample size of the present study also weakens generalizability of findings,
which may be further compounded by attrition at 12 months. Nonetheless, baseline
characteristics of subjects were generally similar to those reported in the wider LAGB
literature [43] and available weight data did not indicate a difference in weight loss at
12 months when study non-completers were compared with completers. Furthermore,
retention for the primary six month intervention period was good, exceeding
benchmarks for controlled intervention trials [247]. Attrition is a widespread problem
in weight loss dietary interventions and in this context, 12 month attrition rate was
within usual limits [248].

It is possible that poor compliance with the intervention was influenced by factors
associated with the intervention protocol. Although the intervention group received 4-
6 weekly guidance regarding the protein-enriched diet, participants may have required
more regular, intensive support specifically regarding protein intake in order to better
comply with the intervention diet. An intervention with more intensive guidance
regarding protein intake may not however translate well to practice given the range of
diet-related issues that require attention following LAGB within the confines of usual clinical consultations. Another composition of the protein-enriched diet may have also achieved better adherence with the intervention. For example, although the neutral-flavoured protein powder was intended to be practical in that it could be added to usual foods and drinks without imparting additional flavours, we found that compliance was poor. The most commonly documented reasons for non-compliance were forgetting to use the supplement and dislike of taste and/or texture of the powder when added to foods/fluids. Thus it cannot be discounted that a liquid or flavoured protein supplement may have achieved better compliance.

Sub-optimal reliability and validity of the dietary intake data may have also contributed to the lack of differences between the intervention and usual care groups and inconsistencies within results, including the counter-intuitive finding for higher relative protein intake and lower FFM at 12 months. It is also possible that non-dietary factors which were not accounted for in the current analysis, such as physical activity, may have impacted on results.

Finally, the study only captured the first 12 months after surgery and as such the longer-term impact of protein intake on outcomes remains unclear. Ultimately, these longer-term outcomes are of greatest importance. Further research that includes dietary assessment over an extended follow-up period is required to provide greater insight into the impact of dietary factors on weight, body composition and health outcomes in the longer-term after LAGB. Further research is also required for other types of obesity surgery, including RYGB, in order to better inform protein intake recommendations and other dietary management guidelines for these patient groups.

In conclusion, difficulties in achieving compliance with an enhanced protein intake after LAGB were highly evident from this study. Thus the feasibility of implementing a sustainable protein-enriched diet in individuals who have LAGB appears to be limited. Compliance issues are likely to remain a key consideration for clinical practice in this area, and may negate any potential utility of higher protein intakes or other dietary interventions after LAGB in the real-world setting. Methods to enhance compliance,
whilst remaining translatable to practice, must be developed in order to define optimal
dietary regimes following LAGB in future larger-scale studies. Further research into
dietary factors and intervention strategies beyond macronutrient composition of the
post-surgery diet may also be valuable in developing evidence-based guidelines for
optimisation of outcomes for individuals who have LAGB.
Chapter 5  Eating behaviour after laparoscopic adjustable gastric banding: relationship with weight loss, quality of life and dietary outcomes

This chapter has been submitted to Appetite to be considered for publication.

5.1 Abstract

This study examines the relationship between eating behaviours (restraint, disinhibition and hunger) and weight loss, quality of life, dietary intake and food tolerance in the first 12 months after LAGB. Forty-seven subjects (38 females, 9 males) were recruited for the study (mean baseline BMI: 42.1±7.6 kg/m$^2$, mean age: 44.5±10.5 years). The three factor eating questionnaire was used to assess eating behaviours at baseline, 3, 6 and 12 months after LAGB. Repeated measures linear mixed models were used to analyse the relationship between eating behaviours and outcomes of interest. Higher post-operative disinhibition scores were modestly associated with less weight loss (0.3%, $P=0.004$) and lower mental wellbeing after surgery (1.2 lower mental component summary score, $P=0.007$). Higher post-operative hunger scores were modestly associated with higher daily energy (165kJ, $P=0.012$) and fat (2g, $P=0.014$) intakes after surgery. Dietary restraint was not significantly associated with weight loss, quality of life, dietary intake or food tolerance outcomes. Results support that individuals with greater susceptibility to uncontrolled and emotional eating after surgery remain vulnerable to poorer outcomes following LAGB. There is a need to identify sensitive tools to detect problematic eating behaviours after LAGB, and to develop tailored interventions for minimising non-hungry eating after surgery.

5.2 Introduction

This paper explores the relationship between eating behaviour and weight loss, quality of life, dietary intake and food tolerance after laparoscopic adjustable gastric banding (LAGB). Surgery is presently the most effective treatment strategy for obesity [43, 249], with LAGB representing the second most popular surgical option worldwide [28].
Although LAGB has greater weight loss efficacy than lifestyle interventions and is considered the lowest risk and only reversible surgical weight loss procedure [43, 249], there is growing evidence that weight loss outcomes following LAGB are variable, where many individuals fail to lose weight or experience significant weight regain in the medium to long term after surgery [234, 235, 250]. Problematic eating behaviour and dietary compliance are commonly implicated in unsuccessful weight loss following LAGB [83, 251], yet it remains unclear the extent to which different eating behaviours may influence weight loss outcomes.

Several previous studies have examined eating behaviour and weight loss after LAGB, with some indicating that emotional-type eating behaviours, including uncontrolled eating, grazing, disinhibition and perceived hunger may be related to poorer weight loss [105, 109, 139], yet other studies have not found a definitive link between specific behaviours and weight outcomes [134, 138]. Given these inconsistencies, scope remains to further elucidate the relationship between eating behaviour and weight loss after LAGB. This is important in order to better inform potential eating behaviour targets for interventions aimed at optimising weight loss after LAGB.

Beyond weight loss, few previous studies have investigated the influence of eating behaviours on other outcomes of LAGB, including quality of life, dietary intake and food tolerance, despite the theoretic potential for eating behaviour to influence these outcomes in a clinically significant way. Only one previous study has examined the relationship between eating behaviour and quality of life after LAGB[82, 109], finding lower mental wellbeing in ‘uncontrolled eaters’ when compared with individuals who were not classified as uncontrolled eaters [109]. Colles et al. also noted inverse associations between physical wellbeing and disinhibition and hunger after surgery [82].

The research of Colles et al. also represents one of the only studies to explore the relationship between eating behaviours and dietary intake, where uncontrolled eaters were found to report higher postoperative energy intakes and fat intake as a percentage of daily energy when compared with non-uncontrolled eaters [109]. Colles
et al. also identified weak inverse association between dietary restraint and energy intake, and weak inverse associations between disinhibition and hunger and energy intake [82], with no further assessment of other dietary variables reported [82].

Although food tolerance, defined broadly as ability to eat foods without negative symptoms related to surgery (including vomiting or regurgitation) [191], is commonly reported as problematic after LAGB [191, 220], only two previous studies have assessed whether postoperative eating behaviours have a mediating role in food tolerance after surgery [60, 109]. Colles et al. and Busetto et al. both assessed food tolerance in terms of vomiting/regurgitation symptoms, with both studies suggesting a positive link between uncontrolled eating (including binge-eating and grazing) and higher postoperative vomiting frequency [60, 109]. Although these studies are valuable in providing evidence that maladaptive-type eating behaviours may contribute to increased vomiting after LAGB, they did not assess the potential for eating behaviour to mediate other aspects of food tolerance, including satisfaction with eating ability and ability to eat different types of foods after surgery.

Overall, the uncertainty regarding which behaviours may be most influential on weight loss, dietary intake and food tolerance outcomes after LAGB represents a key gap in the existing evidence base for the best practice dietary management of LAGB patients [217]. Early detection of problematic eating behaviours may help to identify ‘at risk’ individuals who may benefit from more intensive intervention to promote best possible outcomes for these individuals. Therefore, this study aims to examine the relationship between eating behaviours (restraint, disinhibition and hunger) and weight loss, quality of life, dietary intake and food tolerance in the first 12 months after LAGB. This will contribute to the relatively limited evidence base in this area and offer additional insight for the development of intervention strategies for optimising diet-related outcomes of LAGB.
5.3 Materials and methods

5.3.1 Participants, procedures and measures

Data for this study was collected as part of a 12 month pseudo-randomised control trial examining the feasibility of a protein-enriched diet after LAGB, with detailed methods for the study described elsewhere [252]. In brief, participants were males and females who had undergone LAGB (n=47). Participants were allocated to follow a protein-enriched diet or usual dietetic care for the first six months after surgery, and were followed-up for a further six months. There were no differences in baseline characteristics, weight loss or dietary intake outcomes between the intervention and control groups, reflecting problematic compliance with the dietary intervention undertaken [252]. As such, data has been pooled for the purpose of the current analysis. Time points for the study were: baseline (1-2 weeks following surgery) and three, six and 12 months post-surgery.

Eating behaviour was assessed using the three factor eating questionnaire (TFEQ) [141]. The TFEQ is a standardised, validated 51-item questionnaire assessing three dimensions of eating behaviour: dietary restraint, reflecting the intention to consciously restrict food intake for weight loss (score range: 0-21); disinhibition, reflecting susceptibility to overeating in response to emotional and situational triggers (score range: 0-16); and hunger, reflecting subjective sensations of hunger (score range: 0-14) [141]. Higher scores for each dimension reflect a greater tendency to exhibit the given characteristic. The TFEQ was provided as a self-administered survey at baseline (reflecting pre-operative eating behaviour) and three, six and 12 months post-surgery. Responses were verified during follow-up interviews at each time point.

Body weight was measured to the nearest 0.1kg using an electronic scale (Tanita, Model BF-310) with participants wearing light clothing and no shoes. The primary method for expressing weight loss was percentage weight loss from initial body weight, calculated as: (Follow-up weight – baseline weight)/baseline weight ×100. Quality of life was assessed using the Short-Form 36v2© (SF-36v2) (Quality Metric,
USA), with physical component summary (PCS) and mental component summary (MCS) scores used as markers of overall physical and mental wellbeing [221]. PCS and MCS scores were calculated using Quality Metric scoring guidelines [221] and Australian norm data [225].

Diet histories were taken at baseline as a measure of usual pre-operative dietary intake. Dietary intake was assessed at three months using three-day food records based on household measures. Due to the suboptimal return of three day food records in the initial stages of six month data collection which threatened continuation of the study, dietary intake at six and 12 months was primarily assessed using 24 hour recalls, conducted on the day of follow-up assessments to capture the previous day’s intake. Although 10 subjects provided three day food records at six months, there were no statistically significant differences in reported energy intake at six months according to dietary assessment methodology used. All dietary data was collected by the same qualified dietitian and was analysed using Foodworks 2009 Professional® (Version 6.0.2562, Xyris Software, Australia). Dietary intake variables included in the present analysis are: estimated energy intake, total carbohydrate intake, sugar intake, protein intake and total fat intake.

Food tolerance was assessed using the food tolerance checklist, described in detail elsewhere [220]. In brief, the checklist assesses: self-rated satisfaction with eating ability, ability to eat certain core foods (including red meat, white meat, fish, bread, rice, pasta and vegetables) and frequency of vomiting/regurgitation after obesity surgery [220]. A quantitative overall food tolerance score can be derived from the tool (score range: 1-27), with higher scores reflecting better food tolerance [220]. In addition to the overall food tolerance score, the following subsets of food tolerance were also evaluated: satisfaction with eating ability (score range: 1=very poor to 5=excellent); ability to eat certain foods (score range: 0-16, with higher scores reflecting less difficulty); and frequency of vomiting/regurgitation (score range: 0=daily to 6=never).

The study was approved by the University of Newcastle’s Human Research Committee and all subjects provided informed, written consent to participate.
5.3.2 Data analysis

All data were analysed using IBM© SPSS© Statistics 20. Repeated measures linear mixed models (LMMs) were used to assess the relationship between post-operative eating behaviours and percentage weight loss, PCS score, MCS score, post-operative dietary intake (energy, protein, total fat, saturated fat, total carbohydrate and sugar) and food tolerance in the first 12 months after surgery. Pre-operative eating behaviour scores were included as covariates in all analyses to assess the potential influence of pre-operative behaviours on outcomes of interest. Age and baseline BMI were included as potential control variables in preliminary modelling, but were not included in final models due to low significance ($P > 0.6$ for each) unless otherwise specified in results. Percentage weight loss and pre-operative PCS and MCS scores were included as covariates in quality of life analyses to account for the potential influence of these variables on post-operative measures. Gender and diet allocation were also included as fixed factors in all analyses, for which no statistically significant relationships were identified.

An unstructured covariance matrix was used for the analyses of percentage weight loss, physical wellbeing and dietary intake variables, and a first-order autoregressive covariance matrix was used for analyses of mental wellbeing and food tolerance variables, in accordance with best-fit for the data in each model. Residuals were assessed for normality and non-random patterns via visual inspection of residual histograms and scatterplots to verify validity of analyses [253]. Statistical significance was set as $P < 0.05$ for all analyses.

5.4 Results

Forty-seven subjects were recruited to participate in the study (38 females, 9 males; mean age: 44.5±10.5 years; baseline weight: 117.7±20.5 kg; baseline BMI: 42.1±7.6 kg/m²) and one participant dropped out at baseline. Thus eating behaviour data was available for 46 subjects at baseline, (98%), 38 subjects (81%) at three months, 40 subjects (85%) at six months and 34 subjects (72%) at 12 months. Estimated marginal mean weight loss
as a percentage of initial body weight (95% confidence interval) was: 3.2% (0.9-5.6) at three months, 6.4% (4.0-8.8) at six months and 8.1% (5.7-10.5) at 12 months ($P < 0.001$).

After surgery, restraint increased significantly and disinhibition and hunger decreased significantly when compared with preoperative levels, yet there were no significant changes in eating behaviours between three and 12 months post-surgery (Figure 5.1, Table 5.1). Longitudinal changes in quality of life, dietary intake and food tolerance variables are also provided in Table 5.1.

![Figure 5.1 Changes in eating behaviour dimensions over time](image)

Results presented as estimated marginal mean and 95% CI from linear mixed model analysis. **A**: restraint; **B**: disinhibition; **C**: hunger. **P <0.001** vs. baseline. Sample sizes for each time point: 0 (n=46), 3 (n=38), 6 (n=40) and 12 (n=34).

Postoperative disinhibition scores were significantly associated with weight loss over the 12 month study period, with every one point increase in disinhibition corresponding with 0.3% less weight loss, $F(1,55)=8.9$, $P=0.004$. Postoperative restraint and hunger were not significantly related to percentage weight loss.

No postoperative eating behaviours were associated with physical wellbeing after surgery; however lower baseline BMI, $F(1,34)=5.7$, $P=0.03$, and greater postoperative weight loss, $F(1,53)=5.0$, $P=0.03$, were both related to higher PCS scores. Postoperative disinhibition was significantly associated with mental wellbeing, with every one point increase in disinhibition corresponding with a 1.2 point decrease in MCS score, $F(1,91)=7.6$, $P=0.007$. In the same model, higher pre-operative MCS score was significantly associated with a higher post-operative score, $F(1,37)=7.6$, $P=0.009$. 

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Table 5.1 Eating behaviours, quality of life, dietary intake and food tolerance in the first 12 months after surgery

<table>
<thead>
<tr>
<th>Eating behaviour</th>
<th>Baseline (n=46)</th>
<th>3 months (n=38)</th>
<th>6 months (n=40)</th>
<th>12 months (n=34)</th>
<th>p for time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restraint (0-21 pts)</td>
<td>7.4 (6.1-8.7)</td>
<td>12.5 (11.2-13.8)*</td>
<td>12.5 (11.1-13.8)*</td>
<td>12.1 (10.7-13.5)*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Disinhibition (0-16 pts)</td>
<td>12.0 (11.0-13.0)</td>
<td>6.5 (5.4-7.6)*</td>
<td>6.4 (5.3-7.5)*</td>
<td>6.1 (4.9-7.3)*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Hunger (0-14 pts)</td>
<td>8.7 (7.7-9.7)</td>
<td>3.6 (2.6-4.7)*</td>
<td>3.4 (2.4-4.5)*</td>
<td>3.2 (2.1-4.4)*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical component summary score</td>
<td>40.4</td>
<td>46.9*</td>
<td>51.0†</td>
<td>49.9*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mental component summary score</td>
<td>38.2</td>
<td>48.7*</td>
<td>45.3†</td>
<td>45.8*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Dietary intake</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy (MJ/day)</td>
<td>11.4 (10.3-12.5)</td>
<td>5.7 (5.2-6.1)</td>
<td>5.8 (5.2-6.3)</td>
<td>6.3 (5.5-7.1)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Protein (g/day)</td>
<td>123 (110-135)</td>
<td>73 (66-79)*</td>
<td>74 (64-84)*</td>
<td>67 (57-77)*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Fat (g/day)</td>
<td>106 (92-119)</td>
<td>45 (39-51)*</td>
<td>47 (40-54)*</td>
<td>56 (43-69)*†</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Saturated fat (g/day)</td>
<td>44 (37-50)</td>
<td>17 (15-20)*</td>
<td>19 (16-22)*</td>
<td>23 (18-28)*†</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Carbohydrate (g/day)</td>
<td>294 (265-323)</td>
<td>146 (133-159)*</td>
<td>145 (130-160)*</td>
<td>161 (143-178)*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Sugar (g/day)</td>
<td>139 (119-159)</td>
<td>73 (65-82)*</td>
<td>74 (64-83)*</td>
<td>79 (66-91)*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Food tolerance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall food tolerance score (0-27 pts)</td>
<td>24 (23-25)</td>
<td>21 (20-22)*</td>
<td>20 (19-21)*</td>
<td>19 (18-20)*†</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Satisfaction with eating ability (1-5 pts)</td>
<td>3.9 (3.6-4.1)</td>
<td>3.7 (3.4-3.9)</td>
<td>3.7 (3.4-4.0)</td>
<td>3.8 (3.5-4.1)</td>
<td>0.7</td>
</tr>
<tr>
<td>Ability to eat certain foods (0-16 pts)</td>
<td>15.2 (14.7-15.8)</td>
<td>12.8 (12.2-13.4)*</td>
<td>12.6 (12.0-13.2)*</td>
<td>12.2 (11.5-12.9)*</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Vomiting/ regurgitation frequency (0-6 pts)</td>
<td>5.1 (4.7-5.5)</td>
<td>4.3 (3.9-4.8)†</td>
<td>3.9 (3.4-4.3)*</td>
<td>3.4 (2.9-3.9)* †</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Postoperative hunger was associated with postoperative energy intake, with every one point increase in hunger corresponding with an estimated additional 165kJ energy intake per day, F(1,67)=6.7, P = 0.012. Hunger was also significantly associated with protein and fat intake after surgery, with every one point increase in hunger corresponding with a two gram per day increase in protein, F(1,63)=4.2, P=0.045, and fat intake, F(1,63)=6.3, P=0.014, respectively. No other statistically significant relationships were found between postoperative hunger, restraint or disinhibition and dietary intake variables (including total carbohydrate, sugar and saturated fat intake) after surgery.

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a Results are based on repeated measures linear mixed model analyses and are presented as estimated marginal mean (95% confidence interval).

b n for dietary intake variables at 3 months = 37
c n for dietary intake variables at 6 months = 38
d n for dietary intake variables at 12 months = 33
* P < 0.001 versus baseline
† P < 0.05 versus three months
‡ P = 0.003 versus baseline
No significant relationships were found between eating behaviours and overall food tolerance after surgery, ability to eat certain foods or frequency of vomiting/regurgitation after surgery. Disinhibition tended to associate with the satisfaction with eating ability subset of food tolerance, with higher disinhibition scores corresponding with lower satisfaction, however this did not reach statistical significance, $F(1,98)=3.1$, $P=0.08$.

Pre-operative eating behaviours were not associated with percentage weight loss, quality of life, dietary intake or food tolerance after surgery, with the exception of preoperative disinhibition score and sugar intake, whereby every one point increase in baseline disinhibition score corresponded with 3.3 grams less sugar intake in the post-operative period, $F(1,32)=8.7$, $P = 0.006$.

### 5.5 Discussion

This is one of the first studies to investigate the relationship between restraint, disinhibition and hunger and weight loss, quality of life, dietary intake and food tolerance outcomes after LAGB. Given that mean weight loss in this study was less than other reports examining eating behaviour after LAGB [217], this study also uniquely analyses these factors in a sample population for whom the development of targeted intervention strategies to promote more optimal outcomes is most needed. Other strengths of this study include its multiple time-point longitudinal design and the use of linear mixed models, which represents a more sophisticated mode of analysis than previous studies in this area, which have been predominantly correlational [82, 134, 138, 254].

Overall changes in restraint, disinhibition and hunger were similar to previous studies in the LAGB population [82, 134, 135, 138]. The present study highlights that changes in eating behaviour were significant and sustained in the first 12 months following LAGB, yet there was no further improvement or deterioration in restraint, disinhibition or hunger between three and 12 months post-surgery.
Disinhibition was the only eating behaviour variable significantly associated with weight loss, whereby higher post-operative disinhibition scores were marginally associated with poorer weight loss. This differs from previous research by Colles et al. (2008a, 2008b) who although found restraint, disinhibition and hunger to be weakly correlated with weight loss, reported only hunger as a significant predictor of percentage weight loss at 12 months post-surgery. Schindler et al. (2004) also reported hunger, but not restraint or disinhibition, to tend to correlate with change in body weight. Given that disinhibition and hunger have previously been demonstrated to measure the same underlying construct, namely a susceptibility to uncontrolled and/or emotional eating [255], collectively the results from the present and previous studies support that individuals who are more susceptible to uncontrolled eating after surgery remain vulnerable to poorer weight loss outcomes. This is also reflected in other studies that have assessed related behaviours, including postoperative binge-eating and grazing [82, 105, 109, 139, 254, 256].

Given that the magnitude of the effect of disinhibition on weight loss was small, and that no relationship was found between hunger or restraint and weight loss despite significant changes in these variables after surgery, results of the present study also support the conclusions of earlier research in this field by Lang et al. (2002), who found no association between any TFEQ variable and BMI, suggesting that the specific changes in eating behaviour that promote weight loss may not be adequately reflected using standardised self-report tools such as the TFEQ, or that other factors remain more important in determining weight loss after LAGB.

The inverse relationship between mental wellbeing and disinhibition identified in the present study is consistent with the previous findings of Colles et al.[82, 109], providing further support for the need for interventions to help minimise disinhibited or uncontrolled eating, given that this may impact negatively on wellbeing in addition to weight loss outcomes. The significant positive relationship between physical wellbeing and baseline BMI and percentage weight loss is congruent with some previous research in this area [223] (baseline BMI ) and [82, 222] (percentage weight loss); with
the present findings suggesting that these weight-related variables are stronger
determinants of physical wellbeing than restraint, disinhibition or hunger. This
however remains to be confirmed by larger studies.

Although several statistically significant relationships were found between hunger and
dietary intake variables after surgery, the magnitude of these effects was negligible,
which limits the clinical significance of findings. Despite this, results indicating higher
levels of hunger are related to higher estimated energy intake are supportive of the
previous research of Colles et al. [82], suggesting that higher levels of subjective hunger
may act as a barrier to optimal reductions in energy intake after LAGB. Notably,
because the type of hunger measured by the TFEQ is more closely related to emotional
eating behaviours than physiological hunger, band adjustments alone are unlikely to
be sufficient in assisting susceptible individuals to achieve optimal reductions in
energy intake for successful weight loss.

There was no suggestion that restraint, disinhibition or hunger were significant
determinants of overall food tolerance, ability to eat certain foods or frequency of
vomiting/regurgitation after surgery in the present study. This suggests that band-
related factors (for example level of restriction in the band) may be more influential
than broad eating behaviours in determining food tolerance outcomes. However, it is
probable that behaviours more specific than those reflected by the TFEQ remain
important in contributing to food tolerance after LAGB. These may include post-
operative binge eating and ‘grazing’ as identified by previous studies [60, 109] as well
as specific behaviours related to the mechanical ingestion of food (for example failure
to adequately chew foods or eating too quickly). These should be considered when
evaluating food tolerance after LAGB in future studies.

The only significant relationship identified for pre-operative eating behaviour and
post-operative outcomes indicated that higher pre-operative disinhibition actually
corresponded with lower sugar intake after surgery. This and the overall lack of
association between pre-operative eating behaviours and outcomes of interest supports
previous research suggesting that pre-operative eating behaviours are not necessarily
good predictors of weight loss, dietary intake or food tolerance outcomes after LAGB or other restrictive procedures [133, 254, 257]. As such, there remains a need for early post-operative detection and intervention for individuals for whom surgery alone (in conjunction with standard post-operative care) proves inadequate in driving eating behaviour change for optimal weight loss and other outcomes following LAGB.

There are several limitations of this study that need to be acknowledged. Firstly, although LMMs were used to minimise the impact of missing data [253], the small sample size and attrition may reduce robustness and generalisability of findings. Secondly, potential confounders including physical activity, band adjustments and frequency of follow-up after surgery were not accounted for in the present analysis. Thirdly, validity of the dietary intake data may be questionable due to the different intake assessment methodologies used at different time points. Nevertheless, the reported dietary intakes in this study are not dissimilar to some other longitudinal reports of dietary intake after LAGB [106, 108]; and overall, the estimated energy intakes reported are consistent with the modest levels of weight loss achieved by the study sample, providing some support for the potential validity of this data.

The study is also limited by reliance on self-report data for eating behaviours, dietary intake and food tolerance, which is vulnerable to typical limitations of self-report data in this field, including under-reporting and social desirability and recall bias. Finally, the short-term nature of the study precludes insight into longer-term changes in eating behaviour and long-term outcomes of LAGB. Given the increasing evidence of longer-term weight regain after LAGB [234, 258], the examination of eating behaviour in individuals experiencing weight regain in the longer-term after surgery would have strengthened this study, however it was beyond the scope and capacity of the present research to examine such outcomes.

In conclusion, results support that individuals with greater susceptibility to uncontrolled or emotional eating after surgery may remain vulnerable to poorer weight loss, mental wellbeing and dietary outcomes after LAGB. There remains a need to identify sensitive tools to reliably detect problematic eating behaviours after LAGB,
and to develop tailored postoperative interventions for minimising non-hungry and uncontrolled eating behaviours. Further research in this area will be valuable for the development of evidence-based strategies to help optimise weight loss and dietary outcomes for all individuals who have LAGB.
Chapter 6  A snapshot of eating behaviour, food tolerance and dietary intake after laparoscopic adjustable gastric banding

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Supplementary results for functional health and wellbeing (SF-36v2® domains) not included within the submitted manuscript and qualitative feedback provided by respondents as part of the survey are provided in Appendix 19

6.1 Abstract

Background: This study aimed to describe eating behaviours, food tolerance, and dietary intake after LAGB, explore associations between these variables, and to examine the relationship between diet-related factors and percentage weight loss and quality of life after surgery.

Methods: A cross-sectional survey was mailed to subjects who had previously undergone LAGB in Newcastle, Australia.

Results: Sixty seven subjects responded (55 females, 12 males; mean age 49±11.5 years; postoperative BMI 34.5±5.4 kg/m²). Reported average weight loss since surgery was 20.5± 9.2% (26.6±13.0kg). Restraint (including flexible and rigid control) and disinhibition were higher than community norms and hunger trended towards being lower. The majority of respondents rated their eating ability as good (n=27, 40.3%) or excellent (n=15, 22.4%). Median reported energy intake was 4833kJ (3823-5961) per day. Protein and fat intake as a percentage of daily energy intake were within acceptable distribution ranges, although saturated fat intake exceeded recommendations. Fibre and several micronutrients were below estimated average requirements. BMI at time of surgery and satisfaction with eating ability were significantly associated with reported
weight loss after surgery (adjusted $R^2=0.32$, $P<0.001$); and satisfaction with eating ability and rigid control were significantly associated with physical wellbeing (adjusted $R^2=0.19$, $P=0.001$).

**Conclusions:** This study highlights that potential remains to improve aspects of eating behaviour, food tolerance and diet quality in some individuals who have undergone LAGB, and endorses the need for further development of multifactorial interventions to help optimise a range of diet-related factors after LAGB.

### 6.2 Introduction

Bariatric surgery is presently the most efficacious treatment strategy for obesity [43], with laparoscopic adjustable gastric banding (LAGB) accounting for approximately 40% of bariatric surgery procedures worldwide [28]. Despite the relative effectiveness of LAGB compared with non-surgical treatment strategies and favourable risk profile when compared with other types of bariatric surgery [26], the efficacy of LAGB is often debated in the scientific literature and popular media due to variability in weight loss outcomes, weight regain and relatively high failure rates [46, 250].

Although previous research highlights that LAGB generally promotes positive changes in eating behaviour and significant reductions in energy intake [217, 237], diet-related outcomes of LAGB are often questioned in the ongoing efficacy debate, where it has been suggested that LAGB can promote maladaptive eating behaviours (for example inappropriate ‘soft-calorie’ intake) and poor tolerance of nutrient-dense solid foods, which may impact negatively on weight loss, quality of life and dietary intake after surgery [52, 191, 220, 259]. These issues remain relatively underexplored in individuals who have had LAGB, where few previous studies have concurrently assessed eating behaviour, food tolerance, dietary intake, weight loss and quality of life following surgery, despite the potential for these factors to interact in a clinically significant way.

The prospective research of Colles et al. [82, 109] provides the most comprehensive data in this area, with key findings suggesting that postoperative uncontrolled eating and grazing are significantly associated with poorer weight loss, greater energy intake
and poorer mental health-related quality of life following surgery [109]. Colles et al. further identified lower levels of subjective hunger as an independent predictor of higher percentage weight loss [82]. These emotional-type eating behaviours have also been linked with poorer weight outcomes in other observational studies, yet overall there remains inconsistency in the evidence base regarding the impact of eating behaviours on weight loss and other outcomes following LAGB [217].

Although food tolerance was not the focus of Colles et al. research, they also reported a significant increase in intake of liquid foods and decrease in energy intake from solid foods in the first 12 months after surgery, yet consistency of food intake was not related to percentage weight loss [82]. Busetto et al. reported similar changes in the consistency of food intake in their early research into eating patterns after LAGB, finding intake of solid foods to be inversely correlated with vomiting frequency; yet the relationship between food consistency and weight loss was not directly examined [60]. It remains unclear if the consistency of food intake is a significant determinant of weight loss following LAGB, despite concerns regarding the potential for the development of ‘soft-calorie syndrome’ following restrictive surgery [259].

Despite the depth of Colles et al. research, it did not include an overall assessment of dietary intake in terms of adequacy or quality. This has also been overlooked by most other studies examining dietary intake after LAGB, despite the theoretic potential for LAGB to promote less optimal food choices with respect to nutrient density [52]. Furthermore, although Colles et al. examined correlations between some diet-related factors and quality of life, percentage weight loss remained the primary focus for results of the research undertaken. Quality of life is increasingly being recognised as a major outcome measure following obesity surgery [260], and while it is well-established that LAGB generally achieves significant and sustained improvements in physical and mental wellbeing, it is less known how diet-related factors, including eating behaviour and food tolerance, may contribute to quality of life outcomes after surgery.
Several recent studies have assessed the impact of food tolerance symptoms on quality of life after LAGB [123, 219, 222, 260]. The large cross-sectional study of Burton et al. found inability to eat certain foods to be the most ‘troublesome symptom’ reported by respondents, and that mean dysphagia score was moderately high, reflecting a general ability to eat foods with softer textures but not thicker textures [123]. Despite this, adverse symptoms were not identified as significant predictors of physical or mental quality of life [123]. These findings are supported by the prospective study of Pilone et al., who also found ‘gastrointestinal symptoms’ (including vomiting/regurgitation) not to be related to quality of life outcomes after LAGB [222]. This is surprising given that issues such as pain, discomfort, distress, food avoidance and potential social isolation related to avoidance of eating with others due to fear of food lodgement, vomiting or regurgitation, are conceivably important determinants of quality of everyday living [219]. It has not been established if the results of Burton et al. [123] and Pilone et al. [222] are replicable using an obesity surgery-specific food tolerance assessment tool, which may account for the lack of association between food tolerance symptoms and quality of life in these studies.

Overall, despite the existing research that has been conducted into diet-related outcomes following LAGB, it is arguable that scope remains to further explore eating behaviour, food tolerance and dietary intake after LAGB, including relationship between these factors and weight loss and quality of life after surgery. This line of research will provide deeper insight into the diet-related outcomes of LAGB and further research in this area may be particularly warranted given the ongoing speculation regarding the overall desirability of LAGB as surgical treatment option for obesity.

The aims of this study were to: (i) describe eating behaviours, food tolerance, and dietary intake in individuals who have undergone LAGB; (ii) explore associations between eating behaviour, food tolerance and dietary intake variables; (iii) examine the relationship between eating behaviour, food tolerance, dietary intake and percentage
weight loss; and (iv) examine the relationship between eating behaviour and food tolerance and quality of life outcomes.

6.3 Materials and Methods

6.3.1 Cross-sectional survey

A cross-sectional study involving self-administered mail-out surveys was undertaken between July and November 2010. The survey was sent to individuals who had undergone gastric banding between January 2008 and December 2009 at two major private gastric banding practices in Newcastle, Australia. Subjects were selected based on patient databases kept by the gastric banding practices. Ethical approval for the study was granted by the Human Research Ethics Committee of the University of Newcastle, Australia.

The survey consisted of nine sections including: self-reported anthropometrics (current weight, height, weight prior to surgery, weight loss since surgery), demographics, current health/medical conditions, frequency of post-surgery follow-up, functional health and wellbeing, eating behaviour, food tolerance, physical activity and general dietary practices, including use of meal replacements/food supplements and vitamin/mineral supplementation. This report focuses on the eating behaviour, food tolerance and dietary intake components of the survey.

Eating behaviour was assessed using the Three Factor Eating Questionnaire (TFEQ) [141], which has three dimensions of eating behaviour: restraint, reflecting the intention to restrict food intake as a measure to control weight; disinhibition, reflecting a susceptibility to eat in response to emotional and situational triggers; and hunger, reflecting subjective perceptions of feeling hungry [141]. Two subscales of restraint, flexible and rigid control [261], were also calculated. Flexible control reflects a relatively moderate approach to controlling food intake, allowing for non-core foods to be eaten in small quantities without guilt whereas rigid control represents an ‘all-or-nothing approach to eating, dieting and weight’ [261]. Higher scores for each of the
TFEQ dimensions and subscales reflect a greater tendency to exhibit the given characteristic. TFEQ mean scores were compared with available normative data [261].

Food tolerance, reflecting satisfaction with eating, ability to eat certain foods and frequency of vomiting or regurgitation symptoms was measured using the Food Tolerance Checklist, developed specifically for use in bariatric surgery populations [220]. Scores were calculated for overall food tolerance (score range 1-27), satisfaction with eating ability (score range 1-5), ability to eat certain foods (score range 0-16) and frequency of vomiting/regurgitation (score range 0-6), with higher scores reflecting better levels of food tolerance for each domain assessed [220].

Functional health and wellbeing was measured using the SF-36v2® Health Survey (Quality Metric, USA) [221]. For the purpose of this report, physical health and mental health component summary scores (reflecting aggregated scores from each domain of the SF-36v2® [221]) are reported as markers of overall quality of life. This data is reported as population norm-based scores based on Australian data [225], with a population-norm mean of 50 and standard deviation of 10 [221].

6.3.2 Food frequency questionnaire

Survey recipients were also asked to complete a validated 74-item food frequency questionnaire (FFQ) (Dietary Questionnaire for Epidemiological Studies, Cancer Council Victoria) [232]. Dietary intake data was compared against Australian Nutrient Reference values [244]. Specifically, estimated average requirements (EARs) were used for comparisons where available, as recommended for assessing adequacy of intake in groups [244]. Adequate intake (AIs) were used for nutrients for which EARs have not been set and suggested dietary targets (SDTs) for chronic disease prevention were also assessed for selected nutrients (fibre, sodium and potassium). To examine proportion of energy intake according to food consistency, food intake data from the FFQ was divided into three consistency categories (solid, soft and liquids) based on the definitions used by Colles et al. [82].
6.3.3 Statistical analysis

All data were analysed using PASW statistical software Version 18.0. Normally distributed data are reported as mean ± SD and skewed data as median and interquartile range (IQR). Incomplete data for each survey item were excluded on a case-by-case basis. Paired t-tests were used to assess difference between reported weight at time of surgery and reported weight at time of survey completion. Independent samples t-tests (for normally distributed data) or Mann-Whitney U tests (for nonparametric data) were used to compare differences in characteristics between males and females and gastric banding practice. One-sample t-tests were used to compare TFEQ scores with relevant population norms [261]. Associations between eating behaviour, food tolerance and dietary intake variables (macronutrient intake, distribution of macronutrient intake, food consistency and fibre) were explored using Pearson or Spearman rank correlation coefficients depending on normality of variables. Associations with a correlation co-efficient of <0.4 are not reported.

Multiple linear regression analysis (forced-entry method) was used to examine the relationship between diet-related variables and reported weight loss (expressed as percentage weight loss from pre-surgery body weight) and quality of life measures (based on SF-36v2© physical and mental health component summary scores). Percentage weight loss was calculated from self-report weight data from the survey [(weight pre-surgery – weight post-surgery)/weight pre-surgery × 100]. Preliminary regression modelling was conducted with the inclusion of theoretically important variables and/or variables previously indicated in the literature as predictors of weight and/or quality of life outcomes (including gender, age, current BMI, BMI at time of surgery and percentage weight loss). Non-significant control variables were eliminated from further analyses in order to maximise statistical power given the relatively small sample size. Backwards regression modelling with the inclusion of potential control variables was further undertaken to confirm that identified best-fit models did not omit potentially important control variables. All regression analyses were checked for
normality of residuals, outliers, multicollinearity and homoscedacity. Statistical significance was set as $P < 0.05$ for all analyses.

6.4 Results

6.4.1 Response rate and respondent characteristics

The initial survey was mailed to 340 subjects ($n=208$ from practice one and $n=132$ from practice two). Sixty-seven surveys were returned [$n=37$ from practice one (18%) and $n=30$ from practice two (23%)] providing an overall response rate of 20%. There were no differences in general characteristics or reported weight loss between respondents from each gastric banding practice. The majority of respondents were female (82.0%) with a mean age of 49 ± 11.5 years and BMI of 34.5 ± 5.4 kg/m$^2$. Average time since LAGB was 1.7±0.5 years, with a mean reported weight loss of 26.6 ± 13.0 kg (20.5 ± 9.2% of initial body weight) since surgery ($P < 0.001$). The maximum weight loss reported was 52kg (40% of initial body weight) and minimum weight loss was 5kg (4.6% of initial body weight). There were no significant differences in BMI or percentage weight loss between males and females. A summary of participant characteristics is provided in Table 6.1.

Approximately 55% of respondents indicated that they currently receive dietetic follow-up every two to six months. A further 30% indicated that they seek follow-up less frequently than every six months. Eight respondents (12%) indicated that they do not currently see a dietitian at all. The median number of band adjustments since surgery was five (IQR: 3-6).
Table 6.1 Respondent characteristics including current health, anthropometrics, functional health and wellbeing, eating behaviour, food tolerance and physical activity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (Female/Male)</td>
<td>67 (55/12)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>49 ± 11.5</td>
</tr>
<tr>
<td>Time since surgery (years)</td>
<td>1.7 ± 0.5</td>
</tr>
<tr>
<td>Current medical conditions (n/% of sample)</td>
<td></td>
</tr>
<tr>
<td>- Hypertension</td>
<td>30 (45%)</td>
</tr>
<tr>
<td>- Depression</td>
<td>22 (33%)</td>
</tr>
<tr>
<td>- Dyslipidemia</td>
<td>17 (25%)</td>
</tr>
<tr>
<td>- Type II diabetes</td>
<td>12 (18%)</td>
</tr>
<tr>
<td>- Sleep apnoea</td>
<td>12 (18%)</td>
</tr>
<tr>
<td>- Osteoarthritis</td>
<td>10 (15%)</td>
</tr>
<tr>
<td>- Gastro-oesophageal reflux</td>
<td>10 (15%)</td>
</tr>
<tr>
<td>- Hypothyroidism</td>
<td>9 (13%)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>98.4 ± 16.2</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>34.5 ± 5.4</td>
</tr>
<tr>
<td>Reported weight at time of surgery (kg)</td>
<td>124.4 ± 21.2</td>
</tr>
<tr>
<td>BMI at time of surgery (kg/m²)</td>
<td>43.6 ± 7.1</td>
</tr>
<tr>
<td>Reported weight loss since surgery (kg)</td>
<td>26.6 ± 13.0</td>
</tr>
<tr>
<td>% of initial weight</td>
<td>20.5 ± 9.2</td>
</tr>
<tr>
<td>Physical Component Summary Score c</td>
<td>52.1 ± 7.8</td>
</tr>
<tr>
<td>Mental Component Summary Score c</td>
<td>46.7 ± 12.3</td>
</tr>
<tr>
<td>Dietary restraint score (out of 21)</td>
<td>11.6 ± 4.5</td>
</tr>
<tr>
<td>- Flexible control score (out of 7)</td>
<td>4 (2-5)</td>
</tr>
<tr>
<td>- Rigid control score (out of 7)</td>
<td>3 (2-5)</td>
</tr>
<tr>
<td>Disinhibition score (out of 16)</td>
<td>5.5 (4-10)</td>
</tr>
<tr>
<td>Hunger score (out of 14)</td>
<td>3 (1-6)</td>
</tr>
<tr>
<td>Total food tolerance score (out of 27)</td>
<td>18 (16-20)</td>
</tr>
<tr>
<td>- Satisfaction with eating score (out of 5)</td>
<td>4 (3-4)</td>
</tr>
<tr>
<td>- Ability to eat certain foods score (out of 16)</td>
<td>11 (10-12)</td>
</tr>
<tr>
<td>- Vomiting/regurgitation score (out of 6)</td>
<td>4 (2-4)</td>
</tr>
</tbody>
</table>

a Results reported as mean ± SD, median (interquartile range) or counts depending on variable type and distribution of data.
b BMI calculated from self-report height and weight data.
c Summary scores for physical and mental health domains of the Short-Form 36v2 based on Australian population norm T-scores [225].

6.4.2 Eating behaviour, food tolerance and dietary intake

Eating behaviour (n=64) and food tolerance (n=67) scores are summarised in Table 6.1. There were no significant differences in eating behaviour or food tolerance between males and females. Eating behaviours differed from normative data, where restraint, flexible control, rigid control and disinhibition were significantly higher than population norms and hunger tended to be lower, although this did not reach statistical significance (Figure 6.1).
Respondents most frequently rated their overall satisfaction with eating ability as good (n=27, 40%) and the majority of respondents reported vomiting/regurgitating frequency as rare (n=39, 58%) (Figure 6.2a and Figure 6.2b). Red meat, white meat and bread were most frequently reported as being somewhat difficult to eat; whereas vegetables, salad, fish and pasta were most frequently reported as easy to eat (Figure 6.2c).

Respondents reported consuming a median of one serve of fruit (IQR: 1-2), three serves of vegetables (IQR: 2-3), two serves of dairy (IQR: 2-3) and one serve of meat/chicken/fish per day (IQR: 1-2). Forty-eight respondents (71.6%) reported taking some form of nutritional supplement, with multivitamins the most commonly reported form of supplementation (n=39, 58%). Only nine subjects (13.4%) reported regular or occasional consumption of food-based dietary supplements (such as Sustagen®) or meal replacement products.
Figure 6.2 Food tolerance sub-components

A: Satisfaction with eating ability; B: Vomiting/regurgitation frequency; C: Ability to eat certain foods.

Thirty-six subjects (29 females and 7 males) completed the FFQ in addition to the basic information on selected core foods included in the initial survey, representing 54% of initial survey responders and 11% of the overall survey sample population. When compared with subjects who did not complete the FFQ, completers had a lower current body weight (94.0kg versus 103.4kg, \(P=0.017\)) and a lower current BMI (33.1 kg/m\(^2\) versus 36.1 kg/m\(^2\), \(P=0.025\)). There were no differences in reported weight loss, general characteristics (including age, gender and banding practice attended) or reported intake of selected core foods reported between FFQ completers and non-completers.

Median energy intake for subjects who completed the FFQ was 4833kJ per day (Table 6.2). Based on percentage of daily energy intake, fat and protein intakes were within acceptable macronutrient distribution ranges (AMDRs), saturated fat was above suggested targets and carbohydrate intake was below the AMDR (Table 6.2). Magnesium, folate, vitamin E, fibre and potassium intakes were below estimated
average requirements and/or adequate intakes, as was calcium for women aged greater than 50 years and zinc intake in males (Figure 6.3).

### Table 6.2 Reported dietary intake

<table>
<thead>
<tr>
<th>Dietary variable</th>
<th>Reported intake a,b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (kJ/day)</td>
<td>4833 (3823-5961)</td>
</tr>
<tr>
<td>Energy from protein (% of daily energy intake)</td>
<td>23.3±3.3</td>
</tr>
<tr>
<td>Energy from carbohydrate (% of daily energy intake)</td>
<td>40.1±6.0 e</td>
</tr>
<tr>
<td>Energy from total fat (% of daily energy intake)</td>
<td>34.4 ± 6.8</td>
</tr>
<tr>
<td>- Saturated fat (% daily energy)</td>
<td>14.5 ± 3.5 d</td>
</tr>
<tr>
<td>- Polyunsaturated fat (% daily energy)</td>
<td>3.9 (3.6-5.8)</td>
</tr>
<tr>
<td>- Monounsaturated fat (% daily energy)</td>
<td>12.1 ± 2.5</td>
</tr>
<tr>
<td>Solid foods (% total food intake)</td>
<td>48.4 ± 16.3</td>
</tr>
<tr>
<td>Soft foods (% total food intake)</td>
<td>10.4 ± 8.4</td>
</tr>
<tr>
<td>Liquid foods (% total food intake)</td>
<td>41.2 ± 16.7</td>
</tr>
<tr>
<td>Protein (g/day)</td>
<td>64.7 (51.3-82.6)</td>
</tr>
<tr>
<td>Carbohydrate (g/day)</td>
<td>117.4 (99.6-157.3)</td>
</tr>
<tr>
<td>- Sugars (g/day)/(% carbohydrate intake)</td>
<td>69.2 ± 25.1/54.0 ± 14.5</td>
</tr>
<tr>
<td>- Starch (g/day)/(% carbohydrate intake)</td>
<td>53.1 (37.1-69.3)/45.4±14.6</td>
</tr>
<tr>
<td>Total fat (g/day)</td>
<td>43.8 (33.1-57.8)</td>
</tr>
<tr>
<td>- Saturated fat (g/day)</td>
<td>20.6 ± 9.0</td>
</tr>
<tr>
<td>Alcohol (g/day)</td>
<td>2.1 (0.6-7.4)</td>
</tr>
<tr>
<td>Fibre (g/day)</td>
<td>13.6 (8.7-17.3) e</td>
</tr>
<tr>
<td>Sodium (mg/day)</td>
<td>1437 (1156-1919) e</td>
</tr>
<tr>
<td>Potassium (mg/day)</td>
<td>2309 ± 734 e</td>
</tr>
<tr>
<td>Calcium (mg/day)</td>
<td>910 ± 351 e</td>
</tr>
<tr>
<td>Iron (mg/day)</td>
<td>8.1 (5.6-10.8) e</td>
</tr>
<tr>
<td>Zinc (mg/day)</td>
<td>7.6 (6.5-9.7) e</td>
</tr>
<tr>
<td>Magnesium (mg/day)</td>
<td>210 (175-274) e</td>
</tr>
<tr>
<td>Folate (µg/day)</td>
<td>178 (136-219) e</td>
</tr>
<tr>
<td>Thiamin (mg/day)</td>
<td>0.87 (0.68-1.13) e</td>
</tr>
<tr>
<td>Riboflavin (mg/day)</td>
<td>1.9 (1.5-2.3) e</td>
</tr>
<tr>
<td>Niacin (niacin equivalents mg/day)</td>
<td>25.2 (19.6-32.3) e</td>
</tr>
<tr>
<td>Vitamin C (mg/day)</td>
<td>78.7 (46.4-120.3) e</td>
</tr>
<tr>
<td>Vitamin A (retinol equivalents (µg/day)</td>
<td>4.0 ±1.6 e</td>
</tr>
<tr>
<td>Vitamin E (mg/day)</td>
<td>4.0 (2.7-4.9) e</td>
</tr>
</tbody>
</table>

a n=36. Normally distributed variables reported as mean ± standard deviation. Non-normally distributed variables reported as median (interquartile range).

b Results highlighted in bold reflect deviations from Australian Nutrient Reference Values [244]

c Acceptable macronutrient distribution range (AMDR) for carbohydrate is 45-65% of daily energy intake [244]

d AMDR for saturated fat intake is <10% of daily energy intake [244]

e Nutrient reference values are gender and/or age specific. Refer to Figure 3 for gender and age-specific comparisons with recommended intakes.
Inter-relationships between eating behaviour, food tolerance and dietary intake

Although several weak associations were found between eating behaviour, food tolerance and dietary intake variables, very few moderate ($r > 0.4$) or stronger correlations of potential clinical significance were identified. No relationships were found between eating behaviour and overall food tolerance score, vomiting/regurgitation frequency or ability to eat certain foods; however satisfaction with eating ability was inversely correlated with disinhibition (Spearman’s rho=-0.425, $P<0.001$).

No significant associations were found between energy intake and eating behaviours or food tolerance; yet energy intake was positively correlated with solid food intake (Spearman’s rho=0.424, $P=0.01$) and inversely correlated with liquid food intake (Spearman’s rho=-0.477, $P=0.003$). The consistency of food intake (percentage intake of solid, soft and liquid foods) was not associated with eating behaviour or food tolerance.
scores. Protein intake as a percentage of daily energy intake was inversely associated with disinhibition and hunger (Spearman’s rho=-0.437, \(P=0.009\) and -0.470, \(P=0.004\) respectively) and sugar intake (grams per day) was inversely correlated with eating score (Spearman’s rho=-0.432, \(P=0.009\)). No relationships were found between dietary intake and total food tolerance score, ability to eat certain foods or vomiting and regurgitation frequency.

6.4.3 Factors associated with postoperative weight loss and quality of life

BMI at time of surgery (\(\beta=0.467, P<0.001\)) and satisfaction with eating score (\(\beta=0.446, P<0.001\)) explained 32% of the variance in percentage weight loss after surgery (\(P<0.001\)). No other eating behaviour, dietary intake or food tolerance variables were identified as significantly related to reported weight loss in multiple regression analyses.

Restraint (\(\beta=-0.342, P<0.001\)) and satisfaction with eating ability (\(\beta=0.284, P=0.018\)) were modestly related to physical wellbeing, explaining 16% of the variance in physical component summary (PCS) score (\(P=0.002\)). Because the relationship between restraint and PCS score was not in an intuitive direction, sub-scales of restraint were further explored. Rigid control (\(\beta=-0.374, P=0.002\)) but not flexible control, was identified as a more strongly related to physical wellbeing than overall restraint, explaining 19% of the variance in PCS score (\(P=0.001\)) in conjunction with satisfaction with eating ability (\(\beta=0.239, P=0.042\)). Satisfaction with eating ability (\(\beta=0.418, P<0.001\)) alone was identified as significantly related to mental wellbeing, explaining 16% of the variance in mental component summary score (\(P<0.001\)).

6.5 Discussion

This study examined a comprehensive range of diet-related factors following LAGB; providing a detailed contribution to the existing profile of eating behaviours, food tolerance and dietary intake in individuals who have LAGB and further insight into
how these factors may relate with weight loss and quality of life after surgery. Although the study sample was small and the response rate was relatively low, general characteristics of respondents (including gender, age, health conditions and weight and BMI at time of surgery) were similar to other studies involving LAGB patients [123, 217], and outcomes assessed including diet-related variables, reported weight loss and quality of life, were also generally consistent with previous research, including larger studies with more complete follow-up/higher response rates [43, 123, 217, 223, 233, 237]. This suggests that the study population is not dissimilar to other LAGB samples reported in the literature. Overall, the results of this study support that there is variability in diet-related outcomes following LAGB, with both positive and potentially problematic eating behaviour, food tolerance and dietary intake outcomes identified.

Firstly, this study provides further evidence to suggest that eating behaviour after LAGB differs from general community norms. Higher levels of restraint and lower levels of perceived hunger are consistent with the functionality of LAGB, yet significantly higher levels of disinhibition support that emotional-type eating behaviours can remain problematic, as has been demonstrated by previous prospective research [217]. This study also highlights that higher dietary restraint after LAGB may be characterised by greater levels of both flexible and rigid control than population norms. Flexible control generally reflects positive adaptations to food restriction; yet rigid control reflects a tendency towards maladaptive eating patterns and is generally considered as an unhelpful behaviour for weight loss [261]. These results provide further evidence to support the critical need to develop effective post-operative intervention strategies to help reduce emotionally-driven and/or maladaptive eating in susceptible individuals.

Food tolerance findings in the present study were mixed. Notably, only few respondents rated their overall satisfaction with eating ability as poor or very poor and frequency of vomiting and regurgitation was low. Furthermore, despite suggestions in both the present and previous studies [123, 191] that foods such as bread and red meat are problematic after LAGB, nutrient intake data for the present study indicates that
intake of relevant nutrients including carbohydrates, protein and iron are not necessarily compromised, especially in the context of an energy-reduced diet for weight loss. These findings support other research that has failed to find evidence of major nutrient deficiencies following LAGB [79]. It is probable that dietary intake targets can generally be achieved via the successful implementation of appropriate eating methods (for example chewing foods well); the selection of suitable, nutrient-rich substitute foods if a food is genuinely not tolerated; and multivitamin supplementation. Further research in larger samples that concurrently assesses both food tolerance and dietary intake are required in order to strengthen these preliminary observations.

Food tolerance scores were generally higher in the present study when compared with previous reports in LAGB patients [191, 219]. This may reflect the follow-up protocol of the surgical practices involved in the study, where intensive dietary education and follow-up is provided regarding appropriate eating methods and band adjustments are performed on an incremental basis over time, with eating ability and adverse symptoms taken into account, consistent with recommended practice for avoiding adverse food tolerance symptoms [88].

Total food tolerance scores were lower in comparison with reports of other bariatric procedures, including roux-en-Y gastric bypass and SG, however, consistent with previous research in this area [191, 219, 220]. The apparent inferiority of food tolerance outcomes following LAGB has previously led to conclusions that food tolerance is more problematic after LAGB and as such other procedures may be preferable [191, 219]. Interpretation of ‘food tolerance’ following LAGB as per the checklist of Suter et al. [220] may be problematic however, given that LAGB aims to alter food intake behaviours via the creation of a mechanical-physiological barrier to food ingestion. As such, if a patient reports being able to eat a food ‘with some difficulty’, this may reflect the nature of a functioning band (i.e. foods need to consumed slowly, carefully and mindfully) rather than a problem per se. In support of this, eating ability in the present study was not significantly related to any dietary intake variable, suggesting that some
difficulty in eating does not necessarily translate into poorer dietary intake. Caution may therefore be required in the interpretation of lower food tolerance scores following LAGB when compared with other surgical weight loss procedures, given that inherent differences between procedures are likely to impact on subjective interpretations of food tolerance.

The dietary intake results highlight some potentially problematic areas of the post-LAGB diet. Intake of fibre, folate, magnesium and key micronutrients in certain population groups, such as calcium in women aged over 50 years, iron in premenopausal women and zinc in men were below recommended intakes; although these results do not take into account contributions from vitamin and mineral supplements. There were also further markers of sub-optimal diet quality, with saturated fat intake exceeding the SDT and potassium intake was markedly below the SDT. A greater proportion of carbohydrate intake from sugars rather than starch/complex carbohydrates was also found, also potentially indicative of sub-optimal diet quality [262]. Potential diet quality issues after LAGB are similarly highlighted by the cross-sectional study of McGrice and Porter [233], who found that at one year post-surgery, many LAGB patients did not achieve general population intake targets for protein, carbohydrate or fibre in absolute terms (grams/day), yet intake of fat and saturated fat exceeded recommendations [233].

It must be highlighted that diet quality issues cannot be considered as unique for individuals who have had LAGB, with population level dietary intake data for developed countries suggesting a similar pattern of failure to achieve optimal diet quality and chronic disease risk reduction intake targets [244, 263]. Notwithstanding this, results support the need for ongoing education and promotion of nutrient-dense food options as well as multivitamin supplementation to help ensure optimal long-term nutrition after LAGB, consistent with existing recommendations for dietary intake following obesity surgery [89]. Ultimately, further prospective, interventional research is required to better elucidate how to best define and achieve sustained optimal dietary intake patterns after LAGB.
Few associations were found between eating behaviour, food tolerance and dietary intake in the present study. The inverse correlations between disinhibition and hunger and protein intake as a percentage of daily energy intake suggest it is possible that emotionally-driven eating behaviours may lead to less favourable post-operative protein intakes, given that proportionally higher protein intakes are required in order to meet requirements in reduced-energy diets [148]. The positive correlation between intake of solid foods and energy intake differs from the research of Colles et al. and Busetto et al. who did not find any association between food consistency and energy intake [60, 82]. Given that higher energy intakes may be indicative of a non-optimally adjusted band, the results of the present study may reflect that individuals with higher energy intakes may also consume proportionally more solid food as a consequence of sub-optimal band restriction. This highlights that greater intake of solid foods is not necessarily reflective of optimal dietary intake.

Although diet-related factors were the focus of this study, BMI at time of surgery was identified as the strongest explanatory variable for percentage weight loss in regression analysis. There is some inconsistency in the LAGB literature regarding the influence of initial BMI on weight loss outcomes, which may reflect differing methodologies used to define weight loss outcomes. Congruent with the present findings, some previous studies have found higher baseline BMI to be a positive predictive factor [83]; while others have failed to find a relationship [250], or have found individuals with a lower baseline BMI to achieve better weight loss than those with a higher BMI [128, 264]. Snyder et al. further suggest that a BMI greater than 46kg/m² may be a contraindication for LAGB due to higher risk of failure [265]. Very few respondents in the present study sample had an initial BMI greater than 46kg/m² which may help to explain discrepancy in these findings.

Satisfaction with eating ability was the only diet-related variable found to be significantly related with weight loss and quality of life after surgery. Given the subjective nature of this subset of the food tolerance checklist, with the potential for it to be significantly influenced by weight loss [191, 219], it cannot be discounted that
these results reflect a relationship between general satisfaction with weight loss and quality of life rather than demonstrating an objective link between food tolerance per se and these outcomes. In view of this, as well as the observed correlation between satisfaction with eating ability and disinhibition, further development of food tolerance assessment tools to better distinguish physical aspects of food tolerance from behavioural/emotional factors may be beneficial in obtaining more objective data regarding food tolerance and its impact on weight loss and quality of life following obesity surgery.

It is notable that other food tolerance variables were not associated with weight loss or quality of life outcomes in the present study. This is consistent with other recent studies in this area [123, 222]. Schweiger et al. however reported increased excess weight loss to be associated with lower food tolerance, suggesting this may be explained by increased vomiting [191], consistent with the early research of Busetto et al.[60]. Patient follow-up protocol may help to explain discrepancies in these findings, where intensive dietary education and gradual band adjustments are likely to help prevent negative food tolerance outcomes, thereby helping to minimise the impact of food tolerance on weight loss and quality of life after surgery.

One of the most novel findings of this study was the association between the rigid control subscale of restraint and PCS score, with results indicating that increased rigid control is significantly associated with lower physical wellbeing. It is unclear why rigid control was related to physical but not mental wellbeing or weight loss; but given that rigid control represents a more disturbed pattern of restrictive eating, this result nevertheless suggests that rigidity in restricting food intake may have an undesirable impact on quality of life after LAGB, although causality cannot be inferred from the present results. Nevertheless, this highlights that the promotion of positive cognitions related to reducing food intake may represent an important consideration for behavioural interventions aimed at optimising eating behaviours after LAGB.

Several limitations of the present study need to be acknowledged. Firstly, the study sample size was relatively small and the response rate was low. Although
characteristics of the sample population and study outcomes were very similar to previous studies in LAGB patients, the potential for non-response bias and reduced generalisability of findings cannot be discounted. Unfortunately, limited resources prevented implementing methods to improve response rate, including participation incentives or reminders.

Resource limitations also prevented the FFQ being mailed with the initial survey, explaining the particularly low response rate for this component of the study. Given that subjects who completed the FFQ had a significantly lower weight and BMI than the remainder of survey respondents, some degree of bias in the dietary intake data is indicated. Dietary intake results may thus be more generalizable to subjects in the lower obesity BMI categories. As there were no differences in selected intake of core foods, reported weight loss or other general characteristics between FFQ responders and non-responders, this suggests dietary intake data is at least somewhat representative of the wider survey population.

The cross-sectional nature of the study precludes assessment of changes in outcomes over time and does not allow for conclusions to be made regarding causality as a consequence of LAGB or to allow preoperative characteristics to be controlled for. The collection of prospective, longitudinal data would have provided a stronger insight into outcomes of interest. Furthermore, the study does not provide insight into longer-term outcomes given that respondents’ average time since surgery was only 1.7 years. The study is also subject to typical validity and reliability limitations of self-report data, which may help to explain the general lack of relationship identified between variables of interest, and caution is required in the overall interpretation of findings, as is the case for all research of this nature [266, 267].

6.5.1 Conclusions

This study suggests that individuals report a mix of positive and potentially undesirable eating behaviours, food tolerance and dietary intake in the short to medium term after surgery, yet no strong relationships between diet-related factors
and weight loss or quality of life were identified. Although potentially problematic issues related to rigid and disinhibited eating patterns, food tolerance and diet quality were identified, these need to be considered in the broader context of obesity therapy, where it is unrealistic to expect any single surgical intervention to remedy all issues associated with obesity and weight loss. There remains a need for further research into multifactorial intervention strategies to help optimise a range of diet-related outcomes after LAGB.
Chapter 7  Final Discussion

7.1 Overview

This chapter addresses the key findings of the research undertaken for this thesis, beginning with a discussion of overall research findings in the context of existing literature (Section 7.2). The strengths and limitations of the research are then discussed (Section 7.3). The chapter closes with a summary of the implications for practice and future research (Section 7.4) followed by final conclusions of the thesis (Section 7.5).

7.2 Summary of findings and discussion

The overarching aim of this thesis was to contribute to the evidence base informing the dietary management of individuals who have had LAGB, with focus on the optimisation of weight loss after surgery. A series of inter-related components of research addressing various gaps in the evidence base were undertaken, including systematic reviews of dietary intake and eating behaviour after LAGB; a pilot dietary intervention assessing the feasibility and potential utility of a protein-enriched diet after LAGB; and a cross-sectional survey examining a range of diet-related factors within the first two years after LAGB.

Although practical difficulties encountered reduced the capacity of the research undertaken to directly inform best-practice dietary management strategies, the overall body of research nevertheless reveals several themes and key findings important to the dietary management of individuals who have had LAGB and future research in this field. These are discussed below.

7.2.1 The evidence base for the dietary management of individuals who have had LAGB

This thesis demonstrates that there remains a very limited evidence base to underpin best-practice management strategies for individuals who have had LAGB. The practical difficulties encountered during this research are likely to typify some of the underlying
issues that contribute to the paucity of evidence available. This includes: slow recruitment of individuals for the dietary intervention, poor compliance with dietary instruction and completion of study measures and the low response rate for the cross-sectional study, including the low return of food frequency questionnaires. Notably, recruitment difficulties in obesity surgery populations have recently been highlighted by other researchers [268]); and problems in achieving participant attendance at post-operative dietary intervention sessions have also been recently reported in a pilot obesity surgery dietary counselling study by Sarwer et al. [269].

Such issues pose a significant barrier for obtaining high level evidence regarding best practice management strategies for optimising outcomes for LAGB patients, particularly given the relatively small population pool available for research. Although there remains a need for high quality interventional research to enhance the evidence base in this field, additional measures such as the inclusion of the dietary and behavioural outcomes in national obesity surgery registers may provide further opportunity to build the evidence base for these outcomes in lieu of RCT and/or other interventional evidence. In Australia, a national obesity surgery registry (the Obesity Surgery Society of Australia and New Zealand Bariatric Registry) has recently been established and is currently being piloted [270, 271] in line with recent governmental recommendations to establish such a registry [91]. This represents a potential opportunity to capture and longitudinally examine diet-related outcomes in a large dataset of LAGB patients (and individuals who have had other types of obesity surgery).

At the time of thesis write-up, several studies examining dietary and behavioural factors and outcomes of LAGB are reported as underway from the Centre for Obesity Research and Education (CORE) research group (Monash University, Melbourne Australia), including: an RCT examining the effect of meal frequency (two meals versus six meals per day) on weight loss and dietary satisfaction; an RCT examining a low fat versus a low carbohydrate diet for the optimisation of weight loss and dietary satisfaction; and an examination of the influence of a cognitive behavioural therapy
program for ‘LAGB patients at risk of poor weight loss’ [272]. These studies have further potential to build the evidence base regarding best-practice dietary management of individuals who undergo LAGB, and will be valuable to compare and integrate with findings of the body of research undertaken in this thesis when results from these studies become available. Other studies from the recent literature that are integrally related to this thesis and the evidence base for the dietary management of individuals who have had LAGB are incorporated into the proceeding discussion sections of the key findings of this thesis.

7.2.2 Optimising weight loss after LAGB: diet, eating behaviour and patient compliance

The research undertaken for this thesis suggests that the specific macronutrient composition of the post-LAGB diet appears to be less important than behaviours associated with food intake in determining weight loss outcomes following LAGB. This is most clearly demonstrated by results of the intervention study (Chapters 3 and 4), where greater protein intake did not appear to have any favourable effects on weight loss or related changes in body composition after surgery (Chapter 4), whereas postoperative eating behaviours related to uncontrolled eating had a small but statistically significant impact on percentage weight loss in the first 12 months after surgery (Chapter 5). The cross-sectional study (Chapter 6) failed to identify any significant relationship between protein or intake of other macronutrients and weight loss, and although no relationship was found between eating behaviour and weight loss (possibly due to methodological limitations as discussed in Section 7.3.2), the study population did report higher levels of rigid control and disinhibition than the general population, supporting that uncontrolled eating behaviours can remain problematic after LAGB.

These findings are generally consistent with the previous research examining eating behaviours after surgery [217], including the findings of Colles et al. [82, 109], whose prospective research represents the most comprehensive and complete observational
data regarding diet and eating behaviour available to-date. The collective evidence from this thesis and previous research in this field therefore emphasises that uncontrolled and non-hungry eating represents a key postoperative dietary management issue for the optimisation of weight loss following LAGB; and the development of effective post-operative intervention strategies to reduce emotionally-driven eating in individuals who remain vulnerable to maladaptive eating patterns after surgery is critically required.

Problematic compliance with post-operative dietary advice, as highlighted by the results of the protein-enriched dietary intervention, including poor compliance with the protein-enriched intervention diet and the generally lower than expected weight loss for the study sample as a whole (Chapter 4), is another core eating behaviour-related dietary management issue arising from this thesis. It is notable that poor compliance with the protein supplement as part of the intervention diet was widespread despite the supplement being provided free of cost to study participants. Non-compliance with post-operative dietary and lifestyle instructions for weight loss is a recurring theme in the obesity surgery literature, inclusive of LAGB and other surgical procedures [83, 273-276]); and also mirrors the compliance issues that are fundamentally associated with the failure of conventional/lifestyle approaches in maintaining weight loss over the longer term [277].

This highlights that despite the expectation that LAGB ‘forces’ compliance with a reduced-energy diet as a consequence of gastrointestinal modification [125], it does not systematically guarantee successful behaviour modification/compliance with required dietary and lifestyle changes for sustained weight loss. Notably, one of the core eligibility criterions for surgery is several failed attempts at weight loss using conventional methods [278]. Thus by definition, candidates for obesity surgery represent a population group already vulnerable to poor compliance with dietary and lifestyle modifications. This further supports the need to develop postoperative interventions to assist individuals who experience difficulties complying with required
lifestyle changes for weight loss following LAGB, whether these difficulties are mediated by problematic eating behaviours or other behavioural or lifestyle factors.

Despite the overall body of evidence supporting that dietary compliance represents a key issue for suboptimal weight loss following surgery, and more specifically the preliminary evidence from this thesis suggesting that problematic compliance with an increased protein intake diet may negate any potential utility for optimising weight loss, a recent longitudinal examination of protein intake in the first 12 months after RYGB (n=167) found ‘excellent compliance’ with protein intake recommendations of greater than 1g/kg/day [279]; and that higher protein intakes were correlated with greater weight loss, reductions in BMI and reductions in percentage body fat; independent of preoperative BMI, exercise and ‘carbohydrate violations’ (occasions of intake of high carbohydrate foods) [279]. These results are in direct contrast with the findings of this thesis. Although Raftopoulos et al. study involved RYGB patients; it seems unlikely that the difference in surgical procedure alone would account for these contrasting findings, given that the overall literature suggests poor dietary compliance can be significantly problematic following both LAGB and RYGB [83, 275, 276, 280].

To otherwise explain differences in the findings of Raftopoulos et al., the dietary prescription used by Raftopoulos et al. involved a stringent low-carbohydrate, high-protein diet, enforced exclusively by the surgeon during postoperative follow-up care; differing markedly from the advice provided for the dietary intervention in this thesis, as well as the general advice and approach used by the surgical practices associated with the research undertaken. It is interesting that Raftopoulos et al. found excellent compliance with the low carbohydrate, high protein diet following RYGB, when the lifestyle literature examining this type of diet has consistently demonstrated that longer-term compliance with a low carbohydrate, high protein diet is typically low [157, 174, 176, 181]. It is possible that the observed excellent compliance in Raftopoulos et al. is a reflection of the completers-only analysis (n=167/427) that was undertaken. This subjects findings to potential attrition bias, especially given that individuals who do not attend follow-up care are more likely to represent individuals who are
noncompliant with follow-up advice. In addition, Raftopoulos et al. considered only rudimentary measures of other dietary and behavioural variables that may have been potential mediating factors in explaining weight loss; therefore it is possible that ‘protein intake compliance’ may have simply been a marker for overall compliance with postoperative instruction for weight loss, rather than a stand-alone predictor of weight loss per se.

Ultimately, further adequately-powered interventional rather than observational research is required in order to better elucidate whether or not there is an optimal macronutrient composition of the post-operative diet for weight loss following different types of obesity surgeries. The results of this thesis, however, suggest that future interventional research in LAGB patients should foremost target strategies to minimise problematic eating behaviours and enhance overall compliance with dietary advice, rather than focusing on specific nutrients for weight loss.

At the time of writing this thesis, the recent pilot study of Sarwer et al. [269] represents the only intervention undertaken to investigate dietary counselling for the optimisation of weight loss after obesity surgery. The study included LAGB and RYGB patients (n=84), with the intervention (n=41) involving fortnightly 15 minute face-to-face and/or telephone counselling sessions with a registered dietitian for the first four months after surgery [269]. The sessions covered a range of issues including: transitioning from liquids to solid foods after surgery, promotion of protein intake, reducing intake of sugar and fat, and advice for avoiding over-eating, vomiting and dumping [269]. The ‘standard postoperative care’ group (n=43) did not receive any formal dietary counselling; however a dietitian was available as required [269]. Weight loss across the 24 month follow-up period was very similar between the two groups; however the intervention group reported marginally higher levels of dietary restraint and lower levels of perceived hunger [269].

Overall, the insight provided by Sarwer et al. study into specific techniques that may assist with the optimisation of weight loss is unfortunately limited. This may be largely attributable to the design of their study, where the described dietary intervention is not
dissimilar to typical postoperative dietary care reported elsewhere in the literature [45, 60, 81, 82, 88], including the dietary intervention undertaken for this thesis [252], rather than examining specific or targeted dietary or behavioural strategies for the optimisation of weight loss. This remains to be elucidated by future research.

7.2.3 Optimising other dietary-related outcomes after LAGB

Although limitations of the dietary intake assessment methodologies used in this thesis (Section 7.3.2) lessen the overall reliability of the dietary intake data collected, several preliminary insights regarding nutrient intake, diet quality and food tolerance as other key factors in the dietary management of individuals who have had LAGB arise from this data. These may provide a basis for future research to better inform the dietary management of LAGB patients and are discussed below.

7.2.3.1 Nutrient intake and diet quality

Protein intake

Protein intake data for both the pilot dietary intervention and cross-sectional study was very similar to previous reports of protein intake after LAGB [233, 237], falling within the range of approximately 50-80 grams per day; and mean/median intake was consistently above 60 grams per day, consistent with existing recommendations for individuals who have had obesity surgery, albeit non-evidence based [89]. Post-operative protein intakes as a percentage of daily energy were within AMDRs for both studies, and mean protein intake relative to body weight was within estimated average requirements (0.6-0.7g/kg/day) in the intervention study. Although relative protein intake was not specifically calculated for the cross-sectional study, it is notable that the range of protein intakes and mean post-operative body weights reported in the cross-sectional study are comparable with 12 month post-operative data for the intervention study. It is also notable that loss of FFM was not clinically significant in the intervention study, for which protein intake is recognised as a contributing factor during weight loss [148]. Collectively these results suggest that inadequate protein
intake following LAGB is not necessarily problematic, especially when considered in the context of an energy-restricted diet.

A recent cross-sectional analysis of dietary intake at 12 months post-LAGB conducted by McGrice and Porter[233], although using the same FFQ methodology as the cross-sectional study in this thesis and reporting very similar macronutrient intake data, suggested that protein intake is inadequate after LAGB in the context of recommended dietary intakes (RDIs) [233]. However, given that the Australian RDIs used as a reference point in McGrice and Porter’s study represent a level of intake sufficient to meet the nutrient needs of 97-98 per cent of healthy individuals within a given life stage and gender group [244], the applicability of these RDIs following LAGB is questionable given that post-operative dietary intakes are typically characterised by significant restrictions in energy intake, for which general population RDIs may not be realistically achievable. Furthermore, RDIs are not recommended for the assessment of group intakes [244], reducing the validity of McGrice and Porter’s findings.

These difficulties in interpreting the adequacy of protein intake after LAGB highlight that is a need for further research to better establish specific protein intake targets for individuals who have had obesity surgery; taking into account the prevention of protein deficiency as well as optimal intake for favourable weight loss and body composition outcomes, whilst maintaining overall dietary balance in the context of an energy-restricted diet. Until such research and evidence becomes available, this thesis indicates that there is no clear evidence to support that inadequate protein intake is a key dietary issue after LAGB.

Other nutrients

Beyond protein intake, adequacy of intake of a more diverse range of macro and micronutrients did not appear to be generally problematic in the cross-sectional study; however intakes of fibre, potassium, folate, magnesium, calcium in women aged over 50 years, iron in premenopausal women and zinc in men were below respective recommended intakes; whilst saturated fat intake as a percentage of daily energy intake exceeded the SDT for chronic disease risk reduction, indicative of suboptimal
diet quality after surgery. In support of these findings, similarly low levels of fibre and high levels of saturated fat intake were recently observed by McGrice and Porter [233] (with other nutrients not examined in the study of McGrice and Porter). This supports that there is scope for the improvement of diet quality following LAGB, and that this represents an important component of dietary follow-up after surgery.

Carbohydrate intake as a percentage of daily energy intake was lower than AMDRs in both the cross-sectional study of this thesis and McGrice and Porter, with intakes of approximately 40% of daily energy intake reported in both studies (Chapter 6),[233]. This also supports that there is potential to improve diet quality after LAGB by promoting the intake of wholegrain-based carbohydrate foods in place of foods high in saturated fat, which would also be beneficial for promoting increased fibre intake after surgery. The proportionally lower intake of carbohydrates than recommended may reflect difficulties in eating such foods, given that foods such as bread, pasta and rice were commonly reported as somewhat difficult to eat in both the interventional and cross-sectional studies [281], (Chapter 6); highlighting that concurrent advice regarding eating methods to prevent food tolerance may be of particular importance in promoting greater intake of wholegrain carbohydrates/high-fibre foods.

### 7.2.3.2 Food tolerance

Since undertaking the systematic review component of research for this thesis in 2009/2010, for which no specific food tolerance outcomes were identified within studies that met criteria for inclusion in the review, several papers have been published regarding food tolerance after LAGB [123, 191, 219, 222, 260], highlighting this as an emerging issue for the dietary management of individuals who have had LAGB. Overall there are inconsistencies in this literature regarding the scope and significance of problematic food tolerance after LAGB, where there is some indication that food tolerance is particularly problematic after LAGB when compared with other procedures [191, 219, 220]; yet there is also some evidence that food tolerance does not impact significantly on overall weight loss or quality of life outcomes [123, 222].
Overall, the findings of this thesis are supportive of the existing literature examining food tolerance, weight loss and quality of life after LAGB, where no significant relationship were identified between overall food tolerance score and weight loss or quality of life in the cross-sectional study (Chapter 6). Although the impact of food tolerance on these outcomes was not assessed in the dietary intervention study, it is notable that food tolerance scores were higher (reflecting better food tolerance) in both the dietary intervention and cross-sectional study (Chapters 5 and 6) than other reports of food tolerance that have used the food tolerance checklist [191, 219]. It must also be acknowledged that some elements of potentially problematic food tolerance were identified in this thesis, primarily the reported difficulty in eating some nutrient dense foods, including meat and complex carbohydrate foods such as bread. This is consistent with the findings of previous research [123, 191].

Collectively, this suggests that although food tolerance remains an important clinical concern at an individual level, poor food tolerance may not be a ubiquitous problem for all individuals who have LAGB. It is important to note that food tolerance has the potential to be mediated significantly by post-operative follow-up; including dietary and behavioural counselling for appropriate eating methods and band adjustment protocols. If an individual can adopt the required behaviours and are supported to do so via ongoing follow-up, food tolerance issues may be to a large extent avoidable or manageable. This however needs to be further explored by interventional research in order to better define dietary management strategies for the optimisation of food tolerance outcomes.

With respect to the measurement of food tolerance after obesity surgery, for which there are no wholly validated or universal tools currently available, findings from both the intervention and cross-sectional studies suggest that the ‘satisfaction with eating ability’ sub component of the food tolerance checklist may be influenced by behavioural constructs, with both studies identifying an inverse association between disinhibition and satisfaction score (Chapters 5 and 6), although results did not reach statistical significance in the intervention study. This relationship has not been
examined in previous research utilising the food tolerance checklist, and suggests that further development of the food tolerance checklist may be warranted to better distinguish ‘physical’ aspects of food tolerance from psychological constructs.

7.2.4 Overall insights into LAGB arising from this thesis

Results from both the intervention study and cross-sectional study within this thesis (Chapters 3-5) mirror the variability in the wider literature regarding weight loss following LAGB. There have been increasing reports of high ‘failure’ rates, inadequate long-term weight loss and weight regain following LAGB in recent years [71, 234, 250, 258] and irreversible procedures such as SG and RYGB are being increasingly promoted and undertaken in place of LAGB [66, 250, 282, 283]. This is reflected by the decline in LAGB procedures undertaken in Australia since the commencement of this thesis in 2008, when LAGB reached a peak in popularity (Figure 1.4, Chapter 1).

Beyond weight loss, variability in dietary intake, eating behaviour and food tolerance outcomes following LAGB are also evident from this thesis, consistent with the wider literature in this area [60, 82, 109, 123, 217, 233, 237]. Although findings support that improved/positive eating behaviours and reduced energy intakes are achievable following LAGB; findings relating to continued vulnerability to emotional eating, problematic dietary compliance, suboptimal diet quality and difficulties in eating some nutrient-dense foods, also highlight that positive outcomes for a range of diet-related factors are not guaranteed following LAGB. Variability in outcomes and subjective experiences of LAGB is also exemplified by the qualitative feedback provided by respondents of the cross-sectional study (Appendix 19), with positive feedback regarding weight loss and wellbeing supporting that LAGB is highly beneficial for many obese individuals; yet negative comments regarding inadequate weight loss, persistent emotional eating and difficulties with eating certain healthful foods also supports the potential for negative or suboptimal outcomes to ensue after surgery.

Considering the complexity of obesity in terms of its multifactorial aetiology and refractory nature [284], it is well recognised that it is unlikely there will be one single,
completely efficacious treatment strategy for obesity in the foreseeable future. Within this context, obesity surgery remains the most effective treatment option available, and LAGB is uniquely placed as a low risk procedure the only reversible procedure with proven weight loss efficacy [43]. Given that all obesity surgery procedures are subject to limitations in terms of operational risk, postoperative complications, potential for inadequate weight loss and/or weight regain and other potential adverse health outcomes including poor nutrition [35, 285, 286], arguably it may be more beneficial to identify and implement effective intervention strategies for patients who experience difficulties in modifying dietary and lifestyle behaviours after LAGB, rather than recommending alternative, irreversible procedures as a first line response to poor weight loss following LAGB.

7.3 Research strengths and limitations

In addition to the strengths and limitations of each component of research undertaken as outlined within the published/submitted papers of the preceding chapters, collective strengths and limitations of the body of research are detailed below. Following this is further discussion of limitations of the individual components of original research undertaken, which must be taken into account when interpreting overall findings and significance of this body of work.

7.3.1 Strengths

The body of research undertaken for this thesis considered a comprehensive range of outcomes that are relevant to the dietary management of individuals who have had LAGB. This included: weight loss, body composition, dietary intake, eating behaviours, food tolerance and quality of life after surgery. To our knowledge, this represents the one of the widest ranges of dietetically relevant factors following LAGB to be examined in one body of research. Despite the collective limitations of the research undertaken (Section 7.3.2), this thesis therefore contributes a depth of data to the existing evidence base for diet-related outcomes after LAGB. The value of this in providing insights for practice, future research and data for future meta-analyses is significant given the
currently limited evidence base available to inform the best practice dietary management of individuals who have had LAGB.

This thesis includes the first systematic reviews of dietary intake and eating behaviour outcomes exclusively after LAGB, as well as the first dietary intervention study to examine a potential dietary strategy for the optimisation of weight loss and body composition in individuals who have had LAGB. The systematic reviews highlight the paucity of evidence currently available to inform the best practice dietary management of individuals who have had LAGB, and make a valuable contribution to informing future research in this field. Ultimately this may assist the ongoing development of best practice dietary management practices for individuals who have had LAGB.

Although the intervention was a pilot study, results obtained represent the first contribution to the evidence base from an interventional study design; and the implications of key findings relating to compliance difficulties in a ‘real world’ setting provide a valuable, practical contribution to dietary management practices for LAGB patients.

The cross-sectional study represents one of the most comprehensive diet and eating behaviour-related surveys undertaken in the LAGB population; and to the best of our knowledge includes the most in depth assessment of dietary intake against national dietary intake guidelines in LAGB patients, with the inclusion of micronutrient intakes and consideration of chronic disease risk reduction targets.

Notwithstanding the relatively small sample sizes of the studies within this thesis, the sophisticated statistical analyses that were used are an additional strength of this body of work, maximising the power and insightfulness of results obtained. Key advantages of the use of linear mixed models to analyse intervention effects and longitudinal data for the dietary intervention include: maximal inclusion of all available data given that LMMs have the capacity to accommodate missing data, assisting to minimise bias arising from listwise deletion of subjects with incomplete data; flexibility to include fixed factors (including gender and diet allocation) as well as time-dependent and non-time dependent covariates in a model, maximising the range of factors that can be
evaluated; and the capacity to consider different covariance structures (relating to how repeated observations across time are correlated) in order to better establish a best-fit model for the data[287]. The inclusion of multiple regression analyses within the cross-sectional study enabled the relationship between multiple diet-related factors and weight loss and quality of life after LAGB to be simultaneously examined, whilst also allowing for potential control variables/confounders to be accounted for.

A final overall strength of the research undertaken for this thesis is that all components of investigation exclusively involved LAGB patients. Thus the results of this research are not confounded by the inclusion of other surgical procedures, which is a limitation of some previous research in this area. This is important given that the dietary management needs of individuals who have had different types of obesity surgery differ according to the specific anatomical alterations and physiological effects of the procedure undertaken.

### 7.3.2 Limitations

#### 7.3.2.1 Broad limitations

Several broad limitations of the research undertaken for this thesis need to be acknowledged. Firstly, the intervention and cross-sectional studies (Chapters 4-6) involved small samples derived from the private healthcare setting only, thus findings are not necessarily generalisable to the wider LAGB population. Given that LAGB is predominantly privately funded in Australia, the private healthcare setting of this research is however representative of the norm for LAGB in Australia. Attrition from the intervention study (Chapters 4 and 5) and potential non-response bias in the cross-sectional study (Chapter 6) may further impact on generalisability of conclusions made. However, with the exclusion of weight loss in the intervention study (discussed in Section 7.3.2.4) general characteristics of subjects and dietary outcomes were generally similar previous reports of LAGB patients, providing support that the sample populations were somewhat representative of the wider LAGB population.
The relatively short-term nature of the research undertaken is another overall limitation of this research. It must be acknowledged that long-term outcomes remain of most importance, and there is a great need for further long-term research in the areas of weight loss and dietary management of individuals who have had LAGB given that weight regain in the longer term after surgery represents one of the greatest known shortcomings of LAGB.

Although the exclusive focus on LAGB patients can be considered a research strength given that it ensures specific applicability to individuals who have had LAGB without confounding from other obesity surgery procedures; given the declining global popularity of LAGB since project inception in 2008, the potential reach of thesis findings may be lessened in accordance with the reduced numbers of individuals who have had LAGB in recent years. Nevertheless, LAGB remains the most popular procedure in Australia and one of the most commonly performed procedures worldwide [28], supporting the ongoing importance of research into the dietary management of individuals who have had LAGB.

7.3.2.2 Factors not examined in the research

Issues identified from systematic reviews
The systematic reviews of dietary intake and eating behaviour identified several gaps in the evidence base that were not included as a focus for the other components of research undertaken for this thesis. This includes eating frequency, diet quality, food consistency (i.e. solid versus liquid foods) and specific eating disorders such as binge eating and night eating syndrome. These remain important considerations for future studies.

Physical activity
Physical activity is well-recognised as an integral determinant of energy balance and an important contributor to successful weight loss. A recent systematic review of exercise after obesity surgery (including LAGB and RYGB) reported a positive relationship between increased exercise and weight loss in the majority of studies.
included in the review (n=15/17) [288], highlighting the likely importance of physical activity in contributing to weight loss after surgery. Although it was attempted to assess physical activity in the interventional and cross-sectional studies using the International Physical Activity Questionnaire (short version) [226], this data was not included in final analyses due to poor reporting by study participants and the generally low reliability of self-report physical activity data in small study samples [230, 289]. The non-inclusion of physical activity in the assessment of weight loss and body composition outcomes represents a notable shortcoming of the overall findings regarding these outcomes.

Markers of metabolic health

The importance of metabolic health as a key outcome following obesity surgery is well-recognised, with important markers of metabolic health including blood lipid profile and insulin metabolism [31, 290]. Although it was attempted to collect this data as part of the intervention study, poor attendance for the collection of longitudinal pathology samples limited the analysability and insightful of this data. Thus it was not included as an outcome in the papers arising from the intervention study. Given that metabolic health is a major determinant of overall health outcomes, this is an important additional outcome for future studies to consider, especially those examining the effectiveness of different dietary and behavioural interventions for improving outcomes of surgery.

Complications of surgery

Medium to long term complications (for example band slippage and pouch dilatation) are also emerging as a significant issue following LAGB, where it has been suggested that high long-term complication rates reduce the overall viability of LAGB [234, 250]. Complications have the potential to impact negatively on weight loss, food tolerance and other diet-related outcomes in the longer-term; and it has also been suggested that maladaptive eating behaviours may increase/influence the development of complications [132, 291]. It was beyond the scope of this research to assess complications or the relationships these may have with diet and/or eating behaviours;
and this would not have been feasible due to the small sample population and relatively short-term nature of the studies undertaken. The potential impact that eating behaviour may have in the development of complications is another consideration for future longer-term research.

### 7.3.2.3 Methodological limitations

**Study design**

The systematic review component of research identified observational study designs and methodological weaknesses as inherent limitations of the evidence base for dietary intake and eating behaviour following LAGB. With the exception of findings related to the dietary intervention component of this research (Chapter 4), given the observational nature of the analysis of eating behaviour (Chapter 5) and cross-sectional study (Chapter 6), these components of research do not provide a higher level of evidence (based on NHMRC guidelines) than previous research in this area. Nevertheless, the research within this thesis contributes further depth and insight into the existing evidence base for diet and eating behaviour after LAGB, and will be of value for informing future interventional research into best-practice dietary management strategies for individuals who have LAGB.

**Assessment of dietary intake**

Misreporting of dietary intake is a ubiquitous limitation of studies examining dietary intake via self-report data without an objective validation marker [266]. It must be acknowledged that the unknown validity and reliability of the self-report dietary intake assessment methods used in this thesis represents a significant limiting factor in the interpretation and application of dietary intake findings overall. Specific limitations of the dietary intake methods used in each component of research are further addressed in Section 7.3.2.4.
Assessment of eating behaviour

In addition to the observational nature of eating behaviour findings in this research, the use of the TFEQ to assess eating behaviour may be considered another limitation of this research. Although the TFEQ is a standardised tool with previously published validity [141] and is the most frequently used eating behaviour assessment tool in the existing LAGB literature [217, 218], it is also subject to several shortcomings, including: a tendency to measure intended rather than actual behaviour [292-294]; an overall lack of specificity in behaviours measured [134]; and construct validity uncertainties, including the multidimensionality of restraint (relating to flexible and rigid control) [261] and the overall stability of disinhibition and hunger as separate constructs [255]. These limitations reduce the potential depth of insight regarding eating behaviours in this research.

7.3.2.4 Specific limitations of each component of research

Systematic reviews

The scope and significance of the systematic reviews undertaken was limited by the paucity and low quality of research undertaken in the LAGB population. The scope of the reviews was further limited the by the inclusion of published studies only, thus it is possible that the reviews do not reflect the entirety of the evidence base given that data from theses and/or other non-published scholarly works was not considered.

There are several inconsistencies between the two systematic review papers (divided into two papers due to word-limit confines for publication) that need to be acknowledged. Specifically, the dietary intake review paper designates a ‘level of evidence’ rating to cross-sectional studies, whereas the eating behaviour review does not. Additional details are also provided in the dietary intake paper pertaining to study funding as part of the quality assessment undertaken. This is a consequence of the differential peer-review processes for these papers, and these discrepancies do not impact significantly on the overall interpretation of the results for this component of investigation.
Lastly, the systematic review process was undertaken during 2009/2010, thus the reviews do not incorporate new studies published from February 2010. It was not possible to systematically update these reviews within the timeframe for thesis completion; however, studies that are integral to the outcomes of this thesis that have been published since February 2010 have been incorporated into this final discussion chapter.

**Protein-enriched dietary intervention**

It was originally intended that the pilot dietary intervention (Chapter 4) would be a full-scale randomised intervention examining the efficacy of a protein-enriched diet for improving weight loss, body composition, metabolic and resting energy expenditure outcomes following LAGB. However, circumstances beyond the control of the researchers necessitated the remodelling of this study to a pilot study. Due to the change in the aims of the study after its commencement, not all elements traditionally included in a feasibility assessment were systematically assessed, including: willingness of subjects to be randomised, feasibility of recruitment strategies and formal process evaluation relating to acceptability of the intervention and study measures/materials [295].

Despite this, meaningful feasibility implications were still evident from the study, including that: compliance with the powdered protein supplement was suboptimal and as such was not a viable modality for delivering enhanced protein intakes; the frequency of intervention contact (every 4-6 weeks) may not be adequately intensive to achieve compliance; and the immediate post-operative period may not be the most optimal time to implement such an intervention given the extensive dietary changes that individuals need to adjust to following surgery. Furthermore, difficulties in achieving adequate participation in the collection of various specialised study measurements that required attendance at several different facilities (including blood samples, DXA measurements and REE expenditure measurements) suggests that a more streamlined approach to undertaking study measurements would be required for the successful collection of this data.
With respect to the diet model for the intervention, it could be argued that the protein-enriched intervention as intended was not reflective of minimum targets for a “high protein” diet in terms of protein intake relative to body weight [116]. The protein-enriched eating plan was designed however to be consistent with anticipated reduced volumes of food intake following LAGB. In this context, it was considered neither ethical nor practical to prescribe a higher level of protein intake without potential introduction of dietary imbalances and/or adverse effects on renal function, given the vulnerability of bariatric surgery populations to such problems [296]. Regardless, even the modestly increased protein intake targets were not achieved by the intervention group.

Due to practical difficulties at the commencement of recruitment, allocation to the intervention or control group was not randomised, reducing the strength of the study design. It is also possible that this resulted in the intervention group being slightly heavier than the usual care group at baseline (approximately 6kg difference; BMI: 42.8 versus 40.3 kg/m$^2$). This difference was not statistically significant however; and baseline weight was controlled for to minimise the potential impact of this on study findings.

It must also be acknowledged that the validity of the dietary data collected is likely to have been suboptimal. Under-reporting of energy intake at baseline was also identified in 28% of the study population, and it is possible that under-reporting may have worsened during the study period, as has been demonstrated in overweight and obese individuals after participating in a behavioural weight loss intervention [297]. This potential for misreporting is likely to have been compounded by the mixed methodologies used to assess dietary intake.

Although the validity of mixed methodology for collecting longitudinal dietary data is questionable, the change in dietary intake methodology after study commencement was unavoidable given that the poor return of three day food records at the commencement of six month data collection threatened the viability of continuing with the study. Participant burden was identified as the primary cause for the poor return of
food records, whereby most participants who failed to return their food record (despite several reminders/requests from the student researcher) reported having insufficient time available to complete their record. It was deemed better to change the dietary intake methodology to 24-hour recalls in order to: (i) reduce participant burden; (ii) maximise the completeness of dietary intake data for the remainder of the study sample; and (iii) maximise ability to assess overall dietary compliance with the intervention, given the high risk of having insufficient data available for any dietary analyses to be conducted.

Despite the collective limitations of the dietary intake data collected, reported energy and macronutrient intakes from the study are similar to previous studies in LAGB subjects [233, 237], thus it is arguable that misreporting is unlikely to be any more problematic in this study when compared with the existing literature. The inclusion of doubly-labelled water and/or urinary nitrogen excretion will be valuable for internal validation of dietary intake and compliance data for future studies in this field [239].

As highlighted in the discussion of Chapter 4, weight loss in the intervention study was less than most previous reports of weight loss following LAGB. With respect to generalisability of findings, this suggests that the study sample population was innately different from previous studies. In explaining this, the study required volunteers to participate in a specific dietary intervention; whereas the bulk of the evidence base for weight loss after LAGB is derived from observational studies, which imply a different level of participation. It is possible subjects who felt they would benefit from additional support were more likely to volunteer to participate in a research study that provided an opportunity for cost-free, additional dietetic assistance. It cannot be discounted that study participants may have represented a subgroup of patients who were predisposed to poorer weight loss outcomes, potentially mediated by lower self-efficacy or other underlying behavioural characteristics. Although this may be considered a limitation, arguably this population group is representative of individuals who are most in need of evidence-based interventions that may help to maximise weight loss after surgery.
Finally, information regarding psychological input was not collected as part of the study, which may have contributed further insight into behavioural issues associated with adherence to the intervention diet and eating behaviour outcomes. The practices involved in the study typically referred individuals to psychology services on an “as needs” basis at the time the study was undertaken. It is possible that more routine psychological support may have promoted better dietary adherence and eating behaviour outcomes in the study population; however it was beyond the scope of this research to modify usual care pathways within the practices involved in the study.

Eating behaviour analysis

In addition to the overall limitations of assessing eating behaviour using the TFEQ and the mixed dietary intake methodologies utilised, this paper assessed eating behaviour outcomes as a static measure at each time rather than change scores. There is some evidence from both the surgical and non-surgical weight loss literature to suggest that magnitude in change of behaviour is of more predictive value/insight than static measures of eating behaviour [256] [142] and it is possible that this paper may have offered additional insight if change scores were included within the analysis. However, due to the incomplete nature of the prospective eating behaviour data that was collected, it was deemed that the use of change-scores would be likely to amplify difficulties associated with attrition bias/incomplete data bias given that change scores rely on the availability of paired data from each successive time point, and thus can result in more cases being excluded from analyses in situations of missing data.

It also needs to be acknowledged that there are some inconsistencies in participation and retention rates between the eating behaviour analysis and the pilot intervention from which data was derived, impacting on continuity between studies. These reflect differences in the availability of specific data for each investigation. Retention for the intervention was based on weight and body composition data, whereas retention for the eating behaviour analysis was based on eating behaviour data. Specifically, one subject participated in weight and body composition measures at baseline, but did not provide survey data, accounting for the difference in reported sample sizes (46 versus
At three months, several participants who remained with the study did not complete/return survey booklets (n=7), resulting in the smaller retention rate for the eating behaviour analysis; whereas at 12 months, one participant mailed in survey data but did not attend weight or body composition measurement sessions, resulting in a slightly higher reported retention rate (72% versus 70%).

Cross-sectional study

Funding limitations prevented the distribution of surveys beyond the local study area; thus the survey had only a small reach. To protect the privacy of individuals within the LAGB practices participating in the research, the distribution of surveys was facilitated by the practices, whereby the researchers had no direct contact with potential respondents. It was not possible to send survey recipients reminders to complete the survey (in line with best practice for maximising response rate) as this would have imposed an unacceptable additional workload for the practices involved. Consequently the response rate for this component of research was unavoidably low.

The lack of relationship between eating behaviour, dietary intake and weight loss in the cross-sectional study was not intuitive. It may be explained by limitations of the TFEQ in measuring eating behaviour, social desirability bias in responding to questions about eating behaviour and the potential misreporting of dietary intake data. The FFQ used may have been vulnerable to under-reporting given that it did not include food categories for items such as soft drinks and various miscellaneous snacks/sweets, and is also subject to the typical limitations of FFQs, including reliance on an extended period of recall for past food intake, potentially inaccurate estimation of portion sizes and limited potential for food specification [298]. The small number of subjects who completed the FFQ component of the study may have also limited power to detect significant relationships between weight loss and dietary intake variables.

Finally, although the cross-sectional nature of the study largely precludes its utility for informing practice per se, findings of the study remain of potential value for future research into the development evidence-based dietary management strategies for individuals who have had LAGB.
7.4 Implications for practice and future research

The primary implication for practice arising from this thesis originates from the pilot dietary intervention component of research, which indicates that the potential utility of a protein-enriched diet in the early postoperative period after LAGB, or potentially any diet of a specific macronutrient composition aimed at optimising outcomes, is vulnerable to negation due to problematic compliance. Given that this conclusion is based on pilot data only, further larger-scale, adequately powered trials are however needed to better establish the potential utility of such diets, with methods to enhance compliance that translate easily to practice being a core consideration for such research.

This thesis also identifies several important directions and considerations for future research into best practice dietary management strategies for optimising a range of outcomes following LAGB. Firstly, there is a critical need for further interventional research into: i) overall dietary management protocols that promote best possible, sustainable changes in eating behaviour as a whole following LAGB, and ii) effective post-operative intervention strategies for minimising emotional-type eating behaviours in susceptible individuals. Integral to the latter is the need to identify/develop reliable and sensitive tools to detect individuals who are ‘at risk’ of poorer outcomes (weight, behavioural and/or dietary) during the early postoperative period so that appropriate and tailored interventions may be undertaken.

The selection of eating behaviour measurement tools, and/or the development and validation of tools that more specifically capture problematic eating behaviours following obesity surgery, is a vital consideration for future studies examining the relationship between eating behaviour, weight loss and other outcomes of LAGB. Given the inherent difficulties associated with defining and measuring specific eating behaviours, it may be more beneficial for future research to focus on developing: reliable postoperative screening tools for problematic eating behaviours after surgery for the identification of individuals may benefit from more intensive behavioural intervention, rather than attempting to define or predict specific behaviours associated
with ‘success’ or ‘failure’ as a candidate selection tool for surgery which has been the focus of much previous research [95, 127, 137, 299-301].

Fundamentally linked to the need for further research into eating behaviour interventions is the need for further exploration of methods/interventions to enhance compliance with required dietary modifications, particularly for individuals ‘at risk’ of poor compliance and subsequently poorer outcomes. Future directions for intervention studies aimed at improving dietary compliance and eating behaviour for improved outcomes may include: further development of multifactorial/interdisciplinary management protocols (involving medical/surgical, dietetic and psychological care) [285, 302]; assessment of the utility of best-practice elements of lifestyle interventions for weight loss (including for example, cognitive behaviour therapy, self-monitoring of weight and dietary intake and continued/extended patient-provider contact [302]), motivational interviewing [275]; web-based interventions for improving compliance [303] and social support group programs [304]. Future research into intervention strategies to promote sustainable physical activity after LAGB may also provide an important adjunct for achieving optimal weight loss after surgery [288].

There is also a need to establish the best timing for behavioural interventions for suboptimal weight loss after LAGB, with consideration given to different subsets of individuals including: i) individuals who experience inadequate weight loss from the outset, for which early and sustained post-operative intervention may be most beneficial; and ii) individuals who initially achieve weight loss targets (for example within the first 12 months of surgery) but reach an early plateau in weight loss and/or experience weight regain in the longer-term, for whom ‘back on track’ programs are required [305].

This thesis also highlights that there remains a need for specific evidence-based nutrient intake guidelines for individuals who have undergone obesity surgery to be developed, with attention given to the differing physiological effects of different types of surgery. There also remains a need for further research into best practice management strategies for the optimisation of a range of dietary-related factors
following LAGB, including: diet quality, food tolerance, eating frequency, food consistency and the management of specific eating disorders such as binge eating.

In response to the methodological limitations within the research undertaken for this thesis, larger scale dietary intervention trials should include an objective marker of dietary intake validity (for example doubly labelled water) and use improved/consistent assessment methods for dietary intake. Similarly, more specific methods of measuring eating behaviour are also required for research examining eating behaviour as a key variable. Future intervention studies should also include an objective measure of physical activity (e.g. accelerometers or pedometers) to better assess/account for the potential influence of exercise on changes in weight and body composition. Future studies should also include quality of life as a key overall outcome of LAGB.

Given the difficulties associated with undertaking dietary interventional research in this population group, it may also be important for diet and eating behaviour outcomes to be included in national obesity surgery outcome databases in order to maximise data available for analysing these outcomes in lieu of adequately powered, randomised intervention studies.

Finally, there is a need to extend research regarding optimal dietary management strategies to other popular and emerging surgical procedures, taking into account the unique needs for each type of surgery based on physiological alterations as well as issues associated with compliance and non-hungry eating.

7.5 Final conclusions

This research highlights that there remains a limited evidence base available to guide best practice dietary management of individuals who have had LAGB. Results of this thesis suggest that the specific nutrient composition of the post-operative diet appears to be of lesser importance than eating behaviour in influencing weight loss outcomes after surgery. Results also support that emotional eating and problematic compliance represent key targets for future interventions investigating the optimisation of weight
loss outcomes after LAGB; and there remains a critical need to develop effective interventions for individuals identified as ‘at risk’ of poorer outcomes. Overall, although LAGB remains well-placed as a surgical treatment option for the management of obesity, this thesis highlights that further well-designed, adequately-powered interventional research is required to better inform management strategies for the optimisation of weight loss and other diet-related outcomes following LAGB.
References


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Appendices
Appendix 1  
Author contribution statements for each publication
1) "A systematic review of dietary intake after laparoscopic adjustable gastric banding"

I attest that Research Higher Degree candidate Alison A Fielding contributed to the following paper:


Alison A Fielding developed the review protocol, conducted the literature search and contributed to identification of studies for inclusion in the review, conducted quality assessments and data extraction for included studies and drafted the manuscript.

Associate Professor Surinder Baines was the second reviewer for the systematic review, and therefore contributed to selection of studies for inclusion in the review, conducted quality assessments and verified data extraction. Associate Professor Surinder Baines and Associate Professor Helen Warren-Forward both contributed to the development and critical review of the manuscript within the capacity of their role as PhD supervisors.

.......................................................... Date: 26/11/2012
Alison Fielding

.......................................................... Date: 19/12/2012
Surinder Baines

.......................................................... Date: 6/12/13
Helen Warren-Forward

.......................................................... Date: 3/1/12
John Rostas, Faculty of Health Deputy Head (Research and Research Training)
2) "Changes in eating behavior after laparoscopic adjustable gastric banding: A systematic review of the literature"


Alison A Fielding developed the review protocol, conducted the literature search and contributed to identification of studies for inclusion in the review, conducted quality assessments and data extraction for included studies and drafted the manuscript. Associate Professor Surinder Baines was the second reviewer for the systematic review, and therefore contributed to selection of studies for inclusion in the review, conducted quality assessments and verified data extraction. Associate Professor Surinder Baines and Associate Professor Helen Warren-Forward both contributed to the development and critical review of the manuscript within the capacity of their role as PhD supervisors.

Allison Fielding .................................. Date: 24/11/2012
Surinder Baines .................................. Date: 19/10/2012
Helen Warren-Forward ......................... Date: 6/12/2013

John Rostas, Faculty of Health Deputy Head (Research and Research Training)
3) "Feasibility of a protein-enriched diet after laparoscopic adjustable gastric banding: results from a pilot intervention"

I attest that Research Higher Degree candidate Alison A Fielding contributed to the following paper:


Alison A Fielding contributed to the conception and design of the study, provided dietetic instruction related to the intervention, conducted data collection, analysed data and drafted the manuscript. Associate Professor Surinder Baines and Associate Professor Helen Warren Forward contributed to the conception and design of the study and to the preparation and critical review of the manuscript within the capacity of their role as PhD supervisors.

Alison Fielding
Date: 26/11/2012

Surinder Baines

Helen Warren Forward

Date: 6/12/2012

John Rostas, Faculty of Health Deputy Head (Research and Research Training)
4) "Eating behaviour after laparoscopic adjustable gastric banding: relationship with weight loss, dietary intake and food tolerance outcomes"

I attest that Research Higher Degree candidate Alison A Fielding contributed to the following manuscript:

Eating behaviour after laparoscopic adjustable gastric banding: relationship with weight loss, dietary intake and food tolerance outcomes, currently submitted to *Appetite* for consideration for publication.

Alison A Fielding contributed to the conception and design of the study, collected the data, conducted data analysis and drafted the manuscript. Associate Professor Surinder Baines and Associate Professor Helen Warren Forward contributed to the conception and design of the study and to the preparation and critical review of the manuscript within the capacity of their role as PhD supervisors.

.............................................. Date: 26/11/2012
Alison Fielding

.............................................. Date: 27/12/2012
Surinder Baines

.............................................. Date: 6/1/2012
Helen Warren Forward

.............................................. Date: 3/1/2012
John Rostas, Faculty of Health Deputy Head (Research and Research Training)
5) "A snapshot of eating behaviour, food tolerance and dietary intake after laparoscopic adjustable gastric banding"

I attest that Research Higher Degree candidate Alison A Fielding contributed to the following paper:

A snapshot of eating behaviour, food tolerance and dietary intake after laparoscopic adjustable gastric banding, currently submitted to Bariatric Surgical Patient Care for consideration for publication.

Alison A Fielding contributed to the conception and design of the study, conducted data analysis and drafted the manuscript. Associate Professor Surinder Baines and Associate Professor Helen Warren Forward contributed to the conception and design of the study and to the preparation and critical review of the manuscript within the capacity of their role as PhD supervisors.

........................ Date: 26/11/2012
Alison Fielding

........................ Date: 9/12/2012
Surinder Baines

.............................. Date: 6/12/12
Helen Warren-Forward

........................ Date: 30/12/12
John Rostas, Faculty of Health Deputy Head (Research and Research Training)
Appendix 2  Quality assessment tool
Selection bias

- Are the individuals selected to participate in the study likely to be representative of the target population?
- What percentage of selected individuals agreed to participate?

Study design

- Indicate the study design
- Was the study described as randomized?
- If Yes, was the method of randomization described?
- If Yes, was the method appropriate?

Confounders

- Were there important differences between groups prior to the intervention?
- If yes, indicate the percentage of relevant confounders\(^a\) that were controlled (either in the design (e.g. stratification, matching) or analysis)?
- For observational studies, were study settings, interventions and clinicians described in detail? Were confounding factors controlled for in analysis or considered in discussion?

Blinding

- Was/were the outcome assessor(s) aware of the intervention or exposure status of participants?
- Were the study participants aware of the research question?

Data collection methods

- Were data collection tools shown to be valid?
- Were data collection tools shown to be reliable?

Withdrawals and drop-outs

- Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?
- Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

\(^a\) Potential confounders considered included: race, sex, body mass index, age, socioeconomic status, education and health status. Additional potential confounders that were considered as relevant to dietary intake after LAGB include: medications, band adjustments, post-operative follow-up and nutritional/dietary advice provided.

Source: adapted from the Quality Assessment Tool for Quantitative Studies, Effective Public Health Practice Project [97].
Appendix 3  Protein-enriched dietary intervention: Original research aims and questions
Study Aims

This study aims to determine the usefulness of a high protein diet in optimising nutrition-related health outcomes in obese individuals who have LAGB.

Aim One

To determine if there are any differences in weight loss, body composition, resting metabolic rate, waist circumference, blood lipid profile, inflammation, glucose metabolism, quality of life, eating behaviour, physical activity and food tolerance in individuals who receive a high-protein diet for six months following gastric banding surgery when compared with usual care.

Aim Two

To determine if any differences found in Aim One are sustainable over the six to 12 month period following gastric banding, to assess whether or not a six month high protein diet has any longer term benefits for individuals who have had gastric banding when compared with usual care.

Research Questions

Aim One

1. Is there any difference in percentage weight loss from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

2. Is there any difference in fat mass changes from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

3. Is there any difference in changes in FFM from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

4. Is there any difference in bone mass from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?
5. Is there any difference in waist circumference from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

6. Is there any difference in blood lipid profile (total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides) from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

7. Is there any difference in C Reactive Protein (a routine biomarker of inflammation) from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

8. Is there any difference in blood glucose levels and insulin (as measures of glucose metabolism) from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

9. Is there any difference in quality of life from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

10. Is there any difference in eating behaviour from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

11. Is there any difference in physical activity from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

12. Is there any difference in food tolerance from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?

13. Is there any difference in resting metabolic rate from baseline to six months between individuals who consume either a protein-enriched or usual care diet for six months following gastric banding surgery?
Aim Two

1. Are any differences in the nutrition-related variables specified in the Research Questions for Aim One sustainable for the following six months after the diet intervention?
Appendix 4  Protein-enriched dietary intervention: Participant Information Statement
Information Statement for the Research Project:

Nutrition Practice after Gastric Banding
Document Version 7; dated 14/08/09

You are invited to participate in the clinical trial identified above. This research is being conducted by Miss Alison Dodsworth (postgraduate student in Nutrition and Dietetics), Dr Surinder Baines (Senior Lecturer in Nutrition and Dietetics) and Dr Helen Warren-Forward (Associate Professor in Medical Radiation Science) from the School of Health Sciences at the University of Newcastle.

The research is part of Alison Dodsworth’s doctoral studies at the University of Newcastle, supervised by Dr Surinder Baines and Assoc. Prof. Helen-Warren Forward.

Why is the research being done?
The purpose of the research is to investigate the influence of protein intake on weight loss, body composition and nutritional outcomes following gastric banding. Currently there is little high quality evidence to guide nutrition recommendations for people who have had gastric banding. It is important to determine if there is a type of diet that best promotes healthy weight loss, body composition and nutritional outcomes following gastric banding. This will hopefully help to maximise the effectiveness of gastric banding, which is becoming an increasingly popular treatment strategy for weight management.

Who can participate in the research?
We are seeking women and men aged 18-65 years with a Body Mass Index >30kg/m$^2$ who are going to have gastric banding to participate in this research. You have been contacted because you are considering undergoing gastric banding or have recently had gastric banding.

Unfortunately you are not eligible to participate in this study if you:
- Have a condition that requires a highly specialised diet (for example kidney failure). If you require a specialised diet for other conditions (for example diabetes requiring insulin) or if you are vegetarian, the researchers will determine your eligibility on a case by case basis.
- Have a food allergy that presents a significant obstacle for complying with this study
- Are pregnant or breastfeeding
- Have a pacemaker or other electronic implant
- Cannot write or read English

In some circumstances your surgeon may decide that participation in the study may not be suitable for you. This will be confirmed by the researchers with your consent.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. Your care will continue with your surgeon and dietitian regardless of your decision to participate.
If you do decide to participate, you may withdraw from the project at any time without giving a reason. If you wish to withdraw you have the option of withdrawing any data which identifies you within a three month period of withdrawing.

The researchers may withdraw you from the study if you become pregnant or are diagnosed with any condition that will not allow you to follow the study eating plan (for example diabetes that requires insulin, coeliac disease). You may also be withdrawn from the study if your surgeon decides it is in your best interest to do so. If this happens, the researcher(s) will explain why and advise you about any follow-up procedures and your care will continue with your surgeon and dietitian without any disadvantage to you.

If you decide not to participate you are not required to take any further action.

What would you be asked to do?

This study will be 12 months in duration, consisting of two six-month phases. If you agree to participate, you will be asked to:

PHASE 1 (First six months)

1. Return a signed consent form.

2. Be assessed for your eligibility in the study. This will involve a telephone interview with Alison Dodsworth or another qualified dietitian and will take about 10 minutes.

3. If you are eligible to participate, you will be asked to attend an interview with Alison Dodsworth at either the University of Newcastle or your gastric banding dietitian’s clinic (subject to room availability). This interview will take place in a private consultation room. Alison Dodsworth or another qualified dietitian will complete all parts of the interview. At this session, you will:

   a) Have a diet history taken – this will involve a series of questions about your usual diet and timing of meals and/or snacks

   b) Have measures taken including:
      • Your height – only shoes need to be removed, standing on scales
      • Your weight – only shoes removed
      • Your waist – using a tape measure, which may require loosening of belt
      • Your body fat and fat free mass – using bioimpedance analysis, which is similar to standing on an ordinary set of scales

   c) Complete some questions/surveys relating to:
      • Your physical health and medications
      • Your quality of life
      • Factors that affect your eating behaviours
      • Physical activity
      • Food tolerance

   d) Be asked to follow either the usual healthy eating plan that your dietitian recommends or the study intervention that involves a high protein eating plan. This eating plan includes a protein powder supplement. The supplement is derived from whey protein in milk, however it is lactose free. You will still receive care from your gastric banding dietitian regardless of which group you are allocated to. You will be randomly assigned to one of the two eating plans using a computer-generated random number system. The eating plan you are allocated to follow will be explained to you in full at the interview. You will also be provided with helpful tips and have the opportunity to ask any questions.
e) Be given a referral for a blood sample. The blood sample will be taken for the purposes of assessing your lipid levels (eg cholesterol), CRP (a routine biomarker for inflammation), glucose levels, insulin sensitivity, thyroid function. The blood sample will also be analysed for urea, electrolytes and creatinine as a marker of compliance with the study diet. Blood samples will be taken at a Hunter Area Pathology Service convenient to you. The blood sample has to be taken within 3 weeks of having your gastric banding procedure.

f) Be given a referral to have your muscle, fat and bone mass measured taken using dual energy x-ray absorptiometry (DXA) at the John Hunter Hospital. DXA involves having a very low dose radiation x-ray. All scans will be taken by a qualified DXA operator. The DXA scan also has to be taken within 3 weeks of having your gastric banding procedure.

4. Be phoned twice by Alison Dodsworth during the first six months of the study (at weeks 6 and 18) to discuss how you are going with your eating plan. This will include answering questions about your food and drink intake. You will also have the opportunity to ask questions and raise any concerns you may have about the eating plan. This call also provides you with a chance to chat to a dietitian without having to take time out to travel to the dietitian’s clinic.

5. Attend follow-up interviews with Alison Dodsworth at three and six months. Subject to room availability, these interviews will be held at your usual dietitian’s clinic (scheduled to coincide with your regular follow-up appointments) or the University of Newcastle. These sessions will follow a similar format to the first interview where you will be asked to:
   • Have your physical measures taken (eg weight)
   • Complete the same questions/surveys as from the first interview
   • Prior to the interviews you will be asked to record your food intake for three days (a food record booklet will be mailed to you). These records will be reviewed for completeness during the interview.

At these interviews you can also discuss any difficulties you may be having in following the eating plan and you will be provided with different dietary strategies to help keep you on track.

6. Provide blood samples at three and six months. You will be given referrals for these blood tests at your three and six month interviews. You will need to have this sample taken within two weeks of attending the face-to-face interviews.

7. Have DXA scans at the John Hunter Hospital at six months. You will be given referral for this at your six month interview. You will need to have the DXA scans within two weeks of attending the face-to-face interview.

PHASE 2 (Second six months)

1. After you have finished following your allocated eating plan for six months, you will be asked to attend two more face-to-face interviews with Alison Dodsworth at your dietitian’s clinic or the University of Newcastle (one at nine months and one at 12 months). This interview will be the same as those described in point number 5 above.

2. You will also be asked to provide blood samples at 9 and 12 months and have another DXA scan at 12 months.

OPTIONAL
There is also an optional component of the study to have you resting metabolic rate measured. If you consent to having this measured, you will be required to attend the University of Newcastle for three measurement sessions: one at the start of the study and one at six and 12 months. You will be required to fast overnight (~12 hours) and not exercise or drink alcohol in the 24 hours prior to the sessions to allow accurate assessment of your resting metabolic rate. You will be asked to lie quietly in the laboratory while the amount of oxygen you use while
resting will be measured. You will have a hood that you can see through over your head and you will be able to breathe normally. You will receive a nutritious breakfast after completing the tests.

*How much time will it take?*

- The first interview will take approximately 1 hour.
- The interviews at three, six, nine and 12 months will take approximately 45 minutes each.
- The phone calls at 6 & 18 weeks should take no more than 10 minutes.
- Each blood sample will take about 5-10 minutes to collect. There will be five samples in total: at the start of the study and at three, six, nine and 12 months.
- Each DXA scan will take about 20 minutes. There will be three DXA scans in total: at the start of the study and at six and 12 months.
- Optional resting metabolic rate measurements will take about 30 minutes each. There will be three measurements in total: at the start of the study and at six and 12 months.

*What are the risks and benefits of participating?*

We cannot promise you any additional benefit from participating in this research. Taking part in this research will provide you with more accurate measures of your body fat, muscle mass, bone density and metabolic rate than you would normally receive. You can also be provided with more information about your cholesterol levels and other biomarkers in your blood than you might normally. This may be of interest to you and may assist you to maintain or improve your health. You will also receive extra support from the research dietitian which may help you to better achieve your weight loss and health goals after your gastric banding procedure. All interviews, tests and measurements taken as part of the study will be free.

There is always a slight risk in having blood tests. So that any added risks will be minimised, all blood samples will be taken by a suitably qualified person. This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from all three DXA examinations, using a DXA Prodigy unit is estimated to be less than 0.2 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure and the risk from the radiation is believed to be minimal. Both eating plans will be nutritionally adequate and following either of the plans used in the study is not anticipated to increase your risk of harm in any way.

Feedback on fat, muscle and bone mass as well as blood samples will be available either during a telephone call or face-to-face interview at your request. Also, any measurements taken at the face-to-face interview sessions can be given to you at your request. If abnormal results are found in any of the measurements taken during the course of the study, the researchers will notify you by mail and advise you to seek follow-up with your doctor.

*How will your privacy be protected?*

Information collected for this study will be stored securely in a locked filing cabinet and a password protected computer in a locked room in the School of Health Sciences at the University of Newcastle. Access to the information will only be available to the researchers involved in this study. Any information collected by the researchers which might identify you will be stored securely and will only be accessed by the researchers unless you consent otherwise, except as required by law.

Your data will remain confidential, as your personal details will not be recorded on any data collection forms. An identification number will be assigned to your data and any identifiable information will be stored separately in a locked file in a locked room and will be accessible only by the research team. Any identifying information will not be stored electronically.
Your blood samples will be appropriately stored by Hunter Area Pathology Services (HAPS) for 12 months. Only Hunter Area Pathology staff has access to these samples. Your samples will only have the study number and participant number as identifiers. Your gender and year of birth will also be provided to Hunter Area Pathology to assist in assessing your blood samples appropriately. Disposal of the samples will be through an accredited contractor organised by HAPS who will incinerate all samples.

All data will be securely stored on compact discs for 15 years and then appropriately destroyed, in compliance with the National Health and Medical Research guidelines.

**How will the information collected be used?**

The information collected will be used in a thesis to be submitted for Ms Alison Dodsworth’s PhD and also reported in scientific journals and conferences. Individual participants will not be identified in any reports arising from the project. All participants will be provided with a summary of the overall results of the research after the research has been completed.

**What do you need to do to participate?**

Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact Alison Dodsworth or Dr Surinder Baines on the phone numbers listed below. If you would like to participate, please complete and return the attached Consent Form in the reply paid envelope provided. I will then contact you to arrange a time convenient for you to check your eligibility to participate in the study and to arrange an initial interview.

**Further information**

If you would like further information please contact Miss Alison Dodsworth on (02) 4921 7486 or Dr Surinder Baines on (02) 4921 5643.

Thank you for considering this invitation.

Surinder Baines            Alison Dodsworth            Helen Warren-Forward
Principle Research Supervisor Research Student Co-Supervisor

This project has been approved by the University’s Human Research Ethics Committee, Approval No. H-2008-0345. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.
Appendix 5  Protein-enriched dietary intervention: Consent Form
Consent Form for the Research Project:
Nutrition Practice after Gastric Banding
Document Version 2; dated 25/09/09

The Research Team:
- Dr Surinder Baines, Faculty of Health at the University of Newcastle
- Miss Alison Dodsworth, Faculty of Health at the University of Newcastle
- A/Prof Helen Warren-Forward, Faculty of Health at the University of Newcastle

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing. I understand that if I withdraw I can request to have any of my data withdrawn within a three month period of withdrawing.

I consent to:
- Allowing the researchers to contact my surgeon to approve my participation in the study.
- Follow the suggested eating plan for six months as explained in the Information Statement.
- Attending three dietetic consultations during the first six months of the study where I will complete the surveys and have the measures taken as explained in the Information Statement.
- Attending two dietetic consultations in the second six months as explained in the Information Statement.
- Being contacted every six weeks by phone for six months to discuss how I am going with the eating plan.
- Attending the John Hunter hospital for DXA scans at the start of the study and at six and 12 months as explained in the Information Statement.
- Providing blood samples at HAPS at the start of the study and at three, six, nine and 12 months as explained in the Information Statement.
- Allowing the researchers to utilise information collected during the course of the study in future projects.

Optional:
If you are interested in attending the University of Newcastle to have your resting metabolic rate measured as explained in the Information Statement at the start of the study and at six and 12 months, please tick this box: ☐

I understand that my personal information will remain confidential to the researchers. I have had the opportunity to have questions answered to my satisfaction.

Print name: ________________________________
Contact phone number: (1) ____________________ (2) ____________________
Postal address: ______________________________
Email address: ______________________________
Name of your surgeon: _________________________
Signature: _________________________ Date: ________________________
Print name: ________________________________
Appendix 6  Protein-enriched dietary intervention: Participant resource booklet
Your Protein-Enriched Eating Plan

Nutrition after Gastric Banding - The Research Team:

- Miss Alison Dodsworth (APD, PhD Student)
- Dr Surinder Baines (APD, Senior Lecturer in Nutrition and Dietetics)
- A/Prof Helen Warren-Forward (Professor in Medical Radiation Science)

If you have any questions or concerns please contact:

1. Alison Dodsworth, Phone: (02) 4921 7486, Email: alison.dodsworth@newcastle.edu.au

2. Dr Surinder Baines, Phone: (02) 4921 5643, Email: surinder.baines@newcastle.edu.au

Gastric banding nutrition study – University of Newcastle 2009
YOUR PROTEIN-ENRICHED EATING PLAN

Welcome to your new healthy eating plan! It is designed to introduce a way of eating that is healthy, balanced, flexible and enjoyable to help you lose weight and gain health!

There are two main parts to your plan:

1. Having a protein-powder supplement every day
2. Following a protein-rich food and drink plan

1. Protein-Powder Supplement
   - You will be given a protein powder supplement to help you get the extra protein we need you to have during the study
   - The protein powder supplement is flavourless and can be added to drinks, soups and casseroles and other foods
   - You can have the powder at any time of the day (meaning you do not have to have it all at once)

★ You need to have 3 tablespoons of protein powder every day during the study ★

2. Your Protein-Rich Food and Drink Plan

Because this study is interested in the effects of having a protein-enriched diet, it is important that in addition to your protein supplement you have enough regular foods and drinks that are high in protein. This includes lean/low fat meat and meat alternatives and dairy foods.

You should aim to have the following number of protein-rich foods/drinks every day:

<table>
<thead>
<tr>
<th>Food group</th>
<th>Number of serves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meats and meat alternatives</td>
<td>4</td>
</tr>
<tr>
<td>Milk and milk-based products</td>
<td>2</td>
</tr>
</tbody>
</table>

To ensure your eating plan is balanced and nutritious, you also need to include a variety of foods from the other food groups as well. As a guide you should aim for:

<table>
<thead>
<tr>
<th>Food group</th>
<th>Number of serves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breads / cereals / starchy vegetables</td>
<td>3</td>
</tr>
<tr>
<td>Fruit</td>
<td>1</td>
</tr>
<tr>
<td>Non-starchy vegetables</td>
<td>3</td>
</tr>
<tr>
<td>Extra fats</td>
<td>2</td>
</tr>
</tbody>
</table>

Please use the food exchange list provided to help you choose foods and drinks that fit in with your protein-rich eating plan.
PROTEIN-RICH FOODS AND DRINKS

Meat and Meat Alternatives

Meat, poultry and fish – A single serve can be:
- 35 g (approx. ¼ cup) lean beef, lamb or pork (cooked weight)
- 35g (approx ¼ cup premium/heart smart mince)
- 35 g (approx. ¼ cup) lean chicken (cooked weight)
- 50 g (approx. ⅓ cup) grilled fish
- 50 g canned tuna or salmon
- 50 g (approx 2-3 slices) lean luncheon meat varieties including:
  - lean leg ham, chicken loaf or roast beef luncheon meat, shaved roast chicken breast
- 50g prawns (approx. 8 large prawns)

Meat Alternatives - A single serve can be:
- 2 small eggs
- 70 g cottage cheese (approx. 3.5 tablespoons)
- 30 g no-fat or reduced fat cheese (approx. 1.5 slices)
- 120g of firm Tofu/bean curd (approx ½ cup)
- ½ cup reduced fat ricotta cheese
- ½ cup cooked legumes (eg baked beans, three bean mix, kidney/cannellini beans, lentils)

Milk and Milk-based Products - A single serve can be:
- 1 cup (250ml) skim/low-fat milk
- 1 tub (200g) plain low-fat/light, natural yoghurt
- 1 tub (200g) reduced fat/light, fruit flavoured yoghurt
- 30 g (1.5 slices) no-fat or reduced fat cheese
- 1 cup (250ml) calcium enriched, low fat soy milk (eg So Good Lite Soymilk)
- 1 cup (250g) low fat custard*  

*Note: Custard is very high in sugar therefore it is not recommended that you include it in your everyday eating plan as it may slow down your weight loss. It is better to have custard as a sometimes food (eg 1-2 times/week)

HANDY TIPS

- Include a protein source with every meal that you have
- Try to include lean red meat, chicken, pork and fish as your main protein serves, as these foods are highest in protein
- Try to eat your protein source first when you have a meal
- Include protein rich snacks in your day if you are feeling hungry (eg yoghurt, crackers with cheese, a boiled egg)
- If you are finding it difficult to consume the required amount of meat and/or meat alternatives, you should contact Alison Dodsworth for further advice

Note: Remember to have your 3 tablespoons of protein powder per day as well as having your protein-rich foods and drinks
## OTHER FOODS AND DRINKS

### Breads, Cereals and Starchy Vegetables

#### Breads, crispbreads and crackers
- 1 slice bread (sandwich size)
- 1 small slice fruit loaf
- 1 small or ½ large pita pocket, ½ lavash (eg: Bazaar Lavash Bread, Buttercup Wrap ‘Ems)
- 4 traditional size Vita-Wheat biscuits
- 1.5 Wholemeal Salada’s; 2 Ryvitas
- 4 Corn / Rye Cruskits
- 3 Premium, 98% Fat Free Kraft Crispbreads
- 3 Vive Lites Wholemeal Paradise Crispbreads
- 3 Woolworths 97% Fat Free Crispbreads
- 3 thin rice or corn cakes (eg Sunrice Ricecakes, Realfoods Corn Thins)
- 11 plain rice crackers

#### Breakfast cereals
- 2 breakfast biscuits (eg Weetbix, VitaBrits)
- ½ cup Sultana Bran (approx. 24g)
- ½ cup Special K (approx. 20g)
- ½ cup Uncle Toby’s Plus Fibre Lift (approx. 23g)
- ½ cup Just Right (approx 20g)
- ¼ cup raw oats (approx. 23g uncooked weight)
- ½ cup cooked oats
- ¼ cup untoasted muesli (eg Woolworths Select Apricot & Almond, Kellogg’s Komplete Oven-Baked Muesli)

#### Other cereals and grains
- ½ cup cooked pasta
- ½ cup cooked rice noodles
- ½ cup cooked egg noodles (eg Hokkien); ½ cup cooked rice

#### Starchy Vegetables
- 1 small potato (approx. 70-80g, 6cm diameter)
- ½ cup mashed potato
- 85g sweet potato (approx. 1 med. ring)
- 1 small cob of corn (approx. 10cm long)
- ½ cup corn kernels
- ½ cup green peas

### Fruits
- 1 small banana
- 1 medium apple
- 1 cup diced rockmelon
- 1 cup fresh cherries (measure with stalks on)
- ½ medium mango
- 1 small-medium orange
- 1 medium-large peach
- 15 medium grapes
- 6 medium strawberries
- 1 cup watermelon cubes (1 thick slice or ¼ circle)
- 2 small kiwi fruit
- ¾ cup fresh fruit salad
- ½ cup drained canned fruit salad
- ½ cup drained canned peaches

### Non Starchy Vegetables
- 1 cup of salad vegetables (eg lettuce, tomato, cucumber, carrot, onion, sprouts)
- ½ cup of cooked non-starchy vegetables (eg carrots, zucchini, broccoli, cauliflower)

### Extra Fats
- ½ tablespoon of oil
- 2 teaspoons margarine
- ¼ avocado (1 tablespoon mashed)
- 1 tablespoon mayonnaise/salad dressing
- 3 teaspoons peanut butter
- 20g raw nuts

### Free Foods and Drinks
- Instant gravies (1 serve = ¼ Cup)
- Fat free salad dressings
- Herbs and spices
- Diet jelly
- Water
- Low joule/diet cordial
- Low joule/diet soft drinks
- Tea/coffee (made with water)
SAMPLE MEAL IDEAS

Breakfast
- 1 slice toast with scrambled eggs (2 small eggs)
- ½ cup baked beans with ½ an English muffin
- 1 rasher lean bacon (grilled) with 1 egg and 1 slice toast
- 2 rashers lean bacon with grilled mushroom and tomato
- ½ cup baked beans with grilled mushroom and tomato
- 1 slice cheese with tomato on 1 slice toast
- 2 Weetbix (or any other cereal from the list) with 250ml low fat milk
- Breakfast cereal from list with 125ml low fat milk and 1 piece of fruit
- 1 slice toast with 1 poached/boiled egg and grilled tomato and mushroom
- ¼ cup untoasted muesli with 1 tub low-fat yoghurt

Lunch / Light Meals
- Chicken or tuna/salmon salad made with ¼ cup grilled chicken or 50g tinned tuna/salmon plus free salad veggies (eg lettuce, tomato, carrot, cucumber) and 1 tablespoon salad dressing. Optional: add: 3 crispbreads or 1 slice bread
- Chicken and cheese salad wrap made with ½ a lavash wrap, 35g chicken, 30g shredded reduced-fat cheese and free salad vegies plus 1 tablespoon mayonnaise/salad dressing/hummus
- Ham, cheese and tomato melt made with 2 slices of lean shaved ham, 1 slice or reduced fat cheese and 1 slice bread
- 50g tinned tuna/salmon with 4 rye cruskits
- ¼ cup stir-fried beef, pork or chicken with non-starchy vegies and stir through sauce.
- Chicken and vegetable soup

Dinner
- ½ cup (approx 70g) marinated steak/chicken/fish with ½ cup mashed potato and non-starchy vegetables from list. Serve with a tomato-based sauce
- Beef casserole with ¼ to ½ cup of beef pieces with non-starchy vegetables from list. Optional: Serve with ½ cup pasta or add 1 small potato to casserole
- Bolognese sauce with: ½ cup lean mince, tomatoes and other vegetables with ½ cup pasta or 1 slice toast
- ¼ cup beef/chicken stir fry with non starchy vegetables from list and stir through sauce (eg oyster/soy). Optional: add 120g tofu
- Ham and cheese omelette (made with 1 egg, 125ml milk, 30g reduced fat cheese and 50g lean ham) and salad vegies with dressing
- Hearty chicken or beef stew made with ¼ to ½ cup chicken or beef pieces with non-starchy vegies. Optional: add 1 small bread roll or ½ cup mashed potato

Snacks
- Tub of yoghurt
- Rice crackers with cheese
- Boiled egg
- Cheese stick
- Fruit
OTHER IMPORTANT INFORMATION AND TIPS

Take Away and Eating Out

General tips

• Try to select foods from the menu that best fit with items included in your healthy eating plan
• Order small or entrée sizes if possible
• Avoid high fat and deep-fried foods (eg fast food hamburgers, fries, fried chicken)
• Select options that are indicated as low fat or heart smart
• When ordering salad or meals with sauces, ask for the dressing or sauce to be served on the side
• Ask for no butter on vegetables
• Stop eating when full, even if you have food left on your plate (sometimes you might choose to share a meal with someone else)
• Below are some examples of “good” options for different cuisines and fast foods for when you eat out or get take-away foods

Example of “good” choices when eating out

• Grilled or poached meat, chicken or fish dishes with salad or steamed vegetables (no chips). You can include a small serve of potato (not fried or baked in fat)
• Meat, chicken or fish stir-fries with extra non-starchy vegetables with a small side serve of boiled rice or noodles
• Chicken breast or seafood salad
• Omelette or frittata (no pastry) with salad or non-starchy steamed vegetables

Example of “good” fast food choices

• Subway 6 inch sub with lean meat (eg grilled chicken breast) and salad veggies with low fat dressing (or salad dressing/mayonnaise from extra fat allowance)
• Subway 6 inch sub with reduced fat cheese and salad veggies with low fat dressing
• McDonalds Roast Chicken Salad
• McDonalds Lean Beef Burger (remove top hamburger bun)
• BBQ chicken (no skin) with small coleslaw (with low fat mayonnaise if available)
• Meat or cheese + salad sandwich

Alcohol

Alcohol is high in calories and low in vitamins and minerals and therefore not recommended as part of your daily healthy eating plan. It is okay to have an occasional drink, however try to limit your alcohol intake. If you do have an alcoholic beverage, try to avoid drinks with extra sugar (eg drinks mixed with ordinary soft drink or juice) and remember to stick with your eating plan as best as possible
FOOD AND DRINK SUPPLEMENTS

Sustagen
Sometimes you may not be able to consume regular foods or you may need to temporarily have a fluid diet (for example when you have had a band adjustment). To ensure your nutrient needs are met during these times, your dietitian might recommend that you have a supplement drink such as Sustagen.

- If you have Sustagen instead of a meal (eg 250ml Ready-to-Drink tetra pack or Sustagen powder made up on water), this is equal in protein to one meat/meat alternative serve.
- If you make Sustagen powder up with skim/reduced fat milk, this is equal in protein to one meat plus one milk serve.

Optifast
If you have an Optifast product as a meal replacement (eg shake, soup, bar or dessert) this is equal in protein to two meat serves

NOTE: You still need to have your 3 teaspoons of protein powder in addition to any supplement you have as a meal replacement

Vitamin and mineral supplements

Although your protein-rich eating plan is designed to be balanced and healthy, because your food intake is very restricted after gastric banding may difficult for you to meet all of your vitamin and mineral needs through food alone.

Therefore we recommend that you take a daily multivitamin supplement to ensure you best meet your nutrient needs.
Appendix 7  Protein-enriched dietary intervention: Recruitment poster
Are you interested in good nutrition and health after gastric banding?

We require men and women to participate in a nutrition research study investigating the influence of diet on weight loss, health and wellbeing after gastric banding.

We are looking for people who:
- Are going to have gastric banding or have recently had gastric banding
- Are aged between 18 and 65
- Have a body mass index greater than 30kg/m²

Unfortunately you cannot participate if you are pregnant or require a highly specialised diet due to illness or food allergy/intolerance.

What is required?

During the 12 month study participants will be required to:
- Follow a specified eating plan for 6 months after gastric banding
- Attend the John Hunter Hospital for specialised measurements of body composition.
- Have blood samples taken
- Answer questions about food intake, health and wellbeing

Interested?

For further information please contact Alison Dodsworth via:

Email: Alison.Dodsworth@newcastle.edu.au

Or phone: 4921 7486
Appendix 8    Protein-enriched dietary intervention: Eligibility checklist
## Eligibility checklist

<table>
<thead>
<tr>
<th>Participant Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- [ ] Are you going to have gastric banding in the Newcastle/Lake Macquarie region?

- [ ] Are you aged between 18 and 65 years of age?

- [ ] *Participant’s BMI is > 35 kg/m²* (ask for height and weight and calculate)

  - Height_______
  - Weight________
  - BMI__________

- [ ] Do you have a chronic condition that requires a special diet? *(for example, diabetes requiring insulin, chronic renal failure, celiac disease)*

  - *(If yes, ask about specific dietary requirements and make judgment regarding appropriateness of study diet) – list in space below:*

- [ ] Do you follow a vegetarian diet? *(If yes, ask about what foods are included/excluded from diet and make judgment regarding ability to follow study diet) – list in space below*

- [ ] Are you pregnant or lactating?

- [ ] Do you have a pacemaker or any other electronic implant?

- [ ] Do you have any food allergies or intolerances? *(Researcher to use clinical judgment to determine likelihood that subject’s response will affect their health or compliance with the study)*

- [ ] Can you read and write in English?
Appendix 9  Protein-enriched dietary intervention: Survey booklet
Instructions:

- Please complete the following survey booklet as part of our research into nutrition and gastric banding.

- The booklet has five sections:
  - Section 1 – Questions about your medical conditions, medications and supplements
  - Section 2 – Questions about your general health and wellbeing
  - Section 3 – Questions about your eating habits/behaviours
  - Section 4 – Questions about your physical activity
  - Section 5 – Questions about foods you can eat (food tolerance)

- Please take your time to complete each section and be sure not to miss any questions.

- The booklet should take you approximately 30 minutes to complete.

- If you have any questions whilst completing the booklet, please don’t hesitate to contact your research dietitian (Alison Dodsworth) on: 4921 7486

- Thanks kindly for your time.
SECTION ONE: MEDICAL INFORMATION

1. Medical conditions: Please list any illnesses, conditions or disabilities you have:
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

2. Medications: Please list all the medications that you are currently taking (include doses if known):
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

3. Vitamins, minerals, and other therapies: Please list all the supplements and similar products that you are currently taking (include doses if known):
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

Thank you for completing this section.
😊
Section Two: Your Health and Well-Being

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
</tbody>
</table>

2. Compared to one year ago, how would you rate your health in general now?

<table>
<thead>
<tr>
<th>Much better now than one year ago</th>
<th>Somewhat better now than one year ago</th>
<th>About the same as one year ago</th>
<th>Somewhat worse now than one year ago</th>
<th>Much worse now than one year ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
</tbody>
</table>
3 The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

- a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports .................................................. □ 1 □ 2 □ 3
- b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf .................................................. □ 1 □ 2 □ 3
- c. Lifting or carrying groceries .......................................................... □ 1 □ 2 □ 3
- d. Climbing several flights of stairs .................................................. □ 1 □ 2 □ 3
- e. Climbing one flight of stairs ........................................................... □ 1 □ 2 □ 3
- f. Bending, kneeling, or stooping ............................................................ □ 1 □ 2 □ 3
- g. Walking more than a kilometre ............................................................ □ 1 □ 2 □ 3
- h. Walking several hundred metres ......................................................... □ 1 □ 2 □ 3
- i. Walking one hundred metres .................................................................... □ 1 □ 2 □ 3
- j. Bathing or dressing yourself ................................................................... □ 1 □ 2 □ 3
4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cut down on the amount of time you spent on work or other activities</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>2. Accomplished less than you would like</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
</tr>
<tr>
<td>3. Were limited in the kind of work or other activities</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
</tr>
<tr>
<td>4. Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
</tr>
</tbody>
</table>

5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cut down on the amount of time you spent on work or other activities</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>2. Accomplished less than you would like</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
</tr>
<tr>
<td>3. Did work or other activities less carefully than usual</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
</tr>
</tbody>
</table>
6. *During the past 4 weeks,* to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

7. How much *bodily* pain have you had during the *past 4 weeks*?

<table>
<thead>
<tr>
<th>None</th>
<th>Very mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

8. *During the past 4 weeks,* how much did *pain* interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks**…

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

- Did you feel full of life?
- Have you been very nervous?
- Have you felt so down in the dumps that nothing could cheer you up?
- Have you felt calm and peaceful?
- Did you have a lot of energy?
- Have you felt downhearted and depressed?
- Did you feel worn out?
- Have you been happy?
- Did you feel tired?

10. During the **past 4 weeks**, how much of the time has your **physical health** or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

© Quality Metric, USA
11. How TRUE or FALSE is each of the following statements for you?

<table>
<thead>
<tr>
<th></th>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don’t know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

1. I seem to get sick a little easier than other people

2. I am as healthy as anybody I know

3. I expect my health to get worse

4. My health is excellent

Thank you for completing these questions!
### SECTION THREE: EATING BEHAVIOUR

**Part I: Please circle T (True) or F (False):**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>T</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>When I smell a freshly baked pizza, I find it very difficult to keep from eating, even if I have just finished a meal.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>2.</td>
<td>I usually eat too much at social occasions, like parties and picnics.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>3.</td>
<td>I am usually so hungry that I eat more than three times a day.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>4.</td>
<td>When I have not eaten my quota of calories or fat, I am usually good about not eating any more.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>5.</td>
<td>Dieting is so hard for me because I just get too hungry.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>6.</td>
<td>I deliberately take small helpings as a means of controlling my weight.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>7.</td>
<td>Sometimes things just taste so good that I keep on eating even when I am no longer hungry.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>8.</td>
<td>Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have some more.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>9.</td>
<td>When I feel anxious, I find myself eating.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>10.</td>
<td>Life is too short to worry about dieting.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>11.</td>
<td>Since my weight goes up and down, I have gone on reducing diets more than once.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>12.</td>
<td>I often feel so hungry that I just have to eat something.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>13.</td>
<td>When I am with someone who is overeating, I usually overeat too.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>14.</td>
<td>I have a pretty good idea of the number of calories or grams of fat in common foods.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>15.</td>
<td>Sometimes when I start eating, I just can’t seem to stop.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>16.</td>
<td>It is not difficult for me to leave something on my plate.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>17.</td>
<td>At certain times of the day, I get hungry because I have gotten used to eating then.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>18.</td>
<td>While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>19.</td>
<td>Being with someone who is eating often makes me hungry enough to eat also.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>20.</td>
<td>When I feel blue, I often overeat.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>21.</td>
<td>I enjoy eating too much to spoil it by counting calories, counting grams of fat, or watching my weight.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>22.</td>
<td>When I see a real delicacy, I often get so hungry that I have to eat right away.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>23.</td>
<td>I often stop eating when I am not really full as a conscious means of limiting the amount that I eat.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>24.</td>
<td>I get so hungry that my stomach often seems like a bottomless pit.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>25.</td>
<td>My weight has hardly changed at all in the last ten years.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>26.</td>
<td>I am always hungry so it is hard for me to stop eating before I finish the food on my plate.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>27.</td>
<td>When I feel lonely, I console myself by eating.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>28.</td>
<td>I consciously hold back at meals in order not to gain weight.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>29.</td>
<td>I sometimes get very hungry late in the evening or at night.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>30.</td>
<td>I eat anything I want, any time I want.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>31.</td>
<td>Without even thinking about it, I take a long time to eat.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>32.</td>
<td>I count calories or grams of fat as a conscious means of controlling my weight.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>33.</td>
<td>I do not eat some foods because they make me fat.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>34.</td>
<td>I am always hungry enough to eat at any time.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>35.</td>
<td>I pay a great deal of attention to changes in my figure.</td>
<td>T</td>
<td>F</td>
</tr>
<tr>
<td>36.</td>
<td>While on a diet, if I eat a food that is not allowed, I often then splurge and eat other high-calorie foods.</td>
<td>T</td>
<td>F</td>
</tr>
</tbody>
</table>
Part II: Please answer the following questions by circling the number above the response that is appropriate to you.

37. How often are you dieting in a conscious effort to control your weight?

1 Rarely 2 Sometimes 3 Usually 4 Always

38. Would a weight fluctuation of 2.5 kg affect the way you live your life?

1 Not at all 2 Slightly 3 Moderately 4 Very much

39. How often do you feel hungry?

1 Only at mealtimes 2 Sometimes between meals 3 Often between meals 4 Almost always

40. Do your feelings of guilt about overeating help you to control your food intake?

1 Never 2 Rarely 3 Often 4 Always

41. How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?

1 Easy 2 Slightly difficult 3 Moderately difficult 4 Very difficult

42. How conscious are you of what you are eating?

1 Not at all 2 Slightly 3 Moderately 4 Extremely

43. How frequently do you avoid buying a large amount of tempting foods?

1 Almost never 2 Seldom 3 Usually 4 Almost always

44. How likely are you to shop for low-calorie or low-fat foods?

1 Unlikely 2 Slightly unlikely 3 Moderately likely 4 Very likely

45. Do you eat sensibly in front of others and splurge alone?

1 Never 2 Rarely 3 Often 4 Always
46. How likely are you to consciously eat slowly in order to cut down on how much you eat?

1 2 3 4
Unlikely Slightly likely Moderately likely Very likely

47. How frequently do you skip dessert because you are no longer hungry?

1 2 3 4
Almost never Seldom At least once a week Almost every day

48. How likely are you to consciously eat less than you want?

1 2 3 4
Unlikely Slightly likely Moderately likely Very likely

49. Do you go on eating binges even though you are not hungry?

1 2 3 4
Never Rarely Sometimes At least once a week

50. On a scale of 1 to 5, where 1 means no restraint in eating (eat whatever you want, whenever you want it) and 6 means total restraint (constantly limiting food intake and never 'giving in'), what number would you give yourself? (Please circle one of the numbers below that best describes you)

0 Eat whatever you want, whenever you want it
1 Usually eat whatever you want, whenever you want it
2 Often eat whatever you want, whenever you want it
3 Often limit food intake, but often 'give in'
4 Usually limit food intake, rarely 'give in'
5 Constantly limiting food intake, never 'give in'

51. To what extent does this statement describe your eating behaviour?

'I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow.'

1 2 3 4
Not like me A little like me Pretty good description of me Describes me perfectly

Thank you for completing this section.
SECTION FOUR: PHYSICAL ACTIVITY

Part 1:

1. In the last 2 weeks, have you walked for sport, recreation or fitness? (Please circle)
   Yes – go to question 2
   No – go to question 4

2. How many times did you walk in the last 2 weeks?
   Number ____________

3. What was the total amount of time you spent walking in the last 2 weeks?
   ______ Hours ______ minutes

4. I will now ask about moderate and vigorous exercise apart from walking.
   In the last 2 weeks, did you do any exercise that caused a moderate increase in your heart rate or breathing, that is, moderate exercise? (Please circle)
   Yes – go to question 5
   No – go to question 7

5. How many times did you do any moderate exercise in the last 2 weeks?
   Number ____________

6. What was the total amount of time you spent doing moderate exercise in the last 2 weeks?
   ______ Hours ______ minutes

7. In the last 2 weeks did you do any (other) exercise that caused a large increase in your heart rate or breathing, that is vigorous exercise? (Please circle)
   Yes – go to question 8
   No – go to part 2 of physical activity component

8. How many times did you do any vigorous exercise in the last 2 weeks?
   Number ____________

9. What was the total amount of time you spent doing vigorous exercise in the last 2 weeks?
   ______ Hours ______ minutes
Part 2:

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 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. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?
   
   ___ days per week

   [ ] No vigorous physical activities – Skip to question 3

2. How much time did you usually spend doing vigorous physical activities on one of those days?
   
   ___ hours per day
   ___ minutes per day

   [ ] Don't know/Not sure

Think about all the moderate activities that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the last 7 days, on how many days did you moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.
   
   ___ days per week

   [ ] No moderate physical activities – Skip to question 5

4. How much time did you usually spend doing moderate physical activities on one of those days?
   
   ___ hours per day
   ___ minutes per day

   [ ] Don't know/Not sure

Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.
5. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

___ days per week

☐ No walking – *Skip to question 7*

6. How much time did you usually spend *walking* on one of those days?

___ hours per day

___ minutes per day

☐ Don’t know/Not sure

The last question is about the time you spent *sitting* on weekdays during the *last 7 days.* Include time spent at work, at home, while doing course work or during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

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

___ hours per day

___ minutes per day

☐ Don’t know/Not sure

Thank you for completing this section...
SECTION FIVE: FOOD TOLERANCE CHECKLIST

1. How would you rate your overall satisfaction regarding how you can eat presently?
   - Excellent  
   - Good  
   - Acceptable  
   - Poor  
   - Very Poor

   Why?  

2. How many meals do you eat a day? __________

3. Among the following meals, which one do you have?
   - Breakfast  
   - Lunch  
   - Dinner

4. Which of them is your daily main meal?

5. Do you eat between meals?  
   - Yes  
   - No

   If yes, when?
   - Morning  
   - Afternoon  
   - Evening

6. Can you eat everything?  
   - Yes  
   - No

7. More specifically, how can you eat:
   - Red meat  
     - Easily  
     - With some difficulties  
     - Not at all
   - White meat  
   - Salad  
   - Vegetable  
   - Bread  
   - Rice  
   - Pasta  
   - Fish

   Are there other types of food that you cannot eat at all?

8. Do you vomit/regurgitate?  
   - Daily  
   - Often (> 2x/week)  
   - Rarely  
   - Never
Thank you very much…

YOU HAVE COMPLETED THE QUESTIONNAIRE.

Please check that you haven’t missed any questions.
Appendix 10  Protein-enriched dietary intervention: Data collection form and diet history template
DATA COLLECTION FORM – BASELINE INTERVIEW

Partic. No.___________________________
Date___________________________

1. **Personal details**

   (i) Gender:  Female / Male

   (ii) Date of birth ______________ (iii) Age: ______________

2. **Preferred phone number to ring to contact you and the best times of the day to contact you and which day you’d prefer to be contacted.**

   Preferred phone number to contact you on ________________________________

   Preferred **day** and **time** to contact you ________________________________

3. **Gastric banding surgery details:**

   Date of surgery:____________ Surgeon:____________
   Dietitian:____________

4. **Pre-surgery Optifast:**

   Did you do Optifast prior to surgery?  Y / N

   If yes, how long? (weeks):____________________

   Weight loss (kg): ________________

5. **Weight History:**

   Weight at time of surgery: ________________

   Highest wt past 5 years: ________________

   Lowest wt past 5 years (prior to surgery): ________________

6. **Anthropometric measures**

   Weight: ________________

   Height: ________________

   Waist: ________________ Measure point: ________________

   Fat mass: ________________ % body fat: ________________

   FFM: ________________
7. Pre- surgery (and pre-Optifast) Diet History:
DATA COLLECTION FORM – BASELINE INTERVIEW

Partic. No.___________________________
Date___________________________

Food frequency checklist (amount per day/week):

<table>
<thead>
<tr>
<th>Item</th>
<th>Type, amount per day / week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat, poultry, fish</td>
<td></td>
</tr>
<tr>
<td>Milk, cheese, dairy</td>
<td></td>
</tr>
<tr>
<td>Eggs</td>
<td></td>
</tr>
<tr>
<td>Bread, cereals, rice, pasta</td>
<td></td>
</tr>
<tr>
<td>Potatoes</td>
<td></td>
</tr>
<tr>
<td>Other Vegetables</td>
<td></td>
</tr>
<tr>
<td>Fruit</td>
<td></td>
</tr>
<tr>
<td>Fats / oils</td>
<td></td>
</tr>
<tr>
<td>Sweets, desserts</td>
<td></td>
</tr>
<tr>
<td>Snack foods</td>
<td></td>
</tr>
<tr>
<td>Juice</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td></td>
</tr>
<tr>
<td>Coffee / tea</td>
<td></td>
</tr>
<tr>
<td>Other beverages (eg soft drinks, cordial)</td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
</tr>
</tbody>
</table>

Other information:
Family members in household:
Who purchases foods, and cooks the meals:

Frequency & type eat out/take-away:

Differences in weekend meals:
Appendix 11  Protein-enriched dietary intervention:
Three-day food record
3 Day Food Record (#1)

★ You need to complete this record in the week prior to your interview with the research dietitian ★

Instructions:

1. Write down ALL the foods and drinks you consume for THREE days. If possible include TWO weekdays plus ONE weekend day.

2. Record the date and circle the day of the week at the top of the page for each food record day.

3. If possible, fill out the record immediately after you have had a meal or snack to help ensure the record is as accurate as possible.

4. Record the time of each meal.

5. If possible, record exact quantities of foods and drinks. If you cannot weight your foods, please use household measures such as cups and spoons.

6. Record the specific type of food, brand names and cooking methods used (if known).

7. If you have a mixed dish (e.g., sandwich, stew or stir-fry) please list the individual ingredients included in the meal as well as the quantity of each ingredient consumed.

8. If you are eating out or having takeaway, record foods eaten as accurately as possible, (for example include the name of the restaurant/establishment).

9. Include any food or drink supplements (e.g., Sustagen or Optifast) that you have.

10. Also record your protein powder supplement, including: when you have it, what you have with and how much you have had. At the bottom of each day also record the total amount of powder you had for the whole day.

11. Please bring your completed 3 day record to your interview with the research dietitian, who will check through the record with you.

There is an example of how to complete your food record on the next page of this booklet.
### Food Record: Sample Record

**DATE:** 12 /02/2009

<table>
<thead>
<tr>
<th>MEAL</th>
<th>TIME</th>
<th>FOOD / DRINK (Provide as much detail as possible including: specific type, brand name and cooking methods)</th>
<th>QUANTITY</th>
</tr>
</thead>
</table>
| Breakfast  | 8am  | Sanitarium Weetbix  
Skim milk *(Coles brand)*  
Coffee with:  
- Instant coffee  
- Water  
- skim milk  
- sugar                                                                 | 2  
200ml  
1 tsp  
200ml  
30ml  
1 tsp |
| Snack      | 11am | Banana  
Water  
Protein powder (mixed with water)                                                                                           | 1 medium  
1 cup  
1 tsp |
| Lunch      | 1pm  | Greenseas tinned tuna in oil *(drained)*  
Wholegrain Vita-Weats  
Raw tomato  
Water                                                                                                                     | 95g tin  
4  
4 thin slices  
½ cup |
| Snack      | 3.30pm | Kraft Cheese Stick  
Cottee’s Diet Raspberry cordial  
Protein powder (mixed with cordial)                                                                                         | 1  
200ml  
2 tsp |
| Dinner     | 6.30pm | Grilled steak *(lean cut, trimmed fat before cooking)*  
Mashed potato with:  
- potato  
- Flora margarine  
- Skim milk  
- Steamed carrots  
- Steamed green peas  
- Gravox Brown Onion Gravy *(made with water from packet powder)*  
Red wine  
Red wine                                                                                                                      | 100g  
¼ cup  
10g  
50ml  
¼ cup  
¼ cup  
150ml |
| Snack      | 9pm  | Arnott’s milk arrowroot biscuits  
Tea (no milk or sugar) - made from tea bag                                                                                   | 2 biscuits  
200ml |

**Total amount of protein powder consumed:** 3 level tablespoons
FOOD RECORD DAY 1: 

<table>
<thead>
<tr>
<th>MEAL</th>
<th>TIME</th>
<th>FOOD / DRINK (Provide as much detail as possible including: specific type, brand name and cooking methods)</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snack</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Lunch</td>
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<td></td>
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<td>Snack</td>
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<td>Dinner</td>
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<tr>
<td>Snack</td>
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</tbody>
</table>

Total amount of protein powder consumed: ________________________________
FOOD RECORD DAY 2:  DATE____________________

Day of Week (please circle):  MON  TUES  WEDS  THURS  FRI  SAT  SUN

<table>
<thead>
<tr>
<th>MEAL</th>
<th>TIME</th>
<th>FOOD / DRINK (Provide as much detail as possible including: specific type, brand name and cooking methods)</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td></td>
<td></td>
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<tr>
<td>Snack</td>
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<td>Lunch</td>
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<tr>
<td>Snack</td>
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<tr>
<td>Dinner</td>
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<tr>
<td>Snack</td>
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<td></td>
</tr>
</tbody>
</table>

Total amount of protein powder consumed: ____________________________
FOOD RECORD DAY 3: DATE____________________

Day of Week (please circle): MON TUES WEDS THURS FRI SAT SUN

<table>
<thead>
<tr>
<th>MEAL</th>
<th>TIME</th>
<th>FOOD / DRINK (Provide as much detail as possible including: specific type, brand name and cooking methods)</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snack</td>
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<tr>
<td>Lunch</td>
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<td>Snack</td>
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<tr>
<td>Dinner</td>
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<td></td>
</tr>
<tr>
<td>Snack</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total amount of protein powder consumed: __________________________
Appendix 12  Protein-enriched dietary intervention: Participant Information Statement for the collection of data from clinic records
Nutrition after Gastric Banding Research Study:
Request for consent to collect information from your clinic records
(Document Version 2; 25/05/2010)

Dear _______________

Thank you for participating in the Nutrition after Gastric Banding Research Study. We are pleased to say that the study has progressed well. We would like you to please consider the following request to collect information from your clinic records in order to support and strengthen the information you have already provided during the course of the study. This information is needed to assist Miss Alison Dodsworth with analysis of results from the study.

The information we wish to collect is detailed below:

- Dates that you visited your dietitian and surgeon in the first 12 months after your surgery
- Dates of any band adjustments you have had in the first 12 months after surgery
- Your weight prior to surgery and your weight at your first visit with the dietitian after surgery

What choice do you have?

Providing consent for this information to be collected is entirely your choice. Only people who give their informed consent will have this data collected. Whether or not you decide to give permission, your decision will not disadvantage you and your decision will not have any impact on your ongoing participation in the overall study.

How will your privacy be protected?

The researchers will not access your records at any stage. Information will be collected by a nominated staff member at your gastric banding clinic under the guidance of the practice surgeon. Data will be recorded in a password protected electronic database and this database will then be given to Miss Alison Dodsworth for analysis. Any identifying information will be deleted and your data will be stored in coded form on a password protected computer in a locked room in the School of Health Sciences at the University of Newcastle. Access to the information will only be available to the researchers involved in this study.

What do you need to do to provide consent?

If you agree to the above information being collected from your clinic records, please complete and return the attached Consent Form via the reply paid envelope provided.

Further information

If you would like further information or have any questions please contact either Miss Alison Dodsworth on (02) 4921 7486 or Dr Surinder Baines on (02) 4921 5643.

Thank you kindly for considering this request and your ongoing participation in the study.

Surinder Baines
Principle Research Supervisor
Appendix 13  Protein-enriched dietary intervention: Consent Form for the collection of data from clinic records
Consent Form for the Research Project:
Nutrition Practice after Gastric Banding
Document Version 2; dated 25/09/09

The Research Team:
- Dr Surinder Baines, Faculty of Health at the University of Newcastle
- Miss Alison Dodsworth, Faculty of Health at the University of Newcastle
- A/Prof Helen Warren-Forward, Faculty of Health at the University of Newcastle

I agree to participate in the above research project and give my consent freely.
I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.
I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing. I understand that if I withdraw I can request to have any of my data withdrawn within a three month period of withdrawing.
I consent to:
- Allowing the researchers to contact my surgeon to approve my participation in the study.
- Follow the suggested eating plan for six months as explained in the Information Statement.
- Attending three dietetic consultations during the first six months of the study where I will complete the surveys and have the measures taken as explained in the Information Statement.
- Attending two dietetic consultations in the second six months as explained in the Information Statement.
- Being contacted every six weeks by phone for six months to discuss how I am going with the eating plan.
- Attending the John Hunter hospital for DXA scans at the start of the study and at six and 12 months as explained in the Information Statement.
- Providing blood samples at HAPS at the start of the study and at three, six, nine and 12 months as explained in the Information Statement.
- Allowing the researchers to utilise information collected during the course of the study in future projects

Optional:
If you are interested in attending the University of Newcastle to have your resting metabolic rate measured as explained in the Information Statement at the start of the study and at six and 12 months, please tick this box: □

I understand that my personal information will remain confidential to the researchers. I have had the opportunity to have questions answered to my satisfaction

Print name: ____________________________
Contact phone number: (1) ________________ (2) ____________________________
Postal address: ____________________________
Email address: ____________________________
Name of your surgeon: ____________________________
Signature: ____________________________ Date: ____________________________
Print name: ____________________________
Appendix 14  Cross-sectional study: Participant Information Statement
Information Statement for the Research Project:

Nutrition, Health and Lifestyle after Banding
Document Version 2; dated 25/05/2010

You are invited to participate in the research project identified above which is being conducted by Miss Alison Dodsworth (postgraduate student in Nutrition and Dietetics), Dr Surinder Baines (Senior Lecturer in Nutrition and Dietetics) and Dr Helen Warren-Forward (Associate Professor in Medical Radiation Science) from the School of Health Sciences at the University of Newcastle.

The research is part of Alison Dodsworth’s doctoral studies at the University of Newcastle, supervised by Dr Surinder Baines and Assoc. Prof. Helen-Warren Forward.

Why is the research being done?
The purpose of the research is to examine eating behaviours, dietary intake and related health outcomes in Australian adults who have had gastric banding. Currently little research has been conducted in this area. This study will provide valuable insight into nutrition and health after gastric banding.

Who can participate in the research?
We are seeking women and men aged 18-65 years who have had gastric banding in 2008-2009 in the Newcastle and Lake Macquarie region to participate in this research. You have been contacted by your gastric banding clinic on behalf of the researchers as their records indicate you have had gastric banding in 2008-2009.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you.

What would you be asked to do?
If you agree to participate, you will be asked to complete the enclosed survey booklet, which contains questions about your: gender, age, date of birth, gastric banding surgery and weight, health and medications, quality of life, eating behaviours and eating patterns and physical activity. The survey also contains an optional sectional regarding your education, work and level of income.

Optional:
- You will also be given the option of being sent an additional survey about your food intake (a food frequency questionnaire), which asks questions about the types and quantities of foods you usually eat. If you are happy to complete this questionnaire, please indicate this on the “Optional Contact Form” enclosed and we will send you this survey to complete as well.
- If you are willing to be contacted for possible participation in future follow-up surveys, you may also choose to provide your details to the researchers for future contact. If you do choose to provide these details, this does not obligate you to participate in future research however.

How much time will it take?
- The survey booklet should take about 20-30 minutes to complete
- The optional food frequency questionnaire should take about 20-30 minutes to complete
What are the risks and benefits of participating?
It is not expected that there will be any specific benefits or risks to you by participating in this research.

How will your privacy be protected?
The questionnaire is anonymous and it will not be possible to identify you from your answers. If you agree to provide your contact details for future follow-up, any information collected that identifies you will be stored securely at the university and only accessed by the researchers unless you consent otherwise, except as required by law.

If you do choose to provide your contact details, an identification number will be assigned to your data and any identifiable information will be stored securely in a separate location from your data and will be accessible only by the research team.

Data will be retained for at least 5 years at the School of Health Sciences, University of Newcastle. All data will be stored in a locked file in a locked room and any data that is identifiable will be accessible only by the research team.

How will the information collected be used?
The information collected will be used in a thesis to be submitted for Ms Alison Dodsworth’s PhD and also reported in scientific journals and conferences. Individual participants will not be identified in any reports arising from the project.

You will be provided with a summary of findings after the research has been competed if you choose to provide your contact details to the researchers.

What do you need to do to participate?
Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researchers.

If you would like to participate, please complete and return the attached anonymous questionnaires in the reply paid envelope provided. This will be taken as your informed consent to participate.

Optional
If you consent to also completing the food frequency questionnaire and/or being contacted by the researchers in the future, please fill out the enclosed “Optional Contact Form” and return this with your completed questionnaire. This will be taken as your informed consent to be contacted by the researchers in the future.

Further information
If you would like further information please contact Miss Alison Dodsworth on (02) 4921 7486 or Dr Surinder Baines on (02) 4921 5643.

Thank you for considering this invitation.

Surinder Baines        Alison Dodsworth
Principle Research Supervisor        Research Student

Complaints about this research
This project has been approved by the University’s Human Research Ethics Committee, Approval No. H-2008-0345.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au
Appendix 15  Cross-sectional study: Optional Consent Form
Optional Contact Details Form for the Research Project:
Nutrition, Health and Lifestyle after Banding
Document Version 1; dated 11/02/10

The Research Team:
- Dr Surinder Baines, Faculty of Health at the University of Newcastle
- Miss Alison Dodsworth, Faculty of Health at the University of Newcastle
- A/Prof Helen Warren-Forward, Faculty of Health at the University of Newcastle

NOTE: You only need to complete this form if you:
- Are willing to also be sent a food frequency questionnaire to complete
- And/or you wish to provide your contact details to the researchers

If you would prefer to remain anonymous, you do NOT need to return this form.

I agree to participate in the above research project and give my consent freely. I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I understand that my personal information will remain confidential to the researchers. I have had the opportunity to have questions answered to my satisfaction.

I consent to (please tick all that apply):
- Being sent a food frequency questionnaire to complete and return to the researchers
  - YES □ □ NO □ □
- Providing my contact details for the researchers to contact me in the future for further follow-up surveys
  - YES □ □ NO □ □
- I would like a summary sheet of the project findings
  - YES □ □ NO □ □

Contact Details:
Print name: ____________________________________________________________
Phone number: (1) _____________________________ (2) _____________________________
Address: ___________________________________________________________________
Email: ___________________________________________________________________
Signature: _____________________________ Date: _____________________________
Appendix 16  Cross-sectional study: Non-standard/self-developed survey items
The Gastric Banding Survey

Nutrition, Health & Lifestyle after Banding

University of Newcastle 2010

The Research Team

- Dr Surinder Baines, Faculty of Health, University of Newcastle
- Miss Alison Dodsworth, Faculty of Health, University of Newcastle
- A/Prof Helen Warren-Forward, Faculty of Health, University of Newcastle
How to complete this survey

Please read the instructions for each question very carefully:

• For questions asking you to mark the box, Please mark the one box that best describes your answer with a cross, like this: 

• If you make a mistake, simply scribble it out and clearly mark the correct answer with a cross

• Please PRINT clearly in block letters for questions asking you to write your answer, like this:

  What is your age?
  (Please write in boxes) 45 years

Please answer every question that you can:

• If you are unsure about how to answer a question, mark the response for the closest answer to how you feel.

• If you need help to answer any questions, please ring:

  Alison Dodsworth on 02 4921 7486

If you are concerned about any of your health experiences and would like some help, please contact:

• Your general practitioner for advice about who would be the best person in your community for you to talk to

• If you feel distressed NOW and would like someone to talk to, you could ring Lifeline on 131114 (local call).

Please try to return this survey within 7 days (or as soon as possible)...thank-you for your participation!
Section One: General Information

1. Date
(Please write date in boxes)

2. What is your postcode?
(Please write in boxes)

3. What is your date of birth?
(Please write month and year in boxes)

4. What is your age?
(Please write in boxes)

5. Are you male or female?
(Please circle)

6. How tall are you without shoes?
(If you are not sure, please estimate)

7. How much do you currently weigh without shoes?
(If you are not sure, please estimate)
Section Two: Gastric Banding Details

1. What was the date of your gastric banding surgery?  
   
<table>
<thead>
<tr>
<th>DAY</th>
<th>MONTH</th>
<th>YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   (If known)

2. How much did you weigh when you went in for gastric banding surgery?  
   (If unsure, please give your best estimate)

<table>
<thead>
<tr>
<th>kg OR st pounds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

3. How much weight have you lost since surgery?  
   (If unsure, please give your best estimate)

<table>
<thead>
<tr>
<th>kg OR st pounds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

4a. Did you use Optifast (or a similar meal replacement program) prior to your surgery?  
   (Please circle)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

4b. If you did use Optifast (or similar), how long did you use it for prior to your surgery?  
   (Please mark)

<table>
<thead>
<tr>
<th>Less than 1 week</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 week</td>
<td>2</td>
</tr>
<tr>
<td>2 weeks</td>
<td>3</td>
</tr>
<tr>
<td>3 weeks</td>
<td>4</td>
</tr>
<tr>
<td>4 weeks</td>
<td>5</td>
</tr>
<tr>
<td>5 weeks</td>
<td>6</td>
</tr>
<tr>
<td>6 weeks</td>
<td>7</td>
</tr>
<tr>
<td>More than six weeks</td>
<td>8</td>
</tr>
</tbody>
</table>
5. **At present, how often do you have follow-up appointments with a dietitian? (Please mark)**

<table>
<thead>
<tr>
<th>Weekly</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fortnightly</td>
<td>2</td>
</tr>
<tr>
<td>Monthly</td>
<td>3</td>
</tr>
<tr>
<td>Every 2 months</td>
<td>4</td>
</tr>
<tr>
<td>Every 3 months</td>
<td>5</td>
</tr>
<tr>
<td>Every 4 months</td>
<td>6</td>
</tr>
<tr>
<td>Every 6 months</td>
<td>7</td>
</tr>
<tr>
<td>Greater than 6 months</td>
<td>8</td>
</tr>
<tr>
<td>I don’t see a dietitian</td>
<td>9</td>
</tr>
</tbody>
</table>

6. **How often do you have follow-up appointments with your surgeon? (Please mark)**

<table>
<thead>
<tr>
<th>Weekly</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fortnightly</td>
<td>2</td>
</tr>
<tr>
<td>Monthly</td>
<td>3</td>
</tr>
<tr>
<td>Every 2 months</td>
<td>4</td>
</tr>
<tr>
<td>Every 3 months</td>
<td>5</td>
</tr>
<tr>
<td>Every 4 months</td>
<td>6</td>
</tr>
<tr>
<td>Every 6 months</td>
<td>7</td>
</tr>
<tr>
<td>Greater than 6 months</td>
<td>8</td>
</tr>
<tr>
<td>I haven’t seen my surgeon since surgery</td>
<td>9</td>
</tr>
</tbody>
</table>

7. **How many band fills / adjustments have you had since surgery? (please circle - if unsure, please estimate)**

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>More than 6</th>
</tr>
</thead>
</table>
Section Three: Medical conditions, medications and supplements

1. Have you ever been told by a doctor that you have any of the following conditions? (Mark all that apply)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
a | 1. Type II diabetes |
b | High blood pressure |
c | High cholesterol |
d | Osteoarthritis |
e | Depression |
f | Anxiety disorder |
g | Sleep apnoea |
h | Reflux |
i | None of these conditions |

2. Do you have any other medical conditions? Please list below:

________________________________________________________

________________________________________________________

________________________________________________________

________________________________________________________

________________________________________________________

________________________________________________________

________________________________________________________

________________________________________________________

________________________________________________________
3a. Do you take any medications prescribed by your doctor / specialist?  
(Please circle)  
Yes 1  No 2

3b. If yes, please list your medications below (include dosage if known):

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

4a. Do you take any vitamins / minerals / herbs or other natural supplements?  
(Please circle)  
Yes 1  No 2

4b. If yes, please specify below (include name of product and dosage if known):

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

5a. Do you usually have any food supplements or meal replacements? (eg Sustagen, Optifast)  
(Please circle)  
Yes 1  No 2

5b. If yes, please specify the name/s of products you use and how often you would usually have the product/s:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Sections Four to Six

Section Four: SF-36v2©
Section Five: Three Factor Eating Questionnaire
Section Six: Food tolerance checklist

Refer to Appendix 9 (Protein-enriched dietary intervention survey booklet) for a copy of these survey items
Section Seven: Intake of Selected Foods

The following questions ask about how often you usually eat certain foods.

*Please mark the box that best reflects the number of serves you would *USUALLY* have of each food type.*

1. How many SERVES of fruit (fresh or canned or frozen) do you usually eat each DAY?
   (ONE serve = 1 medium piece of fruit or 2 small pieces of fruit)
   Number of serves: None □ 1 □ 2 □ 3 □ 4 □ 5 □ More than 5 □

2. How many SERVES of vegetables (fresh or canned or frozen) do you usually eat each DAY?
   (ONE serve = 1 cup salad vegetables or 1 small potato or ½ cup cooked vegetables)
   Number of serves: None □ 1 □ 2 □ 3 □ 4 □ 5 □ More than 5 □

3. How many SERVES of milk, yogurt or cheese do you usually have each DAY?
   (ONE serve = 1 cup milk or 2 slices cheese or 1 small carton yogurt or 1 cup custard)
   Number of serves: None □ 1 □ 2 □ 3 □ 4 □ 5 □ More than 5 □

4. How many SERVES of meat, poultry or fish do you usually eat each DAY?
   (ONE serve = 65-100g cooked beef, lamb, pork or chicken.; 1/2 cup of mince, 2 small chops, 2 slices of roast meat; 80-120g cooked fish fillet or 1 small can of tuna/ salmon)
   Number of serves: None □ 1 □ 2 □ 3 □ 4 □ 5 □ More than 5 □
Section Eight: Physical Activity

Refer to Section 4, Part II of Appendix 9 (protein-enriched dietary intervention survey booklet) for a copy of the International Physical Activity Questionnaire.
Section Nine: Education, Work and Income

Please answer the following questions only if you feel comfortable in doing so. If you would prefer not to answer this section, please skip forward to page 25.

1. What is the highest level of education you have completed? *(Please mark one only)*

<table>
<thead>
<tr>
<th>Level of Education</th>
<th>Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>No formal qualifications</td>
<td>1</td>
</tr>
<tr>
<td>Year 10 or equivalent (eg School Certificate)</td>
<td>2</td>
</tr>
<tr>
<td>Year 12 or equivalent (eg Higher School Certificate)</td>
<td>3</td>
</tr>
<tr>
<td>Trade / apprenticeship (eg hairdresser, chef)</td>
<td>4</td>
</tr>
<tr>
<td>Certificate / diploma (eg child care, technician)</td>
<td>5</td>
</tr>
<tr>
<td>University degree</td>
<td>6</td>
</tr>
<tr>
<td>Higher University Degree (eg Grad Dip, Masters, PhD)</td>
<td>7</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>8</td>
</tr>
</tbody>
</table>

2. Which of the following best describes your main occupation now? *(Please mark one only)*

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manager or administrator (eg magistrate, farm manager, general manager, director of nursing, school principal)</td>
<td>1</td>
</tr>
<tr>
<td>Professional (eg scientist, doctor, registered nurse, allied health professional, teacher)</td>
<td>2</td>
</tr>
<tr>
<td>Associate professional (eg technician, manager, youth worker, police officer)</td>
<td>2</td>
</tr>
<tr>
<td>Tradesperson or related worker (eg hairdresser, gardener, florist)</td>
<td>3</td>
</tr>
<tr>
<td>Advanced clerical or service worker (eg secretary, personal assistant, flight attendant, law clerk)</td>
<td>4</td>
</tr>
<tr>
<td>Intermediate clerical, sales or service worker (eg typist, word processing / data entry operator, receptionist, child care worker, nursing assistant, hospitality worker)</td>
<td>5</td>
</tr>
<tr>
<td>Intermediate production or transport worker (eg sewing machinist, machine operator, bus driver)</td>
<td>6</td>
</tr>
<tr>
<td>Elementary clerical, sales or service worker (eg filing / mail clerk, parking inspector, sales assistant, telemarketer, housekeeper)</td>
<td>7</td>
</tr>
<tr>
<td>Labourer or related worker (eg cleaner, factory worker, general farm hand, kitchenhand)</td>
<td>8</td>
</tr>
<tr>
<td>No paid job</td>
<td>9</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>8</td>
</tr>
</tbody>
</table>
3a. **What is the average gross (before tax) income of your household each year?** *(Please mark one for yourself and one for your household)*

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Self</th>
<th>Household</th>
</tr>
</thead>
<tbody>
<tr>
<td>No income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to $20,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$20,001 to $40,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$40,001 to $60,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$60,001 to $80,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$80,001 or more</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3b. **How many people (including you) are dependent on this household income?** *(Please write in boxes)*

<table>
<thead>
<tr>
<th>Number of People</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Have we missed anything?

If you have **ANYTHING** else you would like to tell us, please write on the lines below.

_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
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_________________________________________________________________

*This is the end of the survey booklet, thank you for participating!*
Please remember to send this back in the reply paid envelope...

...and also include your completed contact details form if you are happy to:

- Complete a food frequency questionnaire
- Be contacted again for future surveys

*If you have any further queries, please do not hesitate to contact either:

Dr Surinder Baines (Chief Investigator), APD
Senior Lecturer, Discipline of Nutrition and Dietetics
Phone: 02 4921 5643
Email: surinder.baines@newcastle.edu.au

*or*

Miss Alison Dodsworth (PhD Student Researcher), APD
Phone: 02 4921 7486
Email: Alison.dodsworth@newcastle.edu.au
Appendix 17  Dietary Questionnaire for Epidemiological Studies Version 2 © (Cancer Council, Victoria Australia)
Dietary Questionnaire

QUESTIONS ABOUT WHAT YOU USUALLY EAT AND DRINK

INSTRUCTIONS:
This questionnaire is about your usual eating habits over the past 12 months. Where possible give only one answer per question for the type of food you eat most often. (If you can't decide which type you have most often, answer for the types you usually eat.)

- Use a soft pencil only, preferably 2B.
- Do not use any biro or felt tip pen.
- Erase mistakes fully.
- Make the stays marks.

MARK LIKE THIS:

Please fill in the date you completed this questionnaire:

<table>
<thead>
<tr>
<th>DAY</th>
<th>MTH</th>
<th>YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>JAN</td>
<td>2004</td>
</tr>
<tr>
<td>☐</td>
<td>FEB</td>
<td>2005</td>
</tr>
<tr>
<td>☐</td>
<td>MAR</td>
<td>2006</td>
</tr>
<tr>
<td>☐</td>
<td>APR</td>
<td>2007</td>
</tr>
<tr>
<td>☐</td>
<td>MAY</td>
<td>2008</td>
</tr>
<tr>
<td>☐</td>
<td>JUN</td>
<td>2009</td>
</tr>
<tr>
<td>☐</td>
<td>JUL</td>
<td>2010</td>
</tr>
<tr>
<td>☐</td>
<td>AUG</td>
<td>2011</td>
</tr>
<tr>
<td>☐</td>
<td>SEP</td>
<td>2012</td>
</tr>
<tr>
<td>☐</td>
<td>OCT</td>
<td>2013</td>
</tr>
<tr>
<td>☐</td>
<td>NOV</td>
<td>2014</td>
</tr>
<tr>
<td>☐</td>
<td>DEC</td>
<td>2015</td>
</tr>
</tbody>
</table>

1. How many pieces of fresh fruit do you usually eat per day? (Count 1/2 cup of diced fruit, berries or grapes as one piece.)
   - I didn't eat fruit
   - less than 1 piece of fruit per day
   - 1 piece of fruit per day
   - 2 pieces of fruit per day
   - 3 pieces of fruit per day
   - 4 or more pieces of fruit per day

2. How many different vegetables do you usually eat per day? (Count all types, fresh, frozen or tinned.)
   - less than 1 vegetable per day
   - 1 vegetable per day
   - 2 vegetables per day
   - 3 vegetables per day
   - 4 vegetables per day
   - 5 vegetables per day
   - 6 or more vegetables per day

3. What type of milk do you usually use?
   - none
   - full cream milk
   - reduced fat milk
   - skim milk
   - soya milk

4. How much milk do you usually use per day? (Include flavoured milks and milk added to tea, coffee, cereal, etc.)
   - none
   - less than 250 ml (1 large cup or mug)
   - between 250 and 500 ml (1-2 cups)
   - between 500 and 750 ml (2-3 cups)
   - 750 ml (3 cups) or more

5. What type of bread do you usually eat?
   - I don't eat bread
   - high fibre white bread
   - white bread
   - wholemeal bread
   - rye bread
   - multi-grain bread

6. How many slices of bread do you usually eat per day? (Include all types, fresh or toasted and count one bread roll as 2 slices.)
   - less than 1 slice per day
   - 1 slice per day
   - 2 slices per day
   - 3 slices per day
   - 4 slices per day
   - 5-7 slices per day
   - 8 or more slices per day

7. Which spread do you usually put on bread?
   - I don't usually use any fat spread
   - margarine of any kind
   - polyunsaturated margarine
   - monounsaturated margarine
   - butter and margarine blends
   - butter

8. On average, how many teaspoons of sugar do you usually use per day? (Include sugar taken with tea and coffee and on breakfast cereal, etc.)
   - none
   - 1 to 4 teaspoons per day
   - 5 to 8 teaspoons per day
   - 9 to 12 teaspoons per day
   - more than 12 teaspoons per day

9. On average, how many eggs do you usually eat per week?
   - I don't eat eggs
   - less than 1 egg per week
   - 1 to 2 eggs per week
   - 3 to 5 eggs per week
   - 6 or more eggs per week

10. What types of cheese do you usually eat?
    - I don't eat cheese
    - hard cheeses, e.g. parmesan, romano
    - firm cheeses, e.g. cheddar, edam
    - soft cheeses, e.g. camembert, brie
    - ricotta or cottage cheese
    - cream cheese
    - low fat cheese
For each food shown on this page, indicate **how much on average you would usually have eaten at main meals during the past 12 months**. When answering each question, think of the **amount** of that food you usually ate, even though you may rarely have eaten the food on its own.

*If you usually ate more than one helping, fill in the oval for the serving size closest to the **total amount** you ate.*

**Q11.** When you ate potato, did you usually eat:
- Less than A
- A
- Between A & B
- B
- Between B & C
- C
- More than C

**Q12.** When you ate vegetables, did you usually eat:
- Less than A
- A
- Between A & B
- B
- Between B & C
- C
- More than C

**Q13.** When you ate steak, did you usually eat:
- Less than A
- A
- Between A & B
- B
- Between B & C
- C
- More than C

**Q14.** When you ate meat or vegetable casserole, did you usually eat:
- Less than A
- A
- Between A & B
- B
- Between B & C
- C
- More than C
### Times You Have Eaten

<table>
<thead>
<tr>
<th>Cereal Foods, Sweets &amp; Snacks</th>
<th>NEVER</th>
<th>less than once</th>
<th>1 to 3 times</th>
<th>1 time</th>
<th>2 times</th>
<th>3 to 4 times</th>
<th>5 to 6 times</th>
<th>1 time</th>
<th>2 times</th>
<th>3 or more times</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Bran™</td>
<td>A1</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Sultana Bran™, FibrePlus™, Branflakes™</td>
<td>A2</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Weet Bix™, Vita Brits™, Weeties™</td>
<td>A3</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Cornflakes, Nutrigrain™, Special K™</td>
<td>A4</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>Porridge</td>
<td>A5</td>
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<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Muesli</td>
<td>A6</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Rice</td>
<td>A7</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Pasta or noodles (include lasagne)</td>
<td>A8</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Crackers, crispbreads, dry biscuits</td>
<td>A9</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Sweet biscuits</td>
<td>A10</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Cakes, sweet pies, tarts and other sweet pastries</td>
<td>A11</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Meat pies, pastries, quiche and other savoury pastries</td>
<td>A12</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Pizza</td>
<td>A13</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Hamburger with a bun</td>
<td>A14</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Chocolate</td>
<td>A15</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Flavoured milk drink (cocoa, Milo™, etc.)</td>
<td>A16</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Nuts</td>
<td>A17</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Peanut butter or peanut paste</td>
<td>A18</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Corn chips, potato crisps, Twists™, etc.</td>
<td>A19</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Jam, marmalade, honey or syrups</td>
<td>A20</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>Vegemite™, Marmite™ or Promite™</td>
<td>A21</td>
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</tbody>
</table>

### Dairy Products, Meat & Fish

<table>
<thead>
<tr>
<th>Cheese</th>
<th>Ice-cream</th>
<th>Yoghurt</th>
<th>Beef</th>
<th>Veal</th>
<th>Chicken</th>
<th>Lamb</th>
<th>Pork</th>
<th>Bacon</th>
<th>Ham</th>
<th>Corned beef, luncheon meats or salami</th>
<th>Sausages or frankfurters</th>
<th>Fish, steamed, grilled or baked</th>
<th>Fish, fried (include take-away)</th>
<th>Fish, tinned (salmon, tuna, sardines, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>B2</td>
<td>B3</td>
<td>B4</td>
<td>B5</td>
<td>B6</td>
<td>B7</td>
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<td>B11</td>
<td>B12</td>
<td>B13</td>
<td>B14</td>
<td>B15</td>
</tr>
</tbody>
</table>

### Fruit

<table>
<thead>
<tr>
<th>Tinned or frozen fruit (any kind)</th>
<th>C1</th>
<th>C2</th>
<th>C3</th>
<th>C4</th>
<th>C5</th>
<th>C6</th>
<th>C7</th>
<th>C8</th>
<th>C9</th>
<th>C10</th>
<th>C11</th>
<th>C12</th>
<th>C13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit juice</td>
<td>○</td>
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<tr>
<td>Oranges or other citrus fruit</td>
<td>○</td>
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<tr>
<td>Apples</td>
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<tr>
<td>Pears</td>
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<tr>
<td>Watermelon, rockmelon (cantaloupe), honeydew, etc.</td>
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<td>Pineapple</td>
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<tr>
<td>Strawberries</td>
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<tr>
<td>Apricots</td>
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<tr>
<td>Peaches or nectarines</td>
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<tr>
<td>Mango or paw paw</td>
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### Times You Have Eaten

**CONTINUED**

<table>
<thead>
<tr>
<th>VEGETABLES (INCLUDING FRESH, FROZEN AND TINNED)</th>
<th>NEVER</th>
<th>less than once per month</th>
<th>1 to 3 times per month</th>
<th>1 time</th>
<th>2 times</th>
<th>3 to 4 times</th>
<th>5 times</th>
<th>1 time</th>
<th>2 times</th>
<th>3 or more times per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potatoes, roasted or fried (include hot chips)</td>
<td>D1</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>Potatoes cooked without fat</td>
<td>D2</td>
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<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Tomato sauce, tomato paste or dried tomatoes</td>
<td>D3</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Fresh or tinned tomatoes</td>
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<tr>
<td>Peppers (capsicum)</td>
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<td>☐</td>
<td>☐</td>
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<tr>
<td>Lettuce, endive, or other salad greens</td>
<td>D6</td>
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<tr>
<td>Cucumber</td>
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<td>Celery</td>
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<tr>
<td>Carrots</td>
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<tr>
<td>Cabbage or Brussels sprouts</td>
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<td>Cauliflower</td>
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<tr>
<td>Broccoli</td>
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<tr>
<td>Silverbeet or spinach</td>
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<tr>
<td>Peas</td>
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<tr>
<td>Green beans</td>
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<tr>
<td>Bean sprouts or alfalfa sprouts</td>
<td>D17</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>Nuked beans</td>
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<tr>
<td>Soy beans, soy bean curd or tofu</td>
<td>D19</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Other beans (include chick peas, lentils, etc.)</td>
<td>D20</td>
<td>☐</td>
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<tr>
<td>Pumpkin</td>
<td>D21</td>
<td>☐</td>
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<tr>
<td>Onion or leeks</td>
<td>D22</td>
<td>☐</td>
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<tr>
<td>Garlic (not garlic tablets)</td>
<td>D23</td>
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<tr>
<td>Mushrooms</td>
<td>D24</td>
<td>☐</td>
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<tr>
<td>Zucchini</td>
<td>D25</td>
<td>☐</td>
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</table>

### Times That You Drank

<table>
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<tr>
<th>NUNVER</th>
<th>less than once a month</th>
<th>1-2 days per month</th>
<th>3 days per week</th>
<th>5 days per week</th>
<th>10 days per week</th>
<th>12 days per month</th>
<th>15 days per month</th>
<th>30 days per month</th>
<th>3-5 months per month</th>
<th>6 months per month</th>
<th>9 months per month</th>
<th>12 months per month</th>
<th>1 year more</th>
<th>2 years more</th>
<th>3 or more years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beer (low alcohol)</td>
<td>1</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Beer (full strength)</td>
<td>2</td>
<td>☐</td>
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<tr>
<td>Red wine</td>
<td>3</td>
<td>☐</td>
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<tr>
<td>White wine (include sparkling wines)</td>
<td>4</td>
<td>☐</td>
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<tr>
<td>Fortified wines, port, sherry, etc.</td>
<td>5</td>
<td>☐</td>
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<tr>
<td>Spirits, liqueurs, etc.</td>
<td>6</td>
<td>☐</td>
<td>☐</td>
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</table>

When answering the next two questions, please convert the amounts you drank into glasses using the examples given below. For spirits, liqueurs, and mixed drinks containing spirits, please count each nip (30 ml) as one glass.

1. 1 can or stubby of beer = 2 glasses
2. 1 bottle wine (750 ml) = 6 glasses
3. 1 large bottle beer (750 ml) = 4 glasses
4. 1 bottle of port or sherry (750 ml) = 12 glasses

### Over the last 12 months, how often did you drink beer, wine and/or spirits?

#### Total Number of Glasses Per Day

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10 or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beer (low alcohol)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Beer (full strength)</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<td>☐</td>
</tr>
<tr>
<td>Red wine</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<td>☐</td>
</tr>
<tr>
<td>White wine (include sparkling wines)</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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</tr>
<tr>
<td>Fortified wines, port, sherry, etc.</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
</tr>
<tr>
<td>Spirits, liqueurs, etc.</td>
<td>☐</td>
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</tbody>
</table>

### Over the last 12 months, on days when you were drinking, how many glasses of beer, wine and/or spirits altogether did you usually drink?

### Maximum Number of Glasses Per 24 Hours

<table>
<thead>
<tr>
<th>Maximum Number</th>
<th>1-2</th>
<th>3-4</th>
<th>5-6</th>
<th>7-8</th>
<th>9-10</th>
<th>11-12</th>
<th>13-14</th>
<th>15-16</th>
<th>17-18</th>
<th>19 or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beer (low alcohol)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Beer (full strength)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Red wine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>White wine (include sparkling wines)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Fortified wines, port, sherry, etc.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Spirits, liqueurs, etc.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

© Copyright The Cancer Council Victoria 2005. Thank you for completing this questionnaire.

Do not write in this area.
Appendix 18  Protein-enriched dietary intervention: Supplementary results
Results not included in final published paper (Chapter 4):

1. Dietary intake data for intervention versus control group (Table 1)
2. Differences in weight and body composition outcomes according to diet allocation including BMI, waist circumference, percentage body fat and fat mass as measured by BIA (Figure 1)
3. Differences in body composition outcomes (percentage body fat, fat mass and fat free mass) according to diet allocation at and fat mass as measured by DXA (Figure 2).

Table 1. Reported dietary intake at baseline, three, six and 12 months according to diet allocation

<table>
<thead>
<tr>
<th></th>
<th>Baseline (n=47)</th>
<th>3 months (n=37)</th>
<th>6 months (n=38)</th>
<th>12 months (n=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UC (n=23)</td>
<td>PE (n=24)</td>
<td>UC (n=17)</td>
<td>PE (n=20)</td>
</tr>
<tr>
<td>Energy (MJ/d)</td>
<td>11.3 (9.7-12.9)</td>
<td>11.4 (9.8-12.9)</td>
<td>5.6 (4.9-6.3)</td>
<td>5.7 (5.1-6.4)</td>
</tr>
<tr>
<td></td>
<td>5.8 (5.0-6.5)</td>
<td>5.8 (5.0-6.5)</td>
<td>6.3 (5.1-7.4)</td>
<td>6.3 (5.3-7.4)</td>
</tr>
<tr>
<td>Protein (g/d)</td>
<td>123 (104-141)</td>
<td>123 (105-141)</td>
<td>71 (61-80)</td>
<td>74 (65-83)</td>
</tr>
<tr>
<td></td>
<td>75 (60-89)</td>
<td>73 (58-87)</td>
<td>67 (52-82)</td>
<td>67 (53-80)</td>
</tr>
<tr>
<td>Carbohydrate (g/d)</td>
<td>286 (244-327)</td>
<td>302 (261-343)</td>
<td>142 (123-161)</td>
<td>149 (131-169)</td>
</tr>
<tr>
<td></td>
<td>141 (120-171)</td>
<td>149 (128-171)</td>
<td>150 (124-176)</td>
<td>170 (146-193)</td>
</tr>
<tr>
<td>Fat (g/d)</td>
<td>107 (87-126)</td>
<td>105 (85-124)</td>
<td>47 (38-55)</td>
<td>43 (35-51)</td>
</tr>
<tr>
<td></td>
<td>49 (39-58)</td>
<td>45 (35-55)</td>
<td>62 (43-82)</td>
<td>51 (33-68)</td>
</tr>
<tr>
<td>Protein (g/kg/body weight)</td>
<td>1.0 (0.9-1.1)</td>
<td>1.0 (0.8-1.1)</td>
<td>0.7 (0.6-0.8)</td>
<td>0.7 (0.6-0.8)</td>
</tr>
<tr>
<td></td>
<td>0.7 (0.6-0.8)</td>
<td>0.7 (0.6-0.8)</td>
<td>0.6 (0.5-0.8)</td>
<td>0.6 (0.5-0.8)</td>
</tr>
<tr>
<td>% energy from protein</td>
<td>19 (17-20)</td>
<td>19 (17-20)</td>
<td>23 (20-25)</td>
<td>23 (21-25)</td>
</tr>
<tr>
<td></td>
<td>23 (19-26)</td>
<td>22 (18-25)</td>
<td>17 (15-20)</td>
<td>19 (17-22)</td>
</tr>
<tr>
<td>% energy from Carbohydrate</td>
<td>42 (39-45)</td>
<td>43 (40-47)</td>
<td>42 (38-45)</td>
<td>44 (40-49)</td>
</tr>
<tr>
<td></td>
<td>43 (37-49)</td>
<td>45 (40-51)</td>
<td>43 (37-49)</td>
<td>45 (40-51)</td>
</tr>
<tr>
<td>% energy from fat</td>
<td>34 (31-37)</td>
<td>33 (31-36)</td>
<td>30 (26-33)</td>
<td>28 (24-31)</td>
</tr>
<tr>
<td></td>
<td>30 (26-31)</td>
<td>29 (24-33)</td>
<td>33 (26-39)</td>
<td>30 (24-35)</td>
</tr>
</tbody>
</table>

UC = usual care group, PE = protein enriched group. Results are based on linear mixed models analysis and are reported as estimated marginal mean (95% confidence interval). There were no significant differences between the usual care and protein-enriched groups for any dietary variable at any time point.

a Within-subjects effect: P <0.05 vs. baseline
b Within-subjects effect: P <0.05 vs. 3 months
c Within-subjects effect: P <0.05 vs. 6 months
Figure 1. Changes in weight (A), Body mass index (B), waist circumference (C), percentage body fat (D), fat mass (E) and fat free mass (F) over the 12 month study period from study baseline according to diet allocation.

Usual care (–); protein-enriched (—). Body composition measured by BIA. Results presented as estimated marginal mean ± SEM. Sample sizes for each time point for A, B, D, E and F: 0 (n=47), 3 (n=45), 6 (n=41) and 12 (n=35). Sample sizes for C: 0 (n=44), 3 (n=43), 6 (n=38) and 12 (n=31). Between-subjects effects for time × diet allocation: A. $P=0.3$, B. $P=0.3$, C. $P=0.08$, D. $P=0.9$, E. $P=0.6$, F. $P=0.6$. Within-subjects effects: $^a$ $P<0.05$ vs. baseline; $^b$ $P<0.05$ vs. three months.
Usual care (○); protein-enriched (■). Results presented as estimated marginal mean ± SEM. Sample sizes for each time point: 0 (n=39), 6 (n=33) and 12 (n=26). Between-subjects effects for time × diet allocation: A. $P=0.6$, B. $P=0.6$, C. $P=0.2$, D. $P=0.9$, E. $P=0.6$, F. $P=0.6$. Within-subjects effects: $^a$ P<0.05 vs. baseline.

**Interpretation notes for body composition data**

It is unclear why fat free mass (FFM) increased significantly for both the intervention and control groups from baseline to three months according to BIA and for the control group only as measured by DXA at six months. It is possible that baseline FFM measurements may have been reflective of pre and immediate post-surgery FFM losses (as a consequence of the pre-operative VLED phase as well as typically limited energy...
intakes during the first week after surgery), with the observed increases in FFM at three/six months reflecting potential recovery of short-term FFM losses. It is not surprising that there was no distinguishable improvement in FFM in the intervention group given that compliance with the intended intervention was low.

Differences between DXA and BIA measurements are likely to reflect inherent measurement error within each methodology. Furthermore, DXA outcomes represented a lower body weight subsample of participants (reflecting weight limit restrictions for DXA). Although trends for change in FFM appear to be different according to diet allocation between BIA and DXA, there were no differences in the statistical significance of between-subject effects according to body composition assessment methodology. Furthermore, the practical significance of these differences in FFM findings is limited given that the overall magnitude of change in FMM was small over the 12 month period, regardless of assessment methodology.
Appendix 19  Cross-sectional study supplementary results: Summary of qualitative feedback provided by respondents
**Summary of qualitative feedback provided by respondents**

Thirty-one respondents (46.2%) provided qualitative feedback in the open comments section of the survey, with the most common theme relating to overall satisfaction with LAGB. Many of these respondents indicated a high level of satisfaction with weight loss and improvements in health and quality of life, referring to banding as, for example, “the best thing ever”, a “saving grace” and “lifesaver”. Similarly, multiple respondents remarked that they felt they could not have lost weight without LAGB.

Several respondents commented that weight loss was slower than expected and/or suggested that LAGB did not represent a quick-fix solution; however with considerable effort required to achieve weight loss after surgery. A minority of respondents commented that they would not have the procedure again or recommend it. These remarks were generally related to plateaus in weight loss/weight regain, complications such as band slippages and the need for re-operation, problematic food tolerance and ongoing difficulties with emotional eating.

There was conflicting feedback regarding eating behaviour after LAGB. Multiple respondents indicated that banding did not help with emotional or non-hungry eating, and suggested that psychological counselling would have been a beneficial addition to
their pre-operative and/or post-operative management. Other respondents indicated that their band now controls their eating behaviour rather than emotions, commenting that survey questions relating to eating behaviour were “irrelevant” and that “eating behaviour is now governed by my lap-band and not my mind”.

Food tolerance issues after surgery were also mentioned by several respondents, highlighting that the quality of their food choices is now poorer and/or it is still possible to eat less desirable foods, for example:

Whilst it (gastric banding) has controlled my portion sizes, it has made my food choices very unhealthy. I used to eat very healthy lunches and dinners consisting of proteins and salads and dinners of protein and at least 4-5 vegetables. My choices now consist of foods that I can get down without getting stuck…

I find I have difficulty eating meat and vegetables and I have no difficulty in eating highly processed foods.