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Beyond nutrients: a food pattern approach to examining dietary change in weight loss

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Beyond nutrients: a food pattern approach to examining dietary change in weight loss.

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By

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CERTIFICATION

I, Sara Jane Grafenauer declare that this thesis, submitted in fulfilment of the requirements for the award of Doctor of Philosophy, in the Smart Foods Centre and School of Health Sciences, University of Wollongong, is my own work unless otherwise referenced or acknowledged. This document has not been submitted in whole, or in part, for qualifications at any other academic institution.

Sara Jane Grafenauer

17 December, 2013

DEDICATION

To Andrew, Aidan, Ella, Mum and Dad,

Thank you.

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PUBLICATIONS

Peer reviewed journal publications in support of this thesis

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Other published work during this timeframe

Chapter 8 *Nutrition during the Lifecycle: Pregnancy and Lactation* in *Food, Nutrition and Health* LC Tapsell (Ed.) (2013). Oxford University Press.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

%E	Percentage of Energy
AGHE	Australian Guide to Healthy Eating
AI	Adequate Intake
AMDR	Accepted Macronutrient Distribution Range
ANOVA	Analysis of Variance
BMI	Body Mass Index
DH	Diet History
DQ	Diet Quality
EAR	Estimated Average Requirement
FCS	Food Choices Score
FFQ	Food Frequency Questionnaire
GI	Glycaemic Index
HDL-c	High Density Lipoprotein Cholesterol
IQR	Interquartile range
kJ	Kilojoule
LDL-c	Low Density Lipoprotein Cholesterol
NCFD	Non-core foods and drinks
NRV	Nutrient Reference Values
RCT	Randomised Controlled Trial
RMANOVA	Repeated Measures Analysis of Variance
RR	Ready Reckoner
SDT	Suggested Dietary Target
TG	Triglycerides

PREAMBLE

‘Now to perform a true physician's part, And show I am perfect master of my art,

I will prescribe what diet you should use, What food you ought to take, and what refuse.'

–Publius Ovidius Naso (‘‘Ovid,'' 43 B.C.–A.D.17), Remedia Amoris

This thesis centres on the art of providing advice on specific foods.

"The search for the 'ideological' or intellectual basis of how we eat and why we eat what we eat can seem remote, since after all, we eat all the time. But we could say the same thing about breathing, and it is worth knowing something about how our lungs work... The things we do without thinking are often the things most worth thinking about."

—Adam Gopnik, The Table Comes First, published 2011 A.A. Knopf, Canada p 289

This thesis focuses in on the detail of food specific advice during weight loss.

“It is better to know nothing than to keep in mind fixed ideas based on theories whose confirmation we constantly seek.”

—Claude Bernard, An introduction to the Study of Experimental Medicine (1865)

This thesis questions many assumptions about food categorisation, eating patterns and more.

"I don't like food, I love it. If I don't love it, I don't swallow."

—Food critic Anton Ego in the movie Ratatouille, 2007 Disney/Pixar.

This thesis is grounded in the reality of people making food choices in a weight loss setting.

I am an Accredited Practising Dietitian and although I have held many different positions, in health and in industry, I have a strong clinical grounding that guides me. Reflecting on my diverse work background has helped me write this thesis. The PhD process is rarely straight forward, yet the journey is *always* significant. I began work at the University of Wollongong in 2005 and observed from a distance the clinical trials of the Smart Food Centre, a variety of studies relating to macronutrients (protein), food components (fatty acids and beta-glucan) and single foods (walnuts). I had an interest in food ingredients and components having worked within food industry and I worked on food research projects for the National Centre of Excellence in Functional Foods (NCEFF) based at the University. This work focused on the evidence base for health effects of food, which required a broad perspective.

After NCEFF I commenced a journey of a very different kind and my work was blended with personal layers. My family was building a house. Although this was a busy time, I began my research examining functional food ingredients in test-diets with a mouse model while still teaching within the Nutrition and Dietetics program. Although I gained significant experimental research experience, the results for the three functional food ingredients did not produce changes in the dietary consumption patterns in the mice (Manuscript for submission: Appendix F). It was also not where my heart lay. This led to a period of reflection, and I changed the direction of my research. I was more interested in the reality of changed dietary patterns in humans.

In my clinical practice I heard myself saying to clients “It is the whole diet that counts… it is all the foods together”. Following discussions with my supervisors, I was offered

the opportunity to serve as a clinical trial dietitian in the impending Smart Food Centre dietary trial (HEAL). In return, I could access the dietary data from this and a previous trial to conduct secondary analyses on dietary patterns in the weight loss context. Considering the whole diet and dietary patterns was the inspiration for this thesis.

ABSTRACT

Background

This thesis focuses on dietetic practice supporting weight loss. Whereas dietary intervention research forms the basis for evidence based practice, the focus on nutrients, ingredients or single foods may limit the conclusions that can be drawn for the practice setting. In practice, dietitians assess and provide the dietary prescription only in terms of foods, not nutrients. Observational research has been conducted in terms of foods and dietary patterns however this does not necessarily translate to advice for individuals and the findings of this research needs to be confirmed with randomised controlled trials. Although reducing energy intake relative to expenditure is pivotal in weight loss, questions remain about which foods and dietary patterns optimise weight control. Weight loss is complex, and diet quality may be overlooked in attempts to lower kilojoule intake. A healthy diet can be constructed in numerous ways, but certain features are thought to be important for health and linked to better health outcomes. The foods consumed within the whole diet change over time, but analysis of these changes, particularly in the context of an intervention, may help clarify the most effective dietary changes and provide more specific food advice, augmenting nutrient-level findings. This research explores a whole-of-diet approach where categories of foods were used to monitor dietary change and weight loss in a clinical intervention context forming links between dietary patterns and outcomes.

Research Hypothesis and Aims

The central hypothesis examined in this thesis was that an analysis of dietary patterns reported by overweight participants in a weight loss trial will reveal important practice-relevant information for developing dietary advice.

The aims of the thesis were to:

1. Develop food categories extending from the traditional five food groups to explore dietary patterns within an intervention context.
2. Identify patterns of food choice in the context of a clinical weight loss trial and associations with weight loss and health outcomes.
3. Develop and validate a diet quality tool for weight management, to investigate changing diet quality within a weight loss intervention context.

Methods

This thesis involved a number of investigations using secondary analysis of combined data from two dietary intervention trials [1, 2] conducted through the Smart Foods Centre at the University of Wollongong. Both intervention studies measured a primary outcome of weight loss. For this thesis, to further examine the nutrition-health interface, methods for considering whole foods within the whole diet needed to be developed. This involved developing a system for categorising foods, methods for distilling dietary patterns and approaches to examining links between dietary patterns and outcomes.

Developing food categories for the examination of dietary patterns was central to the thesis framework. Defensible food categories were derived from a review of the literature on associations between food intake and health outcomes, an examination of existing food categorisation systems and a consideration of the culinary use of food. Cluster analysis was utilised to examine dietary data from these new categories at baseline, and the association between weight loss and changing patterns after three months. Dietary modelling was applied to two idealised energy deficit diet models (6500 and 7400kJ) in the development and validation of a diet quality tool, referred to as the Food Choices Score (FCS). The diet models assured adequate nutrient intake based on core food groups. Using this score, dietary patterns were examined between baseline and three months. Consumption of certain food categories (particularly non-core foods and drinks) were examined for up to 12-months in relation to weight change. Comparisons to computerised nutrient analysis, biochemical and anthropometric measures using data at baseline, three months and 12-months were conducted.

Results

Seventeen food categories were derived with some reference to the traditional five food groups to clearly depict dietary patterns. The 17 categories assisted in provision of more descriptive information in assessing the associations between dietary patterns and positive and negative health outcomes than the traditional five food groups. While energy intake was significantly reduced within three months, the weight of food (excluding fluids) was not reduced. This result was primarily due to reductions in consumption of higher energy food choices, non-core foods and drinks (NCFD), fatty

meats and non-wholegrain cereal foods and a corresponding increase in vegetable consumption. Cluster analysis using the same data showed subjects consuming >6 serves of NCFD at baseline lost significantly more weight than those with baseline diets already closer to dietary targets for weight loss. A higher FCS was representative of higher diet quality and a greater improvement in the FCS over three months predicted greater weight loss validating it as a useful tool. The changes in diet patterns in relation to weight loss were further confirmed through logistic regression reinforcing the link with decreasing consumption of NCFD and non-wholegrain cereal foods. Dietary patterns of participants with weight loss >10% over 12-months reported consuming significantly less NCFD and significantly more fruit than those losing <5%.

Major conclusions and relevance to dietetic practice

The analysis based on reported food consumption provided insights in terms of specific food-based dietary advice. The methods employed for examining dietary patterns maintained the detail of the foods described in the original dietary data. The outcomes of this thesis suggest that food-level analyses should accompany analyses of energy and nutrient intakes in the routine examination of dietary changes in dietary intervention trials. The addition of dietary patterns would help facilitate translation of research findings to the clinical setting. In the analysis presented, weight loss was greater in those with higher baseline intakes of NCFD. Thus close examination of the detail of food choices at baseline may help maximise the energy deficit that could be created for individuals desiring weight reduction. In contrast, reporting a dietary pattern closer to guidelines at baseline may mean fewer dietary changes, however reducing energy intake may still be required. Intakes of some foods and drinks may be

more modifiable than others during weight loss. In the analyses reported in this thesis, large reductions in energy intake were possible from foods categorised as NCFD. Monitoring the intake of all foods and drinks over a longer time-frame was shown to be important in monitoring body weight change, especially since the energy density of some foods may influence the amount of total food ingested. Food weight was consistent across the first 3-months, although mean energy decreased >2000kJ, presenting an opportunity for clinicians who could replicate the substitution of light weight yet energy dense foods with relatively heavy foods like vegetables. Diet quality tools, such as the Food Choices Score (FCS) developed specifically for the weight loss setting, may assist in clinical research by providing an opportunity to benchmark the baseline diet against ideals over time. This helps in focusing both the clinician and the client on the issue of diet quality in weight loss and thereby more effective food substitution.

Conclusions

The analysis of change in food choices and dietary patterns at the dietary intervention level was novel and informative for practice. Using the 17 defined food categories proved useful for food pattern analysis and gave a meaningful representation of the reported diet history. Baseline dietary patterns particularly are a significant consideration in correcting dietary exposure for weight loss and a validated Food Choices Score was sensitive to dietary change in a weight loss context. A food-based approach is a valuable adjunct to other analyses in weight loss trials and provides more specific food advice for the practice setting. The 17 food categories developed in this thesis provided a framework for further research at the dietary intervention level.

CHAPTER 1 INTRODUCTION

"Nutrition arguments are almost certainly about single nutrients taken out of their food context, single foods taken out of their dietary context or single risk factors and diseases taken out of their lifestyle context" Marion Nestle [3].

Dietary intervention research has tended to focus on nutrients, ingredients or single foods, in attempting to draw conclusions about diet and health relationships. Over-reliance on examining isolated nutrients or food components in order to define ideal diets may limit the conclusions that can be drawn. This thesis explores a whole-of-diet approach, where the combinations of many foods, arranged into food categories for analytical purposes, may help examine relationships with health outcome measures. The approaches utilised in this thesis emphasise the importance of considering all of the foods consumed in the whole-diet and this has support within the scientific literature [4-9]. Dietary pattern research has usually been conducted through observational studies. The investigations within this thesis utilise analyses typical of observational research evaluating dietary patterns. The techniques are applied to a clinical dietary intervention research context, whereby the changing diets of participants instructed in weight loss were explored. Although reducing energy intake relative to expenditure is pivotal in weight loss, questions remain about which foods and dietary patterns optimise weight loss. Examining the reported food changes over time from free-living weight loss interventions, may help clarify the most effective dietary changes and provide specific food information that is directly translational to the clinical setting [10, 11].

1.1. Weight loss and weight management

The metabolic consequences of overweight and obesity are now among the most frequently discussed public health issues. This includes discussion of the optimal diet prescription for weight loss. Rates of obesity in populations have increased globally, and this is thought to be due to changes in both the types and amounts of food available, in conjunction with decreases in physical activity. Worldwide 500 million people are classified as obese and a further 1.4 billion regarded as overweight [12]. More than half of Australians (63.4%) aged 18 years and over have recently been assessed as overweight or obese, an increase of 7.1 percentage points since 1995 [13]. Men were more likely (70 per cent) to be overweight or obese than women (56 per cent) and one-quarter (25 per cent) of Australian children have a BMI that placed them in this category. Excessive weight impacts on and leads to several serious diseases, in terms of both increased mortality and morbidity, including cardiovascular disease, type-2 diabetes mellitus, hypertension, stroke, certain types of cancer, gallbladder disease, osteoarthritis, respiratory and sleep problems [14]. In 2005, the annual direct costs of overweight and obesity in Australia was found to be $21 billion [15] and in 2008-09 the total annual cost of lifestyle-related illnesses in Australia was estimated at approximately $37.7 billion [16]. Many Australians are concerned about these health implications and are trying to lose weight [17].

While at a population-level, weight and weight gain are complicated by a number of factors, the core issues at the individual level are nutrition and metabolism. Body weight change is a result of the energy consumed, the food eaten and the energy expended by the body to maintain function and perform physically [18]. However,

there are multiple pathways through which food intake, including diet composition and weight of food [19], affects energy balance [20]. Interestingly, individuals seem to consume a constant weight of food each day rather than a constant amount of energy [19, 21-23]. Substitution of lower energy dense foods may be an important feature of diets for weight loss while the restriction of food volume may risk poor compliance with the diet prescription. Furthermore, body weight regulation is a complex system influenced by behaviour, environment and genetic factors. In an attempt to lower kilojoule intake for weight loss, diet quality may be overlooked and although not often discussed, malnutrition exists in obesity [24]. Despite excessive energy intake, micronutrient deficiencies have been noted in overweight populations and specific deficiencies may influence the development or progression to other diseases [24]. The difficulty is providing nutrient-dense food choices that can be applied to each meal of the day, and food advice that can be interpreted and adapted over the long term within an energy restriction.

1.2. Whole-of-diet approach to analysis

As early as 1982, researchers have suggested that examining diets with an eating pattern approach may be useful method monitoring change over time [25]. A dietary pattern approach was declared to be valuable in depicting changing habits both in the direction of "healthier" combinations of foods, while also assisting in identifying diets associated with poorer nutritional health, that is, linking patterns of food consumption with specific health outcomes [25]. This suggestion has been widely adopted for population research, yet dietary interventions continue to focus primarily on nutrient-level changes. It has been said that total diets, including the variation in eating and

dietary patterns compared to nutrient profiles, have been insufficiently tested for their health outcomes [11, 26] and there is lacking consensus on how to define the healthiest diet [27]. At present, although dietary guidelines and clinical practice are communicated through food-based recommendations, research of changing food and dietary patterns from an intervention context are limited.

There are some clearly defined reasons for moving away from a single nutrient focus in research examining diet patterns [7, 9]. Firstly, we eat foods not isolated nutrients, and there are complicated interactions between those nutrients [28]. Secondly, foods are complex and there is a high-level of inter-correlation between nutrients within foods making it difficult to separate these effects in a research context [7, 9]. Since the food supply is made up of a wide variety of food types, food processing adds another layer of influence on physiological processes [29]. The way a food component behaves within a natural food may be different in a manufactured food. Thirdly, there is an acute awareness that single nutrient effects from a normal diet may be too small to detect [7], and so when the analysis is based on a large number of nutrients or food items, there may be forced errors resulting in statistical significance by chance [30]. The tendency to use supplements in dietary research has often been unsuccessful [28] and attempts to produce the hypothesised effects of a particular nutrient or ingredient, has often meant that the optimal “dose” was unobtainable from food sources found in the natural diet [30].

Certain dietary patterns are known to provide beneficial health outcomes, yet even healthful dietary patterns may contain some negative features which could be

improved. Observational studies of dietary patterns within large populations are helpful because they can indicate associations between diets and health outcomes, however they cannot provide evidence of causal relationships. There is a tendency in the literature, and therefore also in the media, to draw conclusions from observations of dietary patterns, without stating specifically that the diet-disease relationship requires testing in randomised controlled trials (RCTs) [31]. However, RCTs often cannot be conducted for long enough to test effects on disease endpoints. The benefit of large observational trials is that they give clues on where to look for specific dietary components. This has been referred to as a “top-down” approach [8], as the observational dietary pattern method may present new ideas of where to look for biologically active compounds in whole foods consumed within whole diets [32] (Figure 1-1). It is thought that this is a more useful approach for informing the diet-disease link because this dietary pattern research provides ideas about specific diet components and feeds into a “bottom up” (nutrient-level) analysis, which identifies and characterises food constituents [33].

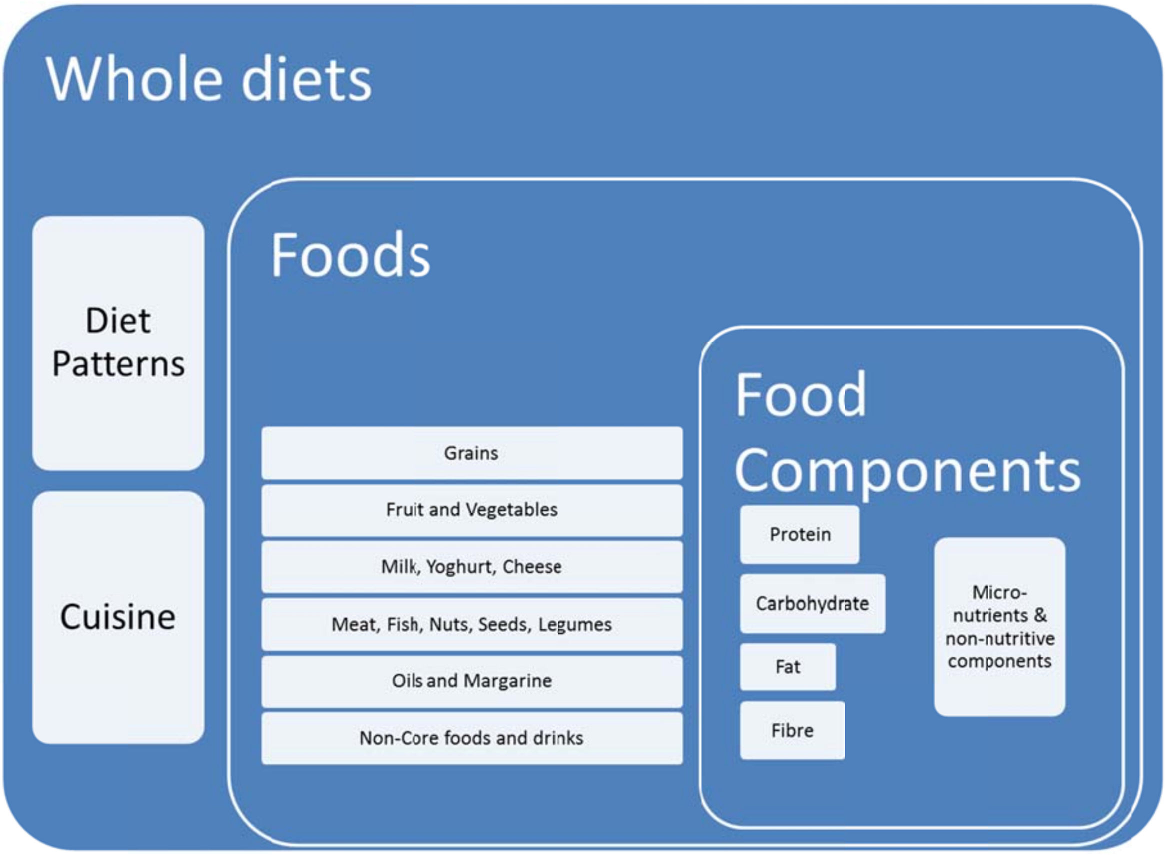

Figure 1-1 A "top down" approach: Whole diets > Foods and Food Groups > Macro-nutrient, micronutrient and non-nutritive food components

Single nutrients have tended to be explained as though they exist outside of foods and also, when foods are classified by their leading macronutrient, there is an assumption that they are equally interchangeable. While it is important to reflect upon macronutrients and micronutrients as part of a framework for studying food components, foods, food groups and dietary patterns, the nutrient intake information alone is unlikely to be helpful in the translation of research back into diet advice about foods for clients. However, when all the information is used together, it is complementary, and will begin to build a better “bottom-up” perspective, reinforcing the dietary patterns revealed at the observational level. The usual practice of working

from nutrients may introduce assumptions about the interactions between nutrients and other components within foods. This thesis provides methods of working with dietary patterns using food categories in concert with the usual analysis of nutrients. In this way, the assessment of nutrient intake forms a confirmatory step in assessing the effect of the total diet on health outcomes.

1.3. Food Synergy as a concept

There have been a number of review papers on the topic of food synergy which are summarised here [8, 9, 28, 32]. Food synergy is based on a perspective that more information can be obtained by looking at foods than at single food components [9]. This theory considers that the food matrix, that is all the components making up the food, have an effect on the biological systems of the human body and that the results may be different to considering one nutrient at a time. Food synergy possibly represents the next major paradigm shift in nutritional research and dietary advice, since there is a recognition that the whole-diet is important [34] and it is the totality of foods consumed that influences overall health outcomes. As evidence builds at the observational level, the important next step is to confirm results through intervention trials. Three notable studies, the Dietary Approaches to Stop Hypertension (DASH) trial [35], the Lyon Diet Heart Study [36] and more recently, PREDIMED (Prevención con Dieta Mediterránea) [37], each showed strong effects on health outcomes with dietary pattern modification and these may be associated with food synergy [6, 8, 28].

In order to better examine the nutrition-health interface, methods for considering whole foods within the whole diet need to be developed. This would involve a system

for categorising foods within whole diets, a system for distilling dietary patterns and for examining the outcomes. However simplistic the study of foods may sound, there is a great deal we do not understand. The synergistic effects of foods are likely to reflect complex interactions arising from the “food structure, preparation methods, fatty acid profile, carbohydrate quality (glycaemic index and fibre content), protein type, micronutrients and phytochemicals” [38] but may not be limited to these [39]. Over time, humans have chosen to eat some foods, or some parts of foods over others [40] (e.g. rhubarb stems but not the leaves), only small amounts of particular foods (e.g. coffee or alcoholic beverages) and have learned to tolerate the effects of consumption, or prepare foods in certain ways to ensure they are edible (e.g. hard grains like rice).

Digestion adds another layer of complexity since foods in nature exist for themselves, containing nutrients and other components to protect and perhaps foster new life if the opportunity arises [28]. Compared with taking a vitamin/mineral supplement which delivers a bolus of a nutrient to the gut, digestion and absorption of nutrients from foods, within a meal, are affected by all other food components [39]. Some food components facilitate absorption in a complementary manner e.g. vitamin C and iron, while others may hinder the process, e.g. phytates and iron [41]. This suggests that synergy exists in digestive processes - between certain foods, or at least within a day of food consumption. A great deal depends on how well the constituents in foods survive digestion.

While it is understood how macronutrients are broken down during digestion, other food constituents may be unaltered by digestive processes and interact with cells of

the body in a way that is not yet fully understood. Knowledge of the operation of bioactive components within plant and animal foods is limited, such that components within foods may have been singled out as the bioactive agent having a health effect, when it is likely that this explanation is incomplete. It is unlikely that foods are metabolised uniformly and more likely that nutritive and other bioactive components work in concert [32]. This is the basic premise of food synergy. A focus on single nutrients or components may oversimplify what is occurring at a biological level, and has been considered reductionist, potentially preventing researchers from developing new hypotheses, or encouraging incomplete conclusions about the whole food, even if the components partly explain some of the health effects. An example is dietary fat, particularly the recognition that fatty acids work differently within the body [32] and that the food source of these food components may be part of this explanation [42].

1.4. Evidence based nutrition and dietary advice

1.4.1. The Problem – knowledge formation

Dietary advice is always given in terms of food or meals. In the clinical setting, dietitians assess and provide a dietary prescription in terms of foods. More broadly, foods are categorised into groups (in assessment and advice), based on nutrient targets (and population-level dietary guidelines). Specific decisions are made about food substitution, referring to individual foods that the person consumes (individual-level advice). However, evidence for advice on food groups (e.g. following Dietary Guidelines) emanates from clinical trials examining individual nutrient requirements. There is a need to optimise diet prescriptions to promote health and at the same time, limit chronic disease morbidity and mortality [43].

The analytical methods for working at the food-level are mostly found in population research. However, the conclusions that are drawn from population-level research should only be applied to individual advice for dietary guidance with caution. The apparent effects from observed associations need to be confirmed within randomised controlled trials [31]. Before the analytical methods for working at a food-level can be applied at an intervention-level, they first need to be aligned with clinical practice in terms of the details of food selection, and then developed with consideration for known therapeutic recommendations. Consequently, in order to conduct food-level analyses from clinical research, a framework for categorising foods and examining food intake patterns is required specifically for the clinical intervention setting. Reviewing methodologies from population survey research is a good starting point.

1.5. Dietary Patterns from a population perspective

1.5.1. Analytical methods

Over the past three decades, nutritional epidemiology has shifted to investigations of foods and dietary patterns [7]. The research approach aims to examine the relationship between patterns of dietary intake, dietary change and health outcomes. Dietary pattern analysis captures the scope of foods consumed using various methods for distilling dietary data (e.g. diet scoring tools or statistical methods), while attempting to maintain the integrity of data on the types of individual foods consumed.

Two broad categories of analytical methods at the population-level have been applied in researching dietary patterns in terms of foods. ***A priori*** methods involve making

decisions about the analytical process *before* data can be collected for example, a pre-designed diet index tool or score or perhaps dietary collection tool such as FFQ. On the other hand, ***a posteriori*** methods tend to utilise statistical techniques, such as cluster or factor analysis, to organise data *after* the data has been collected. In applying either of these methods, the statistical solution or the score is related to health outcome measures. It is thought that combining *a priori* and *a posteriori* approaches may better expose the diet-disease relationships especially where there are multiple dietary factors that play a role in disease management or aetiology. Whereas changes in dietary patterns over time have been assessed within the context of population studies, this has not been a focus among intervention trials with very few published studies using cluster analysis [44, 45] or diet quality tools [11, 46] examining weight change. When studies evaluate dietary change, they tend to track the intervention nutrient, ingredient or food and then macronutrients, ensuring only the variable in question has changed. The analysis of dietary intervention data in the investigations within this thesis are considered novel, and although total-diet approaches are encouraged in educational and advice settings [34], the evidence examining changing patterns of foods at an intervention level are limited. Since substitution with foods has a compensatory effect on the characteristics of the whole diet, the complexity of dietary change is revealed, and it is apparent that this is not restricted to one dietary component [27].

A whole-diet pattern approach is advantageous as it recognises the difficulties in interpreting individual dietary factors in terms of both statistical methods and in isolating single dietary factors in research [7, 30]. The opportunity is best considered

by assessing the aggregated effects of food consumed together [7]. It is also thought that foods or food categories may be easier to compare than nutrients when research is conducted in different countries [47] since the food source of nutrients is probably more important as a comparison tool. However, food categorisation is culturally specific and based on a multitude of factors.

1.5.2. Food Categorisation for Dietary Guidance

The categorisation of food for use in food guidance systems is a long standing technique in nutrition policy and practice. Food-based research has been conducted for developing dietary guidelines aimed at healthy populations, with adaptation over time to more clearly focus and articulate food requirements at the population-level [48]. Dietary guidelines and the food categories used have also been applied in describing dietary patterns. Systems for food guidance are usually based on a small number of staple foods known as *core* food groups (containing nutrients essential to the diet) and over time, their purpose has evolved from recommending the minimum amounts of food required to sustain human life, through to a time where excess food intake is more of an issue.

Dietary recommendations date back to 1894 in the US [49] with the first food guide translating dietary requirements in terms of groups of foods appearing in 1916, then 1942 in Canada [50], 1955 in Australia [51, 52] and in 1994 in the UK [53]. In the Western literature, there is reference to the five-food groups (fruit and vegetables, breads and cereals, meat and meat alternatives, milk and milk alternatives and fats/oils), developed with reference to key nutrient composition. Common to these

population guides is the emphasis on *core* food choices. The differentiation between 'core' foods, and 'non-core' foods and drinks is particularly relevant in terms of nutrient density and these terms will be used throughout this thesis.

Painter *et al* (2002) compared food guides from several countries [54], pointing out the variability in the foods described and portion sizes, but also noting the similarities in terms of food groups and within this, the similarities in the fundamental classification of foods. Interestingly, the greatest degree of dissonance within and between the food groups focuses on potatoes, legumes and nuts. The UK places potato within the breads and cereals group with justification based on nutritional and cultural practices [55], while in other countries, including Australia, potatoes are included with the vegetables group. Legumes are often included with the meats and meat alternatives group due to their protein content but have also been categorised with vegetables or the bread and cereal food group. In some guides, legumes are listed in multiple groups to encourage consumption [50, 56, 57]. Similarly nuts, are often placed in the meat group and in some countries, in the fats group [54].

In Australia since the 1950's, nutrition education tools have been developed with the primary aim of guiding the nutritional intake of the Australian population via emphasis on certain food choices, whilst also reflecting the important social, cultural, economic and practical considerations at the time of their development [58]. There is a need to accommodate the ethnic diversity within the Australian population, however, the studies of dietary patterns overall are quite limited. For this reason, diet pattern

studies are in high demand and will be key to the successful determination of clinical practice and national guideline development in the future.

The Five Food Groups used in Australia and the various updates since 1955 [51, 52], the 12345+ Food and Nutrition Plan [59] and other such pictorial guides developed from the 1950's through to the mid 1990's, have grouped foods into (usually) five distinct groups based on their macronutrient similarity. The focus was to communicate a simple "foundation diet" based on nutrient adequacy [60]. Likewise, The Australian Guide to Healthy Eating (AGHE) [61], launched in 1998 and most recently updated in 2013 [57], does not discuss specific nutrients, although energy and nutrient targets are the basis for the specific groupings and the serve sizes suggested. This education tool includes an additional group of 'extra' or non-core foods and drinks, not necessary for health, but recognised for the energy contribution to the Australian diet, with each serve containing approximately 600kJ and no other distinguishing nutrients. The inclusion of 'extras' signals a change to a "total diet" philosophy, reflecting not just nutrient adequacy, but providing guidance for moderation and flexibility across the food groups including recognition of taller and more active individuals. However, non-core foods and drinks (as it will be referred to), are ubiquitous in the Australian diet [62] and encompass many foods and drinks of differing nutritional composition. Consumers may not understand the impact of overconsumption [63], or be aware of the scope of foods included in this 'non-core' category [64] and therefore may underestimate their exposure to such foods known to be greater than 20% of energy in the adult Australian diet [62].

Due to the broader population perspective, the methods of investigating dietary patterns tend to utilise the food groups found in food guidance systems, as this has been used as a check of (population-based) dietary compliance. Food guidance systems are targeted at healthy populations and have generally tended to be simplified for communication purposes. For this reason, a basic food guidance framework (of five food groups) may not be the best model for food-level clinical research, simply because other aspects of foods and food categories may need to be considered. For example, to categorise dairy foods in a single group based on protein and calcium content does not clearly articulate the wide variation in the macronutrients within a diverse group of foods and beverages which includes cheese and skim milk. In designing a framework of food categories for investigating dietary changes at a clinical level, more specific food-level analysis requires testing.

1.6. Food patterns from a clinical perspective

Individual dietary patterns are complex since food consumption patterns change over time, and in response to a number of factors. For the individual, food preferences, cultural practices, family and peer influences are overlaid with other prevailing factors such as the physical environment, primarily the dynamic and ever-increasing food supply. Whilst certain features of an individual's diet may be retained day-to-day and week-to-week, dietary intake is not static and therefore it is difficult to compare diets and measure health outcomes. An understanding of the food supply and the culinary practices and eating habits of individual clients is also required. In examining the whole diet, it is necessary to distil the dietary information to some extent, in order to be able to pin-point and draw relevant conclusions. The methods used in population-based

research are informative, however some approaches in use at the population-level may not be specific enough for the detail required at the clinical research level.

In order to obtain the most precise results, it is necessary to scrutinise the dietetic consultation process, most importantly the method of dietary assessment. Population dietary pattern research uses methods of dietary data collection that ascertain a good approximation of the breadth of foods consumed in order to approximate energy intake [65]. This is suitable due to the large numbers of subjects from which data is collected. In the clinical setting, where therapeutic diet advice is given in exchange for the collection of dietary data, a greater level of precision is required. The number of subjects not only allows, but requires this level of precision. Food frequency tools are most commonly used at a population-level [65], but this tool predetermines the foods and food groups that can be examined in the analysis that follows. The diet history, is a method of dietary data collection used in clinical practice, and provides a valid reflection of an individual's usual diet [66]. A single diet history takes more time to conduct, but allows greater freedom for manipulating data into food categories and is more relevant than a food frequency questionnaire such as those used in population research. The diet history method also allows the researcher to review and find more detail during the analysis process [67]. There are other examples from the clinical context which require greater detail and precision, for example anthropometric measures. Population studies often use self-reported measures of body weight which would neither be adequate for clinical research over short time frames (three months), nor reflect usual clinical practice. The issue of accuracy is discussed in further detail within the methodology chapter (Chapter 2).

1.6.1. Nutrients versus foods focus in the clinical setting

The requirement for precision in clinical practice when dealing with an individual client has evolved from a time when important links were made between nutritional deficiency and disease. While it may seem that deficiency diseases in Western societies such as Australia, were a thing of the past, deficiencies of vitamin A and iron are a world-wide issues [47, 68, 69] and poor iron intake remains an issue nationally, particularly for young girls and women [70, 71]. Nutrient issues for certain population groups, like folate in the prevention of neural tube defects in pregnancy and vitamin B12 for vegetarians, also need to be highlighted alongside the role that mandatory nutrient fortification of food plays within the food supply system. Prevention of deficiency states and diseases was the original focus of nutrition research and dietary advice [32].

The early focus on disease prevention in nutrition set a precedent for nutrient-based research, and began a practice of translating nutrient targets into food-based recommendations, menus and guidelines. Following the attention on prevention of nutritional deficiency, the work of Ancel Keys [72], gave recognition to the role of diet as the cornerstone in the aetiology and prevention of cardiovascular disease. While optimal nutrient targets are defensible for dietary deficiencies, the application of targets for chronic disease are more difficult to define precisely, and even more difficult to communicate to the general public. For example, a great deal of time over the last half of the 20th century was devoted to pursuing the role of dietary fat in the prevention and management heart disease. Now there is a recognition that the

amount of total energy from fat is less of an issue than previously thought [11, 38], and the role of saturated fats (specific fatty acids) in foods, may also be in question in relation to causation of heart disease [73]. What is emerging is the need for food-level research [28] involving the examination of dietary patterns from dietary interventions.

Diet prescription tends to be focused on achieving an overall nutrient profile such as those set out in Nutrient Reference Values [48] which are then translated into food choices for the client for both prevention and the treatment of disease. Consequently, dietary advice is always given in terms of food or meals, in the case of meal plans. While nutrients are the basis for the suggestions made, these are the domain of nutritional science and are poorly understood by consumers [74, 75]. Foods are mixtures of nutrients and food sources are grouped often by the dominant nutrient, however foods defined in this way from different food sources e.g. fats from whole foods versus culinary oils, may influence the delivery of fuel to the body. However, there are a number of ways a food can be grouped and these are discussed in Chapter 2 (methodology) and Chapter 3. For example, foods have also been determined by local, or culturally based eating styles and cuisines which are determined by food availability and generally over long periods of time [54].

In an endeavour to research new possibilities, and view diet prescription from a food, rather than a nutrient perspective, it is necessary to explore patterns of foods within whole diets. Exploring foods and dietary patterns alongside nutrient composition of diets is relevant, because the results may help reveal relationships that best promote weight management and other therapeutic diet prescriptions. Including nutrient-level

analysis answer questions about the mechanisms behind the changes in particular clinical measures, supporting the use of a particular diet prescription. However, it is food choice that affects nutrient intake [76].

1.6.2. Macronutrients in clinical dietary advice

All animals gain and lose weight based on energy balance, regardless of the nutrient or macronutrient profile of the targeted diet [77]. In seeking solutions for weight loss, macronutrient manipulations were once the focus of research and dietetic practice. However, the range for Suggested Dietary Targets (SDT) aimed at reducing chronic disease are quite large for carbohydrate (45–65%) and for protein (15–25%) [48], and according to Sacks *et al* (2009), this indicates that reducing energy intake is more important for body weight control than the proportion of macronutrients in the diet [77]. Although the main reason for desiring the measurement of macronutrient proportions and specific nutrient intake levels was aimed at refinement of aetiological hypotheses linked with disease, the attainment of the highest possible diet quality and longer-term disease prevention is an important layer in dietary advice. If diet quality is a concern, and foods and meals are discussed with clients in order to influence this parameter, then it is essential to conduct research using foods and the patterns of consumption as the outcome measure and also draw conclusions at the food-level. Energy intake estimated in kilojoules may overlook other important differences in the digestion and metabolism of foods and in particular, the food sources that may be important in weight management [78]. Monitoring the change in patterns of food choice during a weight loss intervention would result in immediate and transferable information more practical for the clinical advice setting than macronutrient ranges.

1.6.3. Measuring dietary change

In a clinical setting, dietetic professionals monitor change in food choice behaviour using simple tools that count major macronutrients such as a 'ready reckoner'. The ready reckoner is a short-hand tool comparable to published food exchange lists [79, 80] derived from nutrient databases which provide detailed nutrient composition. Professional judgment is used to discern which foods belong to which food categories including mixed foods, and then calculate the impact of the nutrients consumed. While the ready reckoner has a significant history of use in practice [79, 80], and use has been recorded as early as 1963 [81], there is limited reference to this tool in peer reviewed literature [82, 83]. This dietetic tool provides a reference point for categorisation of foods within diets and has been adapted for a range of therapeutic diet prescriptions, for example diabetes [82], cystic fibrosis [83] and renal disease. Further, examples of ready reckoners are available for particular key nutrients, such as calcium and iron.

It is important to note that the serve sizes used in a ready reckoner may not necessarily match public food guidance systems such as those described in the Australian Guide to Healthy Eating (AGHE) [84, 85]. This is true for the bread, cereals, rice, pasta and noodles group with one serve of bread or cereal food being equal to 30g or a single slice of bread or half a cup of pasta. This alteration in serve size is important in diet therapy as one slice of bread is considered equivalent to one carbohydrate *portion* or 15g of carbohydrate. Public food guidance systems need not be as specific since they are designed for healthy populations. The ready reckoner is

more specific because it is used with individuals who require therapeutic dietary advice. The serve size depicted in the ready reckoner does not necessarily represent the amount of food consumed in a meal either, but it provides a method for counting the amount consumed as closely to the amount reported in the diet history. Amounts of food consumed vary greatly between individuals and across food categories, for example meat, whereas other foods may be consumed as a single serve, for example, individually bottled alcoholic beverages or portion controlled items such as tubs of yoghurt. There are many reasons for development of food categories and hence, different categories emerge in the research context. For example, in this thesis, the analysis applies a 30g serve for whole grain foods, non-wholegrain (refined) cereal foods, meat, fish, eggs, nuts and higher fat dairy foods (cheese), 150mL per serve for low and medium fat dairy foods, 150g for fruit, 75g for vegetables, 5g for oil and margarine, 400kJ for alcoholic beverages and 600kJ for non-core foods and drinks (NCFD). For dietary analysis, a computerised food and nutrient software database (Foodworks^{TM} Professional, Xyris, Brisbane, Queensland Australia, Version 6, 2009) was selected for monitoring nutrient change complimentary to the food category changes examined.

Just as the food categories need to be clinically relevant, so too do the outcome variables. The analyses undertaken within this thesis utilised the outcome variables common to clinical practice, in this case related to weight reduction interventions: weight loss, including per cent weight loss, change in BMI, measurement of body fat percentage and waist measurements. Throughout the analysis in this thesis, weight loss ≥5% was used as a target since clinical improvements have been noted with even

relatively small amounts of weight loss (approximately 5% to 7%) [86, 87], and the trial data were generally assessed over a short timeframe of three months. Where weight loss over 12-months was assessed, both greater than 5% and greater than 10% were used as weight loss markers. Comparison of clinical and anthropometric measures with changing dietary patterns helped to validate the self-reported dietary data and form links with weight change [88]. It is pertinent to note that this thesis is based on secondary analyses and does not claim to assess the outcome of the primary dietary intervention trials.

1.7. Gaps in the literature – evidence relating to foods

Although specific food advice is necessary for the clinical-advice setting, the focus of weight loss research appears to have centred on testing varying dietary macronutrient manipulations [77]. Alongside this, the temptation in the past has also been to test nutrition-based theory using isolated nutrients (or supplements). However, in some landmark studies, large, randomised controlled trials have not been successful in proving the hypothesised effects of nutrients using this approach [89-97]. Within the Smart Food Centre at the University of Wollongong, studies relating to macronutrients, protein [98] and dietary fats [99], food components such as oat beta-glucan [100] and single foods like walnuts [101], have built to more recent studies of the whole foods within whole diets (vegetables [2] and fish [1]). Increasingly whole dietary patterns have become the focal point. This thesis attempts to articulate this position and provide a system for categorising foods and methods for distilling dietary patterns using secondary analysis of dietary intervention data, forming links between dietary patterns and outcomes.

Dietary advice is always given in terms of foods or meals. While there is dietary pattern evidence relating to weight management at an observational level [11, 102], specific evidence for the changing food and dietary patterns during weight loss is limited [21, 26]. There are strong indications that low energy density dietary patterns improve weight loss [21] and these diets also tend to be of higher diet quality [103]. However, converting food data to energy and nutrient data using computerised software packages assumes that only the selected nutrient targets (and perhaps fibre) within foods are capable of exerting effects at the whole-diet level. In consuming whole foods we take in a whole range of food constituents not yet included in nutrient-focused analyses.

In order to establish a framework for conducting food-level research, food categories that are relevant to the dietetic clinical practice setting need to be developed as a method for conducting food-level research in an intervention context. Capturing the changing diets of participants during weight loss together with other health outcome measures, will help inform clinical practice.

1.8. Limitations of dietary pattern research

While the use of foods or food groups might help to capture some of the complexity of diet that is often lost in nutrient-focused research, some problems also exist with drawing conclusions from an observational food-based approach. For example, whole-grain consumption has been found to be inversely associated with meat intake and positively associated with vegetable, fruit, and fish consumption [104]. So when

conclusions are made about whole-grain intake and the associations with lower disease risk from observations of populations, we perhaps cannot be certain that the result is not due to differences in red meat, fruit or the amount of vegetables consumed [105]. Similarly, the effects on heart disease [106], diabetes [107] and stroke [108] that have been associated with one serving of nuts or whole grains are unlikely to have been brought about by those foods alone. Based on what is known of their nutrient and phytochemical constituents, these results need to be confirmed through dietary intervention trials [31]. Importantly, the results at the observational level demonstrate the importance of considering the diet as a whole and the need to examine the whole diet more closely.

Dietary pattern research is often limited by the method of dietary assessment. While dietary assessment is considered a constraint of all food and dietary research, it is a particular limitation when short-cut methods of assessment are used. This has been discussed in Section 1.5 in relation to dietary patterns at the population-level. Each dietary assessment tool or method has limitations that require consideration both prior to selecting the method and in reflecting on the results [65, 109]. The diet history method is most commonly used in one-on-one assessment of food intake in clinical practice, and captures the patterns of food intake and an impression of both nutrient and energy intake. It was the method of choice for the primary studies utilised within this thesis.

The diet history captures *usual dietary intake*, and can be tailored to reflect an appropriate timeframe. This method captures meals; snacks and portion sizes

consumed and are supported by a food frequency (as a cross-check) in a clinical consultation. The diet history *tells the story* of foods and meals, and captures this within the narrative of the consultation conducted by a skilled dietetic professional [67, 110]. As such, it is sufficiently robust as a method to portray information in a way that is relevant to the individual's dietary pattern. The process of questioning helps to depict a complete picture, as the narrative covers the 'typical day' and variations to account for special occasions and weekends. The food frequency is valuable in rounding off the diet history section of the consultation and identifies foods inadvertently omitted from the history, or foods eaten less frequently, but nonetheless, contributing to the overall energy and nutritional intake. The history method relies on the training of the interviewer to ask pertinent questions and to probe at the appropriate times. It also relies on the interpersonal skills of the interviewer to facilitate an open discussion of foods that may be eaten at various or inappropriate times, indulgence foods, and foods that are eaten in unsuitable amounts.

The overall aim of the diet history method is to quantify the dietary intake, noting brand names [65] and culinary techniques and in doing so, allowing this information to be analysed in terms of specific nutrients, foods or food groups, depending on the purpose and the tools available. In comparison with a paper-based food frequency, the diet history allows the clinician or researcher to delve deeper into food-based eating habits and for the participant to clarify the amounts consumed, to achieve as correct a measure of dietary exposure as possible [109]. It is unclear, whether this system is always acceptable from the clients' perspective or if the common problem of under-

reporting is universal, or isolated only to specific groups, such as those who are overweight [111]. In the analyses presented, misreporting would be systematic and the focus is on dietary change rather than the degree of success relating to the original dietary intervention.

A further constraint common to all dietary research may be via estimations made within nutrient composition databases and therefore software packages based on this data. At a food-level, certain nutrients may be at greater risk of errors than others, for example, the level of beta carotene in a carrot is influenced by the size, the growth, harvesting condition, degree of maturity, processing, storage and cooking method [65], whereas in contrast, selenium (from the soil in given countries) is more constant [65]. Despite the fact that food composition databases now include a greater number of individual items, care with the selection of options is important. When entering a meal, for example, a detailed selection of different cuts of meat are available, and many options for selecting a specific food preparation method, however skill in selecting the most correct option fitting with the participant's diet history is essential in ensuring that optimal results are achieved. Errors may arise when dietary data is entered into computerised analysis programs, and culinary expertise is thought to be of particular importance [112].

1.9. Hypothesis and aim

The central hypothesis examined in this thesis was that an analysis of dietary patterns reported by overweight participants in a weight loss trial will reveal important practice-relevant information for developing dietary advice.

The aims of the thesis were to:

1. Develop food categories extending from the traditional five food groups to explore dietary patterns within an intervention context.
2. Identify patterns of food choice in the context of a clinical weight loss trial and associations with weight loss and health outcomes.
3. Develop and validate a diet quality tool for weight management, to investigate changing diet quality within a weight loss intervention context.

In order to achieve these aims, a number of investigations using secondary analyses of dietary trial data were undertaken.

1.9.1. Thesis structure

The thesis structure is summarised below (Figure 1-2).

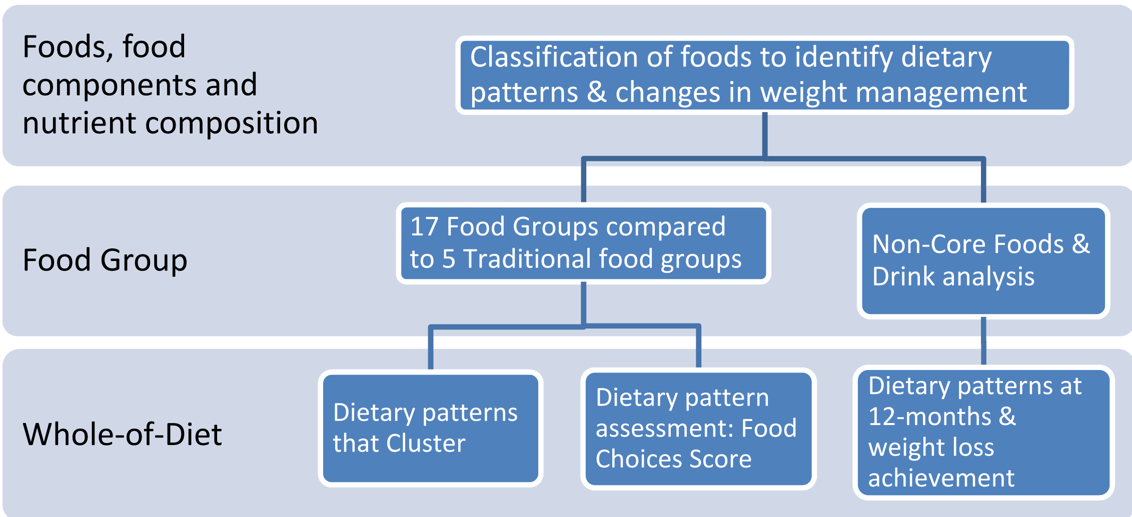

Figure 1-2 Hierarchical research design: From foods, to whole-of-diet patterns

In Chapter 3, the complex issue of food categorisation is addressed for the purpose of defining food categories for examining dietary patterns. The analysis aimed to prove the need for more detailed food categories than the traditional five food groups in describing the changing dietary patterns during weight loss. The primary outcome was based on demonstrating that more and specifically detailed food groups based on positive and negative associations with health outcomes (17 food categories) provided a more meaningful representation of the changing diets during weight loss. Dietary pattern change was linked to changes in measures of weight loss (weight, BMI, % body fat and waist measurement) and selected nutrient changes.

In Chapter 4, the use of foods, together with specific statistical techniques (cluster analysis), aimed at identifying common patterns of food choice between participants at baseline and the outcomes at three months based on the established clusters at baseline. Outcomes were based on the differences in dietary patterns of Cluster 1 and Cluster 2, and the changes made within three months together with anthropometric, clinical and nutrient changes. The outcomes of this analysis emphasised high intakes of NCFD at baseline as a significant consideration in correcting dietary exposure for weight loss. Consequently, the analysis in Chapter 5 investigated further detail of the changing consumption of the NCFD category over 12-months whereas Chapter 4 examined the dietary patterns, based on stratified weight loss achievement (<5%, >5% - <10% and >10%) over the whole 12-month period.

The analysis described in Chapter 7, aimed to develop and validate an *a priori* score system, a Food Choices Score (FCS), based on the highest achievable diet quality for

weight loss within an energy restriction. The score produced by the FCS was compared to outcomes based on weight loss achievement greater than 5% (and less than 5%), the change in score within 3-months and the differences in diet quality (food choices) when scores were in the highest band compared with the lowest band of scores.

1.9.2. Outcome variables

Dietary patterns were examined alongside outcome variables in each of the investigations and these are summarised in Table 1-1.

Table 1-1 Outcome variables

Investigation	**Method**	**Timeframe**	**Variables**
Food Categorisation (*a priori*)	1. Comparison of 17 food categories to the Traditional 5-food groups	Baseline to 3-mo	By food category: Grams (g); Energy (kJ) Macronutrient energy (as %E) Food portions/serves Selected nutrients*
Pattern Analysis (*a posteriori*)	2. Cluster Analysis	Baseline to 3-mo	By cluster: Grams (g); Energy (kJ) Macronutrient energy (as %E) Food portions/serves Selected nutrients* Body weight (kg) BMI; Body fat; Waist (cm) Total Cholesterol (HDL and LDL-C) Triglycerides Glucose; Insulin.

Investigation	Method	Timeframe	Variables
Pattern Analysis (*a priori*)	3. Food pattern analysis based on 8 categories of Non-Core Foods and Drinks	Baseline, 3-mo, 12-mo	By Non-Core Food and drink category: Energy (kJ) Macronutrient energy (as %E)
	4. Food pattern analysis based on weight loss achievement	Baseline, 3-mo, 6-mo, 9-mo, 12-mo	Weight loss
		12-mo	Stratified weight loss groups: <5%; >5%-<10%; >10% Food portions Selected nutrients* Weight/ weight loss/ BMI/ Body fat
Diet Quality tool (*a priori*)	5. Food Choices Score (FCS)	Baseline to 3-mo	By score band (≤60% and ≥70%) Weight loss (<5% and >5%) Per cent weight loss; BMI Food portions Selected nutrients* and Additional nutrients**.

* Protein, Carbohydrate, Fat (±Saturated fat), Dietary Fibre, Calcium, Iron.
** Saturated fat, Polyunsaturated fat, Monounsaturated fat, Alcohol, Vitamin C, Total Folate, Zinc.

1.9.3. Significance of this research

Since we do not fully understand the full impact of food consumption on human physiology, the examination of food, and the dietary patterns they form, may reveal new knowledge relevant for the clinical setting. Dietary pattern research is typically conducted at the population-level. In order to determine and support the use of food categories as a relevant measure of dietary intake at the intervention-level, the investigations within this thesis form the initial important step in establishing food categories relevant for dietary pattern analysis at an intervention-level, providing a framework for future research of this type. Furthermore, the use of the defined food categories using *a priori* and *a posteriori* techniques are confirmatory and demonstrate the changing diets and more specific information regarding food choice of participants involved in weight loss interventions.

CHAPTER 2 METHODOLOGY

2.1. Introduction

Dietary pattern research, based on the natural eating behaviours of participants within dietary interventions may be valuable in understanding the dietary causes of overweight and obesity and in helping individuals trying to control their weight [20]. Thus, dietary patterns are able to characterise eating behaviours and explain the relationship between diet and health, the latter being driven by the research hypothesis [113]. Data from dietary interventions can provide a useful resource for exploring dietary patterns and weight loss following dietary advice. This thesis utilises forms of secondary analysis on data from two dietary trials conducted over a 12-month period at the Smart Foods centre, University of Wollongong. Central to the framework of this thesis is the way in which foods are categorised into food groups, and therefore, the way dietary pattern research is expressed and explained in relation to disease, or in this case, weight management.

Weight loss is complex, and the diet composition and overall quality may be overlooked in attempts to lower kilojoule intake. In the scientific literature, the role of dietary macronutrient composition compared with the consumption of foods or dietary patterns in relation to weight management is an emerging issue. It seems that the macronutrient proportions within the diet may now be less important than once thought in predicting change in weight or waist circumference [42, 77]. In order to systematically analyse the available clinical intervention dietary data using a food-based approach, this chapter explores the methodological issues and the theoretical reasons for questioning current methods of analysis. This chapter also describes the methods of inquiry and how two different approaches (cluster analysis and a diet

quality scoring tool), drawn from the observational research domain, can be applied using defined food categories in an intervention context.

2.2. Dietary patterns and weight

Despite significant weight gain across the population, increases in weight-related disease, and the evidence that health-promoting dietary patterns include a variety of foods in combinations from each of the basic food groups, many people do not make day-to-day food choices that make up a basic healthy dietary pattern [114]. Virtually all epidemiological studies have highlighted lower mortality with a dietary pattern predominantly based on food groups such as vegetables, fruit, whole grains, poultry, fish, and low-fat dairy products compared to other dietary patterns [115], with this effect thought to be due to the greater intake of plant foods, particularly where this is not displaced by meat consumption [115-117]. In contrast, intakes of meat (processed and unprocessed), potatoes, potato chips and sugar-sweetened beverages can be strongly associated with weight gain [118]. Since dietary intervention outcome measures tend to focus on nutrient-level responses, the specific opportunity is to design food and dietary pattern studies which may be more informative for translation into diet advice.

2.2.1. Applying dietary patterns to dietary interventions

Whereas dietary pattern analysis at the observational level is useful for generating hypotheses, predicting disease, and communicating public health messages [119], establishing evidence for foods and dietary patterns at an intervention-level will help provide information that can be readily translated to a clinical practice setting. Dietary

intervention trial research very often examines intakes of nutrients or nutritive components. Yet, foods, and therefore diets, are more complex than the sum of nutrients that are often the primary outcome measure and reference point in the analysis of these interventions. The dietary advice in dietary intervention trials is always prescribed in terms of foods or meals, and the assessment process, the diet history, also records and utilises foods and meals, which are then distilled into nutrients, often with no ability to reference the original diets reported.

Aside from the intakes of macro- and micronutrients typically reported in research, there are thousands of other substances in foods. Consequently there are competing biological reactions within the living tissues of unprocessed foods and the effect(s) of these is generally not well understood [29]. With few exceptions at a nutrient-level, individual compounds have only small documented effects on chronic disease [38] and in any case, it is the pattern of nutrients, rather than single nutrients that indicate associations with future health [120]. In accepting this, foods studied together as dietary patterns, provide information about health outcomes that are more difficult to observe in studies of single foods or nutrients.

It has been stated previously that the variation in eating and dietary patterns making up the total diet, compared to individual nutrients, has been insufficiently tested [26], particularly in relation to dietary change [11]. In utilising the approaches from the observational research domain, the methodological details are of great importance [27]. A major barrier to conducting such research within an intervention context is the lack of a framework for the examination of foods for discerning and measuring the

changing food choices that are also aligned with clinical practice. The quality of the dietary data is also an initial important factor for consideration in assessment of the total diet (See 2.4). Furthermore, within specific therapeutic diet prescriptions, certain foods, categories of foods or sub-categories may be more of a focus than others, for example, in the care of diabetes mellitus where the glycaemic index and carbohydrate content of foods may need to be considered and prioritised. Weight loss, however, is facilitated by creating an energy deficit, yet the actual food choices of dieters during weight loss may also be important. This chapter describes the context of the intervention trials that provided the data for the secondary analyses applied in this thesis. It also outlines the systematic approach that was utilised to ensure that the food categories selected were meaningful and defensible, and discusses the techniques used to expose the dietary patterns of weight loss participants.

2.3. Overview of the randomised controlled trials and the dietary assessment methods providing data for secondary analyses in this thesis.

Each analysis conducted in this thesis utilised dietary data that was combined from two randomised controlled trials conducted through the Smart Food Centre, University of Wollongong. The SMART trial was a National Health and Medical Research Council funded project grant (Project no. 516631 Is a higher intake of omega 3 fatty acids advantageous for weight loss?; Chief Investigators L Tapsell, M Batterham, K Charlton). The published manuscript for the SMART trial can be accessed here [1]. The Healthy Eating and Lifestyle (HEAL) trial was supported by a project grant funded by Horticulture Australia Ltd using the vegetable levy and matched funding from the

Australian government (Project no. VG09037; Chief Investigators L Tapsell, S Johnson, M Gidley *et al*). The published manuscript for the HEAL trial can be accessed here [2]. The candidate was one of three trial dietitians counselling a cohort of patients for the HEAL trial. Each RCT was approved by the University of Wollongong Human Research Ethics Committee (SMART: HE07/323 and HEAL: HE10/192) and registered with Australia New Zealand Clinical Trials Register Network (SMART: 12608000425392 and HEAL: 12610000784011). Descriptions of each trial are provided in Appendix A and B.

Each trial had a control and intervention group and exclusion criteria as summarised in Table 2-1. The trials involved healthy overweight to obese adults from the local area recruited via news media and advertisements. Participants in both trials were blinded to the intervention but not the dietitians. The dietary education for both the control and intervention groups were based on a food-based diet prescription and the same individualised kilojoule restriction for weight reduction.

For each clinical trial, dietary data was available, collected by Accredited Practising Dietitians at baseline, 3-months, 6-months, 9-months (HEAL trial only) and at 12-months. Weight data was available for all time points and for both clinical trials. Participants were asked to report their usual intake of foods and beverages beginning with the first meal of the day and indicating variations within a two to four week period. An estimated four day food record was completed prior to the diet history interview which assisted participants with recall of the types and amounts of foods consumed. In addition, household measures and food models were used for estimation of portion size. A food frequency targeting the consumption of specific

foods was used as a cross-check of items potentially omitted from the history. The diet history data was analysed using a computerised food and nutrient database, Foodworks^{TM} Professional (Xyris, Brisbane, Queensland Australia, Version 6, 2009) to reflect of a weekly pattern of intake. The Accredited Practising Dietitian who consulted with the participant also entered the data into the food analysis software program, minimising errors in translation from the diet history. Anthropometric measurements from each trial, included body weight, height, estimated body fat percentage (using bioelectrical impedance Tanita® scales TBF-662), waist circumference and clinical measures including total cholesterol, LDL-cholesterol, HDL-cholesterol, cholesterol:HDL ratio, triglycerides, glucose and insulin were also performed as fasting measures included in the protocol for the trials.

Combining two clinical trial data bases allowed for analysis of data from 231 participants. Baseline data from each trial are provided in Table 2-1. Independent t-tests revealed no baseline differences between the two sets of trial data in terms of age of participants or per cent fat or carbohydrate intake yet there was a significant difference in the per cent protein (P=0.006) and the reported energy intake (P=0.006). At baseline the reported macronutrients were within the accepted macronutrient distribution range (AMDR) [48] with the exception of carbohydrate for Study 1 (SMART), which was lower than the suggested target of 45-65% E. The baseline BMI was significantly different (P=0.002) as the entry criteria differed for each trial, though there was no difference between trials in the weight lost by three months (P=0.639). Chi square analysis found no difference in gender profile between the two groups. The

commonalities between the HEAL and SMART trials allowed data to be combined and allowed data for men and women to be analysed together.

Table 2-1 Baseline characteristics (Median and IQR) of clinical trial participants

	Study 1/SMART (n=118)	Study 2/HEAL (n=113)	P value
Males	31	28	0.795*
Females	87	85	
Age (mean ±SD)	45±8.4yrs	49.8±9.4yrs	<0.0001
Weight (kg)	88.1 (79.2-97.9)	83.4 (76.6-91.4)	0.007
BMI (kg/m^2)	30.7 (28.5-34.4)	29.9 (27.8-31.9)	0.002
Per cent Body fat	40.3 (34.4-45.0)	39.2 (35.4-43.0)	0.417
Waist (cm)	104.0 (97.9-111.0)	97.8 (91-103.5)	<0.0001
Weight lost by 3mo (kg)	n=87 -4.7±3.1	n=107 -4.5±3.0	0.639
Total Cholesterol (mmol/L)	5.2 (4.5-5.9)	5.3 (4.6-5.9)	0.608
Triglycerides (mmol/L)	1.3 (1.0-1.9)	1.13 (0.8-1.6)	0.015
HDL (mmol/L)	1.4 (1.2-1.7)	1.4 (1.2-1.6)	0.316
Chol:HDL (mmol/L)	3.5 (2.9-4.4)	3.7 (3.0-4.6)	<0.0001
LDL (mmol/L)	3.2 (2.5-3.7)	3.2 (2.6-3.8)	<0.0001
Glucose (mmol/L)	5.0 (4.6-5.3)	5.3 (4.9-5.6)	<0.0001
Insulin (mU/L)	10.3 (8.0-14.2)	10.9 (7.9-14.6)	0.934
Energy (kJ)	9404.2 (7603.4-11069.6)	8404.3 (7296.1-9886.5)	0.006
% Protein	18.2 (16.1-20.3)	19.5 (17.9-21.1)	0.006
% Carbohydrate	41.9 (37.5-46.9)	43.0 (38.4-47.2)	0.155
% Fat	33.6 (30.0-38.9)	32.4 (28.8-35.8)	0.423
Inclusion criteria	18-60yo and BMI 25-≤37kg/m2	18-65yo and BMI 25-35kgm2.	
Common exclusion criteria	Major illnesses, Type 1 and Type 2 diabetes mellitus, thyroid abnormalities, pregnancy/lactation, recent acute or chronic disease, medications that may affect body weight, unstable body weight, food allergies or avoidance of major food groups.		
Other exclusion criteria	Low density lipoprotein > 6 mmol/L, and an inability to take fish oil supplements	Heavy alcohol intake, fluctuating or strenuous exercise > 1hr/day, dietary avoidance (including extreme vegetarianism) or dislike of vegetables.	
Diet prescription	Energy deficit (-2MJ) based on core food groups excluding non-core foods and drinks and alcohol.		

Continued…

Control diet(s) (referencing national dietary guidelines)	Low calorie + placebo supplement (olive oil)	Low calorie with 5 serves of vegetables (75g/serve)
Intervention diet(s) (referencing national dietary guidelines)	Low calorie including fish (180g/day); Low calorie including fish oil supplements (EPA+DHA)	Low calorie with 10 serves of vegetables (75g/serve)
Education level	64% Tertiary education	85% Tertiary education
Smokers/Non-smokers	7/118	2/113
Physical activity	Habitual physical activity assessed by questionnaire# at Baseline and 12-months	

Interquartile range (IQR); #*Baecke et al 1982 [121] ;* Independent samples t-test, 95% CI; Chi Square for categorical variables (*refers to both males and females); Acceptable Macronutrient Distribution Range (AMDR) Protein 15-25%, Fat 20-35%, Carbohydrate 45-65% [48].

2.4. Dietary assessment methodology

A weakness of dietary pattern research conducted at the observational level is that the food categories used may not align with those of interest in clinical practice. In many studies of dietary patterns and disease, the food categories are predicated by the dietary assessment method used to collect the data. This issue relates most to the tools and methods used at the observational level. For expedience, and due to large numbers over longer time-frames, a food frequency tool (or 24-hour recall) is often selected for dietary data collection in these types of studies. As such, little justification is provided regarding the food categories utilised in the analysis, or in describing the dietary patterns representing the group under study [122] because these have been predetermined by the tool selected. In the measurement of the total diet, food frequency tools have the potential to miss foods that may be consumed, including foods that may not be typical of the local cuisine, and may omit new types of food products. Participants may find it necessary to approximate the food they consume by

selecting an option that is listed rather than the exact food item that is consumed. Over-reporting of vegetables by food frequency tools compared with food records has been specifically noted [11]. Thus, the food frequency tool can affect the design, analysis and interpretation of studies [123]. In order to represent dietary patterns accurately, a thorough dietary assessment of the foods (reportedly) consumed is essential.

Dietary interventions are far more likely to utilise the diet history method for dietary data collection, since these studies usually involve smaller participant numbers, over more discrete periods of time. Although the cost in terms of time spent with participants is higher, individual diet history records have the advantage of facilitating quantification of more individual food items like types of fruits and vegetables, and may help discern the types and amounts of foods that may impact on weight loss or other health outcomes [124]. In comparison, portion size may or may not be measured within a food frequency questionnaire. If not, individuals who are consuming small portions of a wide variety of foods may be misclassified as higher energy consumers and conversely, consumers of larger portions of a smaller variety of foods as low energy consumers [120]. The diet history method is reflective of clinical practice and is known to provide accurate estimates of habitual intake [125-129], though misreporting is always possible [111]. Thus, the diet history record represents the food and drinks reported *as consumed* by each participant at any one point in time, which can then be categorised according to the research objectives.

Regardless of the form of dietary assessment method used in dietary clinical trials, participants may adjust their reporting as they became familiar with portion sizes and the requirements of the diet history or other dietary data collection process. However, this is a constraint in all dietary assessment methods. Self-reporting is known to be prone to systematic bias and is affected by factors such as age, gender, approval [111] and social desirability [11]. Further, under-reporting is more common to those who are overweight [111, 130] and this has been noted as a limitation common to the investigations presented within this thesis. In Chapter 7, the Goldberg cut-off (Recorded E/ (BMR x PAL1.2) = 0.76-1.24) [131, 132] was applied to the baseline data (of those completing 3-months of each trial) to examine the issue of under-reporting, and as a result, six participants were removed from that analysis. The PAL level of 1.2 was considered suitable for the study population.

2.5 Food Categorisation - complexities at the food-level

Food categorisation is complex and there are a number of ways in which individual foods can be categorised. Yet, a very simple system of five-food groups forms the framework for dietary guidance generally applied to describe dietary patterns [133]. There is little direction given in nutritional epidemiology on how food items should be grouped and there are complexities inherent in food composition that need to be considered in addressing the aims and research interests of individual studies [134]. The most basic system of categorisation is based on animal versus plant foods and then, building on this, the most objective model uses the estimated nutrient composition analysis of foods to weigh up major macronutrients and key micronutrients. However, categorisation may also be influenced by the culinary use of

foods and culture, since food plays a role in transmitting cultural values and beliefs and also influences food preferences, recipes and dietary patterns [54]. A comparison of food groups from twelve countries revealed fundamental similarities in the main groups of foods - grains, vegetables, fruits, meat, milk and dairy products and fats and sugar. Subtle differences were apparent from within these groups, although when the number of servings and serving sizes were compared, there were reportedly no significant differences [54]. Kerver *et al* (2003) suggests that "fine tuning" food groups may help discern differences in dietary patterns and may improve the associations with markers for disease risk [135].

In order to provide a framework for dietary pattern research purposes, food categorisation needs to be approached systematically. The presumptions within this thesis were based on a number of considerations including nutrient composition, including energy density [21] (e.g. low fat versus higher fat dairy food), the biological characteristics that define categories of food (e.g. fruit, or nuts and seeds) [136], food production parameters (e.g. degree of food processing as seen in refined versus wholegrain cereals) and culinary use (e.g. oils used in cooking) [57]. The evidence base for relationships between food consumption patterns and health outcomes, with specific interest to weight management, was also a factor in forming final food categories. In particular, extensively processed foods, manufactured energy-dense, nutrient-poor foods and drinks and specific food types linked with weight gain, as suggested in the observational literature [118] were taken into account in the formation of food categories.

2.5.1. Nutrient Composition

From a theoretical perspective, the categorisation of foods within food groups using the estimated nutrient composition of foods is well established and preferred over the botanical classifications of foods. Botanical classifications (written in Latin), are not used in food composition tables [137], and such taxonomic classifications may conflict with how a food is actually used in a culinary sense within a modern day dietary pattern. For example, a tomato is consumed as a vegetable rather than a fruit (Figure 2-1) and peanuts are generally categorised as nuts rather than as legumes. However, some research suggests the 18th century model may help highlight some of the lesser known food components such as flavonoids for use in dietary research [137], emphasising the potential of considering multiple systems of food classification.

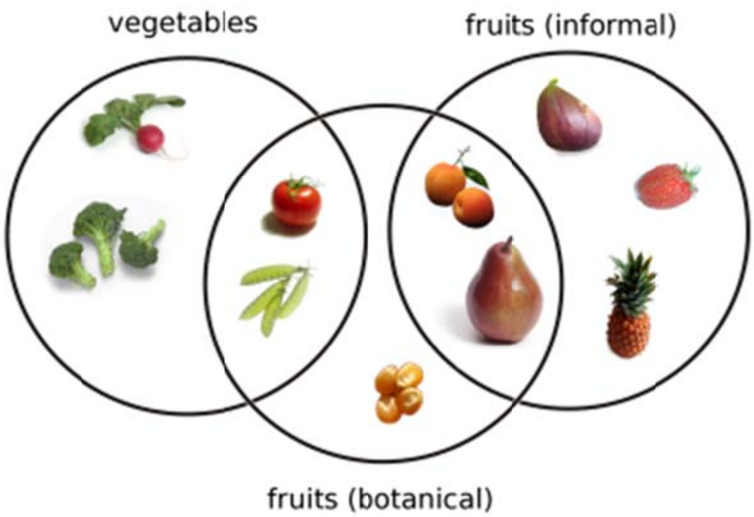

Figure 2-1 Botanical classification: Cross over between select examples of fruit and vegetables.

Source: http://www.growgardentomatoes.com/image-files/fruitvsvegetablediagram.png

The key nutrients in foods, both macronutrients and a range of micronutrients, have been determined by accepted methodologies and databases developed. True nutrient analysis refers to 'an assay of select nutrients done by laboratory analysis' [112]

whereas the nutrient content of manufactured foods included in databases is usually performed by estimating the nutrient content through calculation using Atwater factors [112, 138]. The Atwater factors allow for the calculation of available food energy, however they represent estimates and are not fully accurate [78]. Other components in foods may influence how nutrients are metabolised and it is recognised that there may be energy losses throughout digestion that cannot be easily predicted because the nutrient may not be accessible by the body and even if it is, the specific tissue may not be able to make use of all that is supplied [139-141]. As has been discussed, nutrient composition alone may be a limited approach within dietary research, since foods grouped by nutrients have widely divergent physiological effects, for example, carbohydrate containing foods [142] such as brown rice, white bread, compared with apples [38]. The number of unknown components in foods, and how these components interact with each other during digestion, reveals a gap in our food knowledge. Culinary use and preparation methods are also likely to differentiate foods within categories, for example cooked versus raw vegetables and fruits, as this may result in some losses of vitamins and other changes, since enzymatic reactions occur as plant tissue is cut, prepared and heated [40]. In addition, different forms of food processing, e.g. raw oats versus extruded oat cereals, affects the physiochemical characteristics of foods such as the molecular weight and viscosity [143] and changes in these may alter the responses within the body.

Some would argue that the distinguishing nutrients used in dietary guidelines and food guides, do not adequately separate some food groups. For example, fruits and vegetables are noted as sharing vitamin C, folate, vitamin B6, potassium and fibre,

while certain vegetables also contain beta-carotene. It is on this basis that some research further separates non-starchy vegetables (e.g. into three categories - cruciferous, green leafy and dark-yellow) [144]. The differentiation of the food categories for this research is focused on weight management thus there was an obvious differentiation between the "free", low energy vegetables, and starchy vegetables, which contain a greater proportion of carbohydrate. However, if the aims were different, for example examining antioxidant effects or vitamins and minerals, further categorisation of the vegetable group would be necessary and considered appropriate.

The distinguishing nutrients of the 'meat and meat alternatives' food group include protein, bioavailable iron, zinc, vitamin B12 and long-chain omega-3s and these nutrients are valid descriptors for the animal protein foods, and especially for red meats, poultry and fish. However, there are questions as to the use and appropriateness of describing vegetable protein food sources, such as legumes and nuts in the same way as animal proteins, although they are typically included in the same group. While legumes and nuts contain iron, it is not well absorbed due to fibre components and phytates, which also inhibit zinc absorption within the gut. Neither do legumes or nuts contain long-chain omega-3s or vitamin B12, however, they do contribute dietary fibre, unlike the animal-protein foods listed. Consequently, legumes are often also categorised with vegetables, with similar discordance between the distinguishing nutrients listed for vegetables.

The nutrient composition of foods is also a valuable method for discriminating between foods based on fat content, particularly the type of fat. This was an important consideration for separating nuts [145, 146], fatty meat cuts [147-149], milk and milk alternatives [150, 151] and unsaturated oils and margarine [152] particularly where health outcomes, either positive or negative, have been focus of recent research. In comparison, NCFD, that is, energy-dense, nutrient-poor foods, added sugar and food sources of saturated fat, do not form a readily recognisable food group, and are highly variable in terms of nutrient composition. They most often share higher proportions of refined carbohydrate, and/or added sugars, and/or added fats, particularly saturated fatty acids and/or sodium as a result of being highly processed, manufactured foods. They are 'non-core' because they contain limited nutrients and potentially deleterious ingredients such as excess added sugars and/or saturated or trans-fatty acids. They are ubiquitous in the diet and, as a consequence, this diverse group of foods and drinks deserved further attention in relation to changing consumption patterns for weight management [62].

Beverages are the only food source of alcohol and therefore are singled out as a separate category whereas in food guides, alcoholic beverages are usually considered an 'extra' or 'discretionary' choice. While there is acceptance that within limits, alcoholic beverages provide some benefit to health [26], consumption adds energy disproportionately compared with other food choices, and this is an issue within a weight reduction prescription.

2.5.2. Food components

The known bioactive components within food help to support the categorisation that is achieved through assessing nutrients. However, bioactive components also include competitive compounds that may decrease the nutritional value of food, and more beneficial components such as microbes, isoflavones, antioxidants and phytochemicals [29, 39]. In the first instance, distinguishing between plant and animal food sources is important at a biological level, for example eggs and legumes. Within animal sources there are biological effects of different fatty acids and amino acids that depend to an extent on the food source (meat or fish), as well as the differences between natural food sources versus synthetic (supplement) sources in the case of food folate and folic acid for example.

In addition to the characteristics within the food, food classification systems should ideally consider the effects of the food matrix upon consumption. Different fatty acids within foods exert their biological effects on biomarkers such as blood cholesterol. As such, examination of the optimal health outcomes may become a better method of defining fatty acids and therefore food sources for precise categorisation. At a biological level, the assessment of trans-fatty acids within foods would help further differentiate some food choices, especially as evidence builds regarding possible biological disparity between consumption of industrial trans-fatty acids and ruminant trans-fatty acids on health [26]. The trans-fatty acid content in foods was not available through the conversion of food data to nutrient data using the computerised software package presented within this thesis. Likewise, many other constituents in foods may

be unaccounted for in nutrient databases, although these may become available in the future.

2.5.3. Food Processing

A processed food is defined as any food other than a raw agricultural commodity, and includes any procedure that alters the food from its natural state. Processing also includes the addition of preservatives, flavours, nutrients, food additives such as salt, sugars, and fats [26]. Minimally processed foods retain the physical, nutritional and sensory properties of the original raw agricultural commodity and minimise or exclude added ingredients. Nutrient-dense core-foods like fruit and vegetables may be consumed whole, or minimally processed including sliced, diced, frozen, canned or cooked. Processed NCFD are often entirely made from manufactured food ingredients and may contain excessive sodium, solid fats, refined grains, and added sugars [153]. Processing may further alter the nutrient quality of a food and the lower nutrient density of some processed foods may make them structurally and chemically simpler than whole foods and therefore less demanding to digest [29]. From this point of view, consumption patterns of NCFD may be an even more important consideration in weight management.

Almost all food is processed to a certain extent, however processing divides foods in terms of i) type, ii) intensity and iii) purpose [153], making processed and manufactured foods far from homogenous. While the extremes of food processing are obvious, there are many foods which rely on some degree of food processing, or at least 'culinary transformation' [40] in order to be consumed [154]. This applies to

many legume and grain based foods but also the denaturation of animal proteins. Both wholegrain and non-wholegrain (refined) cereal foods may also be processed to contain added nutrients such as iron, thiamine, riboflavin and niacin to replace those lost during processing, the most obvious example being breakfast cereal products. All bread products, with the exception of organic varieties, are fortified with folate and iodine in Australia as a result of recent changes to legislation [155]. Within the grain and cereal food category there is great debate defining the optimal characteristics and it is unclear as to what extent the fibre content [156], glycaemic index (GI) or nutrient density, play in chronic disease risk and prevention [157]. The effects on body weight of different types of bran, germ and fibres needs to be confirmed [158]. In this thesis, higher fibre and lower GI breads and cereals were included with wholegrain cereal foods.

Total energy is the mechanism through which foods affect weight control [20]. Thus, when calculating the nutrient and energy content of the diet there are necessary assumptions concerning the accuracy of the estimates of nutrients in the available food composition data. New research regarding the cost of digestion and the accessibility of energy and nutrients from whole foods may mean that the estimates vary from what the body actually obtains [20]. This may be as a result of the processing that occurs within the human body. Research of wholegrain foods [29] and nuts like almonds [138] and pistachios [159], have shown that the reported kilojoule values from Atwater factors [160] overestimate the energy in these foods in terms of what the body is able to access and utilise. The impact of the discrepancies between whole

and more processed food types may have implications for body weight control [29] although these adjustments cannot be applied to the current analyses.

Sugars occur naturally in foods such as milk or in fruits, or formed as part of the cooking or manufacturing process, in bread crust via the Maillard reaction [161]. Sugar can be added as a food ingredient, in soft drinks or by the individual to tea or coffee. As with dietary sodium, a greater proportion of added sugar would now be consumed from processed foods, even though many of these foods could still be considered *core* within the diet, for example breakfast cereals and some dairy food choices. While added sugar to beverages like tea and coffee can be captured and quantified separately in a diet assessment, added sugar in processed foods is more difficult to accurately determine. This is significant in the context of weight management, as added sugar (in teaspoons) is probably often mistakenly a target in weight reduction diets, although a greater proportion is probably consumed in manufactured foods, even those considered core foods, like breakfast cereal and yoghurt [162].

2.5.4. Culinary use of foods

The culinary use of foods considers how foods are used in the context of the whole diet, in main meals (breakfast, lunch and dinner) or as mid-meal snacks. These general patterns determine the ingredient combinations used in food today, transcending individual tastes and recipes [163]. The culinary act differentiates us from other animals, since 'we transform foods on a different level', preparing food using heat and combining ingredients [164]. Culinary use was considered important particularly for foods that do not have a good fit with the traditional five food groups, primarily from a

nutrient composition standpoint, or where there are specific recommendations regarding consumption. Culinary oils are given as an example, since these can be used as an addition to foods rather than as an intrinsic component, for example in salad dressings or in cooking meals. Importantly, unsaturated varieties are emphasised over highly saturated fat spreads [57].

Eggs are among the most versatile individual food ingredients. They are used in both savoury and sweet food preparations and can be consumed alone or as an ingredient in meals. Within foods, eggs can be used to generate a variety of structures, light like meringue or heavy like a custard, giving texture to sauces and mayonnaise and protein in pasta. [165]. They can be boiled, fried, baked, roasted and pickled [165]. The egg is 'readily and drastically transformed' due to the proteins denaturing and the innate capacity for the proteins to bond to each other [165]. Despite the ubiquitous use of eggs in cooking, they became a much maligned food due to supposed associations with elevated blood cholesterol levels and incorrect assumptions concerning the cholesterol content of foods in the sequelae to elevated blood lipids. More recent evidence supports consumption within a weekly limit of six eggs with little likelihood of an effect on low density lipoprotein cholesterol (LDL-C) levels [166, 167]. Eggs are an important food source of vitamin D and are upheld as a food with a perfect complement of amino acids and high biological value.

Legumes (beans, peas and lentils) are the second most important plant family in the human diet after the grasses [165]. In contrast to eggs, they are low in the amino acid methionine and in comparison to meat, are limited in vitamin B12, and this can be an

issue if animal protein is totally replaced by legumes in the diet [168]. In a culinary sense, legumes can be used in meals alone, or together with a meat-based dish, and are a particular food source for vegetarian style meals and diets. Their protein-rich composition is derived from a symbiotic relationship with soil bacteria which converts nitrogen from the air to amino acids via the root systems [165]. Legumes are typically consumed whole including chickpeas, lentils, broad beans and split peas, and are primarily made up of protein and carbohydrate, whereas peanuts and soy beans are sources of fat and are cultivated for oil. The evidence for a protective effect of legumes on weight management remains limited with very few clinical trials examining the effect of increased legume intake on longer term weight status [66, 169, 170]. In epidemiological studies, low consumption levels make it difficult to demonstrate clear effects of this food [157]. However, legumes within dietary patterns deserve further attention as a possible marker for other healthy lifestyle practices [157].

Alcohol as a particular food component has been discussed. In a culinary sense, alcoholic beverages may or may not be consumed with poor food choices, thus, it is important for these beverage choices to be reviewed separately from other foods and beverages. Although wine, beer and spirits are very different beverages, here they will be considered together. There is no association between moderate consumption and weight gain [26] but over-time, heavier consumption is associated with increasing weight [171], and many other negative health outcomes [172-174]. Normal cellular function is disrupted when alcohol is consumed and converted to acetaldehyde, interfering with concentration, vision, speech, coordination of movement and memory, depending on the amount that is absorbed into cells. The presence of food in

the gut slows the absorption of alcohol and regular drinkers obtain a greater level of efficiency in metabolism due to increases in alcohol dehydrogenase, the enzyme produced in the liver. Alcohol consumption tends to be restricted in diets when weight loss is desired.

2.5.5. Relevance for weight management

Aside from energy restriction, the actual food choices and therefore dietary patterns consumed by dieters during a period of weight loss may be important in facilitating successful weight loss. Establishing evidence in this area is important translational research for individualising dietary advice and in the development of dietary guidelines for the population. In considering the whole-diet, and examining the change in dietary patterns within the context of a free-living dietary intervention trial may provide useful insights into changes in food choices, especially those made by more successful participants. Furthermore, this approach may be more informative of diet quality than the macronutrient profile. The idea of examining food and dietary patterns in the context of a weight loss intervention, is the focus of this thesis and is a concept that has support in the literature [7, 9, 28, 32, 175].

Dietary patterns that are relatively low in energy density that have been associated with beneficial body weight outcomes, may also be associated with lower risk of complications associated with being overweight such as type-2 diabetes mellitus. These dietary patterns are most often characterised by a high intake of vegetables, fruit and total fibre and a relatively low intake of total fat, saturated fat, and added sugars [176-181]. Lower dietary energy density may also be associated with a dietary

intake pattern characterised by a lower consumption of meat, especially processed (fatty) meats and energy-containing beverages [181]. However, energy-dense foods (unsaturated oils and margarine and nuts) have been associated with improved health outcomes [37], and nuts in particular, have been shown to have compensatory effect on total food consumption [145, 146], assisting weight management. Consequently, nuts can be included in diet even when the energy intake needs to be reduced.

2.6 Dietary Pattern analysis: *a posteriori* and *a priori* approaches

2.6.1 What is dietary pattern analysis?

If the aim is to examine the relationship between dietary intake and health outcomes, dietary pattern analysis captures the scope of foods consumed rather than isolated nutrients or single foods. These methods respect the inter-correlations between nutrients and other non-nutritive food components that are difficult to examine separately, or too small to examine in nutrient based studies [7]. This approach respects the fact that there remains a great deal to be learned about foods themselves. While there has been a great deal of nutrient-based research, and there is an awareness of many food components, there are many components that remain undiscovered. Furthermore, the relationship between foods and the interactions that occur within the human body often cannot be explained by nutrients alone.

The nutrient composition of diets is a valuable analytical technique, but this method alone may hide important food patterns from view. In order to maintain the integrity of the foods reported, there are a number of methods of analysis currently in use, common to the observational research domain. Methods include statistical techniques

applied to the data, characterising the dietary patterns, either by aggregating participants with similar diets (cluster analysis) or specific food items or groups (factor analysis). The selected technique depends on the research question - cluster analysis is chosen when there is interest in the divergent diet patterns among participants and this technique can be used to examine dietary pattern change. Factor analysis is used when the interest is specifically about the foods that tend to be consumed together within patterns. Both are applied *a posteriori* to existing data, and the statistical program organises the output according to the data supplied, which naturally involves a level of subjectively as to the organisation of data. To date, studies applying *a posteriori* analysis of grouped food variables, have done so largely without justification or examination of the consequences of such data manipulation [122] and therefore, defending food categorisation was an important preliminary stage of the research presented in this thesis.

Dietary indices, better known as diet quality tools, are developed *a priori*, and utilise current knowledge and therefore may be limited by the researcher perspective, purpose and the scientific literature available at the time of development [27]. Foods, food groups and nutrients and other dietary features, including supplement use, have all been incorporated into scoring tools developed to date. Diet quality tools do not assist in describing a dietary pattern as they give a summative score, instead they tend to function as confirmatory tools [11] although their value can be broadened in measuring dietary change.

Studies have compared cluster (and/or factor) analysis with diet quality indexes and against biomarkers and health outcome measures such as plasma lipids [182], hypertension [183], cancer risk [184] and mortality [113]. The reproducibility of the results across the different methods tends to be the focus [113]. Both *a priori* and *a posteriori* methods involve a degree of investigator subjectivity, either in the design of the tool or in the evaluation of the results. From the dietary data collection technique through to the defined number of clusters, the exclusion of small clusters, the naming of the groupings and the specific design of the tool can all impact on the conclusions drawn.

2.6.2 Cluster Analysis

Cluster analysis can be applied to available dietary data, to identify dietary patterns of the study population independently of their relevance to health [115]. Cluster analysis aims to answer the questions: 'Which people cluster together with regard to dietary intake patterns within the defined population?; What typifies each cluster's diet?' [184]. Cluster analysis is ideally used when the researcher wants to discern a number of groups within the data set and the analysis process helps to define the groups by minimising the difference between group members, but maximising the differences between the groups within the data. Cluster analysis results in clusters of subjects, distinct, non-overlapping groups based on their shared characteristics, in this instance, dietary intake. It has been suggested that this method can be applied to planning dietary interventions as it allows identification of subgroups and the defined eating patterns alongside outcome measures [185].

Cluster analysis has been applied using foods, food groups and nutrients and while some have chosen to use mean per cent energy contributions from food groups in determining the clusters and in naming the clusters, this is not the best method, especially if there is great variability in what subjects consume [186, 187]. More novel approaches use food servings [186], and while there may appear to be no difference, if the per cent energy from fat is high, then the relative proportion of energy from other macronutrients or subgroups is lowered. In comparison, the number of servings is an absolute number strategy that does not depress other values if fat intake happens to be high [186]. This approach lends itself better to exploration of dietary patterns and may be more sensitive in discerning consumption contributions of low energy dense food groups like fruit and vegetables, which are associated with higher quality dietary patterns and health outcomes. Bailey *et al* (2006) [186] found more consistent results with food servings and this approach may help identify foods or food subgroups not previously emphasised in the context of weight management, and can be translated directly into practice.

Two-step clustering using SPSS (IBM SPSS Statistics, version 19.0.0 IBM Corporation Armonk NY), automatically creates pre-clusters, then it clusters the pre-clusters using hierarchical methods where the number of clusters are unknown. Two-step clustering is able to handle very large datasets, and is the method chosen when data are both categorical like males versus females, and where there are also continuous variables, like body weight. While the number of clusters can be predefined, it is preferable if the clusters are determined using the algorithm within the software program from the variables collected. Predefining clusters introduces an element of subjectivity, whereas

allowing the program to do this is preferred, otherwise there are necessary decisions to be made about the number of clusters, their interpretation and "validation of the cluster solution" [187]. However, two-step clustering using SPSS overcomes these issues. While there are no specific rules about sample size, it is important that there are sufficient participants to limit highly variable data, as small samples are unlikely to form accurate clusters, rather, the data points in too many dimensions [188].

When cluster analysis is applied, the resultant patterns require interpretation in line with current scientific understanding of the population and their dietary habits. In a review, Kant (2004) emphasises advice from Jacobson and Stanton (1986) [189] suggesting that 'researchers should discard factors or clusters with due care because the obtuse factor/cluster may be the one that leads to recognition of new knowledge' [187].

There appears to be a tendency in the literature to over-simplify the clusters, for example, a healthy pattern is often called *Prudent*, and less healthful pattern *Western* [27, 182]. The two identified dietary patterns appear to be rather gross characterisations of the possible range of diets. Applying names to the resulting clusters, other than a name that directly describes the foods in greatest proportion, can be a limitation of this approach. For example, in the Western pattern, red meat is treated as an unhealthy food choice whereas it is highly processed meats that are associated with poor health outcomes [147]. Even more importantly, these labels have a history of use dating back to when food choices were more basic, so their application in more recent years does not adequately describe the foods people are now

consuming. Newby and Tucker (2004) examined 35 cluster papers in a review compared with factor analysis, and found some inconsistencies, yet 'healthy' or prudent patterns were associated with less disease, smaller BMI and some protection from CVD mortality [33] supporting the use of these techniques in identifying patterns related to chronic disease and prevention [185].

It is incorrect to assume that clearly separated clusters will exist in the data set being examined. Instead, cluster analysis is a vehicle to create the most useful segments within the available data. Aldenderfer and Blashfield (1984) [190] aptly note that although the aim of clustering may be "structure-seeking", the way the method works is by imposing structure. The value in using cluster analysis is in knowing when the groups are 'real' and not merely imposed on the data by the method. In consideration of this, Wirfalt and Jeffery (1997) suggest validation of clusters so that the emergent clusters are not as a result of the method or the population being studied but also to "protect against food patterns being selected by chance" [191]. They suggest checking the estimated nutrient intakes in relation to food energy between the clusters. This was an important step in the investigations within this thesis, as low fat patterns do not always mean that nutrient density is high or optimally protective [191]. Likewise, the reverse is also true.

There are limitations of cluster analysis techniques. Cluster analysis is specific to the group being examined and it is likely that that reproducibility of cluster analysis between studies is greater when the population shares similar characteristics. For example, within a comparable overweight population the analysis would most

probably find people who share similar frequency patterns for consumption of foods [184], giving reasonably reproducible results [20, 27, 113, 185] especially since specific foods can cluster, while the overall pattern may differ [192]. Dietary patterns are also likely to vary by culture, economic status, gender, geographical, environmental and social factors [27] and these variations are of great interest, since dietary advice for populations should be able to communicate some of this variance to gain broad acceptance.

2.6.3 Diet Quality tools

Diet quality tools emerged in observational research in order to rate a whole-diet in relation to disease [34] without reducing the nutritional intake to single nutrients. During weight loss, a diet of high quality may be more difficult to achieve within a tight energy restriction, and interventions tend to report energy and nutrient level changes but not changes in diet quality [46]. Several reviews of diet quality tools have been published [103, 187, 193-196] and each attempts to define the methodological process of designing such tools, the differences between the available tools and the validity of *a priori* methods.

The earliest review of diet quality tools by Kant in 1996 (of 56 published papers) found that indexes of overall diet quality were related to risk of disease more strongly than when individual nutrients or foods were assessed [194]. However, Kant commented that few tools had been validated at that time against biochemical, anthropometric or other clinical parameters of nutritional status. In the second review published in 2004, Kant found inconsistencies across studies relating to study design and dietary

assessment [187]. As the complexity and variety of tools in existence has grown, the discussion has focused on the attributes of the different tools for example, the weighting of scores, the inclusion of “diet quality” as an independent element of measure, the suggestion to adjust for kilojoules consumed, and validation of the score against other parameters. Waijers *et al* (2007) [195] examined 20 distinct diet indices and concluded that many arbitrary choices had been made in designing the tools and made recommendations for designing a new tool (detailed in Appendix C). A review by Wirt and Collins (2009) [103] discussed 25 indices of diet quality using a range of measures from nutrients, to food servings or food groupings. This review noted many methodological weaknesses in the tools reviewed but concluded that higher diet quality was inversely related to all-cause mortality with a moderate protective effect (See Chapter 7). Wirt and Collins (2009) recommended examination of nutritional biomarkers alongside diet quality scores and support the development of diet quality tools for clinical practice and possibly also self-evaluation [103]. The two most recent reviews reiterate the earlier published suggestions and emphasise the importance of clarity in the development of specific tools for populations [30, 196]. In regards to weight (BMI), a systematic literature review (30 observational studies, 12 relating to diet quality tools) found that a high diet quality score from diets higher in fruit and vegetables and low in meat and fat were associated with a lower BMI [11]. However, 10 of the 12 diet quality studies found no association between the diet index score and BMI or obesity [11]. Togo *et al* 2001 [11] emphasise that there is a lack of studies assessing weight change in relation to food intake patterns.

In developing a tool, it is important to be clear about what is the intention of the score [195, 196], the use of the score and the relationship of the score to other parameters. The definition of diet quality is highly dependent on the attributes selected by the investigator [194, 195]. However, the foods, food groups or nutrients assessed by the tool have often been predetermined by the method of data collection, usually, a food frequency tool. This is an important issue, because the data may not entirely match the research question [113]. Waijers *et al* (2007) suggests an index contain two macronutrients as an assessment of overall dietary balance, although this is not necessary as it is easy enough to compare scores with the nutrient composition of the diet as a separate analysis. It has also been suggested that a tool quantify overall diet quality, but this is highly subjective. Rather than attempt to score for overall diet quality within a tool, the overall diet quality should be determined by the tool itself and the final score [195].

In published research there are examples where decisions have been made to eliminate or exclude some of the data collected, consequently there are tools that do not cover the whole diet, with some tools representing as little as 40% of the foods possible in the diet. For example, the Healthy Food Index by Osler *et al* (2001, 2002) [116, 197] assesses only fruit, vegetables, bread and butter/lard/margarine. Fundamental issues arise in the analysis of scores that do not represent the totality of the diet and this creates similar weaknesses to selecting certain nutrients or components in food, and ignoring the whole diet perspective.

Since tools have most often been applied to population data, many have been constructed to match the features of the local dietary guidelines [198, 199], and may, or may not, encompass the whole diet. These tools measure compliance with the dietary guidelines selected – and not other health outcomes unless these are specifically measured [195]. Diet quality tools have been criticised for being too subjective especially when they are based on an interpretation of dietary guidelines. Interpreting what a dietary guideline means in terms of an objective measure of food consumption is arbitrary. This is demonstrated by two differently constructed Australian diet quality tools, the Australian Healthy Eating Index [200] and the Dietary Guideline Index [199], where both are based on the same dietary guidelines.

The scores derived by a tool are only relevant to the population being assessed, whether this is a clinical outpatient service or a research cohort. In any case, both the tool design and the population are culturally specific, and therefore each tool should be designed with the population eating habits in mind. In relation to scoring, the score applied to each criteria, should be a range proportional to intake, as this allows for more subtle adjustment of the score and works better especially with foods that have a U-shaped correlation with health outcome. Waijers *et al* (2007) suggest that foods such as dairy foods, meat and alcohol be scored in this way to better represent the degree to which they are, or are not consumed [195]. Since a higher energy intake allowance, such as that for men, enables more food and a more diverse range of foods to be consumed, consequently the score needs to be adjusted for total energy intake so that it can be applied to men and women [77]. Overall, the greatest consideration is the interpretation of the score and understanding the limitations of the tool.

There are criticisms of diet indexes and some believe they have not generated new diet and disease hypotheses [187]. To improve research outcomes, Kant and others have suggested using multiple methods to confirm findings using nutrient or clinical measures [27, 187]. However, in proposing this, researchers need to consider that for many diseases, valid predictive biomarkers are lacking, and disease often develops over many years [27]. Diet quality indices are only as good as the components on which they are based, hence they must be revised to reflect latest science and policy [201].

2.6.4 The Alternative Mediterranean Diet score (aMed) and Mediterranean Diet Score (MDS) as comparison tools.

While many diet quality tools provide a relative measure of diet quality, not all tools are sufficiently valid at an individual level [202] or take into account the whole diet. Neither the Alternative Mediterranean Diet score (aMed) [203, 204] nor the Mediterranean Diet Score (MDS) [205] are specifically related to weight loss, however they utilise food groups and were considered most similar to the tool designed and validated within the studies presented in this thesis. (Appendix D).

The original aMed tool devised by Trichopoulou *et al* (1995, 2003) [203, 204] was based on the reported intake of nine food items: vegetables, legumes, fruits and nuts, dairy, cereals, meat and meat products, fish, alcohol, and the monounsaturated: saturated fat ratio. Participants with food intakes above the median-level intake received one point; otherwise they received zero points. Meat and dairy product

consumption below the median received one point. Fung *et al* (2006) [206] modified the original aMed by excluding potato products from the vegetable group, separating fruits and nuts into two groups, eliminating the dairy group, including whole-grain products only, including only red and processed meats for the meat group, and assigning one point for alcohol intake between five to 15g/d. These modifications were based on dietary patterns and eating behaviours that have been consistently associated with lower risks of chronic disease in clinical and epidemiological studies. The revised aMed tool used by Fung *et al* had nine items: vegetables (excluding potato), legumes, fruits, nuts, wholegrain cereals, meat and meat products, fish, alcohol, and the monounsaturated: saturated fat ratio and therefore the score range for the aMed was 0 to a maximum of nine (Appendix D Table D-1).

Another Mediterranean diet score developed by Panagiotakos, Pitsavos and Stefanadis 2006 [205] was based on professional judgement of the Mediterranean food pyramid. The 11 groups included non-refined cereals, potatoes, fruit, vegetables, legumes, fish, red meat and products, poultry, full fat dairy products, olive oil and alcoholic beverages. Whereas frequency was assessed for food groups, alcoholic beverages were assessed as amounts per day. For alcohol, a score of five was attributed for consumption of less than 300ml per day, a score of zero for consumption of more than 700ml per day or none, and scores one to four for consumption of 300–400, 400–500, 500–600, and 600– 700ml per day (100ml = 12g ethanol) respectively. For food items perceived positively, scores of 0='no consumption', 1='rare', 2='frequent', 3='very frequent', 4='weekly', and 5='daily' were assigned. All the components or food groups making up the MDS contributed equally to the total score. A number of adjustments

were made to these tools to enable comparisons with the more detailed tool developed in this thesis. (Appendix D Table D-2).

The advantages of the Mediterranean diet originated from the Seven Countries Study described by Ancel Keys in the 1950s [207] and was reportedly based on a diet rich in vegetables, fruits, and pasta and sparing in meat, eggs, and dairy products. The aMed and MDS are also purportedly based on the key foods of the Mediterranean diet yet there are a number of food groups that are not included in either of the tools, therefore neither assesses the whole diet. The aMed does not account for dairy foods of any variety, nor non-wholegrain cereal foods, or potato, or 'extra' foods (i.e. energy dense, nutrient poor foods). The aMed tool attributes a single score to both red and processed meats although this is unlikely to be appropriate on health grounds since fatty, processed meats are linked with increased chronic disease [147-149]. The MDS does not account for low fat dairy foods although it does account for full fat dairy foods, nor does it capture non-wholegrain cereal foods, 'extra' foods or nuts. These types of design errors are common to many tools, thus not all dietary components are considered in the final score. For research that aims to develop diet scores, these limitations can be overcome by utilising data from dietary assessment methods that capture the whole diet.

2.6.5 Considerations in developing a Diet Index for weight management

In order to develop an index of diet quality for the clinical dietetic research setting, it was necessary to establish predefined parameters on which the tool would be based. Each decision in the design of a diet quality tool needed to be weighed against the

purpose. As seen with the tools utilised in observational research, a tool for weight management would primarily be based on current knowledge of food groups and individual foods. Construction ideally would also be guided by the current nutrient recommendations from the Nutrient Reference Values (NRVs), including the suggested dietary targets (SDTs) for prevention of chronic disease [48]. For a score to be applied to data in a weight loss context, specific cut-off points for optimal scores and lower scores need to be determined. If the highest score is to be considered optimal, then the score needed to be validated against the current consumption recommendations, with acceptance that a tool developed in this way may eventually become out-dated. It has been said that diet quality tools have had a limited ability to predict longer term health outcomes [187, 193, 195]. However, they are able to detect change in diet quality over time [11] which can be assessed against health outcome measures, such as weight change, and therefore are well suited to studies in an intervention context [196]. Although the evidence suggests that dietary patterns are more important to human health than specific foods or food components, there are limited studies of the Australian population and none that examine clinical intervention outcomes. As such, the concept of a tool for weight management interventions has support in the literature [7, 27, 103, 196]. The specific suggestions made in the review papers regarding development of diet quality tools are further summarised in Appendix C.

Each of the described methodologies allows dietary patterns and the change in patterns to be examined. Whereas cluster analysis separates participants based on common consumption patterns, and a diet quality tool is summative, both can be used to examine the whole diet and the outcomes within interventions. Since the patterns

are described in terms of the specific food consumed, dietary change can be easily explained and the results are transferable to the clinical setting.

CHAPTER 3 DEVELOPMENT OF FOOD CATEGORIES FOR CONDUCTING DIETARY PATTERN RESEARCH WITHIN AN INTERVENTION CONTEXT

Preliminary analysis using the food categories to describe dietary patterns was included in **Grafenauer, S.**, Tapsell, L. and Beck, E. *"Beyond nutrients: Classification of foods to identify dietary patterns for weight management*". **16th International Congress of Dietetics**, *Sydney, Australia (5-8 Sept 2012)*. Nutrition & Dietetics 2012; 69 (Suppl. 1): pp. 2–71.

The remainder of this section is the substantive content of work submitted for publication: Grafenauer, S., Tapsell, L., Beck, E. and Batterham M. *'Five-food groups versus more detailed food categories for monitoring dietary changes in clinical research'*. Prepared for publication.

Chapter 2 provided a description of the methodological considerations for conducting food-level research within an intervention context. In describing the considerations involved in the classification of foods, the previous chapter forms an important foreword for Chapter 3 which describes the food categories in detail, and applies the categories to dietary data to describe the changing dietary patterns in comparison with the traditional five food groups.

3.1 Introduction

There are suggestions in the nutrition research literature that food intake patterns, rather than nutrient intakes, are preferable for assessing diet-health relationships [7, 115, 187], yet there are insufficient studies testing health outcomes at an intervention level with this approach [26]. Focusing only on the precise macronutrient proportions of the diet may be less important than once thought [42] since it is recognised that foods, and therefore diets, are more complex than the sum of nutrients that are often the sole reference point in the analysis of dietary interventions. There is an opportunity to use food-based analysis in the interpretation of dietary change, and examination of food choice patterns may help to capture some of the complexity of diets that is often lost in analyses that focus only on nutrient composition. Analysis at a food-level in intervention research, may help improve the clarity regarding the food-based links with outcomes [9], and as a result, reveal information for the clinical setting [32]. However, few studies have tracked food pattern changes over time in relation to weight loss [208] and an adequate degree of detail at the food-level needs to be obtained for this to be useful method for translation to practice.

Western literature refers to 5 ‘core’ food groups and an additional group of ‘extras’ (including sugar, fats/oils and discretionary food and drink choices) [54, 57]. This framework of 5-food groups may be suitable as a communication tool and food guidance system at the population-level, but it may not be suitable, or specific enough, to capture the complexity of food patterns within the diet which may require change. In the clinical weight loss context in particular, more categories may be required to differentiate between food choices, and better expose dietary change because advice is given in terms of food choice. Food-level analysis can also be directly translated to practice. Our previously published research using cluster analysis on baseline weight loss dietary trial data, showed that subjects with poor baseline dietary patterns lost more weight ($P<0.05$) than those whose dietary patterns more closely aligned with desirable eating patterns [124]. While we were able to differentiate between clusters in terms of the predominant food choice, we identified the need to further investigate the specific food categories in these clusters to see what the most important dietary changes were across the whole sample rather than relying on measures of energy intakes alone. The aim of this investigation was to address dietary change in terms of foods and dietary patterns from clinical weight loss research context. We hypothesised that the traditional 5-food groups would be insufficient for this purpose, and would limit the description of the types of specific foods selected. Furthermore, the analysis of food choice patterns would reveal more practice-relevant information than analysis of energy intakes alone.

3.2 Methods

Participant diet history records were drawn from two registered clinical weight loss trials (ACTRN 12608000425392 and 12610000784011) for secondary analysis. Both trials were randomised controlled parallel interventions with a control and intervention approach to dietary advice. Details of each primary study are provided in the published manuscripts [1, 2]. A set of 5-food groups was identified by referring to national food guidance systems for adults [26, 50, 55, 57, 209]. A second set of 17 food categories (Figure 3-1) of interest in the clinical context was derived with consideration of (i) their biological characteristics to define categories of food (eg. fruit, or nuts and seeds) [136], or (ii) by their means of production (eg. alcohol) [136], or (iii) by their nutrient composition including energy density (eg. milk and milk alternatives), or (iv) by their culinary use, and (v) the evidence base for relationships between food consumption patterns and health outcomes specifically with interest to weight management. The food categories have been utilised in previously published research [124] and similar categories have been used in observational research [118]. Food portions were calculated with reference to a clinical practice ready reckoner [80] using a 30g serve for whole grain foods, non-wholegrain (refined) cereal foods, meat, fish, eggs, nuts and higher fat dairy foods (cheese), 150mL per serve for low and medium fat dairy foods, 150g for fruit, 75g for vegetables, 5g for oil and margarine, 400kJ for alcoholic beverages and 600kJ for non-core foods and drinks (NCFD). Each food and beverage item from the diet history records collected at baseline and 3-months were tabulated by food group using both the 5-food group system and the 17 food categories. The primary outcome measure of this analysis was change in food group consumption (median weight in grams, median energy in kilojoules, mean number of

portions). These were compared to change in body weight / composition, and energy / nutrient intakes.

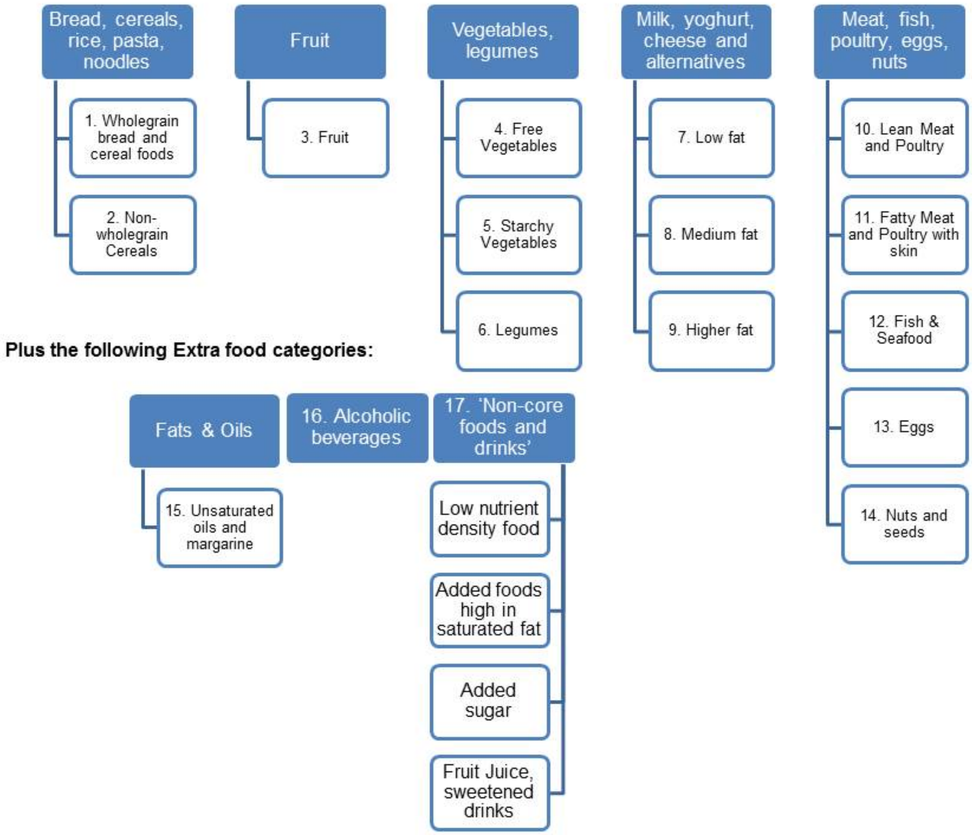

Figure 3-1 Schematic of proposed new classification based on the Traditional food groups

Food Categories

Seventeen food categories (numbered in parentheses as FC, Figure 3-1) were differentiated from the traditional five food groups with the rationale for each new category described. The scope of foods included in each category has been previously published and is identified in Table 3-1 [124].

Breads and Cereals Categories

Breads and cereals were differentiated into two groups, whole grains (FC1) and non-wholegrain (refined) cereals foods (FC2). Both were recognised as key sources of energy and carbohydrate (CHO), however, it was noted that whole grains are emphasised in national dietary guidelines. Whole grains include all parts of the grain, including fibre, B vitamins, vitamin E and unsaturated fats, although the definition, and how it is applied to processed products, is subject to debate [210]. Wholegrain consumption has been associated with lower body weight [211], waist circumference and reduced risk of being overweight [157] inferring that non-wholegrain choices such as white bread and refined breakfast cereals should be decreased in the diet [42, 212] but specific evidence is lacking.

Fruit Categories

Fruit (FC3) was considered an important food category because it contributes vitamins A, C, E, fibre and carbohydrate. There is good reason to separate fruit and fruit juices. While the energy value of 200ml of juice is comparable to a 150g portion of whole fruit [84], the fibre content of juice tends to be lower and there is opportunity to drink larger portions, thereby consuming more energy. Thus juice was categorised with NCFD (FC17). Much of the evidence on fruit consumption has been studied combined with that of vegetables. The evidence review for the 2010 Dietary Guidelines for Americans found that no conclusions could be drawn regarding the relative influence of fruit versus vegetables on weight [211], but we have separated them within this analysis given their typical culinary use and as suggested in the literature [213].

Vegetable Categories

Vegetables are nutritionally diverse containing valuable micronutrients, phytochemicals, pigments and polyphenols. Since the context of our analysis was weight reduction, it was necessary to differentiate between low energy, 'free' vegetables (FC4) and higher energy 'starchy' vegetables (FC5) accounting for the different CHO and energy values [84] and also between plain cooked (e.g. steamed) and fried vegetables (e.g. potato chips).

Legumes (FC6) can be categorised with both vegetables and meat based on the carbohydrate/fibre or the protein content respectively. Evidence for the protective effects of legumes on weight management remains limited [157, 170]. From a culinary perspective, legumes can be used to replace meat in a meal [66, 214, 215], however there would be dietary considerations (relating to low methionine and B12) if meat were to be totally replaced by legumes in the diet [168].

Milk and milk alternatives Categories

Dairy foods form one of the traditional five food groups, providing essential amino acids, vitamins A, D and B2 and a highly bio-available source of calcium. Whereas whole milk comprises approximately 3.5% fat, the fat content in cheese can range from 24-34% [216] yet it contains no carbohydrate. Thus, dairy foods were classed as low fat <3.5% (FC7), medium fat 3.5-10% (FC8) and higher fat >10% dairy food (FC9). Milk alternatives, such as soy beverages, were categorised in the same manner. As dairy foods are a heterogeneous group, this form of categorisation may provide

important insights of relevance for dietary guidance that may otherwise be over-looked [150, 151].

Meat and Meat alternatives Categories

As a protein rich food, meat is usually grouped with fish, seafood, eggs, legumes, nuts and seeds. We divided this group into six sub-groups on the basis that vegetable-based protein sources are not nutritionally equivalent to lean meats, poultry and fish [168]; and that red and white meat supply protein, iron, selenium, zinc and vitamin B12 in varying amounts. Yet, the nutrient differences in red and white meat are of less interest whereas the type or cut of meat and the cooking method were of interest. We noted that Western consumption patterns are high in protein from meat sources, and meat may be a marker of other deleterious dietary or lifestyle patterns linked with body weight [42]. Based on fat content we created a category of lean meat (FC10), and a fatty meat category (e.g. sausages) (FC11). While these are identified qualitatively, the content in the fatty meat category may exceed 50% fat [216]. Table 3-1 provides food examples to explain how lean and fatty meats were categorised.

Fish and seafood became another category (FC12) as these foods are a valuable source of protein and although their culinary use and portion size is comparable to meat, some key nutrients differ markedly. Inclusion of certain types of fish in the diet can help alter the fat profile of a meal, increasing proportions of preferred, unsaturated fat [217-220], justifying the separation from other meats.

Eggs (FC13) were treated as a separate category because they are a source of protein and vitamin D and have versatile culinary application, as an ingredient in a mixed dish or alone, and therefore require individual review. Research suggests as many as six

eggs can be consumed per week as part of a balanced diet with little likelihood of an effect on low density lipoprotein cholesterol (LDL-C) levels [166].

Nuts and seeds (FC14) created another category as they are a source of unsaturated fat, vitamin E, protein, fibre, phytosterols, arginine and other micronutrients [145]. Dietary recommendations for weight management rely on creating an energy-deficit, however there are allowances for foods associated with improved health outcomes. Consuming nuts may have a compensatory effect on total food consumption [145, 146], helping with weight management.

Extra foods and drinks Categories

Culinary oils and spreads, specifically unsaturated oil and margarine varieties (virtually free of trans-fats) (FC15) normally included in 'extra' foods were treated as a separate category. We noted that foods containing unsaturated fats are a source of energy and fat-soluble vitamins and are linked with positive health outcomes [152] and together with foods like avocado, can be exchanged for food sources of saturated fat to influence the proportion of unsaturated fatty acids in the overall diet. In accordance with this, butter was treated as a source of saturated fat and therefore was categorised with NCFD (FC17). We noted that dietary modelling has shown that if total fat exceeds approximately 35% of energy, it becomes difficult to avoid high intakes of saturated fat [48] thus, it is necessary to monitor food sources within the diet to provide preferred replacement options [82, 212].

As a beverage, alcohol (FC16) is normally included with 'extra' foods and drinks in food guides [60]. Alcohol contributes energy and has a deleterious effect on the need for some nutrients and it is the only food containing this food component. Within guideline amounts [221], alcohol may provide some benefit to health, and may not necessarily be associated with weight gain [26] but heavier consumption over-time is associated with weight gain [171], and other negative health outcomes [172-174]. Separating alcoholic beverages into a single category allows examination of consumption patterns since it may not necessarily be consumed with poor food choices.

The main types of foods within the 'extra' foods category we denoted as NCFD (FC17), including added sugar and foods rich in saturated fat. We noted that this category included a diverse range of foods and drinks [62] that contained little nutritional value but a significant energy value [57] and required separate analysis. Table 3-1 outlines the scope of foods included in each of the 17 groups.

Table 3-1 Scope of foods included in each food category

	Category	Scope of food items
1.	**Wholegrain foods**	Wholemeal or wholegrain breads or crisp breads, wholegrain English muffins, dark 'seedy' breads, wholegrain breakfast cereals, wholegrain pasta, brown rice, polenta, barley, puffed whole grains, bulgur, couscous, popcorn and oatmeal. Added brans- wheat germ, oat, and psyllium.
2.	**Non-wholegrain cereal foods**	White bread including fibre enriched, Turkish bread, White flour tortillas and other flat bread, white flour English muffins and crumpets; Refined breakfast cereals, white rice, noodles and pasta.
3.	**Fruit**	Fresh, canned, dried, frozen fruit.
4.	**Free vegetables**	All vegetables except potato, sweet potato, corn, pumpkin, parsnip.
5.	**Starchy vegetables**	Potato, sweet potato, corn, pumpkin, parsnip; no added fat in cooking.
6.	**Legumes**	Split peas, cannellini beans, borlotti beans, lentils (all types), chick peas, kidney beans, broad beans, butter beans, baked beans in tomato sauce (navy beans), bean mixes.
7.	**Low fat dairy foods: <3.5% fat**	All fat reduced or skim bovine milks and yoghurts (including soy-based).
8.	**Medium fat dairy foods: 3.5-10% fat**	Regular full cream milks and regular fat yoghurts (including soy based). Cottage cheese, ricotta, evaporated milk, condensed milk and custard were placed in a group depending on their fat composition [84].
9.	**Higher fat dairy foods: >10% fat**	Soft and hard cheese [84].
10.	**Lean Meat and poultry**	Red meat- beef, lamb, pork, veal, venison, rabbit, kangaroo, goat; Poultry-chicken, turkey or duck; Cut noted to assist in classification into lean or fatty cut; skin or fat trimmed; low fat cooking methods.
11.	**Fatty meat**	Fatty cuts of meat, processed meat, luncheon meat, crumbed and fried meat; poultry skin intact.
12.	**Fish and seafood**	Fresh, tinned, smoked fish and seafood; not fried.
13.	**Eggs**	Eggs, all types; in cooking or as part of the meal.
14.	**Nuts (and seeds)**	Tree nuts and peanuts; seeds and seed mixtures (each 30g).
15.	**Unsaturated oils and margarine**	Monounsaturated, Polyunsaturated oils and margarines (virtually free of trans-fats); olives, avocado.
16.	**Alcoholic beverages**	All alcoholic beverages (each 400kJ)
17.	**Non-Core foods and drinks**	Including foods and drinks of low nutrient density and food sources of saturated fat (butter, cream), added sugar, soft drink/cordial, juice, fruit drinks, snack foods, takeaway including commercial hamburgers, fried foods, sauces, spreads (each 600kJ)

3.3 Statistical analysis

The compatibility of combining the two trial data bases (in terms of age of participants, BMI and reported per cent of macronutrients consumed) proved valid and has been reported previously [124]. Limited gender differences allowed the food category analysis to be conducted across the whole sample.

A Linear Mixed Model with post hoc Bonferroni correction was used to assess change in anthropometric measures (weight, BMI, body fat and waist circumference) and selected nutrients (weight of food, total energy intake, dietary protein, dietary fat, carbohydrate, dietary fibre, calcium and iron) between baseline and 3-months. A paired t-test was used for between group differences for males and females. All food category data was checked for normality using Shapiro-Wilks and median and interquartile range (IQR) were presented for each food category system in grams and kilojoules in addition to mean portions. It is important to note that the median figures for the seventeen groups should not be expected to add to the composite figure of the 5-food groups. Adjustment for multiple comparisons was conducted for the food categories using the method of Benjamini and Hochberg using *p.adjust* in R Studio version 0.97.388 (c) 2009-2012 R Studio, Inc. [222]. All analyses used SPSS Statistics Software (version 19.0.0 IBM Corporation Armonk, NY).

3.4 Results

By 3-months there was a significant reduction in mean energy intake of >2000kJ (9449±2998kJ versus 6348±1400kJ; $P<0.001$) yet there was no significant difference in food weight consumed (1581±455g versus 1594±429g; $P=0.069$) (Table 3-2). For those

reaching 3-months, this was accompanied by weight loss of >5% (-4.6±3.1kg; $P<0.001$). There were no differences between male or female anthropometric measures (body weight, BMI, body fat, waist measurement) at baseline or 3-months. There were also no differences in energy or nutrient intakes (protein, fat, carbohydrate, dietary fibre, calcium, iron) between genders at baseline, however at 3-months there was a gender difference for dietary fibre ($P=0.013$) (Table 3-2).

At baseline, mean portions were compared to the national food guide [85] (Table 3-3). Participants were consuming within the suggested guideline amounts of breads and cereals (6.7 portions) and milk and milk alternatives (3.3 portions), but inadequate fruit (1.3 portions) and vegetables (4.3 portions) and excessive meat and meat alternatives (8.2 portions equivalent to 246g) and excessive 'extra' foods (5.4 portions or ~3000kJ). By 3-months there were significant changes in consumption from all of the traditional food groups except milk and milk alternatives ($P=0.113$) however, the change in (median) kilojoules was significant for milk and milk alternatives ($P=0.016$) (Table 3-3). The number of mean portions fruit ($P=0.007$) and vegetables ($P<0.001$) increased significantly by 3-months however mean fruit consumption remained lower than the national food guide target of two portions per day, whereas vegetables exceeded the target. Consumption of breads and cereals ($P<0.001$), meat and meat alternatives ($P<0.001$) and 'extra' food ($P<0.001$) decreased significantly however the latter two groups remained above suggested intake targets.

The same analysis using the 17 food categories revealed significant changes in 14 of the 17 food categories (Table 3-3). Thus, comparing the 5-food groups to the

seventeen food categories, greater differences were confirmed. For the vegetables group, participants consumed only 3.2 portions of free vegetables/d, almost one portion (0.9) of starchy vegetables and 0.2 portions of legumes per day, less than the amount suggested in food guides as stated. Vegetable consumption increased by 3-months as a result of increased consumption of free vegetables (P<0.001) and legumes (P<0.001) but not starchy vegetables (P=0.924). For the breads and cereals group, participants were consuming more non-wholegrain (refined) cereal foods than wholegrain varieties, however by 3-months this was reversed due to a decrease in non-wholegrain varieties (P<0.001), a detail not apparent from the 5-food group analysis. The meat and meat alternatives group were better defined by the detailed categories, differentiating the group into 4 portions of lean meat, 1.5 portions of fatty meat, plus 1.4 portions of fish and seafood, slightly exceeding the recommendation in the national food guide. Importantly, fatty meat consumption was reduced by two-thirds, apparent only in the detailed analysis (P<0.001). Other protein sources such as eggs (0.5 portions/day), nuts and seeds (0.7 portions/day), were consumed in smaller amounts daily, although these foods provided a meaningful contribution to energy and nutritional intake over a week. For the milk and milk alternatives group, consumption was split between low fat dairy (1.9 portions) and 0.7 portions for each medium and higher fat dairy foods, and this division was not available with the use of 5-food groups. By 3-months consumption of low fat dairy increased (P<0.001) as both medium fat dairy (P<0.001) and higher fat dairy decreased (P<0.001), a change that was only apparent by noting the concurrent change in kilojoules in the 5-food group analysis, but ideally noted through the use of the 17 food categories. When the 'extras' group were categorised in more detail, the reported amount represented 4.2 portions

(>2000kJ) from non-core food and drinks, one portion from alcoholic beverages and 4.2 portions of unsaturated oils and margarine. Thus greater detail, particularly concerning preferred sources of fats in the diet was confirmed through the use of 17 food categories. By 3-months, alcoholic beverages reduced to less than 1 portion/day ($P<0.001$) and NCFD reduced to 1.2 portions, a reduction of 3 portions/day ($P<0.001$).

The more detailed analysis exposed some critical features of the dietary pattern during a weight loss intervention including the change to proportionally more wholegrain foods and less refined cereal foods, the increase in free vegetables together with legumes, the change in consumption of dairy foods to include more low fat varieties, the change in meat consumption reflecting good intakes of fish and seafood and less fatty meats. Each of these changes yielded a reduction in energy intake though the most dramatic change over time was the large reduction in NCFD. Reduced consumption from this category helped reduce energy intake more than any other and these food and drinks were depicted separately from alcohol and the preferred sources of unsaturated fats in the detailed analysis.

The dietary pattern alterations resulted in large reductions in energy from the NCFD (a 73% reduction in energy and 71% by weight) and an increase in energy intake from vegetables (63% increase in energy and 69% increase by weight). Overall, the intake of wholegrain foods, starchy vegetables and fish and seafood appeared more resistant to change in this analysis. They were consumed in appropriate amounts compared with national guidelines and this could be reinforced in dietary counselling.

Table 3-2 Changes in body composition, energy and nutrient intakes between Baseline and 3-months including gender differences (mean ±SD)

				Males			Females			Between Groups P value	
	Baseline (n=231)	3-months (n=195)	P value	Baseline (n=59)	3-months (n=48)	Within group P value	Baseline (n=172)	3-months (n=147)	Within group P value	Baseline	3-months
Weight (kg)	86.9±12.0	82.0±11.7	<0.001	87.5±12.9	83.1±12.2	<0.001	86.7±11.7	81.6±11.5	<0.001	0.637	0.433
BMI	30.7±3.2	28.9±3.0	<0.001	30.6±3.2	29.0±3.0	<0.001	30.7±3.2	28.8±3.1	<0.001	0.803	0.819
Body fat (%)	38.9±6.8	37.0±7.2	<0.001	39.4±6.8	38.4±6.8	<0.001	38.8±6.7	36.5±7.3	<0.001	0.568	0.106
Waist (cm)	101.7±10.9	96.4±9.8	<0.001	101.0±11.3	96.5±10.4	<0.001	101.9±10.8	96.4±9.7	<0.001	0.553	0.955
Energy (kJ)	9449±2998	6348±1400	<0.001	9305±2389	6403±1395	<0.001	9499±3185	6330±1407	<0.001	0.670	0.757
Protein (g)	104.0±31.4	84.5±19.3	<0.001	101.2±29.8	85.0±18.9	<0.001	105.0±31.9	84.4±19.5	<0.001	0.420	0.859
Fat (g)	87.2±36.3	44.4±15.2	<0.001	83.8±30.1	44.6±14.1	<0.001	88.4±38.2	44.3±15.6	<0.001	0.407	0.901
Carbohydrate (g)	233.9±77.0	170.0±40.2	<0.001	236.9±62.6	175.8±41.8	<0.001	232.8±81.5	168.1±39.6	<0.001	0.722	0.248
Dietary Fibre (g)	27.6±9.6	27.2±6.7	0.656	27.5±9.0	29.3±7.1	0.075	27.6±9.8	26.5±6.4	0.281	0.958	0.013
Calcium (mg)	1016.2±451.7	867.6±283.7	<0.001	1000.6±446.9	877.1±287.0	0.138	1021.6±454.5	864.4±283.7	<0.001	0.759	0.789
Iron (mg)	13.8±5.1	11.7±31	<0.001	14.0±4.3	12.4±3.9	0.017	13.8±5.4	11.4±2.7	<0.001	0.870	0.099
Food weight (g)	1581±455	1594±429	0.069								

Linear Mixed Model Post Hoc Bonferroni correction; Paired T-test for within group differences at 3mo.[a] Paired T-test 95%CI; Diet history analysis using FoodWorks® Professional 2009, version 6, Xyris software, Brisbane, Australia; Food weight calculation excludes liquids

Table 3-3 Changes in food contributions from baseline to 3-months using traditional five food groups and 17 derived food categories.

	Median (IQR) weight (g)			Median (IQR) kilojoules (kJ)			Mean number of portions			Food Guide Target
Food Group and portion size	Baseline (n=231)	3-month (n=195)	p adj * value	Baseline	3-months	p adj value	Baseline	3-months	p adj value	
1. Breads and Cereals (30g)	181 (140-244)	140 (99-193)	<0.001	1709 (1349-2169)	1339 (994-1734)	<0.001	6.7	5.2	<0.001	6
2. Fruit (150g)	165 (89-257)	224 (157-280)	0.007	407 (234-675)	541 (392-699)	0.007	1.3	1.5	0.007	2
3. Vegetables (75g)	296 (201-413)	458 (340-576)	<0.001	559 (354-825)	806 (587-1036)	<0.001	4.3	6.3	<0.001	5
4. Milk and Milk alternatives (150ml)	341 (189-555)	394 (262-553)	0.488	944 (564-1364)	896 (655-1190)	0.016	3.3	3	0.113	~4
5. Meat and Meat alternatives (30g)	227 (176-301)	164 (130-203)	<0.001	1930 (1459-2617)	1315 (1035-1693)	<0.001	8.2	5.9	<0.001	~4-5
6. Extras (600kJ)	437 (289-800)	165 (84-323)	<0.001	2818 (1985-3988)	1007 (577-1520)	<0.001	5.4	1.9	<0.001	0-2.5#
1. Wholegrain foods (30g)	79 (45-119)	81 (52-112)	0.445	947 (512-1410)	937 (654-1223)	0.294	3.1	2.9	0.445	5-8
2. Non-wholegrain cereals (30g)	94 (55-150)	50 (25-88)	<0.001	684 (387-1078)	350 (162-634)	<0.001	3.7	2.3	<0.001	Max. 2
3. Fruit (150g)	165 (89-257)	224 (157-280)	0.007	407 (234-675)	541 (392-699)	0.013	1.3	1.5	0.007	2-4
4. Free vegetables (75g)	213 (145-325)	360 (256-464)	<0.001	268 (183-435)	465 (282-615)	<0.001	3.2	4.9	<0.001	3-6
5. Starchy vegetables (75g)	53 (26-87)	58 (31-90)	0.924	192 (91-328)	189 (101-314)	0.286	0.9	0.9	0.924	1-4
6. Legumes (75g)	0 (0-24)	26 (0-57)	<0.001	0 (0-92)	90 (0-207)	<0.001	0.2	0.5	<0.001	Unlimited
7. Low fat dairy foods:<3.5% fat (150ml)	216 (83-438)	359 (229-515)	<0.001	479 (168-834)	720 (474-984)	<0.001	1.9	2.6	<0.001	Total dairy =4 (Higher fat dairy <40g)
8. Medium fat dairy foods:3.5-10% fat (150ml)	0 (0-103)	0 (0-6)	<0.001	0 (0-271)	0 (0-24)	<0.001	0.7	0.2	<0.001	
9. Higher fat dairy foods: >10% fat (30g)	14 (6-25)	3 (0-9)	<0.001	220 (84-364)	48 (0-120)	<0.001	0.7	0.2	<0.001	
10. Lean Meat and poultry (30g)	105 (70-148)	83 (63-122)	0.001	686 (458-1042)	562 (424-841)	<0.001	4	3.3	0.001	<455g/w
11. Fatty meat (30g)	33 (10-62)	8 (0-23)	<0.001	299 (76-566)	70 (0-207)	<0.001	1.5	0.5	<0.001	NR
12. Fish and seafood (30g)	35 (14-58)	34 (20-54)	0.814	231 (90-411)	225 (129-387)	0.788	1.4	1.4	0.814	20-40g/d
13. Eggs (1 egg)	13 (5-21)	10 (5-14)	<0.001	84 (31-154)	62 (31-94)	<0.001	0.5	0.4	<0.001	6/w
14. Nuts (and seeds) (30g)	13 (2-28)	6 (2-14)	<0.001	308 (54-697)	161 (41-366)	<0.001	0.7	0.3	<0.001	Max. 60g
15. Unsaturated oils and margarine (5g)	11 (2-27)	5 (1-13)	<0.001	202 (51-474)	134 (30-337)	<0.001	4.2	2	<0.001	7g oil; 10g margarine
16. Alcoholic beverages (400kJ)	84 (4-235)	49 (0-149)	<0.001	185 (21-563)	110 (0-296)	<0.001	1	0.6	<0.001	NR
17.Non-Core foods and drinks (600kJ)	290 (148-509)	84 (35-166)	<0.001	2096 (1334-3105)	573 (285-984)	<0.001	4.2	1.2	<0.001	Max. 1

*P values adjusted for multiple comparisons within each analysis (5 food groups and 17 food groups) [222]; [85]; #Additional serves from the 5 food groups, unsaturated spreads, oils or discretionary foods [85].

3.5 Discussion

This analysis showed that by differentiating between foods within the traditional 5-food groups, the more defined categorisation system helped pin-point dietary patterns at baseline and the changes in food choices relevant to the weight loss context. The traditional 5-food group analysis limited the description of the types of specific foods selected as the diets changed over time. Whereas the energy and nutrient changes were shown to be significant within the dataset, the use of 17 food categories captured the actual dietary changes in terms of more discrete food types and the magnitude of those changes in the context of the whole diet far better than the 5-food groups. For example, the consumption of milk and milk alternatives in portions did not change using the 5-food group system, yet, with more detailed analysis, we demonstrated that low fat dairy food consumption replaced medium and higher fat dairy food choices. Furthermore, the consumption of the meat and meat alternatives group decreased, yet the more detailed analysis showed that within that group, the consumption of fish and seafood remained stable, slightly exceeding guideline targets [85, 223], while that of fatty meats decreased, indicating an improvement in food choices. These changes in consumption were important for decreasing the overall energy intake and provide suggestions as to the food choices to target in the practice setting.

Considering the reduction in energy intake achieved after 3-months and the corresponding weight loss, our detailed analysis allowed us to identify which specific foods were most responsible for the energy deficit in the intervention setting, in

particular, the NCFD. In examination of a cohort over 4 years, Mozaffarian *et al* (2011) [118] found that weight-gain was linked with consumption of potatoes, potato chips, processed and unprocessed meat and sugar-sweetened beverages. The authors suggest that their findings regarding these foods and drinks may be effectively employed in the advice setting since the dietary changes accounted for substantial difference in weight gain. The present analysis also highlights foods and drinks pertinent to providing weight loss advice and suggests that certain foods and drinks can be targeted, predominantly those from the NCFD category.

This closer view of food aligns well with new research indicating that focusing on the precise macronutrient proportions of the diet may be less important than once thought in predicting change in weight or waist circumference [42]. Seeking solutions at a food-level has been called a “top-down” approach [8], and may present new ideas of where to look for biologically active compounds in whole foods consumed within whole diets [32], not explained by nutrient composition analysis alone. There is also some indication in the literature that the consumption of whole foods versus processed foods may be dealt with differently by the body [29], and in this analysis, there was a decrease in consumption of breads and cereals which was shown to be the result of choosing less non-wholegrain (refined) cereals, a positive dietary change, only identified through the use of 17 food categories.

The inclusion of NCFD (or discretionary choices) in recent food guides [26, 57] reflects the diverse range of food choices made at an individual level. However, this category of foods and drinks varies significantly in nutrient profile. In this analysis we found,

28.8% of baseline dietary energy came from NCFD, exceeding the maximum recommended limit of 20% [62] for healthy populations. A separate look at alcoholic beverages enabled by the more detailed analysis was also of value, as we showed consumption was within guideline amounts for healthy populations [221] and consumption decreased within the trials.

We also noted that foods linked with desirable effects on health outcomes in observational research [118], such as fruit, vegetables, legumes and low fat milk and milk alternatives, were reported as consumed in less than recommended amounts at baseline and improved by 3-months without an increase in total food weight. Rolls (2005) and Lapointe *et al* (2010) have both suggested that individuals consume a constant weight of food rather than a constant amount of energy [19, 23]. Therefore, by substituting lower energy dense foods for higher energy dense foods may be a more important and effective strategy in weight loss than previously recognised [21]. In the analysis conducted, there was a 71% reduction (by weight) in NCFD and a 69% increase in vegetables consumed in the 3-month timeframe. These results indicate the importance and value of detailed food-level analysis in focusing the dietary changes important for practice. Furthermore, increasing the focus on foods, in addition to the analysis of energy and nutrient intakes facilitates translation to the advice setting and the need for this food-level research has been suggested in the literature [42, 133]. Using dietary patterns helps to provide details closer to the actual foods consumed, and provides further insights for weight reduction advice that builds on previous findings using cluster analysis of dietary patterns at baseline [124].

Although the categorisation of foods was based on systematic appraisal, there were limitations. Some research suggests further separation of food categories such as extending free vegetables into three categories - cruciferous, green leafy and dark-yellow [144]. The decisions regarding food classification were justified in terms of energy and nutrient density, biological characteristics, degree of food processing, and were based on the assessment of available literature for weight management. In practice, clinical dietitians' may choose to categorise foods using particular short-cut methods, such as categorising cheese, legumes or nuts with meat. However, these protein rich foods have a diverse culinary usage, and a divergent fat profile in comparison to meat, suggesting they should be categorised separately. The important issue for our research was to account for subtle differences in foods, such that effects could be discerned in terms of outcome measures. Individual diet history records were used in the primary studies in order to quantify more individual food items, and discern as accurately as possible the change in food consumption that may impact on weight loss outcomes [124]. This method of dietary data collection reflects clinical practice and is known to provide accurate estimates of habitual intake [125-129] though misreporting is always possible [111].

3.6 Conclusion

A more detailed food category system was better able to identify specific changes in food choice that would be integral to weight loss in the clinical setting with the 17 food categories providing more relevant information for practice than the 5-food groups. The relative consumption of the 17 food categories provided evidence of where shifts occurred, and highlighted improvements in dietary quality during the interventions.

The maintenance of food weight with decreased energy intake was a significant finding, whereby the decreased consumption of NCFD was matched by an almost equal increase in vegetables, and this knowledge could be applied in the practice setting. Although there are a number of ways in which foods can be categorised, this analysis used food categories of interest in weight management (research and practice) and provided a sufficiently detailed view of food patterns, and appeared sensitive enough to identify changes over time in those attempting weight loss. Analysis of dietary patterns within the context of dietary intervention trials may open up new opportunities for investigating relationships between dietary intake as foods and health outcomes in a range of therapeutic areas informing food-based advice for direct translation to practice.

CHAPTER 4 BASELINE DIETARY PATTERNS ARE A SIGNIFICANT CONSIDERATION IN CORRECTING DIETARY EXPOSURE FOR WEIGHT LOSS.

The majority of this section is the substantive content of work published as: Grafenauer, S., Tapsell, L., Beck, E. and Batterham M. *"Baseline dietary patterns are a significant consideration in correcting dietary exposure for weight loss"*, **The European Journal of Clinical Nutrition**, 67, p. 330–336; doi:10.1038/ejcn.2013.26

Chapter 3 develops food categories extending from the traditional five food groups and describes the changing diets of participants in the context of free-living weight loss interventions. The basis for this categorisation system was to focus on foods of interest in a clinical weight loss setting. Establishing the food categories was important since in observational research the foods or food groups examined are often predicated by the dietary data collection tool, and the application of dietary pattern research to the dietary intervention setting, opens up opportunities to establish a framework for future research. The food categories were formed in consideration of the biological characteristics of foods, food processing and nutrient composition. The culinary use of foods and the associations with weight management were also important. Whereas the traditional five food groups are useful as a broad population education tool, more detail in terms of the foods consumed are required in describing the changing dietary patterns in a clinical setting.

Revealing patterns of changing food choices for various therapeutic diets from interventions may give insights that prove easier to translate to specific advice about food in a practice setting compared with nutrient-based outcomes. Chapter 3 demonstrates that the more defined food categorisation system allowed changing dietary patterns to be described, although there was great variation in the reported eating behaviours. Observational research has provided suggestions of how to better define participant eating behaviours and delineate patterns. Empirical methods, applied *a posteriori* to the data, have been used extensively to describe divergent patterns of eating (factor analysis), however, as this is a clinical investigation of participants undergoing weight loss, the interest is with the changing diets of those

participants. Cluster analysis is therefore the preferred statistical technique and differentiates participants based on their eating behaviours. It is rare that baseline dietary patterns are considered as part of a dietary intervention, however by generating the clusters at baseline and following the participants over three months during weight loss, this chapter outlines the significance of the baseline diet in weight loss achievement.

4.1. Introduction

Dietary advice for weight loss is given in terms of foods or meals, therefore in the clinical setting review of dietary patterns may be most informative. Dietary pattern analysis is conceptually complex [7], and whole-of-diet approaches have now been used in a variety of countries examining a range of diseases [146, 182, 217, 219, 220, 224] but investigations specifically of dietary interventions are limited [44, 45]. Togo *et al* 2007 [11] defined dietary patterns as ‘the distribution (by frequency and/or amount) of foods in the habitual diet' (as distinct from meal patterns). Knowing which foods or patterns in the habitual diet need to change to achieve clinically relevant outcomes is an important adjunct for all dietary therapy.

In clinical practice and research, high quality dietary data is required in the initial dietary assessment. Typically, the diet history interview and seven day food record have interchangeably served as ‘gold standards' [66, 218, 225, 226]. While both provide records of foods consumed, the diet history 'tells the story' of foods and meals *usually* consumed over a defined time period of a week or a month [227], and captures this within the narrative of the consultation performed by a skilled professional [110].

In the clinical setting, the interviewer-administered diet history method may be more precise than a self-administered food record as it allows for quantification of more individual items and greater flexibility to probe for less frequently consumed foods that may be important for behaviour change. As a method of dietary data collection it is less affected by education level as it is not reliant on written instruction, and the method of questioning maintains respondent interest and helps build rapport [225]. The narrative, including portion size and food frequency, can then be distilled manually (in a typical practice setting) or using computer analysis, with data analysed in terms of nutrients, foods or food groups. This output can be utilised to help correct dietary exposure and inform tailored advice to facilitate dietary change [99].

In dietary pattern research, the per cent energy contribution from the food subgroups can be used for cluster analysis but if consumption of a single macronutrient happens to be high, other values are depressed [186]. Using foods for analysis lends itself to exploration of dietary patterns and may be more sensitive in discerning contributions of food groups, particularly foods associated with positive (e.g. low energy vegetables) or negative health outcomes (e.g. high saturated fat foods). Bailey *et al* (2006) [186] found more consistent results with a focus on food in serves, which mimics approaches in the practice setting and allows easy translation of research to practice.

Cluster analysis can be used to segment and identify dietary patterns within the study population independently of their associations with outcomes [115]. Cluster analysis is data driven, however the food groupings, used to organise the data, are the result of a systematic, hypothesis driven approach. This statistical method lends itself well to the

concept of healthy diets, such that one would expect positive (and negative) dietary patterns to cluster together [8]. When applied to population samples, cluster analysis 'groups people who share similar frequency patterns for consumption of foods' [184], such that an individual can only belong to one cluster, for example, 'Prudent' or 'Western' diet patterns [214]. The specific food choices of successful dieters, even those selected prior to a dietary intervention may reveal dietary patterns that are informative for clinical practice.

Cluster analysis was applied to explore dietary patterns at baseline from participants in weight loss dietary interventions. The aim was to identify patterns of food choice in the context of a clinical weight loss trial.

4.2. Methods

Participant diet history records were drawn from the two registered clinical weight loss trials (ACTRN 12608000425392 and 12610000784011) [1, 2].

In many studies of dietary patterns and disease, little justification is provided for the food groups utilised [122] with food groupings predicated by the tool or method used to collect the data. Our work defined and tested the food groups specific to the clinical setting in advance, using a sub-set of dietary data [228]. In defining the food groups, the number of categories was broadened from the usual five core food groups and were based on (i) their biological characteristics to define categories of food (e.g. fruit, or nuts and seeds) [136], or (ii) by their means of production (e.g. alcohol) [136], or (iii) by their nutrient composition including energy density (e.g. milk and milk alternatives),

or (iv) by their culinary use, and (v) the evidence base for relationships between food consumption patterns and health outcomes specifically with interest to weight management. This resulted in seventeen groups including wholegrains, non-wholegrain cereal foods, starchy vegetables, free vegetables, fruit, higher fat, medium fat and low fat milk and milk alternatives, lean and fatty meat, eggs, legumes, fish, nuts and seeds, unsaturated oils and margarine were used for the cluster analysis. Non-core energy dense foods and drinks were categorised separately to alcoholic beverages. Data collected at baseline and three months were tabulated by food group and a ready reckoner (RR) [79, 80] was used to calculate the serves of each food group consumed. In the clinical trial protocol, baseline and three month anthropometry and fasting biochemistry were measured.

In order to explore the diverse nature of the non-core foods and drinks category (NCFD), six additional groups were created for use in subsequent analysis of the NCFD category, specifically in relation to consumption pattern by gender. These groups included juice (100% juice, juice drinks), soft drink (all types, including cordial), sweet treats (chocolate, chocolate bars, sweet biscuits, cake, ice cream), savoury treats (savoury biscuits, dips, crisps), takeaway food items (commercial hamburgers and foods, takeaway meals, fried foods like fish and chips) and other foods/ ingredients (sugar, butter, spreads, sauces). All NCFD were based on 600kJ as per the Australian Guide to Healthy Eating (AGHE) [61], so the weight of the drinks would not influence the number of serves from the NCFD category.

An independent samples t-test (IBM SPSS Statistics, version 19.0.0 IBM Corporation Armonk NY) was used to determine any significant differences between the two trial datasets in terms of age of participants, BMI and reported per cent of macronutrients consumed, and a Chi-square test for gender differences (categorical variables) between the baseline data sets and between clusters. In the dietary pattern analysis, a two-step clustering procedure was used to allow the food group serve data to drive the clustering rather than setting a predefined number of clusters. In the two-step procedure, pre-clusters are formed and then re-clustered using a hierarchical process. A number of alternative cluster solutions were tested to ensure that the natural group structure of the data was adequately defined. The clusters were established with baseline data and were compared alongside changes at three months in serves of food, anthropometric data, biochemical data and selected nutrient data from Foodworks™ using independent samples t-test between the clusters and paired t-tests for within-cluster changes. All data were checked for normality using Shapiro-Wilks and median and interquartile ranges (IQR 25th-75th percentile) were presented where appropriate.

4.3. Results

4.3.1. Cluster analysis

All foods reported from the diet history records were able to be categorised using the outlined 17 food groups. Two distinct dietary patterns were identified at baseline. Cluster 1 (n =193; 83.5%) represented subjects consuming a significantly greater number of portions of low fat dairy foods (*P*=0.001) and unsaturated oils and margarine (*P*=0.012). This cluster also represented a lower mean energy intake at

baseline compared to Cluster 2 (*P*<0.0001). Cluster 2 (n =38; 16.5%) represented subjects reporting consumption of a significantly greater number of portions of NCFD (*P*<0.0001), fatty meat (*P*=0.031), higher fat dairy foods (*P*=0.003) and medium fat dairy foods (*P*<0.0001), alcoholic beverages (*P*=0.003), non-wholegrain cereal foods (*P*<0.0001) and wholegrains (*P*=0.002). Based on these differences, Cluster 1 was referred to as the low-fat dairy pattern and Cluster 2 as the high-non-core food choices pattern as these were dominant groups in the clustering process. These results are presented in Table 4-1.

At three months, there were no differences in any food groups between the two clusters. Between baseline and three months both clusters reported decreased consumption of non-wholegrain cereal foods, higher fat dairy foods, fatty meat, alcoholic beverages and NCFD and these within-group changes were significant. Both clusters significantly increased consumption of legumes and low-fat dairy food. Cluster 1 significantly increased consumption of fruit, free vegetables and decreased lean meat, eggs, nuts and seeds, and unsaturated oils and margarine. Cluster 2 significantly decreased consumption of medium-fat dairy food which included full cream milk. The changes reported in dietary intake between time points resulted in significant differences between the clusters and these are detailed in Table 4-1.

The non-core foods and drinks category was separated into juice, soft drink, sweet treats, savoury treats, takeaway food items and other foods/ ingredients, shown in Table 4-1. Cluster 2 subjects consumed significantly more soft drink/cordial (*P*=0.039), sweet treats (*P*=0.001), takeaway foods (*P* <0.0001) and other NCFD/ ingredients (*P*

<0.0001) at baseline compared with Cluster 1 subjects. By three months, there was no significant difference in NCFD between groups. However within-clusters, all NCFD were significantly reduced with the exception of juice and soft drink for Cluster 2.

There was a gender difference between clusters, with proportionally more men in Cluster 2 (*P* <0.0001), however there were commonalities between sexes within each cluster with regard to serves from the food groups. Males in each cluster reported consuming significantly more alcoholic beverages (Cluster 1 *P*=0.032; Cluster 2 *P*=0.005) and females reported consuming significantly more unsaturated fat (Cluster 1 *P*=0.008; Cluster 2 *P*=0.034). Males reported more meat consumption than females; males consumed more lean meat and poultry (*P*=0.041) in Cluster 1, and more fatty meat (*P*=0.005) and fish and seafood (*P*=0.04) in Cluster 2. Compared with females, males also consumed more non-wholegrain cereal choices (*P*=0.021) in Cluster 1 but not in Cluster 2.

At baseline, Cluster 2 participants were heavier (*P*<0.001), had a higher BMI (*P*=0.046), and a larger waist measurement (*P*=0.005) than Cluster 1 subjects (Table 4-2). Cluster 1 subjects had a higher mean per cent body fat (*P*<0.001) and a higher HDL-cholesterol level (*P*=0.011). There were no other significant differences in clinical parameters between the clusters at baseline. By three months, Cluster 2 subjects had lost more weight (-5.64kg; *P*=0.037) than Cluster 1 (-4.4kg). Cluster 2 had made greater changes in terms of energy intake (-5317kJ; *P*<0.001) in comparison to those in Cluster 1 (-2500kJ) (Table 4-2). Both clusters had significant reductions in total cholesterol and

there were significant within-group changes in LDL-cholesterol, HDL-cholesterol, glucose and insulin for Cluster 1.

In order to assess the nutrient adequacy of the dietary patterns, nutrient values were compared to Australian Nutrient Reference Values [48]. The median (per cent) macronutrient intake of Cluster 1 at baseline reflected the AMDR, however for Cluster 2 the total fat was just above the range (35.7%) and the carbohydrate was lower than the suggested target (40.7%). By three months, both clusters were more aligned with the AMDR although carbohydrate remained lower in Cluster 2. Reported intakes of iron and calcium were within estimated average requirements (EARs) and mean dietary fibre met the adequate intake (AI) of 25g defined for females at baseline and three months for both clusters.

Table 4-1 Core and Non-core food and drinks consumed at baseline, three months and change between and within Cluster 1 and 2.

	Baseline					3-Months					Change		
	Amount consumed by Cluster 1 (n=195)		Amount consumed by Cluster 2 (n=38)			Amount consumed by Cluster 1 (n=165)		Amount consumed by Cluster 2 (n=30)			Cluster 1 (n=165)	Cluster 2 (n=30)	
Food Group	Median (IQR)	Mean Serves	Median (IQR)	Mean Serves	P Value	Median (IQR)	Mean Serves	Median (IQR)	Mean Serves	P value	Mean Serves	Mean Serves	P value
Wholegrain foods	78 g/d (48-117)	2.87	102 g/d (31-162)	4.23	0.077	77 g/d (48-100)	2.68	113 g/d (92-158)	4.24	0.001	-0.19	0.36	0.488
Non-wholegrain cereal foods	90 g/d (53-142)	3.34	158 g/d (71-202)	5.20	0.001	50 g/d (24-85)	2.08	73 g/d (35-174)	3.30	0.042	-1.24**	-1.86*	0.202
Fruit	165 g/d (96-256)	1.24	152 g/d (73-299)	1.49	0.286	223 g/d (158-279)	1.46	228 g/d (154-314)	1.70	0.218	0.21*	0.34	0.658
Free vegetables	214 g/d (145-317)	3.15	194 g/d (132-349)	3.33	0.627	372 g/d (266-469)	5.00	289 g/d (228-348)	4.10	0.014	1.81**	0.72	0.013
Starchy vegetables	53 g/d (27-85)	0.87	54 g/d (11-131)	1.03	0.382	61 g/d (35-91)	0.93	41 g/d (27-68)	0.80	0.375	0.05	-0.30	0.071
Legumes	0 g/d (0-27)	0.25	0 g/d (0-14)	0.14	0.052	26 g/d (2.8-59)	0.52	13 g/d (0-36)	0.35	0.155	0.27**	0.27*	0.982
Medium fat dairy foods: 3.5-10% fat	0 g/d (0-56)	0.27	373 g/d (0-693)	2.98	<0.0001	0 g/d (0-3.3)	0.21	0 g/d (0-37)	0.40	0.355	-0.04	-2.37**	<0.0001
Higher fat dairy foods: >10% fat	14 g/d (5.7-23)	0.56	24 g/d (4.6-65)	1.25	0.003	3 g/d (0-8)	0.22	3 g/d (0-12)	0.26	0.655	-0.34**	-0.80**	0.018
Lean Meat and poultry	102 g/d (69-145)	3.91	117 g/d (77-175)	4.47	0.203	82 g/d (63-120)	3.19	99 g/d (60-158)	3.72	0.221	-0.60*	-0.46	0.815
Fatty meat	33 g/d (10-61)	1.37	36 g/d (11-79)	1.96	0.137	8 g/d (0-22)	0.51	8 g/d (0-38)	0.68	0.363	-0.81**	-1.25*	0.119
Fish and seafood	35 g/d (13-57)	1.37	33 g/d (14-70)	1.78	0.221	33 g/d (20-54)	1.39	44 g/d (24-64)	1.65	0.251	0.02	-0.23	0.440

	Baseline					3-Months					Change		
	Amount consumed by Cluster 1 (n=195)		Amount consumed by Cluster 2 (n=38)			Amount consumed by Cluster 1 (n=165)		Amount consumed by Cluster 2 (n=30)			Cluster 1 (n=165)	Cluster 2 (n=30)	
Food Group	Median (IQR)	Mean Serves	Median (IQR)	Mean Serves	P Value	Median (IQR)	Mean Serves	Median (IQR)	Mean Serves	P value	Mean Serves	Mean Serves	P value
Eggs	12 g/d (3.8-20)	0.50	20 g/d (6.6-25)	0.71	0.039	9 g/d (3.6-14)	0.33	11 g/d (6.3-16)	0.46	0.033	-0.18**	-0.24	0.611
Nuts (and seeds)	11 g/d (1.8-28)	0.65	21 g/d (3.8-56)	1.09	0.051	8 g/d (1-13)	0.30	13 g/d (3-29)	0.56	0.023	-0.34**	-0.59	0.381
Unsaturated oils and margarine	12 g/d (3.3-32)	4.63	7 g/d (0.9-20)	2.15	<0.0001	6 g/d (1.3-14)	1.91	5 g/d (0-13)	2.60	0.409	-2.81**	0.30	0.008
Alcoholic beverages	175 kJ/d (10-424)	0.75	389 kJ/d (33-1456)	1.96	0.003	103 kJ/d (0-284)	0.50	202 kJ/d (0-522)	0.92	0.114	-0.27*	-1.03*	0.005
Non-Core foods and drinks	1932 kJ/d (1195-2953)	3.65	3080 kJ/d (1780-5731)	6.73	<0.0001	572 kJ/d (226-958)	1.17	587 kJ/d (358-1047)	1.35	0.406	-2.44**	-4.78**	0.003
Juice	137 kJ/d (66-240)	0.10	132 kJ/d (79-388)	0.17	0.148	111kJ/d (56-155)	0.05	277 kJ/d (104-414)	0.09	0.365	-0.06*	-0.06	0.928
Soft Drink/cordial	54 kJ/d (4-328)	0.20	114 kJ/d (8-575)	0.42	0.037	8kJ/d (1-74)	0.04	2 kJ/d (1-9)	0.04	0.912	-0.17**	-0.30*	0.484
Sweet Treats	728 kJ/d (369-1460)	1.62	1008 kJ/d (577-2434)	2.54	0.030	117 kJ/d (10-288)	0.39	170 kJ/d (0-390)	0.43	0.768	-1.23**	-2.00**	0.082
Savoury Treats	84 kJ/d (0-272)	0.35	159 kJ/d (0-456)	0.55	0.201	9 kJ/d (0-150)	0.17	0 kJ/d (0-102)	0.11	0.346	-0.19**	-0.46*	0.177
Takeaway Foods	284 kJ/d (60-632)	0.76	683 kJ/d (326-1716)	1.96	0.001	0 kJ/d (0-128)	0.19	87 kJ/d (0-265)	0.34	0.861	-0.06**	-1.03**	0.011
Other Non-Core items	299 kJ/d (136-519)	0.63	557 kJ/d (184-809)	1.11	0.018	141 kJ/d (60-253)	0.34	82 kJ/d (22-248)	0.28	0.849	-0.69**	-0.40**	0.386

Interquartile range (IQR); Grams (g) used to calculate serves per day for each core food group; Kilojoules (kJ) used for Alcohol and Non-Core Foods and Drinks; Kilojoules (kJ); Independent samples t-test, 95% CI; Paired T-test for within cluster differences at 3mo *P<0.05; **P<0.001

Table 4-2 Anthropometric, clinical and nutrient intake data at baseline, three months and changes within and between Cluster 1 and 2.

	Baseline			3-months			Change		
	Cluster 1 n=193 (83.5%)	Cluster 2 n=38 (16.5%)	*P* value	Cluster 1 n=165	Cluster 2 n=30	*P* value	Cluster 1 n=165	Cluster 2 n=30	*P* value
Weight (kg)	85.4±11.3	94.4±12.7	<0.001	80.9±11.2	88.1±12.4	0.002	-4.4**	-5.6**	0.037
BMI	30.5±3.2	31.6±3.2	0.046	28.8±3.0	29.3±2.9	0.417	-1.6**	-1.9**	0.156
Body fat (%)	39.6±6.5	35.4±6.7	<0.001	37.6±6.8	33.2±8.5	0.002	-1.9**	-2.1**	0.808
Waist (cm)	100.8±10.8	106.2±10.3	0.005	95.8±9.6	99.8±10.9	0.051	-5.2**	-6.0*	0.653
Cholesterol (mmol/L)	5.24±0.9	5.21±0.9	0.831	5.04±0.5	4.8±0.9	0.211	-0.3**	-0.3**	0.971
Triglycerides (mmol/L)	1.3±0.6	1.6±1.1	0.094	1.2±0.5	1.4±0.7	0.178	-0.2**	-0.2	0.802
HDL (mmol/L)	1.5±0.4	1.3±0.3	0.011	1.4±0.4	1.3±0.3	0.030	-0.1*	-0.1	0.481
Chol:HDL (mmol/L)	3.8±1.3	4.1±1.1	0.093	3.8±1.02	4.0±1.0	0.261	-0.1	-0.1	0.967
LDL (mmol/L)	3.2±0.9	3.1±0.8	0.768	3.1±0.76	2.9±0.82	0.387	-0.2*	-0.2	0.816
Glucose (mmol/L)	5.2±0.6	5.0±0.5	0.164	5.0±0.46	5.0±0.6	0.524	-0.3**	-0.1	0.425
Insulin (mU/L)	11.9±6.5	12.2±5.5	0.840	9.9±4.51	10.5±5.8	0.550	-2.3**	-1.5	0.445
Energy (kJ)	8659±1845	13464±4291	<0.0001	6130±1251	7599±1567	<0.0001	-2500**	-5317**	<0.001
Protein (g)	97±21.7	139±46.6	<0.0001	82±17.5	99±23.2	0.001	-14.6**	-34.7**	<0.001
Fat (g)	79±25.2	130±51.8	<0.0001	43±14.5	55±14.6	<0.0001	-35.6**	-67.0**	<0.001
Carbohydrate (g)	217±54.9	322±108.5	<0.0001	165±38.2	198±40.1	<0.0001	-51.2**	-113.6**	0.001
Dietary Fibre (g)	27±7.8	33±14.7	0.009	27±6.9	29±5.4	0.253	0.5	-3.3	0.050
Calcium (mg)	921±320.4	1499±670.0	<0.001	847±257.7	983±387.7	0.078	-61.1*	-468.3*	0.003
Iron (mg)	13±3.4	19±8.7	<0.001	11±3.03	13±3.01	0.010	-1.5**	-4.9*	0.050

Mean±SD; Independent samples t-test, 95% CI; Paired T-test for within cluster differences *P<0.05; ** P <0.001;

4.4. Discussion

This research found that participants with poor dietary patterns at entry to the weight loss interventions achieved better results than those with previously reported healthier dietary patterns. Subjects who reportedly consumed larger amounts of NCFD, higher fat and medium fat dairy foods and alcoholic beverages at baseline (Cluster 2) were able to alter their dietary pattern more successfully to achieve an energy deficit. Cluster 2 subjects reduced energy (-5317kJ; $P<0.001$) and lost more weight (-5.64kg; $P<0.05$) over three months compared with Cluster 1. At baseline, subjects in Cluster 1 reported consuming higher amounts of low fat dairy and unsaturated oils and margarine and consumed amounts and types of each food group closer to national dietary guideline recommendations particularly for grains and cereals, milk and alternatives [57]. Over the 3-month period, Cluster 1 subjects achieved a weight loss of -4.37kg, the result of a reduction in some higher energy food groups, though these subjects possibly found it more difficult to substantially alter energy intake. Cluster 1 and 2 subjects were successful in losing weight, but Cluster 2 subjects, made greater changes to their diet composition. Cluster 2 dietary patterns may be clinically meaningful, representing participants with dichotomous, "all-or-nothing" thinking [229] in relation to food choices, particularly relevant to attempts for reduced energy intakes. This behavioural approach to food decision making is known to be an unproductive method of long term weight control, whereas counselling aims to build strategies to alter this habitual behaviour [230]. Cluster analysis differentiated between subjects with respect to dietary patterns observed in the context of a weight loss intervention, and these patterns were related to health indicators [191, 231, 232] and behaviours [42].

Over the three month timeframe participants in both clusters increased consumption of vegetables and consumed adequate amounts of low-fat dairy foods while reducing NCFD and alcoholic beverages. However, targeting NCFD and limiting selection from this food group and making appropriate substitutions appeared key to the greater weight loss achieved by Cluster 2 subjects. All NCFD categories were significantly reduced within Cluster 1, however for participants in Cluster 2, reduced consumption of foods categorised as sweet treats and takeaway foods decreased the baseline NCFD consumption by half. A dietary intervention strategy focussing on reducing the variety of non-core foods consumed was recently proposed and examined in a randomised controlled trial in which the intervention strategy specifically targeted non-core foods on the basis that they are non-nutrient, high energy choices [231, 232]. While participants achieved success in terms of compliance with the diet prescription, there was no difference in percentage weight lost after 18-months as the overall energy intake was not adequately reduced. The authors suggested that more than one energy-dense food category needed to be targeted to achieve desired outcomes. In our analysis, Cluster 2 subjects reduced intake of all problematic food groups that characterised the cluster at baseline. It has been reported [118] that foods such as meat (processed and unprocessed), potatoes, potato chips and sugar-sweetened beverages can be strongly associated with weight gain. Cluster 2 subjects reported consuming more of all of these foods at baseline and by three months reduced lean and fatty meats by over two serves, and all NCFD by 5.75 serves or over 3400kJ.

It has been known for some time that Australians tend to consume large quantities of non-core foods, up to 36% of energy [62] and in this analysis, 31% (including alcohol),

exceeding the maximum recommended limit of 20% of energy for healthy individuals and the serves suggested in the AGHE [57]. Non-core foods and drinks can displace nutrient rich core foods in the diet and influence the overall nutritional profile of the diet. The focus in weight loss needs to be around creatively substituting NCFD with core foods that positively influence diet quality and the nutritional profile of the diet. Due to the known excessive consumption of non-core foods, practice and research based diet prescriptions need to prescribe specific types and amounts of NCFD, such that they are a recognised part of the total energy prescription. This may be important in tailoring dietary advice and maintaining compliance in those wishing to reduce their weight.

As a check of diet quality, Wirfalt and Jeffery (1997) [191] suggest checking nutrient intakes in relation to food energy between the clusters since a reduction in energy does not guarantee that nutrient density is high. This was an important confirmatory step in our investigation, since nutrient composition analysis alongside food-based analysis is complementary and valuable for checking the adequacy of the reported diet. For example, there was a decrease in the number of serves of unsaturated oils and margarine (Cluster 1) by three months. This was not intended, although the change was easily noted via the food-level analysis, and highlights the importance of providing very specific education around food sources of preferred fats in the dietary advice setting. It is also possible that due to the dietary assessment methods, participants may have adjusted their reporting as they became familiar with portion sizes and the requirements of the diet history process. Self-reporting is known to be prone to systematic bias affected by factors such as age, gender, approval [111] and

social desirability [11]. Clinical data supports the dietary changes made by participants, particularly reductions in total cholesterol.

There are limitations to cluster analysis techniques. Cluster methods may involve a degree of investigator subjectivity and this can influence the evaluation of the results, the naming of the cluster and the conclusions made. While we note the limitations of the cluster sizes, the analysis defined only these two groups and each may define different food consumption patterns relevant in clinical practice. Kant, citing Jacobson and Stanton (1986) [189] suggests that 'researchers should discard factors or clusters with due care because the obtuse factor/cluster may be the one that leads to recognition of new knowledge' [187]. In the two-step clustering used, we allowed the data to drive the groupings formed and clusters were named according to the most dominant food groups, therefore the choice was less subjective. In previous studies, there has been a tendency to simplify the naming of clusters for example, 'More healthy' and 'Less healthy' [33, 233] although a range of names have been used [187]. Importantly, dietary patterns are not dichotomous and permanent, and on balance, quantitative naming of clusters as has been used is preferred [33]. Few studies have investigated dietary change using dietary pattern approaches. Reedy *et al* (2005), defined five clusters relating to fruit and vegetable consumption [44] and overall, the research reinforces the value of dietary pattern research in moving away from a single theoretical model of what defines "health protective" behaviour. Madlensky *et al* (2008) define three clusters also based on dietary change and found that even those in the cluster with the poorest dietary quality at baseline made major changes [45].

It is known to be difficult to compare dietary pattern results across studies, since the patterns reflect the actual practices within the population under study and as such, provide useful information for *that* population [234]. However, our analysis provides support for targeting NCFD, and it is likely that within a comparable overweight population, there may be some consistency, making these findings ‘reasonably reproducible’ [20] since specific foods can cluster, while the overall pattern may differ [192]. The results of this investigation provide useful information about the scope of dietary change under supervised conditions and this method of analysis can be applied to other therapeutic areas of dietetics. It would also be valuable to assess dietary patterns in an intervention context over longer periods of time, greater than three months.

4.5. Conclusion

Cluster analysis to derive dietary patterns from diet history data provides useful insights into the diets of overweight participants and the changes that are made at food group level within the context of a dietary trial. Overweight subjects with dietary patterns that are similar to dietary guidelines at baseline may have more difficulty in reducing energy intake than those with poor dietary patterns. Correcting exposure to NCFD was key to successful weight loss. Adequately quantifying discretionary food items at baseline and ensuring advice is given specifically regarding these foods within the diet prescription, may give participants greater awareness of appropriate food choices, serve size and assist with compliance. The analysis highlights the importance of overall diet quality in the context of weight loss, and gives specific insight for targeting non-core foods and drinks.

CHAPTER 5 SHIFTS IN CONSUMPTION OF NON-CORE FOODS AND DRINKS IN A CLINICAL TRIAL CONTEXT OVER 12-MONTHS

Discussion relating to preliminary findings (baseline to three-months) were included in Grafenauer, S., Tapsell, L., Beck, E. and Batterham M. 'Categorisation of non-core foods and drinks consumed by a clinical sample in an intervention trial', **Nutrition Society**, *Wollongong, Australia (27-30 November, 2012)*. *Australasian Medical Journal, vol. 5, no. 12, pp. 710-710, 2012*

Chapter 4 highlighted the significance of the baseline dietary pattern in correcting dietary exposure to non-core foods and drinks. We found high reported intakes of non-core foods and drinks at baseline, reflecting amounts also reported in population-based studies. Reducing consumption of non-core foods and drinks assisted Cluster 2 participants in reducing their energy intake and maximising their weight loss opportunity within three months. This perspective is of value for those in clinical practice, revealing the ubiquitous nature of non-core foods and drinks in the diet of a clinical sample, and alerting practitioners to collect detailed information about these foods and drinks at baseline.

Each of the previous two chapters focused on dietary changes between baseline and three months and each highlighted issues with the category of non-core foods and drinks. Non-core foods and drinks have been shown to make a significant contribution to energy intakes at a population-level therefore it is pertinent to take a longer term view of the changing diet patterns of participants within the context of intervention trials. Chapter 5 explores the non-core foods and drinks (NCFD) category in greater detail over a 12-month period, and examines the change in overall intake of NCFD and the change in sub-categories of foods and drinks making up the NCFD category.

5.1 Introduction

Energy dense, nutrient poor foods are referred to in food guidance systems as "discretionary calories" [26, 60] or "extra" foods [61]. The category spans a diverse range of foods and drinks making effective communication at a public health and clinical level more difficult than other food groups [64]. Consumption guidelines

assume that nutrient requirements from 'core' foods have been met, but perhaps not energy needs. For the purpose of this research, energy dense, nutrient poor foods are referred to as NCFD. National reported consumption data indicates that Australians tend to consume large quantities of NCFD, up to 36% of energy [62] and this pattern of consumption is not restricted to adults. Data from the National Nutrition Survey of children suggest that children (5-12y) and adolescents (13-18y), consume more energy from NCFD than any other food group (41.5 and 43.4%) [235]. While the consumption of NCFD is ubiquitous, the category is difficult to define, and further categorisation of the types of foods and drinks making up the NCFD category may allow for more effective substitution when weight loss is desired [124].

In our previous research of dietary patterns from weight loss interventions, 31% of energy (including alcohol) was consumed from NCFD at baseline [228], exceeding the maximum recommended limit of 20% for healthy individuals and the number of serves suggested in the Australian Guide to Healthy Eating (AGHE) [57]. The inclusion of NCFD can displace nutrient rich core foods, influencing the overall nutritional profile of the diet and possibly the achievement of weight management. There is a need to investigate in greater detail the types of NCFD consumed, and how individuals alter their patterns of eating and this may assist in delivery of more effective dietary advice [208].

The wide variety and availability of inexpensive, palatable NCFD contribute refined grains, added sugars and fats [236] may make providing simple advice about what to eat more difficult for practitioners [237]. Consumption patterns driven by social eating

and other habitual behaviour may also make dietary patterns more difficult to alter as NCFD are so readily available. Furthermore, due to the known ubiquitous consumption of NCFD, practice and research based diet prescriptions should not assume that NCFD will be avoided, even in a supervised weight loss context. For this reason, exploring dietary patterns with a focus on different types of NCFD may be useful in explaining the changes made under longer term weight loss conditions. The aim of this investigation was to evaluate the change in dietary patterns with respect to NCFD in participants from two weight loss trials over 12-months.

5.2. Methods

The trials utilised were two 12-month randomised controlled dietary trials in healthy overweight adults described previously [124], approved by the University of Wollongong Human Research Ethics Committee and registered with Australia New Zealand Clinical Trials Register Network (12608000425392 and 12610000784011) [1, 2].

The NCFD included sources of added sugar and/or saturated fat [124], and were isolated from previously categorised dietary data referencing core foods (fruit, vegetables, cereal and grain foods, lean meat or equivalent, dairy foods, unsaturated oil and margarine) and alcoholic beverages at baseline, three months and 12-months. NCFD sub-categories were formed based on i) reference to published research of NCFD categories [62], ii) eating occasion e.g. meal or snack food item, iii) food form e.g. liquid or solid food. The NCFD sub-categories contributing greater than approximately 1% of total dietary energy at baseline were ranked according to their contribution to

total dietary energy (in kilojoules) and consumption as a percentage of total energy [62].

5.3. Statistical analysis

The compatibility of combining the two trial data bases in terms of age of participants, BMI and reported dietary energy from the macronutrients as a percentage of total energy, and a Chi-square test for gender differences between groups have been reported previously [124]. All food group data were checked for normality using Shapiro-Wilks and the median and interquartile range (IQR) were presented. A mixed model Repeated Measures ANOVA (RMANOVA) was performed to assess differences at baseline, three months and 12-months in terms of total energy intake, total NCFD intake and intake of each sub-category of NCFD. Spearman's rank order correlation coefficient (non-parametric variables) was used to test relationships between serves of NCFD and the 'core' food groups, alcoholic beverages and unsaturated oils and margarine (virtually free of trans-fats) at 12-months. All statistical calculations were performed using IBM SPSS Statistics, version 19.0.0 IBM Corporation Armonk NY.

5.4. Results

5.4.1. Formation of non-core food and drink categories

Eighteen types of NCFD were condensed into eight main categories 1. sweet snacks, 2. savoury snacks, 3. takeaway foods, 4. spreads and sauces, 5.desserts and ice-cream, 6. beverages (soft drinks and juice), 7. added sugar, 8. other miscellaneous items. A number of specific alterations to the food categories used by Rangan *et al* (2009) [62] were made for the purpose of this research (Table 5-1). Alcoholic beverages and

unsaturated oils and margarines were excluded from the analysis of NCFD. Alcoholic beverages contribute energy and have a deleterious effect on other nutrients, yet when consumed within guideline amounts of less than two standard drinks [221], limits risk over a lifetime and may provide some benefit to health. Furthermore, this level of alcohol consumption does not appear to be associated with weight gain [26]. Mono- and poly-unsaturated oils and margarine, were considered preferred fats, and are a source of energy and fat-soluble vitamins that are linked with positive health outcomes [152]. A greater variety of takeaway foods were identified in the dietary data than previously reported in the literature [62] (Table 5-1). In the analysis, sauces, mayonnaise, dressing and spreads contributed less than 1% of total energy each at baseline, and were combined as a sub-category labelled 'spreads and sauces' since they are used similarly as condiments within a meal. The beverage sub-category comprised soft drinks (and cordials including sweetened and artificially sweetened types) and all juices (including 100% juice and juice drinks). Rangan *et al* (2009) also combined sweetened and artificially sweetened beverages [62], however whereas fruit juice drinks were included as an 'extra', 100% juice was excluded. Since the current analyses were applied to a weight loss context, we categorised all juices within NCFD. This considered the values for the energy and fibre content for whole fruit [84] and compared the tendency to drink large volumes of juice without fibre and the greater energy content per serve. 'Other' miscellaneous items comprised food items consumed by very few participants, for example, chicken skin, pork crackle, sweetened refined breakfast cereal and beverage flavouring. Combined, these foods comprised more than 1% of energy at baseline.

Table 5-1 Non-Core Food and Drinks Categories adapted from published research

Existing categories from Rangan *et al* 2009 [62]	Other foods included in this analysis	Categories used for this analysis
Margarine	Categorised as Unsaturated oils and margarine	NA
Beer, Wine, Spirits	Categorised as Alcoholic beverages	NA
Sweet biscuits	Sweet biscuits (including confectionary-style muesli bars); Savoury biscuits (not wholegrain)	1. Sweet snack foods
Cakes and Muffins	Cakes, Muffins, Slice and confectionary type muesli bars	
Chocolate and chocolate bars	Chocolate and Chocolate Bars	
Lollies and Confectionary	Confectionary (all sugar-based sweets /lollies)	
Potato Crisps	Potato and other crisps	2. Savoury snack foods
	Savoury biscuits (not wholegrain)	
Pizza; Meat Pies and savoury pastries	Pizza; Meat Pies and savoury pastries	3. Takeaway foods
	Fried Takeaway (fish, spring rolls)	
	Commercial Hamburgers and sandwiches (not homemade)	
Fried potatoes	Chips and fried potatoes	
Jams and conserves	Sweet and Savoury spreads (vegemite, cream cheese, dip)	4. Spreads and sauces
Salad dressing Tomato and BBQ sauce; gravies	Sauce (all sauces, gravies, soup mixes), mayonnaise and dressing	
Butter and Dairy fats	Butter and Dairy fats (includes lard)	
Sweet Pies and Pastries	Dessert including sweet pies and pastries, mousse, trifle, pavlova	5. Dessert and ice-cream
Ice cream / Ice confection	Ice cream includes sorbet and water ices	
Sugar-based and Artificially - sweetened Soft drink & Cordial	Soft drinks: All soft drinks and cordial	6. Beverages
Fruit drinks	Juice: Fruit drinks and Juice	
Sugar	Sugar	7. Added sugar
Cream	Cream and Coconut cream	8. Miscellaneous
	Chicken skin, pork crackle, small goods, pate and cabanossi, luncheon meat, beverage base, flavoured milks, sweetened refined breakfast cereal.	

5.4.2. Consumption of non-core foods and drink categories over time

From baseline, mean total energy intake decreased from 9408±2963kJ by ~3000kJ (to 6331±1426kJ) when reported at three months ($P<0.001$), increasing only slightly between three and 12-months to 6672±1532kJ ($P=0.356$). At baseline, NCFD contributed 26.5% of dietary energy, a median of 2096kJ/day (IQR 1334-3105kJ). By three months the energy from NCFD category decreased to 573kJ/day (IQR 285-984kJ), and by 12-months, a reported increase in consumption to 745kJ/day (IQR 410-1261kJ) (Table 5-2). The NCFD category was responsible for 59% of the increase in total median energy intake between three and 12-months.

At baseline, sweet snacks (8.1%), takeaway foods and meals (6.2%) and savoury snacks (3.8%) were the top three contributors of dietary energy, contributing in excess of 1000kJ (median) per day (Table 5-2). Significant changes for each sub-category occurred, decreasing between baseline and three months in line with the dietary advice for weight reduction. Several sub-categories appear to trend upwards towards 12-months, however, only desserts and ice-cream were significantly different between three and 12-months (P=0.038), and the increased contribution of dietary energy from this group was minimal.

At the 12-month time point (n=158) there was a negative correlation between serves of NCFD and serves of free vegetables (rho -0.238; P=0.003) and starchy vegetables (rho= -0.265; P=0.001), and positive correlations between NCFD with alcoholic beverages (rho= 0.196; P 0.030), higher fat dairy (rho= 0.228; P=0.009), eggs (rho= 0.184; P=0.033) and non-wholegrain (refined) cereals (rho= 0.181; P=0.027).

Table 5-2 Reported Non-Core Food and Drink categories: consumption at baseline, three months and 12-months, median energy (IQR), per cent energy and differences between time points.

Food Group	Energy in kilojoules (Median & IQR)						Per cent Total Energy (Mean)			P value*	
	Baseline (n=230)		3-mo (n=195)		12-months (n=158)		Baseline	3-mo	12-months	BL-3mo	3mo-12mo
Total diet	8958	(7425-10528)	6072	(5394-7044)	6365	(5567-7657)	100	100	100	<0.001	0.168
Total Non-Core foods and drinks*	2096	(1334-3105)	573	(285-984)	745	(410-1261)	26.5	11.7	14.3	<0.001	0.162
1. Sweet snack foods	554	(224-1059)	87	(0-258)	223	(56-599)	8.1	3.0	4.5	<0.001	0.193
2. Savoury snack foods	201	(0-513)	0	(0-77)	39	(0-243)	3.8	1.2	1.4	<0.001	1.000
3. Takeaway Total	341	(79-757)	0	(0-157)	87	(0-363)	6.2	2.0	1.8	<0.001	1.000
4. Spreads and Sauces	107	(22-290)	84	(23-197)	100	(28-236)	2.3	2.3	2.5	0.012	1.000
5. Desserts and Ice-cream	61	(0-206)	0	(0-35)	11	(0-132)	1.7	0.8	1.7	<0.001	0.038
6. Beverages	34	(0-290)	0	(0-28)	1	(0-112)	2.2	0.9	0.8	<0.001	1.000
7. Added Sugar	0	(0-92)	0	(0-5)	0	(0-34)	0.9	0.4	0.3	<0.001	1.000
8. Other miscellaneous items	92	(22-223)	0	(0-0)	10	(0-116)	1.6	0.5	0.9	<0.001	0.214

*Linear Mixed Model

5.5. Discussion

A large variety of food choices are grouped together in the NCFD category and this may be problematic for communication strategies at both the public health and clinical level. The NCFD category accounted for 26.5% of dietary energy with an additional 2.5% from alcoholic beverages at baseline in the weight loss trials examined, exceeding healthy recommendations. At baseline, the reported consumption of particularly sweet and savoury snack foods (biscuits, fried potato chips, chocolate, chocolate bars, cakes and muffins, confectionary and crisps), made up >750kJ/day, just less than half of the total reported energy from the NCFD category. At the same time, consumption of fruit and vegetables were below recommended levels (See Chapter 3). Consumption of total NCFD decreased to ~570kJ/day in the first three months of the intervention, and although there was an increase between three and 12-months to ~745kJ/day, this was not statistically significantly. However, the NCFD category was responsible for more than half (59%) of the increase in total median energy intake between three and 12-months. The relaxation of the diet prescription by participants is relevant, as they were assessed and counselled at routine, monthly intervals throughout this period of time.

The Australian Guide to Healthy Eating recommends 0-3 serves of discretionary choices to allow for taller or more active individuals with a suggestion that the additional kilojoules be selected from “core” food groups [57]. Targeting the NCFD category in weight loss consultations may result in greater weight loss if appropriate substitutions are made to facilitate dietary change. In another analysis of data from the same sample of participants, we found those with the highest intakes of NCFD, lost

more weight (-5.6kg versus -4.4kg; $p<0.05$) within a three month time frame compared with those who reported eating less of these foods and beverages [124]. Limiting selection from the NCFD food category was important in the greater weight loss achieved by these participants [124]. Within the NCFD category, the 'sweet treats' (including foods like confectionary and sweet biscuits) and takeaway foods, were responsible for over half of the dietary energy intake from NCFD at baseline for those who lost more weight. This level of intake was decreased by three months, however there are indications from the current analysis that consumption shifts over the longer term and certain foods may re-emerge. Further dietary pattern research considering NCFD may be valuable for long term compliance analysis.

Examination of the 12-month data, indicated that NCFD and alcoholic beverages were positively correlated, indicating that these types of food and drink choices may form part of the same shift in dietary patterns. Changing patterns of behaviour linked to consuming these foods together may influence future weight loss or maintenance of weight loss. This may be especially so if consumption of NCFD is linked with the consumption of high-energy alcoholic beverages. More importantly, there was a negative correlation between intake of vegetables and NCFD, highlighting an opportunity for exchanging high energy dense, nutritionally poor choices, with low energy dense foods to encourage greater weight loss [23, 238].

Rangan *et al* (2009) [62] examined data from the Australian National Nutrition Survey (1995) to show that the highest consumed NCFD were fried potatoes (2.8%), cakes and muffins (2.5%), sugar sweetened soft drink (2.4%) and meat pies (2.2%). A cohort study

examining dietary patterns over four years also revealed that consumption of similar foods appears to be strongly associated with weight gain. These foods included meat (processed and unprocessed), potatoes, potato chips and sugar-sweetened beverages [118]. In our analysis of an over-weight population attempting to lose weight, fried potatoes (2.2%) and sweet snack foods including cakes and muffins (8.1%) contributed proportionally greater energy than was reported at the population-level. The consumption of added sugar was reduced over the timeframe examined, however it is widely acknowledged that a larger proportion of sugar is consumed in pre-prepared foods [162] as an ingredient, so it is more relevant to review the entire dietary pattern rather than only focusing on added sugar consumption.

An emerging issue is the low cost of highly palatable, energy dense, NCFD [236, 239] relative to the cost of 'core' foods within the context of the total diet, and it is unknown how this may impact on the foods selected by those trying to lose weight. Frequent consumption and over-consumption of some NCFD may be related to sensory-specific satiety, whereby the experience of decreased satiety after one serve of food, reinforces further consumption of the non-core food choices [240]. This hedonistic aspect of food consumption, together with the relative low cost of NCFD, may facilitate passive over-consumption [241] and be problematic in the weight loss setting. However, if energy balance can be influenced through targeting NCFD, even by small amounts, as little as 418kJ/day, it is thought that weight gain could be prevented in most of the population [242, 243]. Overweight and obesity has risen among adults in Australia [13], and as such, dietary changes focusing on NCFD may require even greater emphasis. In Chapter 4 using cluster analysis techniques we demonstrated that

a reduction in NCFD was important in reducing energy intake and facilitating the greater weight loss observed in the second cluster.

There are limitations to this analysis. The dietary assessment methods used for this investigation were based on self-reported diet histories known to be prone to systematic bias and affected by the age of participants, gender, approval [111], social desirability [11] and familiarisation with the reporting process over time. Four day food diaries were recorded by subjects in the period prior to dietary interviews to assist subjects' reporting their food consumption pattern as accurately as possible. In previous research, we have reported the clinical and anthropometric measures of this sample [124, 244], which provides some validation of the accuracy of reported dietary intake [110, 218, 245]. If under-reporting occurred within this sample of overweight-obese adults, it is likely that NCFD are most affected, and as such, the reported figures may be conservative estimates. As diet history data at nine months was not available for both of the primary trials examined, the analysis of the change in diets between nine and 12-months could not be performed, although this would have helped depict the consumption patterns in greater detail.

It may appear problematic that there was no statistical difference in reported energy intake between 3- and 12-months. The food analysis helped to explain the lack of difference through closer examination of the dietary pattern. This insight indicates that further dietary pattern research is needed at the clinical level to help understand food choices, since the overall diet quality may also be determining success in weight management.

5.6. Conclusion

Categorisation and analysis of NCFD highlighted the pervasive nature of the foods and drinks normally considered 'discretionary' choices within the diet. In clinical practice, obtaining greater detail of the NCFD choices prior to commencing weight loss counselling, may assist with providing more effective advice and substitute foods, particularly sweet and savoury snack alternatives. This investigation highlights the adoption of dietary advice and change in consumption of NCFD early in weight loss interventions and the subtle reversal of this towards the end of such interventions. Known issues with weight loss and re-gain, suggest that greater focus on the latter part of intervention trials is required to maintain the early, positive changes made in the overall dietary pattern in the clinical setting. Differentiating the types of NCFD in detail may help to target foods and drinks, particularly snack foods, and highlight foods that may be more resistant to change during supervised weight loss.

CHAPTER 6 DIFFERENCES IN DIETARY PATTERNS REPORTED AT 12-MONTHS RELATE TO WEIGHT LOSS ACHIEVEMENT

In Chapter 5, the changing pattern of non-core foods and drinks (NCFD) over 12-months during supervised weight loss was examined. The analysis builds on the findings from Chapter 4, where significant reductions in the consumption of NCFD in the first three months were related to greater weight loss for Cluster 2 participants. A systematic review and meta-analysis of weight loss dietary trials has indicated that the rate of weight loss decreases and weight re-gain may even occur towards the end of longer term dietary trials [86]. Since weight loss intervention studies are notably successful in the short-term, longer-term studies are of interest, and in particular, the reported dietary patterns of participants when diet therapy and counselling are less intensive. This chapter examines the weight loss pattern from baseline, and then at three monthly intervals up to 12-months, and compares the dietary patterns as reported at 12-months, stratified by weight loss group (<5%, >5-<10% and >10% weight loss) achieved over the course of the 12-month period.

6.1. Introduction

Over a longer timeframe (12-months), many dietary intervention trials report issues with slowed weight loss or even weight re-gain [86]. Anthropometric measures and nutrient composition analysis of dietary intakes (via software packages) are useful in assessing compliance in clinical trials and can be compared with weight loss achievement. However, exposing the dietary patterns of successful and less successful participants towards the end of a weight loss intervention may be an important adjunct to nutritional intake analysis, and may be useful in explaining the specific food-level changes made during longer term weight loss. This type of analysis may provide useful information for the advice setting to help guard against weight re-gain.

In designing diets for weight loss, all of the foods and drinks that are consumed count towards the overall energy intake and therefore influence the potential for weight loss, although the quality of food choices making up the diet may also be important [46, 246]. The diet prescription under clinical trial conditions would not include high energy, nutrient poor food choices however there may be circumstances where free-living trial participants choose such foods. When nutrient poor foods are added to the diet, they either displace another food choice or there is an increase in the total food intake, increasing energy intake. Since no single food or drink choice creates a healthful or unhealthy eating pattern, it is important to look at the whole diet pattern and all of the foods consumed.

Chapters 3 and 4 describe results of data from two combined dietary weight loss intervention trials regarding the alterations in patterns of food consumption during weight loss between baseline and three months [124, 244]. The findings were pertinent to the delivery of more effective dietary advice [208], particularly in terms of the information obtained through the diet history at baseline [124]. Although even short term weight loss may have important clinical effects, maintenance over the longer term is desirable. A systematic review and meta-analysis of dietary counselling for weight loss has shown modest net weight loss with diminishing net effects as the duration of the dietary intervention increases [247]. Studies suggest there are a number of factors that are important in continuing weight loss, including continued intervention contacts [248], which often are often less frequent towards the end of a 12-month trial. Therefore the examination of weight loss achievement in comparison to the reported dietary pattern at the end of longer term trials may reveal information

that may assist dietitians in improving compliance with the dietary prescription. The aim was to depict the dietary patterns and intakes of selected nutrients, between those losing <5%, >5-<10%, >10% body weight by the end of a 12-month weight loss trial.

6.2. Methods

Participant diet history records from the two registered clinical weight loss trials (ACTRN 12608000425392 and 12610000784011) were analysed at baseline, 3-months, 6-months and 12-months [1, 2]. Nine month diet history data was not available from both trials so this time point could not be used in this analysis. Anthropometric data collected from both primary trials at baseline (n=231), three months (n=195), six months (n=170), nine months (n=151) and 12-months (n=156) was also used in this secondary analysis. The participant numbers include a drop-out of 33% over 12-months however there were very few drop-outs between nine and 12-months (n=6).

Dietary data was categorised into 17 food categories referencing core foods, alcoholic beverages and non-core foods and drinks (NCFD), including sources of added sugar and/or saturated fat as described in Chapter 3. Defined serve sizes were used in a consistent manner in each analysis and are also outlined in Chapter 3. Anthropometric data that had been collected at baseline, three months, six months, nine months and 12-months and were combined from each main trial and presented graphically. Participants were stratified into three groups pertaining to the weight loss achieved by the end of the 12-month trial: <5% (n=51), >5-<10% (n=75) and >10% body weight loss (n=30).

6.3. Statistical analysis

The compatibility of combining the two trial data bases in terms of age of participants, BMI and reported dietary energy from the macronutrients as a percentage of total energy, and a Chi-square test for gender differences between groups have been detailed previously [124]. An independent samples t-test was used to test for weight and BMI difference between genders at baseline and 12-months. As there was no gender difference in weight at baseline (*P*=0.732) or in per cent weight loss (*P*=0.470), the data for males and females were analysed and presented together. There was also no difference between males and females in body weight lost between nine and 12-months (-0.3±1.5kg versus 0.2±1.8kg; *P*=0.155).

An independent samples t-test was used to test for differences between weight gainers and weight losers (including those maintaining weight) at 12-months. A Linear Mixed Model with PostHoc Bonferroni adjustment was used to test for differences between weight loss groups (<5%, >5-<10% and >10% body weight loss) and their respective diet pattern reported in serves. A one-way ANOVA was used to check for change in energy intake between three months and 12-months. All statistical calculations were performed using IBM SPSS Statistics, version 19.0.0 IBM Corporation Armonk NY.

6.4. Results

6.4.1. Weight loss over 12-months

The weight loss results for the 12-month period are shown (Figure 6-1) with a mean loss of 6.6±4.6kg by nine months. A weight gain of 0.2±1.7kg between nine and 12-months was observed, reducing the overall weight loss to 6.4±5.0kg in 12-months. There was a statistically significant increase in energy intake from three months to 12-months (6331±1426kJ versus 6672±1532kJ; $P=0.013$). While there was no mean difference in body weight between nine and 12-months for the sample, there was a significant difference between those who gained weight (n=78; 1.3±1.0kg) and those who maintained, or lost further weight (n=69; -1.3±1.2kg; $P<0.001$) by the end of the 12-month timeframe.

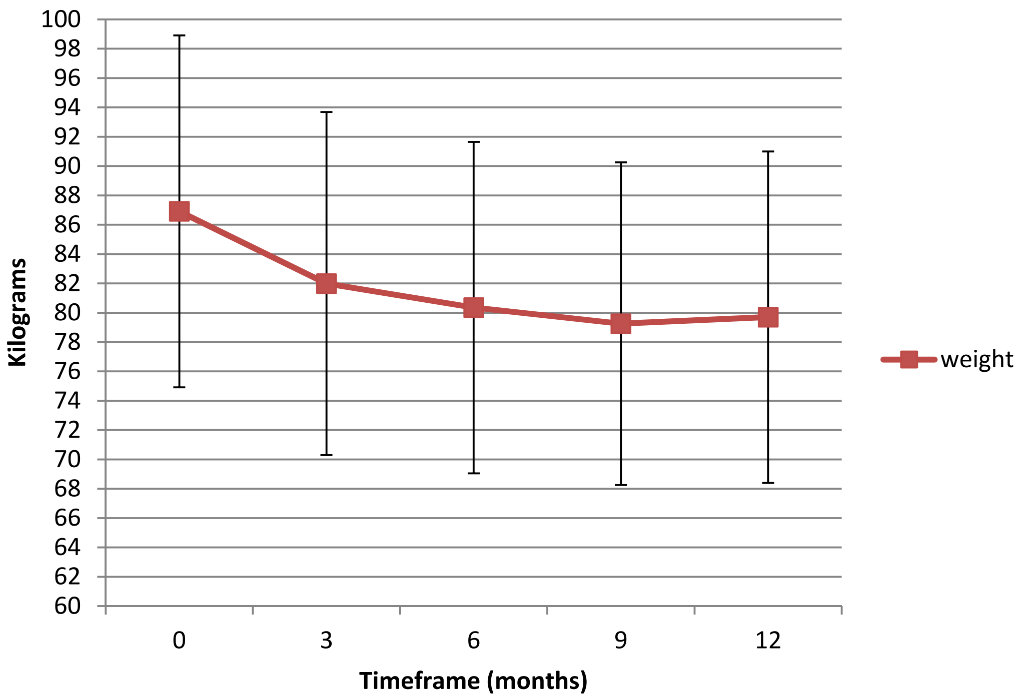

Figure 6-1 Weight loss, baseline, 3-months, 6-months, 9-months and 12-months of combined data from two weight loss trials (mean ±SD).

6.4.2. Differences in diet patterns and foods selected based on weight loss by 12-months

Mean weight loss between the three stratified weight loss groups from less than 5%, between 5 to 10% and greater than 10% differed significantly (-1.5±2.4 kg versus -6.8 ±2.0 kg versus -13.7±3.8 kg; $P<0.001$). The change in BMI and per cent body fat loss matched the change in weight and per cent weight change across the groups (from the lowest to highest amount of weight lost) and each were significant at $P<0.001$ (95% CI). There was a significant difference between groups in reported consumption of serves of NCFD (2.0±1.8 serves versus 1.5±1.0serves versus 0.9±0.8 serves; $P<0.001$), serves of fruit (1.3±0.9 serves versus 1.6±0.9 serves versus 1.7±0.5; $P=0.033$), saturated fat (17.8±7.4g versus 16.2±7.0 versus 13.8±5.3g; $P=0.046$) and dietary fibre (25.1±6.4g versus 27.1±6.8g versus 29.2±7.9g; $P=0.038$). There were no differences in reported energy or major macronutrients (Table 6-1).

Table 6-1 Number of food category serves, energy intake, key nutrient intake and anthropometric measures at 12-months by weight loss group (mean ±SD)

	<5% weight loss		>5-<10%		≥10% weight loss		F statistic
Variable	(n=51)		(n=75)		(n=30)		P value
1. Wholegrain foods	2.7	±1.8	2.7	±1.7	2.6	±1.6	0.916
2. Non wholegrain cereals	2.7	±2.1	2.3	±2.2	2.3	±1.9	0.457
3. Fruit	1.3	±0.9 [a]	1.6	±0.9 [a]	1.7	±0.5	0.033
4. Free vegetables	4.2	±1.9	5	±2.3	4.9	±2.0	0.104
5. Starchy vegetables	1	±1.1	0.8	±0.8	1.1	±0.7	0.249
6. Legumes	0.3	±0.5	0.5	±0.6	0.5	±0.6	0.247
7. Low fat dairy foods: <3.5% fat	2.5	±1.9	2.5	±2.0	2.4	±1.8	0.993
8. Medium fat dairy foods: 3.5-10% fat	0.1	±0.5	0.4	±1.1	0.3	±0.6	0.276
9. High fat dairy foods: >10% fat	0.4	±0.4	0.4	±0.9	0.3	±0.7	0.859
10. Lean Meat & poultry	3.3	±1.9	3.6	±1.9	3.1	±1.6	0.416
11. Fatty meat	0.6	±0.7	0.4	±0.7	0.6	±0.8	0.371
12. Fish & seafood	1.4	±0.9	1.4	±1.1	1.5	±1.0	0.888
13. Eggs	0.5	±0.5	0.5	±0.4	0.4	±0.3	0.376
14. Nuts and seeds	0.5	±0.6	0.4	±0.4	0.4	±0.6	0.771
15. Unsaturated oils & margarine	1.9	±2.2	2.6	±3.0	1.5	±2.7	0.165
16. Alcoholic beverages	0.7	±1.2	0.7	±0.8	0.6	±0.9	0.802
17. Non-Core foods & drinks	2.0	±1.8 [a]	1.5	±1.0	0.9	±0.8 [a]	0.001
Energy (kJ)	6832	±1770	6659	±1419	6422	±1398	0.511
Protein (g)	87.1	±22.1	86.8	±18.8	85.7	±14.8	0.944
Fat (g)	51.8	±16.2	50.4	±16.9	44.5	±18.2	0.157
Saturated fat (g)	17.8	±7.4 [a]	16.2	±7.0	13.8	±5.3 [a]	0.046
Carbohydrate (g)	177.7	±53.2	170.6	±40.7	171.9	±39.0	0.672
Dietary Fibre (g)	25.1	±6.4 [a]	27.1	±6.8	29.2	±7.9 [a]	0.038
Calcium (mg)	889	±351.1	844.9	±310.2	892.3	±310.0	0.683
Iron (mg)	11.2	±2.7	11.6	±2.8	11.9	±2.8	0.565
Weight at Baseline (kg)	85.6	±11.3	85.8	±12.0	87.6	±12.1	0.732
BMI at Baseline	30	±3.3 [ac]	30	±2.9 [ab]	31.8	±2.8 [ac]	0.017
Weight loss in 12mo (kg)	-1.5	±2.4b [bc]	-6.8	±2.0 [ab]	-13.7	±3.8 [ac]	<0.001
Per cent weight change (%)	-1.7	±2.7 [bc]	-7.9	±1.9 [ab]	-15.6	±3.2 [ac]	<0.001
BMI change	-0.5	±0.8 [bc]	-2.4	±0.7 [ab]	-5.0	±1.2 [ac]	<0.001
Body fat change (%)	-0.4	±2.2 [bc]	-4.2	±5.6 [ab*]	-6.8	±2.8 [ac]	<0.001

Post Hoc Comparisons (Bonferroni adjustment) P<0.05*; P<0.001 [ac, ab, bc]

6.5. Discussion

Participants completing the 12-month weight loss interventions achieved an overall mean weight loss of 6.4±5.0kg (or -7.4% weight loss). Both >5% and >10% body weight loss have been suggested as suitable targets to define success in weight loss [248-250]. The observed decrease in the rate of weight loss between nine and 12-months is frequently reported in weight loss trials [86]. One explanation may be metabolic adaptation to weight loss [251-253], but we have shown the slower weight loss between nine and 12-months was accompanied by an increase in energy intake which has implications for changes in food choice patterns. Those who maintained weight losses >10%, appeared not to experience the same shifts in food consumption patterns as those losing less weight over the 12-month period. Although the differences between groups in terms of energy intake and food choices were modest, this method demonstrates the relevance of investigating the dietary patterns and food choices of more successful participants compared with those who are less successful. The differences in diet quality, based on the types of food selected may be more important to success than we are able to realise through current methods of diet analysis [29]. Food composition tables giving nutrient values are not perfect [140, 141] and could differ considerably from a direct chemical analysis of duplicate food portions. There are also indications of differences in available energy between non-processed and highly-processed foods in the scientific literature demonstrating the potential limitations and errors that are likely when comparing groups who are consuming different dietary patterns but similar energy intakes [29].

Nutrient-level analyses of diets aims to highlight the effects of nutrients (and fibre) resulting from the ingestion of foods. With few exceptions, changing single nutrients have been shown to only have small proven effects on chronic disease [38] and in any case, it is the pattern of nutrients rather than single nutrients that would show associations with future health [120]. On the other hand, analyses that examine the intake of foods and dietary patterns together with nutrient intakes may provide more information on health risk compared with considering only nutrient-level effects. By consuming whole foods, we take in a whole range of food constituents, many of which are not included in the typical analysis of foods or accounted for in food composition data bases. The notion of food kilojoules calculated using Atwater factors is also being challenged alongside the cost of digesting different foods relative to the reported kilojoule values [78]. For example, whole versus processed foods as mentioned [29], research testing almonds [138] and other nuts [159], and maybe even raw and cooked vegetables. This research suggests that once a food is ingested, the total energy value is not just a simple average of the macronutrients it contains, and the degree of error likely to be involved from these preliminary food focused studies suggest that more food-based research in the context of a mixed diet is warranted particularly in weight loss [9, 78].

In our analysis, the reported consumption of fruit was higher and that of NCFD were lower in the highest weight loss group. Furthermore, the differences in dietary patterns were also supported by significantly lower saturated fat and higher fibre intakes in the highest weight loss group, a result of all the foods making up the diet pattern.

6.6. Conclusion

The difference in food choices, particularly fruit and NCFD between the stratified weight loss groups is reflected in significant differences in dietary fibre and saturated fat intake but not energy. We do not fully understand how the nutrients and non-nutritive components from foods are working within the body and to date dietary intervention research has primarily focused on obtaining results that are meaningful at a nutrient-level. While the nutrient composition of dietary intake remains an important analytical tool, the analysis of the foods and drinks represented as dietary patterns revealed particular food choices that may be relevant in the discussion of dietary interventions. The changing food choices and overall diet quality may be particularly pertinent in light of the differential in weight loss achievement over 12-months, and the observed trend towards weight re-gain.

CHAPTER 7 DEVELOPMENT AND VALIDATION OF A DIET QUALITY TOOL APPLIED TO WEIGHT LOSS

The majority of this section is the substantive content of work submitted for publication: Grafenauer, S., Tapsell, L., Beck, E. and Batterham M. *"Development and validation of a Food Choices Score modelled on diet quality for clinical weight loss interventions".* **British Journal of Nutrition**, 111 (10); p. 1862-1870; doi 10.1017/S0007114514000063

While the use of *posteriori* cluster analysis (Chapter 4) at an intervention-level was novel and provided a method of differentiating between participants based on a similar dietary pattern, *a priori* methods, diet quality tools are able to provide a view of the dietary pattern from a summative perspective. In epidemiological research, diet quality scoring tools have been developed *a priori* and applied to data. The issues that have been noted in the development of the various tools in current use have been discussed in Chapter 2 (methodology). In short, the tools in existence have not been developed for clinical research, but more often for the assessment of compliance against dietary guidelines. If the tool has been used to assess foods, food groups or nutrient levels, there are examples of research where the whole diet has not been assessed because major food groups are not included in the tool or, there are some tools that weight the score too heavily towards some groups and not others. Many of the methodological issues also relate back to, or are predetermined by the dietary data collection method. Chapter 7 outlines the development and validation of a diet quality tool specifically developed to monitor the changing diets of participants during weight loss.

7.1. Introduction

Weight loss results from an energy deficit although the quality of food choices making up the diet may also be important [46, 246]. In examining this idea, an observational cohort study of 4 year weight change found that weight gain was most strongly associated with intakes of meat (processed and unprocessed), potatoes, potato chips and sugar-sweetened beverages and inversely associated with free vegetables, fruit, whole grain foods, nuts and yoghurt [118]. This study provided some suggestions of

specific foods of interest in weight loss. The recognition that we “eat foods, not nutrients” sounds simplistic [234], but it signals a paradigm shift from focusing on nutrient composition to food composition of the whole diet, embracing the concept of food synergy [4, 5, 32, 254-257]. Encompassing this concept, diet quality tools have emerged in epidemiological research moving the focus from single nutrients, to a whole-diet based perspective in relation to disease [34] and research now focusing entirely on the macronutrient proportions of the diet may be of limited value [42]. The definition of diet quality used in constructing a tool depends on the attributes selected by the researcher [194]. In a review, Reul [258] found no official definition of dietary quality, yet the concept of quality of kilojoules is gaining support at the research level [259]. Historically, dietary quality referred to nutrient adequacy, and implied that the diet met requirements for essential nutrients within energy requirements [258]. In the management of chronic conditions such as obesity [103] and metabolic syndrome [152], a diet of high quality food choices is essential, and forms an integral layer of dietary advice. However, high diet quality may be more difficult to achieve within an energy restriction, and interventions tend to report energy and nutrient level changes but not changes in diet quality [46].

A diet quality tool is a predefined measure based on food groups and/or nutrients, or dietary guidelines and creates a single quantifiable rank or score by subject [11]. Several reviews of diet quality tools have been published [11, 103, 187, 193-196, 260] defining important considerations in the methodological process of designing such tools and the differences between tools. The most recent review by Wirt and Collins [103], examined twenty-five indices of diet quality or diet variety that used a range of

measures from nutrients, to food servings or food groups. This review noted many methodological weaknesses in the existing tools, but concluded that higher diet quality was inversely related to all-cause mortality with a moderate protective effect. The "moderate" effect size was generalised since the predictive capacity of most indices were in a similar range. Reportedly all-cause mortality was reduced by 17-42%, CVD mortality was reduced by 18-53%, CVD risk was reduced by 14-28%, cancer mortality was reduced by 13-30%, and all-cancer risk was reduced by 7-35% [103].

A number of diet quality tools are available for dietary pattern research, yet many are based on dietary guidelines including the Diet Quality Index [261], Healthy Eating Index [262] and Dietary Guideline Index [199] and only some have been validated for certain populations [195, 199, 202]. Few studies have assessed the effect of diet quality in terms of weight change in an intervention setting [11, 46]. The published studies have tended to use an existing tool that includes both foods and nutrients [246, 263] or a tool based on dietary guidelines [46, 264] or a tool that does not include all of the possible foods and drinks consumed [265, 266]. None have used a tool specifically designed for clinical weight loss and this setting may require a more specific tool to correctly depict dietary change. The aim was to develop and validate a diet quality tool based on food categories to monitor dietary change in clinical weight loss interventions.

7.2. Method

Reference data for the analyses described here was obtained from diet history records from two clinical weight loss trials and includes the participants completing 3-months

(n=195) described previously [1, 2]. Both trials were based on an individualised kilojoule restriction (80% of BMR x PAL 1.25 using the Mifflin St Jeor equation [267]) and focused on achieving a prescribed intake of core foods with high dietary quality. Diet history data reflective of a weekly pattern of intake was collected by Accredited Practising Dietitians. Prior to this interview, participants had completed a 4-day food record which assisted with recall of types and amounts of foods consumed. A checklist of specific foods was also used for items that may have been omitted from the history including their frequency of consumption. Household measures and food models were used as a prompt for serve size. All food records were analysed using a computerised food and nutrient database, Foodworks™ Professional (Xyris, Brisbane, Queensland, Australia, Version 6, 2009). Under-reporters were excluded using the Goldberg cut off (0.76-1.24) [131, 132] reducing the sample size for the analysis presented (n=189) [268].

The Food Choices Score (FCS) was developed based on seventeen food categories and the scope of foods from within each food category have been adopted from previous research [124]. Each food item reported in the diet history interviews entered into the computerised food and nutrient database was categorised according to the described groups, then analysed in grams and kilojoules. The number of serves of each food category was calculated from grams (except for alcoholic beverages and the non-core food and drinks category where kilojoules were used to calculate the number of serves). Serve sizes were adapted from two ready reckoners [79, 80] and have been used in previously published research [124].

The 3-month diet history data was used to guide development of the scoring scale as this data represented the improved, prescribed diet. In order to define the scoring scale for each food category, the number of serves (per day) for each food category were ranked from lowest to highest consumption and this was examined graphically, noting the range (and the maximum and minimum number) of serves consumed. The highest score was adjusted as required in line with the recommended serves for each food group [48, 223]. Reverse scoring, that is lower scores for highest consumption, was applied to food categories where consumption limits (associated with negative health outcomes) have been documented in the literature e.g. fatty meats have been linked with chronic disease [147-149]. A U-shaped scoring scheme was used for foods where benefits exist with limited consumption but negative consequences are seen with excess [195] e.g. alcohol. Within guideline amounts [221], alcohol may provide some benefit to health, and is not necessarily associated with weight gain [26], but heavier consumption over-time is associated with weight gain [171] and other negative health outcomes [172-174].

A scale in serves per day with scores from zero to five aligned with increments for each food category were identified producing a maximum Food Choices Score of 85 (Table 7-1). The highest score applied to each food category reflected the optimal range of intake based on the described considerations. Scores were applied to the serve-based data of each trial participant (n=189) at baseline and 3-months using equations in Microsoft Excel (2010) to ensure accuracy of the composite score.

Table 7-1 Range in serves/day attributed to scores utilised in the Food Choices Score

	Positive scoring range by food category in serves						Reverse scoring	
Food Category and serve size	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**
1. Wholegrain foods (30g)	0	0.01-2.0	2.01-3.0	3.01-4.0	5.01-100	4.01-5.0		
2. Non-wholegrain cereal foods (30g)	0	3.01-4.0	0.01-0	2.01-3.0	0.01-1.0	1.01-2.0		
3. Fruit (150g)	0	0.01-0.5	0.51-1.0	1.01-1.5	1.51-2.0	2.01-100		
4. Free vegetables (75g)	0	0.01-2.0	2.01-4.0	4.01-6.0	8.01-100	6.01-8.0		
5. Starchy vegetables (75g)	0	2.01-2.5	0.01-0.5	1.51-2.0	1.01-1.5	0.51-1.0	2.51-100	
6. Legumes (75g)	0	0.01-0.25	1.51-100	0.26-0.5	1.01-1.5	0.51-1.0		
7. Low fat dairy foods: <3.5% fat (150mL)	0	0.01-1.0	1.01-2.0	4.01-5.0	2.01-3.5	3.01-4.0	5.01-100	
8. Medium fat dairy foods: 3.5-10% fat (150mL)	3.01-100	1.51-3.0	1.01-1.5	0.51-1.0	0.251-0.5	0-0.25		
9. High fat dairy foods: >10% fat (30g)	0.411-100	0.381-0.41	0.351-0.38	0.321-0.35	0.291-0.32	0-0.29		
10. Lean Meat and poultry (30g)	0	0.01-2.0	5.01-6.0	4.01-5.0	2.01-3.0	3.01-4.0		6.1-100
11. Fatty meat (30g)	2.01-100	1.01-2.0	0.51-1.0	0.26-0.5	0.01-0.25	0		
12. Fish and seafood (30g)	0	0.01-0.25	0.26-0.5	0.51-1.0	1.01-1.25	1.26-100		
13. Eggs (1 egg)	0	1.071-1.14	1.01-1.07	0.931-1.0	0.851-0.93	0.01-0.85	1.141-100	
14. Nuts and seeds (30g)	0	0.01-0.25	0.26-0.5	1.01-2.0	0.51-0.75	0.76-1	2.01-100	
15. Unsaturated oils and margarine (5g)	8.01-100	6.01-8.0	5.01-6.0	4.01-5.0	3.01-4.0	0-3.0		
16. Alcoholic beverages (400kJ)	2.01-100	1.51-2.0	1.01-1.5	0.51-1.0	0	0.01-0.5		
17. Non-Core foods and drinks (600kJ)	1.51-100	1.01-1.5	0.51-1.0	0.26-0.5	0.01-0.25	0		

Content validity involved a qualitative check of possible methodological weaknesses according to the latest review of diet quality scores [103, 195]. This check addressed key issues relating to the content of the diet quality score as described by Waijers *et al* [195], including the choice of the index components and the assignment of foods to food categories (Table 7-2). For example, distinguishing between whole grains and refined grains [103, 269], assessing dairy and dairy alternatives by fat content rather than just calcium [195] and providing separate categories for fruit and vegetables [195] and for fish and seafood [195]. Food preparation was also taken into account in accordance with our previously published work [124]. For example, plain boiled or steamed starchy vegetables were included with starchy vegetables while fried potatoes (or chips) were included with non-core foods and drinks (NCFD). Similarly, fried meats like schnitzel, were included with fatty meats.

Table 7-2 Validation plan outlining content and construct validity considerations*

Content Validity	Construct Validity
Food Category considerations — Other published indices — Choice of food categories e.g. fish separate from meat [195] and dairy foods categorised by fat rather than calcium content [195] — Need to reflect the diet, the extremes of consumption and recommended consumption. — Sub-categories based on food type — Food preparation effects e.g. higher fat cooking methods — Food processing effects e.g. refined and whole grains [103, 269] **Nutrients** — Nutrients not included – separate analysis performed **Diet Quality score** — Overall diet quality determined by the tool rather than as a subjective measure	**Diet models considering** — Energy — Food recommendations — Nutrient Reference Values **Scoring** — Reverse scoring and U-shaped scoring (for meat and alcohol) or a combination of these [195, 270] — More than two scoring points per category [193] **Scores achieved by participants** — Baseline — 3-months — Change in score compared to weight loss

*[30, 103, 195, 196]

Construct validity evaluated quantitatively how well the scoring system measured what it was supposed to measure. This was assessed in two ways. Firstly, two theoretical diet models were constructed (based on 6500kJ and 7400kJ) representing the highest diet quality of 85. The upper and lower boundary for energy intake was based on the mean (SD) reported energy intake of females (6031kJ ± 1100kJ) and males (7274kJ ± 1752kJ) at the three month time-point, and the range in energy of the diet prescriptions for female (5000-7500kJ) and male participants (6500-9000kJ). Both the mean (reported) and prescribed energy were taken into consideration in order to accommodate both men and women within the highest score and this score was validated through the modelling of food categories [195] (Table 7-3). The tool was specifically designed to prevent higher diet quality being the result of purely increasing

energy intake, rather higher diet quality was based on specific food choices and specifically reflected lower energy intake to result in weight loss (Table 7-3). The nutrient value of the associated range of serves by food category were tested using data entered into Foodworks^{TM} Professional software system (Xyris, Brisbane, Queensland, Australia, Version 6, 2009) in comparison to food guide recommendations (in serves) in use for the healthy population [223], and Nutrient Reference Values (Suggested Dietary Targets and Estimated Average Requirements) [48] (Table 7-3). Secondly, using the trial data, change in FCS was compared with weight loss achieved at 3-months in the trials. Thus, internal validity was demonstrated by comparing diet quality scores in idealised diets using the diet models, nutrient values and recommended number of serves from national guidelines [85], while external validity was demonstrated by comparing the highest (≥70%) and the lowest (≤60%) scores in relation to food categories, energy and nutrient intakes.

7.3. Statistical analysis

The compatibility of the two combined trial databases in terms of age of participants, BMI, reported per cent of macronutrients consumed, and a Chi-square analysis tested for gender differences between groups at baseline has been established and reported previously [124]. Independent samples t-tests were used to evaluate differences in FCS at baseline and 3-months between genders to ensure there was no gender effect.

To test the validity of the FCS i) the maximum FCS, was calculated using the idealised diet model and ii) the FCS values were used to estimate the relationship between the score, food categories and weight loss. The mean (SD; 95% CI) and the range in FCS

values and the change in score was calculated for the total sample at each time point. Values were compared for those who lost weight compared with participants who did not lose weight, for those that lost greater than (and less than) 5% body weight and for those scoring greater than the mean change in score using independent samples t-tests. Three score bands were formed differentiating those below 60% of the total score (≤44/85) and those scoring above 70% of the total score (≥56/80). Food category data (at baseline and 3-months), energy intake and nutrients consumed were analysed with a one-way ANOVA and post hoc Bonferroni correction. Normality of the data was determined using the Shapiro-Wilks test and then Pearson's correlation coefficient was used to compare weight change with score change. Logistic regression was used to determine whether weight loss was predicted by increasing or decreasing intakes of particular food categories in the total sample. All statistics were performed using IBM SPSS Statistics (version 19.0.0 IBM Corporation Armonk, NY).

Table 7-3 Energy Deficit Diet Model for the highest Food Choices Score rating of 85

	Proposed Serve range		Food Guide Recommendations (healthy population) *	
Food Category	Lower Bound	Upper Bound	Minimum	Maximum
1.Wholegrain foods (30g)	4	5	5	8
2.Non-wholegrain cereals (30g)	1	2	NR	2
3.Fruit (150g)	2	2	2	4
4.Free vegetables (75g)	6	8	3	6
5.Starchy vegetables (75g)	0.5	1	1	4
6.Legumes (75g)	0.5	1		Unlimited
7.Low fat dairy foods: <3.5% fat (150mL)	3	4		Total Dairy: 4 (Higher fat dairy <40g/d)
8.Medium fat dairy foods: 3.5-10% fat (150mL)	0	0.25		
9.High fat dairy foods: >10% fat (30g)	0	0.29		
10.Lean Meat & poultry (30g)	3	4		<455g/w
11.Fatty meat (30g)	0	0		NR
12.Fish & seafood (30g)	1	1.26		20-40g/d
13.Eggs (1 egg)	0.01	0.86		Max. 6/week
14.Nuts (and seeds) (30g)	0.7	1		30-60g/d
15.Unsaturated oils & margarine (5g)	3	3		7g oil; 10g margarine
16.Alcohol (each 400kJ)	0.5	0.5		NR
17.Non-Core foods & drinks (each 600kJ)	0	0		1
	Nutrient analysis		Suggested Dietary Targets or Estimated Average Requirement †	
Energy (kJ)	6499	7381		
Protein (g)	85 (21%)	93 (21%)	15%	25%
Fat (g)	50 (27%)	59 (30%)	20%	35%
Saturated-fat (g)	12.4 (7%)	15 (7.5%)	-	<7%
Polyunsaturated-fat (g)	10.0	11.6	-	-
Monounsaturated-fat (g)	23.0	27.5	-	-
Carbohydrate (g)	181 (44%)	188 (42%)	45%	65%
Alcohol (g)	6.5	6.5	-	-
Dietary-fibre (g)	34.0	34.5	F 28	M 38
Vitamin C (mg)	288.0	296.0	F 190	M 220
Total-folate (µg)	486.0	466.0	300	600
Calcium (mg)	992.0	1096.0	840	1100
Iron (mg)	11.5	13.0	F 8	M 6
Zinc (mg)	11.0	11.3	F 6.5	M 12

NR = no recommendation; M= Males; F=Females; * National Health and Medical Research Council (NHMRC) (2013) A modelling system to inform the revision to the Australian Guide to Healthy Eating: Commonwealth of Australia; NHMRC (2013) The Australian Dietary Guidelines, Department of Health and Aging, Canberra, Commonwealth of Australia.; †Australian Government (2006) *Nutrient Reference Values for Australia and New Zealand*. Department of Health and Ageing, Ministry of Health.

7.4. Results

The maximum diet score of 85 was shown to meet food guide recommendations (in serves) and Nutrient Reference Values (Table 7-3). The Goldberg cut-off excluded six participants due to under-reporting at baseline reducing the sample size (n=189). There were no differences at baseline between men and women in reported energy intake or nutrients consumed (carbohydrate, protein, fat, dietary fibre). At 3-months, males reported a significantly reduced energy intake compared with females (-3935 ±3017kJ versus -2715 ±1832kJ; P=0.010). The mean FCS at baseline was 42.6 ±8.6 (range 19-61/85) and at 3-months, 49.1 ±7.6 (range 28-68 out of 85). There was no difference in mean FCS at baseline comparing those who lost weight (n=177) with those who did not (42.7 ±8.7 versus 41.1 ±6.5; *P*=0.531) whereas at 3-months there was a difference between those that lost weight and those who lost no weight (49.4 ±7.4 versus 44.4 ±10.0;*P*=0.027).

In differentiating participants who lost more than 5% in body weight (n=100/189), there was a difference in score at baseline (40.9 ±8.5 versus 44.5 ±8.3; *P*=0.003), in favour of the group who lost less weight at 3-months. At 3-months, there was no significant difference in score (49.1 ±7.1 versus 49.2 ±8.2; *P*=0.967) although there was a difference in the change in score (Δ=8.3 ±10.9 versus 4.6 ±11.1; P=0.024) in favour of the weight loss group. For the total sample, the mean change in FCS was 7 ±11. When the score change value was greater than the mean change (Δ≥7; n=100) for the sample, BMI change was greater (Δ=-1.8 ±1.1 versus -1.5 ±1.1; *P*=0.044).

Participants with the highest scores at 3-months (FCS≥56/85), had a greater change in score value, significantly higher compared with participants with the lowest scores (Δ=14.4 ±8.4 versus -2.7 ±10.2; *P*<0.001). The change in score between the lowest and the highest score band was also reflected in an improvement in diet quality (in 8/17 food categories), exemplified by a greater consumption of fruit (*P*<0.001), more low-fat dairy foods (*P*=0.003), more legumes (*P*=0.032), lesser amounts medium fat dairy foods (*P*<0.001), less higher fat dairy foods (*P*=0.001), less fatty meat (*P*<0.001), less non-wholegrain (refined) cereals (*P*<0.001) and less NCFD (*P*<0.001). The changes in the dietary pattern resulted in a significant difference in energy intake (*P*=0.018), total dietary fat (*P*<0.001) and dietary fibre (*P*=0.031) (Table 7-4).

Pearson's correlation coefficient determined that a mean score change of 6.5 points (±11.1) was correlated with a mean weight change of -4.7kg (±3.0kg, however while this was significant, the correlation was weak (P=0.023; 0.165) [271]. Logistic regression using the available sample determined that for every one serve increase in NCFD, the odds of weight loss was 0.645 (reduced by 35.5%; *P*=0.004), and that with every one serve increase in non-wholegrain (refined) cereals, the odds of weight loss was 0.825 (reduced by 17.5%; *P*=0.011). Therefore increasing non-core food and drinks and non-wholegrain cereal consumption was less likely to lead to weight loss. Although increasing fruit was less significant in comparison (*P*= 0.061), weight loss was 1.485 times more likely for every one serve increase in consumption.

Table 7-4 Low (≤60%), Medium and High (≥7%) Food Choices Scores by Food Category at 3-months (n=189)

Food Categories	Low scores (n=51) FCS ≤44	SD	Medium scores (n=95) FCS 45-55	SD	High scores (n=43) FCS ≥56	SD	Between groups	Post hoc Low v High
1. Wholegrain foods (30g)	2.8	1.9	3.0	1.8	3.1	1.4	0.690	1.000
2. Non-wholegrain cereals (30g)	3.5	3.0	1.9	1.6	1.7	1.4	<0.001	<0.001
3. Fruit (150g)	1.2	0.6	1.6	0.8	1.7	0.6	<0.001	<0.001
4. Free vegetables (75g)	4.2	2.2	5.1	1.8	5.1	1.9	0.018	0.056
5. Starchy vegetables (75g)	1.0	0.9	0.9	0.6	0.9	0.5	0.754	1.000
6. Legumes (75g)	0.3	0.5	0.5	0.6	0.7	0.7	0.005	0.004
7. Low fat dairy foods:<3.5% fat (150ml)	2.1	1.6	2.7	1.4	3.0	1.2	0.005	0.004
8. Medium fat dairy foods:3.5-10% fat (150ml)	0.6	1.2	0.1	0.3	0.03	0.1	<0.001	<0.001
9. High fat dairy foods: >10% fat (30g)	0.4	0.4	0.2	0.5	0.1	0.1	0.005	0.003
10. Lean Meat & poultry (30g)	3.2	1.7	3.4	2.7	3.0	1.4	0.547	1.000
11. Fatty meat (30g)	0.9	0.9	0.4	0.6	0.3	0.5	<0.001	<0.001
12. Fish & seafood (30g)	1.1	0.9	1.5	1.2	1.7	1.2	0.059	0.091
13. Eggs (1 egg)	0.4	0.5	0.3	0.2	0.4	0.2	0.302	0.805
14. Nuts (and seeds) (30g)	0.4	0.4	0.3	0.4	0.3	0.3	0.326	0.493
15. Unsaturated oils & margarine (5g)	2.4	3.7	2.1	2.5	1.4	1.4	0.174	0.204
16. Alcoholic beverages (400kJ)	0.6	1.0	0.6	0.8	0.5	0.7	0.702	1.000
17.Non-Core foods & drinks (600kJ)	1.8	1.3	1.2	0.8	0.6	0.5	<0.001	<0.001
Nutrients								
Energy (kJ)	6833	1484	6206	1383	6041	1213	0.010	0.018
Protein (g)	86.3	15.1	83.8	21.4	84.4	18.8	0.755	1.000
Fat (g)	52.2	15.8	42.8	14.5	38.9	13.3	<0.001	<0.001
Carbohydrate (g)	181.0	42.4	165.4	39.8	164.3	30.6	0.044	0.114
Dietary-fibre (g)	25.7	6.8	27.1	5.7	29.5	6.4	0.016	0.013

One way ANOVA with post hoc Bonferroni correction

7.5. Discussion

Analyses using the FCS demonstrated the achievement of a maximum score in an idealised diet, and associations between better quality food choices and weight loss, in a setting where high quality foods were advised. The FCS utilised the key suggestions by Waijers *et al* (2007) [195] in terms of content and met the food group and nutrient reference values in an idealised diet model for the highest score of 85. A higher FCS, was consistent with improved diet quality and was associated with increased consumption of fruit, legumes and low fat dairy foods (closer to requirements) and decreased medium and higher fat dairy food, fatty meat, non-wholegrain (refined) cereals and importantly, less NCFD. These food-level changes reflect those also noted by Mozaffarian *et al* 2011 [118] within an observational cohort described earlier. By segmenting participants based on weight loss, it was apparent that those losing the most body weight (>5%), increased their score significantly by 3-months. The highest scores were a reflection of the degree of achievement in terms of diet quality and dietary change over time, although the highest possible score was not achieved by any participants in the sample. Thus we considered the FCS valid and reliable in that the highest score was achieved from an idealised diet model, and the identified changes in consumption of foods using the FCS was consistent with observational studies of foods negatively associated with weight loss. These of course are qualitative assessments, and we were not able to provide an exact measure of precision. Logistic regression using the entire sample suggested that certain foods were more likely to be associated with weight loss and these same food categories were identified by the FCS.

A diet quality tool can fulfil a number of purposes and to date they have been used to support disease predictions, outcome measures, monitoring of foods, food groups, nutrients or combination of these [103, 194, 195]. Many of the tools developed provide a relative score, or an assessment against Dietary Guidelines [195] and have not been tailored for the intervention setting [202]. It has been suggested that a diet quality tool would be suited to the diet assessment process [103]. Furthermore, there are suggestions in the literature [246] that choosing particular foods such as nuts [138] and whole-foods versus more processed-foods [29] may better support weight maintenance. One of the arguments is that the metabolisable energy of the unprocessed food is less than the estimated available energy (reflected in food composition tables) whereas processing may increase the availability of energy. So a measure of diet quality is helpful. Specifically, this analysis highlighted a decreased consumption of non-wholegrain (refined) cereals and NCFD in weight loss, as confirmed by logistic regression further supporting the conclusions using the FCS.

Designing an index of diet quality is highly complex. Many tools have been validated in populations but may have been incorrectly applied in different contexts [195, 199, 202]. There are many forms of dietary scores and there are calls in the literature to be clear regarding the intention of the score [103, 195]. If an index is based on dietary guidelines, it provides a relative measure against that standard, or, if the index is designed with specific culturally based dietary elements, it should really only be applied to that specific population. The FCS was developed to measure diet quality specifically in a weight loss context in which the dietary advice focused on high quality foods. Many arbitrary choices have been made in designing past tools and applying

scores [195]. The advantage of the FCS is that it was developed using context sensitive dietary data and pre-tested with theoretical diet models. This differentiated the FCS from tools appropriate for use at the population-level. In order to develop this clinical research tool, there was a need to define sensible, data-driven cut-off points for each food category so as to not over-emphasise a single food category variable. It is not plausible that all index components contribute equally to the total score or to the same health outcome [195] and this is an issue for some existing tools. The score range for each food category was then validated within the theoretical diet models to ensure the highest score could accommodate current nutrient targets and food recommendations without exceeding the energy range for males and females. Consequently, an alignment with energy, nutrient and food targets was considered of importance in designing the FCS. While energy restriction is pivotal to weight loss, this can compromise nutrient intake or nutritional status [272]. In recent research of dietary patterns at the baseline stage of a clinical trial, we found that weight loss was more easily achieved when poor quality diets were improved [124]. This led us to consider the concept of a diet quality score and how this might change over time in the trial. The emphasis on diet quality in a weight loss context recognises the inter-relationships between foods and food components, and considers the relationship between the dietary pattern and overall health. Importantly the FCS was able to capture as much detail on all foods and drinks consumed in the diet and points to particular foods and drinks as possible targets for the weight loss setting.

Waijers *et al* (2007) has suggested that a diet quality tool include a measurement of two macronutrients as an assessment of overall dietary balance [195], however a

check of nutrients can be easily conducted as an additional analysis without needing to be incorporated into the tool itself. We were able to demonstrate relevant nutrient changes alongside the food category changes. Rather than include a subjective score for overall diet quality as part of the tool, the overall assessment of diet quality was determined by the tool itself and the final FCS [195]. Our research demonstrates that the change in FCS discerned differences in diet quality since the total score was able to distinguish those with improved consumption habits. At 3-months the FCS differentiated those with a greater change in BMI and the overall change in score was correlated with weight loss even though all subjects were prescribed the same energy deficit. Application of the FCS demonstrated that participants can achieve weight loss, while improving diet quality, meeting nutrient requirements and reducing intakes of NCFD appears an important step in achieving this outcome.

The FCS diet index tool was based on data from a small population of overweight to obese subjects (n=189). An important consideration is the interpretation of the score and understanding the limitations of the tool and the score. In this analysis, no participants achieved greater than 80% of the possible FCS and it is recommended that the tool is tested with a group within the healthy weight range to further assess validity of the tool. Food classification was central to the way in which the FCS was developed and there are questions as to the classification of foods, firstly in relation to the nutritional homogeneity within the categories [258], and secondly, that food classification is influenced by how foods are viewed culturally [258]. Like all dietary assessment methods the FCS is context sensitive and may need modification for other clinical settings. The food categories and serve size of each category used in the Food

Choices Score have been utilised in previously published research [124] and the food categories selected reflected the current recommendations concerning foods and food groups in consideration of weight loss [195, 258]. Ensuring that the tool captures the current emphasis in diet-disease relationships represents a limitation and the FCS would need to be adjusted as new evidence about specific foods is established. Finally, all dietary studies must deal with the issue of mis-reporting of dietary data particularly among overweight participants [111]. In this analysis, under-reporters were removed using the Goldberg cut-off limits [131, 132].

7.6. Conclusion

The FCS proved valid when applied to an idealised diet and the highest FCS represented higher diet quality discerning differences in energy and nutrient intakes. Furthermore, weight loss was related to the greater improvement (change) in FCS suggesting that examination of the changing pattern of foods consumed during weight loss is informative and compliments the change in macronutrient intakes. Being able to deliver specific food advice in the clinical setting is pivotal to changed dietary behaviour, and these findings suggest particular foods and beverages may be able to be targeted in weight loss advice. The FCS was specifically designed to align with energy, nutrient and food-based recommendations and together, the analysis of the food categories, energy intake, nutrient intakes, body weight loss and change in BMI, helps validate the FCS. The highest scores using the FCS indicated improved diet quality as a result of dietary change and represents increased reported consumption of positive, core food choices and decreased non-core food and drinks and non-wholegrain cereal choices, giving specific direction for advice in practice. The FCS

proved valid for assessing diet quality in clinical weight loss settings, producing maximum scores in the optimised diet models, and demonstrating expected changes in food choice patterns under supervised weight loss conditions.

CHAPTER 8 DIETARY PATTERN ANALYSIS – SUMMARY, SIGNIFICANCE OF THE RESEARCH AND FUTURE DIRECTIONS

8.1. Thesis summary

The central hypothesis examined in this thesis was that an analysis of dietary patterns reported by overweight participants in a weight loss trial would reveal important practice-relevant information for developing dietary advice. Through this research the changes in food patterns made by more successful participants was informative and directly translational for the clinical setting. Using 17 food categories applied in a secondary analysis of trial data was particularly valuable for examining and discussing the dietary patterns in that context. Specifically studying dietary change and the links with health outcome variables proved a useful adjunct to the usual simple reporting of nutrient intakes with implications for food advice in the clinical setting. Importantly, this thesis tested a number of methods for distilling dietary pattern information with the aim of seeking more information about specific food consumption in a weight loss context.

The research presented utilised various methods of dietary pattern analysis. This was achieved by using clearly defined food categories, empirical statistical methods and a validated Food Choices Score. Chapter 3 defined the food categorisation system and confirmed that more detailed food categories were better than the traditional five food groups in conducting this type of food-level research. Each of the investigations utilised the 17-food categories. In Chapter 4 *a posteriori* methods were reported, then in Chapters 5-7 *a priori* methods of analysis were presented. This secondary examination of the intervention data revealed perspectives on how foods and dietary patterns change. The emphasis in this thesis concerned the whole-diet, although particular food categories were singled out for further investigation (See Chapter 5),

and in order to highlight the shifts in consumption in the weight loss context. Primarily trial dietary data from baseline and at three months enabled a view of food consumption in relation to weight loss achievement. In the end, 12-month dietary data proved useful in showing the re-emergence of non-core foods and drinks (NCFD) in the diet (See Chapters 5 and 6).

These food-level analyses were important, since advice in the clinical setting is always given in terms of foods or meals. Thus the research conclusions were readily translated to practice. This thesis suggests value in conducting analyses of food patterns alongside those of nutrient intake analysis in weight loss interventions. It also suggests that *a priori* and *a posteriori* methods are complementary, and valuable in this context.

8.2. Significance of the research

8.2.1. Food patterns and energy restriction in weight loss

Data from free-living intervention trial participants provided an opportunity to explore how foods and meals are consumed day-to-day and over-time while making dietary changes for weight loss. While energy restrictions are applied in diet prescriptions, the analyses presented within this thesis highlight the efficacy of the "top down" approach described by Jacobs *et al* (2003) [8] in exposing consumption of specific foods in the whole diet. There are numerous components in food, and by consuming whole foods, we take in a range of food constituents, so food pattern intake is more holistic than just measures of nutrient intake. Further, there tends to be some consistency in the weight of food consumed day-to-day in comparison with total energy (See Chapter 3), and it is possible the specific types of foods consumed have a significant impact in

weight management. This can be seen through exchanging NCFD with a greater proportion of fruit and vegetables. Only reporting energy and nutrient intakes is limiting as the kilojoule values for foods may not be accurate (as this is using the Atwater factors for the calculation of average proportions of carbohydrate, protein and fat [138, 159]). The cost of digesting different foods relative to the reported kilojoule values [29] introduces error that cannot be realised at this point in time. This suggests that once a food is ingested, the available energy value may simply not be delivered [138, 159], indicating the need for more detailed food research in the context of a mixed diet [9]. The properties of foods may also influence the amount of food ingested, thereby influencing energy intake. Higher fat, refined carbohydrate food choices such as those manufactured foods and drinks categorised as NCFD, may facilitate passive overconsumption [241]. We do not fully understand how foods and their various components (those that are known and the many that remain unknown) are interacting within the body. Examination of foods within dietary patterns brings new knowledge relevant for the clinical setting and may assist in defining healthier diets [27].

8.2.2. Establishing food categories

In this thesis the initial important step was to establish highly descriptive food categories (See Chapters 2 and 3). By retaining the food information as close to that as was reported in the diet history assessment, the intake of specific food types was able to be reported alongside that of nutrient intakes, anthropometric measurements and levels of disease biomarkers.

The categorisation of foods is complex albeit necessary in order to distil very detailed food information and reveal dietary patterns undergoing change. In this thesis methodological issues were considered in order to obtain a meaningful total diet perspective in the clinical context. In order to research food intake patterns, more defined categories of food from within the five food groups used in dietary guidelines were needed. This enabled a more precise description of relevant and changing dietary patterns. In turn, these were related to outcomes, including weight loss and other clinical measures.

It was important to question the degree to which food categories are formed based on nutritional content, and how homogenous food categories should be for the research purpose [258]. This is especially true in light of the number of food components which may be undiscovered. Consideration of the multiple features of foods, together with the evidence base for relationships between food intake and weight management, assisted in developing the food categories aligned with the objectives of this thesis. This suited the task of defining dietary patterns undergoing change. Defined food categories are likely to be highly culturally specific and the scientific evidence to support categories will undoubtedly evolve. This fact may limit the application of the 17 food categories applied in this thesis, particularly in countries where the diet is substantially different, or at a time in the future when new food-specific knowledge is available. The method of dietary data collection used in the trials captured a greater level of food consumption detail through the use of the clinically accepted assessment method (the diet history). This provided an opportunity to account for subtle differences in food consumption and examine the definable differences in the eating

patterns over time. The integrity of the food information collected was maintained and the findings were easily translated back to the clinical setting. The applicability of the research findings to every-day practice is possibly the most immediate reason for recommending the addition of food-based analyses to dietary intervention research.

8.2.3. Food pattern analyses

At a population-level, dietary data are frequently examined for dietary pattern information, and the techniques applied, such as cluster analysis, are novel within an intervention setting. The known links between certain foods [37, 118] and certain dietary patterns were tested in Chapter 4 where the trial sample was categorised into distinct clusters of intakes. Dietary patterns from this clinical setting showed that while some clients reported foods close to dietary guidelines, others did not. Through identifying dietary patterns at baseline it was shown that dietary habits prior to the dietary intervention are important in relation to dietary change. The idea of being able to link a dietary pattern with an outcome was an especially interesting finding and relates well to the dietary advice setting. The need to limit consumption of NCFD to create an achievable energy deficit for weight loss to occur may be obvious to the dietetic professional, however, it may not be so clear to the client regarding which foods to specifically target, and it may be difficult, depending on food availability, to always avoid these options.

In this research “Cluster 2” was defined as having a high consumption from the NCFD category. In order to specifically examine the types of NCFD, six additional groups of NCFD were created. Consumption and consumption patterns by gender were

monitored providing a clearer depiction of the NCFD consumed, and the differences between clusters. While an additional categorisation of NCFD (See Chapter 5) led to a reasonable description of the NCFD category, a longer term view of shifts in consumption (over 12-months), and in terms of weight loss achievement was valuable. This showed that deviating from dietary advice was linked with a tendency for weight re-gain, especially towards the end of the interventions [86] and a lower level of weight loss overall.

The food environment is particularly conducive to energy consumption and as a food category, the NCFDs are not consistently categorised in terms of the component foods compared with other groups like the fruit group. High consumption of NCFD exists despite the recommendation for most age groups to limit consumption from zero to a maximum of one serve per day (i.e. <600kJ) [64]. A reduction in intake of NCFD choices can improve weight loss success [124] in the short-, and the long-term. However, clients need to accurately report the scope of NCFD consumed so that an assessment of exposure can be made at baseline. Overall this research demonstrates that the NCFD are an extremely modifiable food category [124, 228] and since each serve described in this thesis yields 600kJ, reduced consumption made a significant impact on energy intake. Furthermore, this thesis showed that a step-wise reduction in consumption of this category is related to weight loss (See Chapter 7). Particular choices within the NCFD category, possibly relating to convenience and the social aspects of foods consumption, including between-meal snack foods, may be more difficult to manage over longer timeframes and alternatives may need to be provided in the advice-setting.

8.2.4. Diet Quality scores

The diet quality tool enabled further examination of dietary change. It ranked the overall diet with a theoretical score. While numerous versions of diet quality tools exist for population research purposes, it had been suggested that such a tool would be useful in the clinical setting [103]. However, the tool would need to be designed to suit the research objectives and be sensitive at the clinical level. Measuring dietary change in terms of diet quality over time in the context of dietary interventions is valuable as food substitution is an important strategy in weight reduction. While all foods and drinks consumed in a weight loss context are relevant, the overall quality of the weight reduction diet prescription is an important consideration influencing health outcomes.

In this thesis, the change in the Food Choices Score differentiated those who lost weight (Δ in BMI), however, the significance of this research lay in the fact that firstly, while a reduction in kilojoule intake is important, this is not a guarantee of high diet quality. Secondly, there is no consensus regarding the best diet for weight loss and no single dietary, or lifestyle solution for long-term weight loss. However, certain types and amounts of foods are recommended in dietary guidelines. The fact that weight loss was demonstrated to be greater with higher diet quality scores, means that this research contributes to the body of evidence in this area and is a possible resource for future clinical research. The FCS tool was designed using two energy restricted diet models based on suggested dietary targets and other food-based recommendations for optimised nutrition. The outcomes were linked with BMI change as a measure of the validity of the tool. The tool now requires testing in a healthy population (at

baseline) and in other therapeutic areas where weight loss is essential for improved health outcomes.

8.3. Strengths and limitations of thesis

This thesis is novel in that it tested various analytical methods for monitoring the changing food and dietary patterns in the context of clinical weight loss interventions. In exploring dietary patterns, it was not assumed that methods in existence for large observational cohort studies would be sufficient for use in the clinical setting. By creating food categories derived from the traditional five food groups, and comparing the outcomes, the limitations of simpler methods were tested.

It was noted that food categories generally are culturally specific, and this is a limitation. The categories selected for this thesis were defended in a weight loss context and in line with established scientific evidence (See Chapter 3). It is acknowledged that as new evidence comes to light, the food categories may need to be altered to capture more meaningful food types (i.e. the range of foods) or may need to be more specific, for example, a more precise definition for wholegrain foods (>8g/30g) [273]. The categories would also need to be adjusted to cater for other therapeutic diet prescriptions.

The generalisability of the findings in this thesis may be limited by the overall study context. This is especially true considering the high proportion of participants in the primary trials with tertiary education (64% in SMART and 85% in HEAL). Also, the specific food choices emphasised in the primary trials (fish in SMART and vegetables in

HEAL) may influence the dietary patterns reported, however the food choices at baseline and the change in dietary patterns were more important in the conclusions drawn.

A particular strength is the relevance of each investigation in advancing knowledge of food choice behaviour, and the findings that are transferable to the diet-advice setting. Overall, dietary patterns are important for policy development and dietary guidance since they support the role of the whole diet in preventing disease. The research philosophy pays attention to the detail regarding the generalisations made in research and dietary advice in the past, for example the promotion of nutrient supplements in disease aetiology (e.g. vitamin E or β-carotene [274]), the attention given to single nutrients within the diet (e.g. dietary fat [72]) and advice regarding single foods (e.g. eggs [166]). Instead, an approach for examining the whole diet and foods within dietary patterns [28, 275] is preferred. As such, the methods reveal more about specific foods within changing diets which feeds into the dietary advice setting for weight management.

8.4. Future directions

Based on the results of this thesis, the following recommendations are made for future research in order to examine more closely the dietary pattern change in intervention trials:

i. The food pattern analysis using 17 food categories for examining dietary change in the clinical intervention trial context, demonstrates a valuable approach for

evaluating food choice behaviour during weight loss, and relevant, practical outcomes. Determining the implications of consuming specific foods and food categories within dietary patterns, and building links with health outcomes is needed. Therefore, food pattern analysis alongside nutrient level analysis could be built into clinical trial designs to improve interpretation of nutrient-based findings.

ii. Cluster analysis is underutilised in intervention research. Cluster analysis would be valuable in tracking the food intake of participants over longer timeframes and this is recommended since baseline diets may predict outcomes over longer periods than those examined in this thesis. Trial designs could also consider closer examination and documentation of particularly NCFD at baseline. These foods and drinks were identified as both a problematic food category in the current research, and a particular opportunity in correcting the dietary pattern and in weight loss success. Cluster analysis could be a useful research tool in the pre-clinical trial period to separate participants to identify potential subgroups and this is a worthy consideration.

iii. The Food Choices Score (FCS) was designed to align with energy, nutrient and food-based recommendations and the highest band of scores indicated an improved diet quality as a result of significant dietary change during weight loss. Integrating the FCS as a measure of total diet quality in dietary intervention trials would be complimentary to other food pattern analyses and the integration of the tool would help to focus clinicians and participants on achieving the highest

diet quality. Further testing of the FCS is recommended as no participants achieved greater than 80% of the possible score, and integration within consultations would offer the greatest potential for motivating dietary change with specific food advice.

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APPENDICES

Appendix A: SMART TRIAL information

Trial aim	Is a higher intake of omega 3 fatty acids advantageous for weight loss?
Title	The SMART diet: Investigating the role of foods in weight loss http://www.biomedcentral.com/1471-2458/13/1231
Location	Smart Foods Centre, University of Wollongong, Wollongong NSW 2522 Australia
Chief investigators	LC Tapsell, MJ Batterham, KE Charlton.
Grant name	National Health and Medical Research Council project grant #514631. Australia.
Ethical approval	University of Wollongong and South Eastern Sydney Illawarra Area Health Service health and Medical Human Research Ethics Committee. (Reference Number HE07/323)
ACTRN	12608000425392
Subjects	Subjects (45 males, 45 females) will be recruited from advertisements in local media. A screening questionnaire will be applied. Invited subjects will attend an information evening where they will undergo a diet history assessment and receive an accelerometer and physical activity diary.
Inclusion criteria	Aged 18-45 years, BMI >25 and < 32 kg/m^2, waist circumference >102 cm for men and >94cm for women (NHMRC 2003), and generally well.
Exclusion criteria	Major illnesses, Type 1 and Type 2 diabetes, LDL ≥ 6 mmol/l,

lipid-lowering medication, food allergies or habits inhibiting compliance with the study design, illiteracy and inadequate conversational English, inability to stay in the calorimeter (including smokers), currently taking lipid-lowering drugs, regular use of omega-3 supplements, pregnancy/lactation, not weight stable for past six-months, or on a weight-reducing diet.

See Table 2-1 for further information

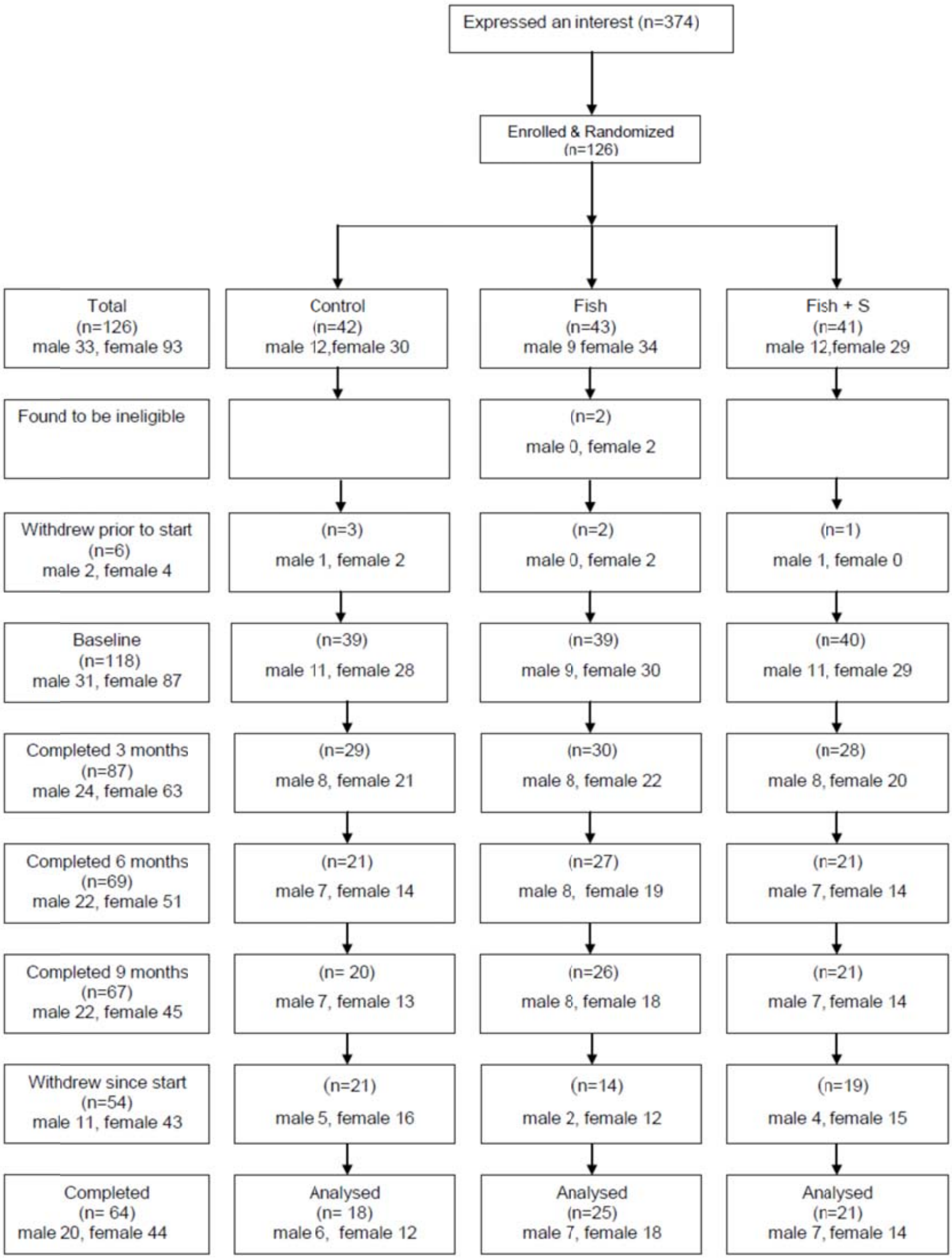


Figure 1. Enrolment, Randomization and Follow-up of Study Participants

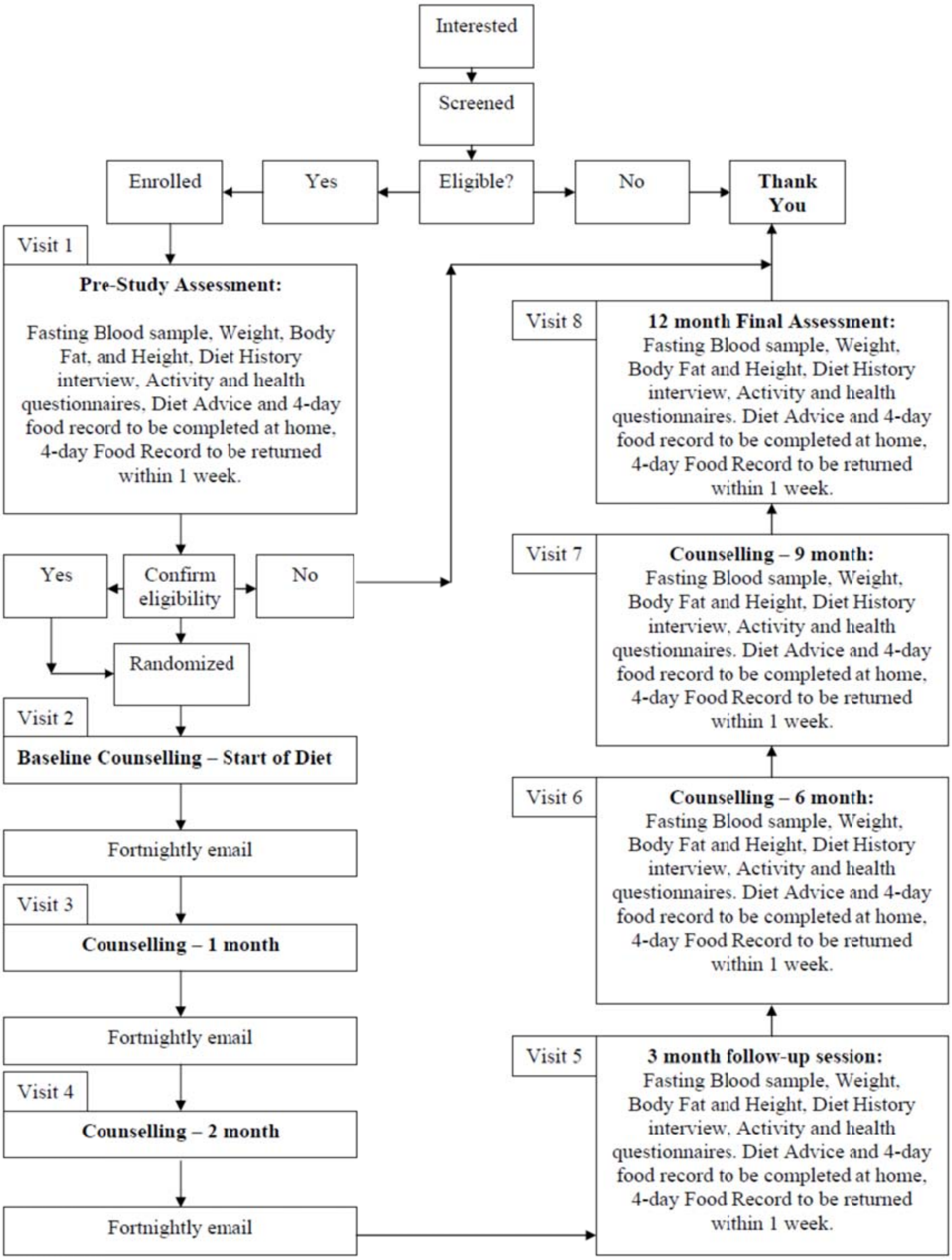
Appendix B: HEAL TRIAL information

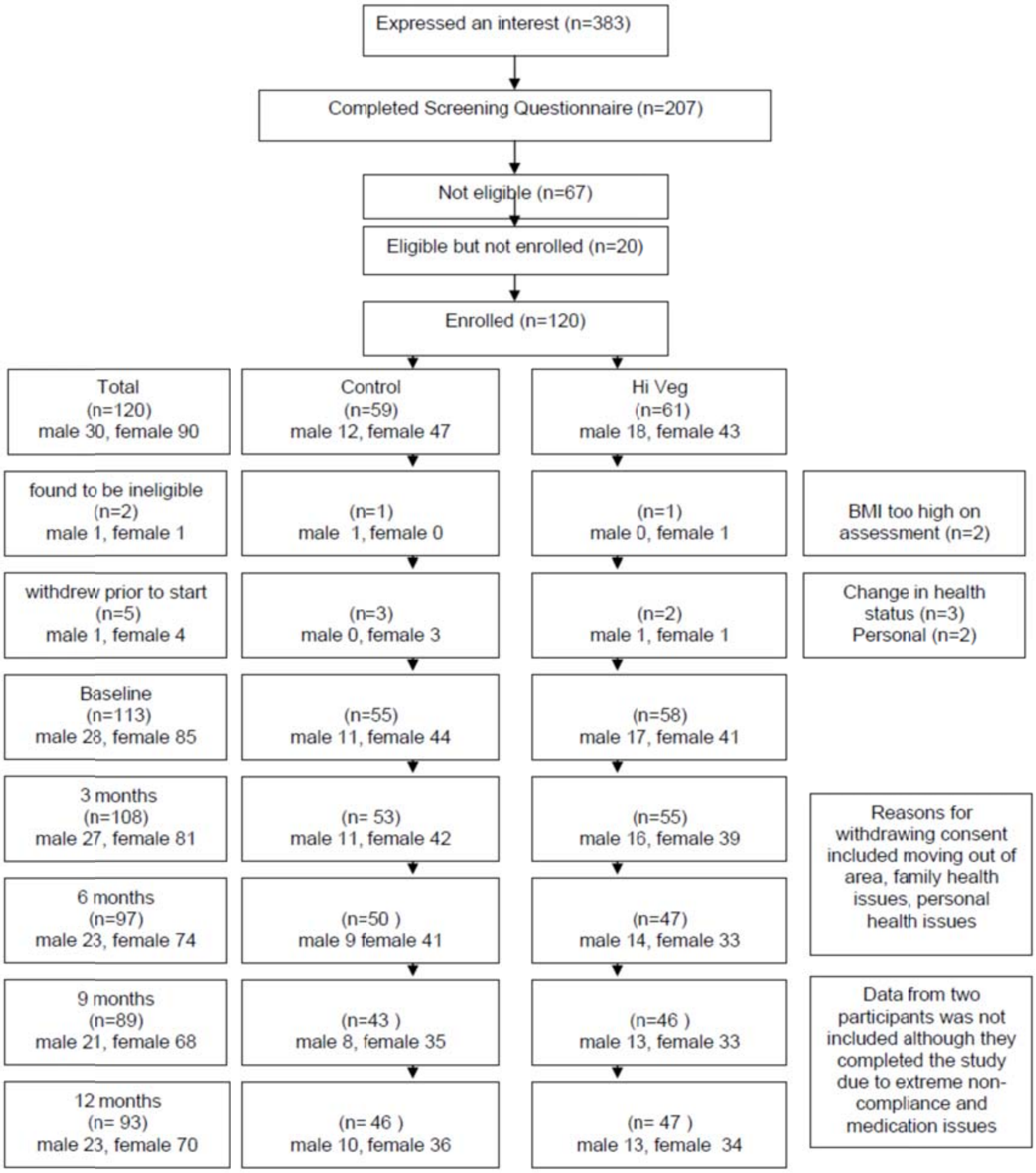
Trial aim	Importance of high vegetable consumption in controlling weight study
Title	Healthy Eating And Lifestyle (HEAL) Trial http://www.nature.com/doifinder/10.1038/ejcn.2014.39
Location	Smart Foods Centre, University of Wollongong, Wollongong NSW 2522 Australia; Together with Curtin University and Queensland Department of Employment, Economic Development and Innovation
Chief investigators	LC Tapsell, M Gidley, S Johnson, D Williams
Grant name/funding	12-month Horticulture Australia Limited (HAL) funded project using the vegetable levy and matched funding from the Australian Government #VG0907
Ethical approval	University of Wollongong and South Eastern Sydney Illawarra Area Health Service health and Medical Human Research Ethics Committee. (Reference Number HE10/192)
ACTRN	12610000784011
Subjects	100 healthy men and women aged 18-65years with BMI > $25kg/m^2$ and < $35kg/m^2$, having no current major medical condition and not pregnant or breast feeding will be recruited through advertisements in local newspapers and television and radio programs and by posted notices in the local community. A screening questionnaire will be applied.

Inclusion criteria	Aged 18 – 65years, BMI > 25 and < 35kg/m2, waist circumference > 94cms for men and > 80cms for women and generally well, have access to the internet, an email address and a mobile telephone.
Exclusion criteria	Major illnesses, Type 1 and Type 2 diabetes mellitus, thyroid abnormalities, history of heavy alcohol consumption; recent acute or chronic diseases likely to affect results; changing medications that may affect body weight; weight loss > 5 kg in last three months; widely fluctuating exercise patterns; strenuous exercise > one hour/day; food allergies or avoidance of major food groups, strict dietary avoidance (including extreme vegetarianism), dislike of vegetables.

See Table 2-1 for further information

The Healthy Eating And Lifestyle (HEAL) Study





Reasons for eligible but not enrolled – spouse of ppt, withdrew interest, or supplementary screening quest not returned

Enrolment based on eligible volunteers who returned supplementary questionnaire – enrolled in order of responses received.

4 participants were unable to attend for complete assessments at 9 month time point. Some paper questionnaires were completed off site.

Figure 1. Enrolment, Randomization and Follow-up of Study Participants

Researcher declaration

Ethics Number: HE10/192

Project Title: Importance of high vegetable consumption in controlling weight study; Healthy Active Lifestyle Study (HAL)

Researchers: Prof Linda Tapsell, Dr Marijka Batterham, A/Prof Philippa Lyons-Wall, Prof Anthony Worsley, Dr Yasmine Probst, Mrs Jane O'Shea, Ms Rebecca Thorne, Mr Qingsheng Zhang

I confirm that I have read the protocol and ethics application for the above project, including the declaration for researchers, and that I understand and accept the responsibilities as described.

Name: Ms Sara Grafenauer

Role in project: PhD student

Qualifications/relevant experience:

BSc (Nutrition) 1991-1993; MSc (Nutrition and Dietetics) 1994-1995; Commenced MSc (Research) in 2008 with planned transition to PhD in 2011. I have an Australian Post Graduate award that will commence with the transition to the PhD program.

Signature:

Date: 30/9/13

Appendix C: Content Validity

Content Validity checklist for Diet Quality indexes adapted from review papers [30, 103, 195, 196]. Ideally, a whole of diet assessment tool would consider the following:

Issue	
Choice of index components making up the score	• Distinguish between whole grains and refined grains[103, 269]. • Include fish as a separate category[195] . • Assessment of dairy and dairy alternatives rather than just calcium; and separate dairy by fat content [195]. • Meat should be divided into fatty and lean choices to assist with discriminating between higher fat cuts, non-trimming of visible fat and higher fat cooking methods. • Alcoholic beverages of should be counted as standard drinks providing equivalent alcohol content or by energy content although this was not considered important by Waijers *et al* [195]. • Fruit and vegetables should be separated [195].
Assigning foods to food groups	• Details regarding the assignment of foods to food categories; See chapters 3 and 4 [244].
cut-off values	• Martínez-González *et al* 2004, suggest that the cut-off points represent the observed dose-response relationships from previous analysis [276]. • Kourlaba *et al* [193] suggested that more than two cut-off points increases the diagnostic capacity and prevents loss of

	information. • Reverse scoring (for meat) and U-shaped scoring (for meat and alcoholic beverages) [195, 270] or a combination of these has been suggested.
Quantification of index components	• Need to ensure that the index components reflect the possible diet i.e. both the extremes of consumption and recommended consumption as per dietary guidelines. For example the Recommended Food Score includes 23 food items, 15 of which are fruits and vegetables. Thus, fruit and vegetables contribute heavily to the food score and do not reflect a balanced diet. • Some indexes are crude and not appropriate for clinical practice. For example the Healthy food index- gives one point for each of the following four diet characteristics: (1) not consuming butter, lard or margarine daily, (2) consuming either raw or boiled vegetables at least once daily, (3) consuming either coarse white or coarse rye bread at least once daily, and (4) consuming fruit at least once daily. These criteria do not adequately quantify intake, they do not match guidelines for consumption or include the totality of food consumed.
Adjustment for energy intake	• The FCS score was adjusted for energy matching dietary data to be able to include males and females. See Chapter 5.

Relative contribution of components to the score	•	Avoid giving equal weight to each of the categories; weight appropriately [103].
	•	The weighting scheme needs to be valid and provide a gradient of intake aligned with scoring. See Chapter 5

Appendix D: The Alternative Mediterranean Diet Score (aMed) and Mediterranean Diet Score (MDS)

Table D-1 aMed scoring

Scoring based on >median=1; <median=0
vegetables (not potato)
Legumes
Fruit
Nuts
whole grains
red and processed meats
fish
alcohol between 5-15g/d
mon:sat ratio

Table D-2 Mediterranean Diet Score (MDS) scoring adapted to daily intake.

	0-0.03/day	**0.031-0.17/day**	**0.171-0.32/day**	**0.321-0.46/day**	**0.461-0.64/day**	**>0.641/day**
non refined cereal (whole grains)	0	1	2	3	4	5
potatoes (starchy vegetables)	0	1	2	3	4	5
Fruit	0	1	2	3	4	5
Vegetables	0	1	2	3	4	5
Legumes	0	1	2	3	4	5
Fish	0	1	2	3	4	5
red meat (all meat)	5	4	3	2	1	0
Poultry	5	4	3	2	1	0
full fat dairy products	5	4	3	2	1	0
olive oil (Unsaturated fat)	0	1	2	3	4	5
Alcohol scored separately	**<3**	**3.1-4**	**4.1-5**	**5.1-6**	**6.1-7**	**>7 or 0**
Alcohol (1 serve =each 400kJ)	5	4	3	2	1	0

Appendix E: Published manuscripts

1. **Grafenauer, S.,** Tapsell, L., Beck, E. and Batterham M. *"Baseline dietary patterns are a significant consideration in correcting dietary exposure for weight loss"*. **European Journal of Clinical Nutrition,** 67, 330–336; doi:10.1038/ejcn.2013.26
2. **Grafenauer, S**., Tapsell, L., Beck, E. and Batterham M. *"Development and validation of a Food Choices Score modelled on diet quality for clinical weight loss interventions".* **British Journal of Nutrition**, Published online: 06 February 2014
3. Tapsell LC, Batterham MJ, Thorne RL, O'Shea, J.E., **Grafenauer, S.J.,** Probst, Y.C., (2014) *"Weight loss effects from vegetable intake: a 12-month randomised controlled trial".* **European Journal of Clinical Nutrition,** advance online publication 26 March 2014.

[illegible]

Appendix F: Preliminary paper

9. Combining functional food components for possible synergistic satiety effects.

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9.1. Introduction

Diet therapy for weight management has typically relied on manipulation of macronutrients and energy. However, there is an emerging greater focus on the types of foods being recommended that may potentially influence satiety, altering the rate of food and energy intake [277]. Different foods vary in their ability to induce satiety effects [278-281] and over an extended period, this may influence body weight. Food components derived from high satiety foods have demonstrated satiety or satiation effects, for example, β-glucan (1→3)(1→4)-β-D-glucan) (BG) from oats [143, 282-285] soy β-conglycinin (Soyβ-C) a fraction extracted from soy protein [286-288] and leucine (Leu), found in whey [289, 290]. The combined and potentially synergistic effect of such food ingredients in relation to satiety has not been tested. This study assesses and compares the potential of these selected ingredients in influencing meal pattern behaviour including satiation, reflecting a decreased consumption of food, meal size and meal duration (intra-meal satiety) and, satiety, a reduced motivation to commence eating the next meal (inter-meal satiety) in mice [291].

Leucine is a branched chain amino acid and is able to cross the blood-brain barrier as a result of post-meal elevations in plasma Leu levels in direct correlation with the amount of Leu in the diet. This is facilitated by the central nervous system (CNS), capillary endothelial cells that act on the hypothalamic neurons and other parts of the CNS [292]. The entry of Leu to the hypothalamus has been found to have a role in regulating feeding behaviour and energy homeostasis in animal studies [289, 290, 293-297] where Leu has been added to drinking water or administered directly via an intracranial catheter. Other studies using Leu show less consistent results [298, 299]. The literature investigating soy protein has identified Soyβ-C as a component having direct action on gut derived satiety signals, particularly cholecystokinin (CCK), but also influencing fat metabolism, helping to promote weight loss and influencing food intake in animals [287, 288] and in humans [286, 300]. In contrast to Leu and Soyβ-C, the influence of BG is dependent on changes in the viscosity within the small bowel lumen, stimulating changes in satiety hormones in a dose dependent manner [143]. Several hormones are involved in this "ileal break", and this has been reported in humans and animals measuring Peptide-YY (PYY) [282, 283] and CCK [143, 285, 301].

Combinations of functional ingredients may be able to stimulate several regulatory hormone systems or pathways simultaneously, thereby strengthening the response, influencing the micro-structure of meals and meal pattern behaviour. A computerised automatic recording system has been used in previous studies [302], and is able to measure meal size, meal number, meal duration, average meal size and inter-meal interval each functional food ingredient was studied singularly and in combination to investigate the impact on meal pattern behaviour and food intake.

9.2. Methods

Animals, diet, and experimental procedures

Thirty two adult C57Bl male mice were obtained from the Animal Resources Centre (Perth, WA, Australia). The mice were housed individually upon arrival in automated ingestive cages or in holding cages, with spill-proof food containers and commenced a one-week acclimatisation period. All mice lived in environmentally controlled conditions (temperature 22°C, light cycle from 0900 to 2100 hours and dark cycle from 2100 to 0900 hours) and allowed ad libitum access to food and water. During this period, mice were fed standard laboratory chow (10% fat, 16% protein and 74% carbohydrate) to allow them to adapt to the new environment (purchased from Y.S. Feeds Pty Ltd, Young, NSW, Australia). Following acclimatisation, the mice were trained over three consecutive days to eat the 100mg control "pill" (containing no functional ingredients) to familiarise them with the treatment protocol and to assess the time needed to consume the test pill. During the experimental period animals were fed homemade lab chow to control the nutritional profile to exact requirements (20% fat; 20% protein; 60% carbohydrate) and added vitamins and minerals in accordance with AIN93 'Diet for Laboratory Rodents' [303]. Table 9-1 provides details of the ingredients used. The food was changed daily during the experimental phase. Outside of this period, mice had their food changed every second day, as per standard animal house procedures.

Treatment and doses

The mice were randomised to one of four treatment groups: control (C), Leu, Soyβ-C or BG, with eight mice per group. The control group received a pill made from cornflour,

purified water and artificially sweetener (Sucralose marketed as Splenda™). Pills were made for each part of the study as a single batch on one occasion and frozen. Each pill was made to weigh 100mg containing ~1.4kJ (0.0014MJ). The treatment groups had one of the three ingredients incorporated into the same mixture without altering the total weight. For each of the three compounds, seven doses (low to high sequentially) were tested in the same group of mice from low to high doses (Table 9-2). The BG (Sigma Life Sciences, β-D glucan from barley) doses were based on local data and others [304]: 0, 3, 6, 12, 25, 38 and 50mg. The Leu (Sigma life Sciences, Reagent grade ≥98%) doses 0, 2.5, 5, 10, 20, 30 and 40mg were based on Lynch *et al* (2003). The Soyβ-C (EPL BIO-Analytical Services) doses 0, 0.3, 0.6, 1.25, 2.5, 3.75 and 5mg were used previously by Nishi *et al* (2003a, 2003b).

Upon initiation of the dark phase and prior to each experimental day, mice were weighed (at 0900 hours) and again after 24 hours as a check of animal health. During the experimental period all of the mice were food deprived for five hours at the start of the dark period. Mice were then administered with the dose (at 1400 hours) without being removed from the food recording cage. The pill was placed on the metal platform in front section of the food recording cage in full view so that consumption could easily be observed. Food was then supplied to each animal behind a trap door and recording of data commenced as soon as the trap door to the feeding basket was opened. Mice consumed food *ad libitum* and ingestive behaviour was recorded for the following 19 hours. The computerised recording system including the frequency of food consumption, interval between meals, termination of feeding, the meal size, and the remaining food and spillage was collected in and under the feeding basket and

recorded automatically by a Lab View™ program (version 7.1/8.2, National Instruments) on a personal computer linked to each cage. Upon completion of the 24-hour period, mice were allowed to feed *ad libitum* for three days between tests (Figure 9-1).

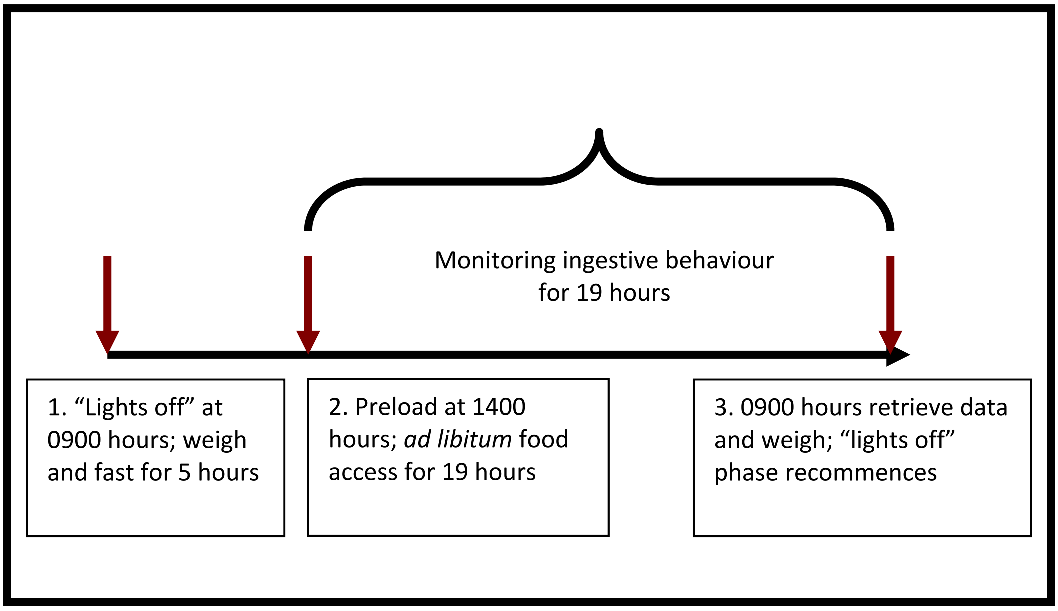


Figure 9-1: 24 hour treatment procedure

The experimental procedure was repeated testing all combinations of the three ingredients (BG+Soyβ-C; BG+Leu; Soyβ-C+Leu and Control). The doses for this study were equivalent to 50% of the maximum dose: Leu 20mg; BG 25mg; Soyβ-C 2.5mg. The pill weight was maintained at 100mg regardless of the ingredients used and the mice remained in the same cage for identification and monitoring purposes but were randomly re-assigned to a group for the second study. All experimental procedures were approved by Animal Ethics Committee, University of Wollongong, Australia and all animal experiments were conducted in compliance with National Health and Medical Research Council (NHMRC) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004)*.

9.3. Statistical Analysis

The digital time series data of food consumed was analysed utilising a windows program developed on the Borland C++ Builder which was designed for analysis of feeding patterns and has been used previously [302]. Built into this program is a set threshold levels whereby food weight is recorded when the scale is altered by more than 0.06 gram over a two second period during a feeding period, thus defining a 'meal' [305]. In order to analyse the period between feeds, that is, the meal interval, the scale must remain undisturbed for a minimum of five seconds. Research has previously defined the inter-meal interval as a period between meals and other feeding bouts of ten minutes [306, 307]. A second custom designed program analysed the grams of food consumed up to the first two hours following the delivery and the

consumption of the pill. Readings were taken at time zero, 5, 10, 20, 40, 60 and 120 minutes.

The meal pattern parameters were calculated as follows: inter-meal interval (min), meal number, meal size (grams) and meal duration (min). The inter-meal interval was calculated as the period between the end of one meal and the initiation of next. Meal size was the weight difference between the initiation and the end of a meal. The meal duration was calculated as the time between the initiation and the end of each meal. Body weight was measured at the beginning of the fasting period and at the end of the 24-hour testing period.

The acute data from the first 120 minutes was analysed using a nested repeated measures ANOVA and a mixed model was used for the full set of data over 19 hours. One way ANOVA was used for the combined ingredient study and to check for change in weight over the 19 hour treatment period with each dose. SPSS 15 statistical package (SPSS, Chicago, IL, USA) was used to analyse the data at 95% CI. Data are reported in the tables supplied as *mean*s ± SD.

9.4. Results

Three mice died of unknown causes during the experimental period unrelated to the experimental procedures.

Single Ingredient effects

Total meal number over time approached significance (*P*=0.054) with fewer meals consumed. Changes in average feed duration (seconds), average meal size (grams), average meal interval (seconds) and total food consumed over 19 hours were not significantly different (Table 9-3 and 9-4).

Total Food Consumed

All mice consumed between 4.6-6.4 grams (96-134 kJ/ 0.096-0.134 MJ) of the home made mouse food over 19 hours and this amount is considered the normal range [308]. There was no significant difference in the amount of food consumed over the test period (19 hours), however in order to capture acute influences of the treatments on the food consumed, data was also selected at 5, 10, 20, 40, 60 and 120 minutes starting from the time when mice were allowed *ad libitum* food intake. There was an influence of dose (*P*=0.022), and dose by time (*P*=0.034), but the individual effects of diet by time by group were not significant (*P*=0.557) (Table 9-5).

Total meal number and average meal interval

The total meal number was not influenced by any of the single ingredient treatments. Mice consumed between eight to ten meals in the 19 hours following the fasting period. At dose four in the BG group (6.9±3.2) and dose five in the Soyβ-C group (6.9±3.4) the total meal number was lower than average and there was a corresponding increase in the average meal interval at the same dose, but neither of these results reached significance.

Average feed duration and average meal size

There were no differences in the average feed duration or the average meal size between the groups.

Body weight

Overall, there was an increase in body weight over time (results not shown) and this is an expected and normal finding as adult mice continue to gain fat mass once they reach adulthood especially under laboratory conditions where ample food is provided at all times and activity is limited by the cage size [309]. There was no difference between pre-test weight and post-test weight during this part of the study.

Combined ingredient effects

There was a tendency towards differences in the total meal number with the combination of Soyβ-C+Leu group (Table 9-6). Mice in this group consumed fewer meals, resulting in a significant difference in the average feed duration ($P<0.05$) (Figure 9-2), and a - 0.4 gram difference in the average amount consumed over 19 hours of feeding, however, this difference was not significant. There was a significant difference between pre-test and post-test weight measurements for this series ($P<0.05$), but no significant difference between groups.

9.5. Discussion

The functional food ingredients selected for these studies have been shown to influence markers of satiety control and body weight and this has been demonstrated

in animals with Leu [290, 295, 310, 311], Soyβ-C [287, 288, 312, 313] and BG [283, 314], and in human clinical trials with Soyβ-C [286, 300] and BG [143, 282]. In this study, the mice were of normal weight and body fat distribution, and the focus of the research was not on weight loss per se, but indications of satiety or satiation effects on meal pattern behaviour.

While there were some interesting trends with longer average meal interval and lower total meal number at dose four in BG group and dose five in the Soyβ-C group possibly indicating some degree of satiety, the results lacked significance. Combining Soyβ-C with Leu resulted in fewer meals on average, having a significant impact on the average feed duration though there was no significant reduction in the food eaten over the period examined. Possibly, the preload "pill" weighing 100mg was enough to blunt the immediate response to the meal that followed the fasting period, and this has been suggested as a limitation by others [302]. Furthermore, it has been acknowledged that in rodents, alterations in meal patterns may not translate into changes in total food intake, since compensatory mechanisms preserve a constant food intake [298].

Following the fast of five hours the mice displayed signs of hunger, clawing at the trap door to the food repository. In humans, increased deprivation results in increased hunger, bite force [315], increased intake and meal duration [316]. The natural reaction of the mice was to feast as soon as food became available after the five hour fast [317]. This drive to eat, may have overridden the potential effectiveness of an oral dose of the food ingredient over the longer timeframe. However, under experimental

conditions, monitoring daily food intake without food deprivation does not help reveal the signalling systems involved in energy balance [317]. From a methodological point-of-view, testing when there is greatest probability that the mice spontaneously consume a large amount of food increases the sensitivity of the test. Foods consumed trigger neural and humoral signals from the gut and liver as digestion progresses [318]. However, it is acknowledged that the time course for different peptides in the gut varies widely [317], and effects may be limited to a single meal [319]. However, whilst we tested ingredients singularly, our hypothesis was based on testing each ingredient in combination, thereby utilising the combined potential and various mechanisms of action of the selected ingredients in a synergistic manner.

The main influence of Leu is via pathways in the brain where it is thought to have a satiety effect. Other studies using Leu administered doses via an intracranial catheter or provided the ingredient in the drinking water so that doses were provided across the study period rather than as a discrete dose, once within the 24 hour period as it was in the current study [289, 310]. Others have noted that in order for specific areas of the hypothalamus to sense Leu, plasma levels need to be significantly increased above normal dietary requirements and this modulates the hypothalamic neuropeptides [320]. In this study, the protein supplied by the diet (20% of energy) was adequate to meet needs [303, 321] and was slightly above what would normally be provided by mouse chow. This amount of dietary protein was also used by Zhang *et al* (2007) in a chronic study of Leu supplementation. Since plasma Leu levels rise in proportion to the protein content of meal, and the uptake across the blood-brain barrier is faster than from any other amino acid [322], even via the oral route, an

influence on the hypothalamus should have been possible. However, Noatsch *et al* (2011) used 53% protein with no effect on body weight or energy homeostasis. It is possible that the imposed fast at the beginning of the dark phase, may have caused an energy deficit and Leu may have been metabolised in the periphery as an energy source by peripheral muscle. Furthermore, as the Leu was administered as a crystalline supplement, not bound within the complex matrix of a whole food, it would have been oxidised quickly [299]. Interestingly others have used much higher doses of Leu delivered orally, between 100-270 mg [311, 323], and logically, those using intracerebral injections of Leu were effective at much smaller doses [289, 290]. Researchers using just 5% fat in the diet have questioned the effect of the background diet in relation to the efficacy of Leu [299], with studies achieving positive effects using a higher fat background diet (60% fat) [311]. However, this suggestion would limit the translation of this research to human dietary recommendations. The home-made diet used the same protein as Zhang *et al* (2007), as this was thought to be the critical component of the diet to maintain in regards to Leu supplementation.

Studies from our laboratory conducted with rodents using oat derived BG showed that a high concentration of BG (7%) had a significant satiety effect in promoting negative energy balance regulation confirmed by weight loss, a reduction in average 24 hour food intake, elevated blood borne satiety hormone of PYY_{3-36} and reduction in the hunger gene expression of hypothalamic arcuate neuropeptide Y (NPY) [283]. An alternative explanation may be due to the physiological nature of BG and its action within the gastrointestinal tract. BG is a viscous fibre source and following consumption of a solid, viscous meal, there is a lag phase [324], delaying gastric

emptying [325]. BG absorbs water as it passes through the gastrointestinal tract, entrapping other food components [326] and increasing the intraluminal viscosity [285] and, due to feelings of fullness, enhanced satiety [314] or more importantly, meal termination. For a clinically relevant physiological response, the increase in viscosity is thought to be necessary, though the gut may adapt to these transient effects [327] and over-ride them.

Reflecting on the results with Soyβ-C, we have considered that it may have been necessary to administer a subsequent dose, or doses, within the 24 hour period in order to observe alterations within the timeframe or, as others have done, include the ingredient in the total diet. A similar simple pill of Soyβ-C was used in human studies yielding results, but this was given as four tablets, twice a day (five grams) [300]. This approach could be adopted, though mice have less distinct meal occasions in comparison with humans and there are some concerns that the brain learns to ignore signals that are not a reliable indicator of calories consumed, including stomach distension [328].

9.6. Conclusion

Certain combinations of the functional ingredients influenced aspects of meal pattern behaviour but were no more effective than the single ingredients. Soyβ-C and Leu together produced an alteration in meal pattern with a significant difference in average feed duration, fewer meals and slightly less food compared with other groups within the 19 hour timeframe, an indication of satiety. There was an optical trend with

some indication of longer average meal interval together with lower total meal number for specified doses of BG (12 mg) and Soyβ-C (2.5 mg), although neither of these measures reached significance. Within the context of nutrition and satiety research, these findings are important in helping to define and challenge previous findings with these ingredients. There may be synergistic effects from the multitude of individual food components available from whole foods, whereby unique combinations of many ingredients across the whole diet possibly assist with satiety effects [9, 28]. However, further investigations would be required to confirm the role of these ingredients in altering meal pattern behaviour and most importantly, overall food intake.

Contribution: X-FH and CP: study concept and design; SJG: data acquisition, data analysis and drafting of the manuscript; X-FH and CP: editing manuscript.

Table 9-1: Ingredient details for home-made Mouse Diet providing 1.2MJ/100g

Ingredient	Amount and Supplier where applicable
Water	400mL
Corn starch	505g, Wheaten Corn flour, FIELDERS
Casein	150g, Acid Casein, FONTERRA
Sucrose	100g
Sunflower oil	100mL, CRISCO
Fibre	50g, MHD
Gelatine	50g, GELITA
Minerals	35g, AIN 93 M mix MP BIOMEDICAL
Vitamins	10g, AIN 93 Vx Vitamin mix MP BIOMEDICAL

Table 9-2: Doses (mg) used for each ingredient together with Corn flour, Distilled water and Splenda™

Doses	β-glucan (mg)	Leucine (mg)	Soy β-conglycinin (mg)
1	0	0	0
2	3	2.5	0.3
3	6	5	0.6
4	12	10	1.25
5	25	20	2.5
6	38	30	3.75
7	50	40	5

Table 9-3: Single ingredients: Total Meal Number, Average Meal size (grams), and Grams eaten over 19 hours (mean ± SD).

Measure	Group	Dose 1 (zero)	Dose 2	Dose 3	Dose 4	Dose 5	Dose 6	Dose 7			
Total meal number	Control	9.9 ± 4.4	10.4 ± 4.6	9.5 ± 5.0	9.5 ± 4.5	9.3 ± 3.0	9.0 ± 1.5	9.6 ± 3.8			
	BG	9.0 ± 3.6	10.4 ± 3.5	9.1 ± 2.7	6.9 ± 3.2	9.4 ± 1.4	10.5 ± 2.7	9.8 ± 2.5			
	Leu	8.8 ± 2.3	9.9 ± 3.1	8.6 ± 2.8	8.4 ± 2.6	8.9 ± 3.7	8.6 ± 4.4	9.7 ± 4.0	**Time**	**Group**	**Interaction**
	Soyβ-C	8.0 ± 2.3	9.5 ± 3.5	8.5 ± 3.3	8.1 ± 3.6	6.9 ± 3.4	8.5 ± 3.0	7.8 ± 2.6	0.054	0.739	0.758
Average meal size	Control	0.5 ± 0.1	0.6 ± 0.3	0.6 ± 0.3	0.8 ± 0.3	0.7 ± 0.4	0.7 ± 0.2	0.7 ± 0.3			
	BG	0.6 ± 0.2	0.5 ± 0.2	0.7 ± 0.2	0.8 ± 0.3	0.7 ± 0.2	0.6 ± 0.2	0.7 ± 0.1			
	Leu	0.6 ± 0.2	0.7 ± 0.2	0.7 ± 0.2	0.8 ± 0.2	0.6 ± 0.2	0.9 ± 0.6	0.6 ± 0.2	**Time**	**Group**	**Interaction**
	Soyβ-C	0.6 ± 0.2	1.0 ± 1.4	0.8 ± 0.5	0.8 ± 0.4	0.8 ± 0.4	0.8 ± 0.5	0.8 ± 0.3	0.154	0.728	0.650
Grams eaten	Control	4.9 ± 0.9	5.8 ± 1.2	4.7 ± 1.5	6.3 ± 1.4	6.3 ± 0.9	6.5 ± 1.1	5.7 ± 1.1			
	BG	5.3 ± 2.3	4.8 ± 2.3	6.1 ± 0.7	5.0 ± 1.9	6.4 ± 1.2	6.3 ± 1.4	6.3 ± 1.1			
	Leu	5.2 ± 0.9	6.2 ± 0.7	5.5 ± 1.3	6.0 ± 0.6	4.7 ± 1.7	6.0 ± 1.8	5.5 ± 0.7	**Time**	**Group**	**Interaction**
	Soyβ-C	5.0 ± 2.4	6.0 ± 1.7	5.2 ± 1.0	5.6 ± 1.0	4.6 ± 1.8	5.9 ± 1.2	5.6 ± 1.4	0.095	0.681	0.140

Table 9-4: Single ingredients: Average feed duration (sec) and Average Meal interval (sec) over 19 hours (mean ±SD).

Measure	Group	Dose 1 (zero)	Dose 2	Dose 3	Dose 4	Dose 5	Dose 6	Dose 7	Time	Group	Interaction
Average feed duration	Control	931.1 ± 758.8	586.1 ± 347.2	699.9 ± 525.2	896.6 ± 771.2	663.8 ± 293.4	632.6 ± 624.5	564.0 ± 349.7			
	BG	890.6 ± 772.3	561.3 ± 287.2	681.9 ± 355.7	941.9 ± 533.5	512.1 ± 153.5	427.1 ± 129.0	506.4 ± 234.2			
	Leu	662.3 ± 250.8	633.9 ± 476.0	566.8 ± 286.0	835.1 ± 612.1	1022.0 ± 1328.3	1407.3 ± 1938.2	771.7 ± 914.2			
	Soyβ-C	685.5 ± 482.9	709.9 ± 759.4	605.0 ± 383.6	1036.0 ± 1406.5	1243.6 ± 1249.2	786.1 ± 509.5	635.0 ± 327.4	0.073	0.860	0.114
Average meal interval	Control	3638.3 ± 1905.8	5029.5 ± 2822.1	5136.9 ± 2367.5	5320.5 ± 2903.6	6553.5 ± 4009.6	4584.0 ± 2113.8	3976.3 ± 1410.2			
	BG	4015.3 ± 2105.0	3603.9 ± 1720.9	6391.8 ± 3114.2	8020.0 ± 9120.4	4591.3 ± 2603.2	5061.5 ± 1663.5	4498.5 ± 2338.0			
	Leu	4182.3 ± 2028.4	4493.1 ± 2215.6	3953.1 ± 1501.7	4097.8 ± 2232.7	4081.6 ± 1633.2	4592.9 ± 877.2	4527.1 ± 1834.1			
	Soyβ-C	5076.4 ± 2791.0	5985.8 ± 5424.2	4305.8 ± 2323.8	4243.1 ± 1551.8	7561.1 ± 9706.3	4880.0 ± 3407.9	4439.4 ± 2186.6	0.543	0.697	0.548

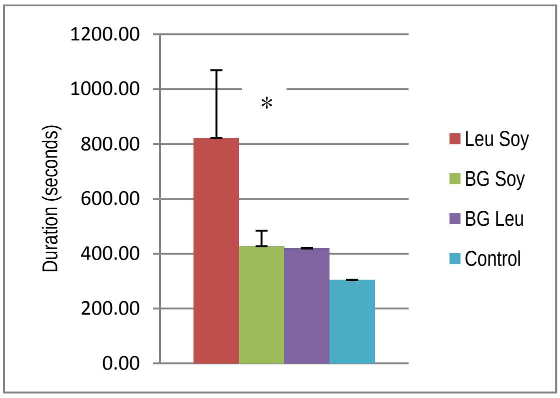
Table 9-5: Single ingredients Food Intake at 5, 10, 20, 40, 60 and 120 minutes (mean grams ± SD).

Dose	Group	5 min	10 min	20 min	40 min	60 min	120 min	
Dose 1 (zero)	Control	0.266 ± 0.126	0.436 ± 0.306	0.758 ± 0.537	1.245 ± 0.702	1.542 ± 0.683	2.412 ± 1.158	
	BG	0.163 ± 0.128	0.311 ± 0.196	0.509 ± 0.335	0.972 ± 0.432	1.396 ± 0.504	2.171 ± 0.662	
	Leu	0.153 ± 0.158	0.438 ± 0.342	0.821 ± 0.343	1.278 ± 0.400	1.630 ± 0.462	2.614 ± 0.693	
	Soyβ-C	0.283 ± 0.332	0.471 ± 0.540	0.726 ± 0.475	1.156 ± 0.565	1.453 ± 0.713	2.032 ± 0.771	
Dose 2	Control	0.252 ± 0.178	0.455 ± 0.346	0.848 ± 0.505	1.465 ± 0.482	1.793 ± 0.528	2.833 ± 0.640	
	BG	0.174 ± 0.115	0.232 ± 0.149	0.412 ± 0.245	1.014 ± 0.416	1.474 ± 0.679	2.288 ± 0.674	
	Leu	0.422 ± 0.414	0.639 ± 0.589	0.892 ± 0.555	1.634 ± 0.508	2.214 ± 0.507	3.104 ± 0.575	
	Soyβ-C	0.289 ± 0.177	0.395 ± 0.207	0.574 ± 0.240	1.008 ± 0.458	1.314 ± 0.623	2.015 ± 1.018	
Dose 3	Control	0.377 ± 0.429	0.480 ± 0.535	0.610 ± 0.648	0.972 ± 0.774	1.551 ± 0.757	2.383 ± 0.767	
	BG	0.265 ± 0.331	0.293 ± 0.200	0.578 ± 0.375	1.093 ± 0.412	1.610 ± 0.473	2.520 ± 0.440	
	Leu	0.230 ± 0.218	0.509 ± 0.416	0.753 ± 0.758	1.177 ± 0.786	1.595 ± 0.659	2.694 ± 0.815	
	Soyβ-C	0.221 ± 0.228	0.380 ± 0.268	0.732 ± 0.430	1.309 ± 0.394	1.617 ± 0.447	1.687 ± 0.529	
Dose 4	Control	0.133 ± 0.226	0.269 ± 0.310	0.655 ± 0.343	1.368 ± 0.581	1.866 ± 0.492	2.996 ± 0.535	
	BG	0.090 ± 0.082	0.135 ± 0.130	0.327 ± 0.272	0.830 ± 0.405	1.191 ± 0.384	2.086 ± 0.650	
	Leu	0.327 ± 0.168	0.549 ± 0.339	0.781 ± 0.493	1.223 ± 0.480	1.695 ± 0.514	2.783 ± 0.738	
	Soyβ-C	0.249 ± 0.133	0.420 ± 0.215	0.622 ± 0.351	1.156 ± 0.589	1.739 ± 0.831	2.765 ± 0.764	
Dose 5	Control	0.237 ± 0.234	0.351 ± 0.311	0.738 ± 0.415	1.168 ± 0.482	1.818 ± 0.464	2.826 ± 0.715	
	BG	0.103 ± 0.109	0.174 ± 0.151	0.402 ± 0.282	0.966 ± 0.494	1.433 ± 0.550	2.301 ± 0.781	
	Leu	0.157 ± 0.203	0.316 ± 0.417	0.663 ± 0.525	1.205 ± 0.722	1.669 ± 0.490	2.473 ± 0.448	
	Soyβ-C	0.200 ± 0.187	0.256 ± 0.121	0.475 ± 0.261	1.133 ± 0.290	1.815 ± 0.471	2.637 ± 0.575	
Dose 6	Control	0.286 ± 0.374	0.451 ± 0.472	0.797 ± 0.472	1.486 ± 0.275	2.222 ± 0.383	3.132 ± 0.759	
	BG	0.178 ± 0.215	0.377 ± 0.235	0.832 ± 0.458	1.566 ± 0.722	2.059 ± 0.823	3.100 ± 0.704	Time: 0.000
	Leu	0.237 ± 0.204	0.439 ± 0.271	0.695 ± 0.436	1.452 ± 0.573	1.783 ± 0.728	2.849 ± 1.133	Group: 0.245
	Soyβ-C	0.196 ± 0.166	0.459 ± 0.285	0.992 ± 0.550	1.937 ± 0.653	2.326 ± 0.659	3.507 ± 0.973	Dose: **0.022***
Dose 7	Control	0.264 ± 0.233	0.646 ± 0.368	0.996 ± 0.572	1.518 ± 0.638	1.951 ± 0.617	2.560 ± 1.043	Dose x Group: 0.879
	BG	0.180 ± 0.160	0.300 ± 0.221	0.729 ± 0.433	1.207 ± 0.384	1.715 ± 0.642	2.577 ± 0.900	Time x Group: 0.207
	Leu	0.225 ± 0.163	0.402 ± 0.405	0.745 ± 0.535	1.178 ± 0.575	1.546 ± 0.652	2.418 ± 0.594	Dose x Time: **0.034***
	Soyβ-C	0.196 ± 0.160	0.347 ± 0.205	0.731 ± 0.356	1.471 ± 0.332	1.864 ± 0.382	1.663 ± 0.572	Dose x Time x group: 0.557

Table 9-6: Longer feed duration in Soy+Leu group influences total meal number and total food consumed compared with other groups.

Group	Total consumed (g)	SD	SEM	Total Meal Number	SD	SEM	Ave Feed Duration (seconds)	SD	SEM
Leu Soy	5.30	1.45	0.55	8.29	4.03	1.52	823.00	602.50	245.97
BG Soy	5.57	1.38	0.49	10.50	2.20	0.78	427.63	159.08	56.24
BG Leu	6.14	0.44	0.16	10.38	1.77	0.63	419.38	75.96	26.86
Control	5.70	0.68	0.24	12.25	2.87	1.01	303.88	46.52	16.45

Figure 9-2 Difference in average feed duration between combined ingredients



*P<0.05