DAA Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults

Report to inform the 2011 revision of the 2005 guidelines

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Table of contents

List of tables

List of figures

Glossary and Abbreviations

Ad libitum	A Latin word meaning as much as one desires. *(Websters Medical Dictionary)*
APD	Accredited Practicing Dietitian
Baseline	The client's initial information at diagnosis, shortly before treatment or before starting a clinical trial. Baseline data is subsequently compared with later tests to indicate change.
Bias	When a point of view prevents impartial judgment on issues relating to the client. Or in a clinical setting when the truth and/or results have been affected by something or someone *(Websters Medical Dictionary)*
Body Image	Body image refers to the picture that a person forms of their body in their mind. A person's body image is influenced by his or her own beliefs and attitudes, as well as ideals in society. One's body image does not remain the same but changes in response to lifestyle events; puberty, pregnancy, disability, illness, surgery, menopause and even different stages in the menstrual cycle. *(Womens Health Queensland)*
BMI	Body Mass Index
Brief Therapy	A short term (usually 10-20 sessions) therapy focussed on helping a person to resolve or effectively manage a specific problem or challenge or to make a desired change. Brief therapy looks more at the here and now rather than the historical aspect of a problem. *(Cognitive Therapy Association)*
Case controlled study	A type of observational analytical study, where all enrolling subjects with the disease (case) are matched to a person with similar profile but without the disease (control) and then compared.
CBT	Cognitive Behavioural Therapy. This is a problem-solving therapy. It is a method that identifies and helps a person to correct specific errors in what he or she is thinking that produces negative or painful feelings. *(Cognitive Therapy Association)*
DAA	Dietitians Association of Australia
Diagnosis	The process of identifying a disease by the signs and symptoms.
Evidence Based	An approach to health care practice in which the clinician is aware of the evidence in support of his/her clinical practice, and the strength of that evidence.
HDL	High Density Lipoprotein. A type of molecule that transports cholesterol from the tissues back to the liver so it can be excreted in the bile. It is considered "good" cholesterol. *(Websters Medical Dictionary)*
Health	Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. *(WHO)*
LDL	Low Density Lipoprotein. A type of molecule that transports cholesterol in the blood from the liver to the tissues of the body. It is considered "bad" cholesterol. *(Websters Medical Dictionary)*

LED	Low Energy Diets .A LED contains 4200 to 5000KJ/day
Mediterranean Diet	A Mediterranean diet is characterised by a large proportion of vegetables, legumes and whole grain. Usually 30 – 40 % of energy is derived from fat; however the fat is predominantly MUFA from olive oil.
Metabolic complications	A secondary disease or negative reaction occurring from the disruption of the metabolism or its related hormones.
Overweight and obesity	A condition of abnormal or excesses fat accumulation to the point where health may be impaired *(WHO)*. The best way to determine overweight or obesity is to measure a person's percentage body fat. However, this is not always practical and BMI definitions and waist circumferences are often used as surrogates, as they have both been found to have strong correlation with total body fat. The WHO has defined overweight as a BMI > 25 kg/m2 and obese as >30kg/m2. In some cases, people can have a high BMI and not be overweight or obese. This can occur in individuals who have a high lean muscle mass and low total body fat e.g. elite athletes.
Pedometer	A small device that is often worn on the belt and predominantly counts the steps a person walks. It can be used as a surrogate for the level of activity. It is generally recommended to maintain health that people achieve around 10,000 steps per day.
Physical Activity	Physical activity is any movement of the body. There are two main types: incidental (which occurs from daily living) and planned or formal activity which is done to expend energy above that of daily living e.g. going for a walk with no other purpose.
Randomised Controlled Trials (RCTs)	A true prospective experiment in which investigators randomly assign an eligible sample of patients to one or more treatment groups and a control group and follow patients' outcomes.
RCT	Randomised controlled trial
RED	Reduced Energy Diet. A RED aims to create a 2000 to 4000 KJ/day deficit in daily energy intake, using initial energy intake as baseline.
Relapses / setbacks	When an individual returns to old habits or does things that are not conducive to weight management.
Resistance training	Often used interchangeably with weight training or strength training. It refers to doing exercises against a "resistance" (normally a weight of some kind).
Restrained Eating	Refers to a eating style that is highly restrictive, that is the person deliberately restricts their intake. People with high levels of restraint often have little control over their eating and display an " all or nothing" pattern of thinking around food.
Risk Factor	A risk factor is something that increases a person's chance of developing a disease. *(Webster's Medical Dictionary)*
Self Esteem	What a person's unconscious believes to be true about how worthy, lovable, valuable and capable they are. It can be thought of as global, which is what they think about their life as a whole, or it can be divided into domains which reflect different aspects of their life such as social aspects, appearance, job

	competency etc
Systematic Review	A review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant primary research, and to extract and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used.
Vigorous Activity	An activity that expends greater energy than 7kcal/min eg race-walking or aerobic walking – 8km/hr or faster (at greater than 75% of the person's maximum heart rate), jogging or running, walking briskly up a hill. *(Center for Disease Control, CDC)* Walking so that the individual is no-longer able to maintain a full conversation without extra breaths.
Visceral Fat	Intra-abdominal fat mass; below the muscle layer and surrounding the organs.
VLED	Very Low Energy Diet. A VLED limits energy intake to 1800 to 2500 KJ/day.
Waist Circumference	Valid measure of abdominal fat mass and disease risk in individuals with BMI less than 35. It is measured half way between the bottom of the last rib and the top of the iliac crest.
WHO	World Health Organisation

Executive summary

Intent of the report

DAA aims to provide leadership in the field of effective dietetic treatments through a range of initiatives. In 2010 DAA commissioned a project to review the current best practice guidelines for dietetic management of overweight and obesity in Australia. The project had four parts:

1. Conduct a systematic review to update the 2005 DAA guidelines (1).
2. Update the 2002 member survey (2)on dietetic services and treatment of overweight and obesity.
3. Undertake a scoping exercise for the development of DAA guidelines for the management of overweight and obesity in children.
4. Liaise with the DAA Obesity reference group in preparation of the revised evidence statements and evidence report.

This document reports the methodology and results for parts one to three.

Part One: Systematic review of the literature

In 2011, a series of systematic reviews and literature reviews were undertaken to inform the revision of the evidence based guidelines. The overall aim of the systematic reviews was to identify the effectiveness of different dietary interventions for overweight and obese adults. More specifically, the following types of dietary interventions were evaluated: Energy restriction, modification of fat composition, modification of carbohydrate composition including glycaemic index (GI) /glycaemic load (GL) , modification of calcium/dairy intake and behavioural/psychological approaches to support dietary interventions. The searches were conducted from 2003 to December 2010.

Each systematic review was undertaken as per the Dietitians Association of Australia Systematic Review Process Manual (3). The methodological quality of all included studies was assessed using the American Dietetic Association's Quality Assessment Checklist. Body of evidence statements were generated as per the National Health and Medical Research Council's process for assessing the body of evidence and formulating recommendations. If the volume of evidence was not sufficient to warrant a body of evidence statement, the evidence was summarised in narrative form.

There was ***Level A evidence*** (i.e. body of evidence can be trusted to guide practice) for the following statements:

- In overweight and obese adults, recommending a very low carbohydrate diet (20 to ≤40g/day with no energy restriction) is not more effective than recommending an energy restricted diet in achieving weight loss in durations of 1 to 5 years
- Achieving a reduction in energy intake, by incorporating meal replacements that are monitored by health professionals, provides greater weight loss in overweight and obese adults than general dietary advice for periods of time varying from 1 to 12 months
- A higher fat / lower carbohydrate diet (30-75%F, 4-45%CHO) is as equally as effective in achieving weight loss in overweight and obese adults as a higher carbohydrate / lower fat diet (20-25%F, 50-65%CHO) for periods of time varying from 6 to 16 weeks, when protein intake and the level of energy intake are held constant.

There was ***Level B evidence*** (i.e. body of evidence can be trusted to guide practice in most situations) for the following statements:

- Recommending a relatively higher intake of MUFAs (up to 23% of total energy) is equally as effective in achieving weight loss as a lower MUFA diet in overweight or obese adults over durations of 4 to 26 weeks.
- Providing calcium supplements (Ca 1000mg/day) as part of an energy restricted diet is as effective in achieving weight loss as a placebo in overweight and obese adults at 6 months.
- A combination of behavioural and psychological therapy and dietary intervention may achieve an additional 2.4-7.7kg greater weight loss than a dietary intervention group alone in interventions of at least 6 months duration but less than 2 years.

There was ***Level C evidence*** (i.e. body of evidence provides some support for recommendations but care should be taken in its application) for the following statements:

- In overweight and obese adults, recommending an energy restriction of a minimum of 2000kJ/day below the current intake or estimated maintenance energy requirements is effective in achieving greater weight loss compared to no treatment in durations of 3 to 6-months.
- In overweight and obese adults, recommending a very low carbohydrate diet (≤20 to <30g/day with gradual increase, and no energy restriction) achieves greater weight loss (average in the range of 2 to 4kg) than recommending an energy restricted diet in durations of 6-weeks up to 6-months.
- A very low energy diet (<4.2MJ/d) that incorporates meal replacements that are monitored by health professionals is as equally as effective in achieving weight loss[#] in overweight and obese adults, as a low energy diet (~4.2-7.5MJ/d) without meal replacements for periods of time varying from 3 months to 5 years.
- A low energy diet (~4.2-5MJ/d) incorporating meal replacements that are monitored by health professionals is as equally as effective in achieving weight loss[#] in overweight and obese adults as a low energy diet (~4.2-5MJ/d) without meal replacements for periods of time varying from 1 to 12 months . At low energy intakes, monitoring of nutrient intakes is important and clients may require multivitamins and/or minerals to optimise nutrient intakes.
- A higher protein / lower carbohydrate diet (25-49%P, 6-45%CHO) is as equally as effective in achieving weight loss in overweight and obese adults as a higher carbohydrate / lower protein diet (12-23%P, 32-75%CHO) for periods of time varying from 1 to 4 months, when fat intake and the level of energy intake are held constant.
- The use of a Mediterranean diet is as equally as effective in achieving weight loss as a range of other dietary interventions with or without energy restrictions in overweight or obese adults.
- Recommending diets that include between 790-2800mg/day of omega three fatty acids (both docosahexaenoic acid and eicosapentaenoic acids) are equally as effective in achieving weight loss in overweight and obese adults in comparison to other dietary strategies that provide lower amounts of omega 3 fatty acids over durations of 3 to 12 weeks.
- In overweight and obese adults, recommending a low GI/GL energy restricted diet of a minimum of 2.1MJ/day reduction (or 30% E restriction) is as equally as effective in achieving weight loss when compared to a moderate or high GI/GL energy restricted diet of a minimum reduction of 2.1MJs/day (or 30% E restriction) diet over a two to six month period.
- A combination of behavioural and psychological therapy and dietary intervention may achieve between 1.4 kg to 4.7kg greater weight loss than a dietary intervention group alone in interventions of less than 6 months duration.
- A combination of behavioural and psychological therapy in conjunction with dietary intervention may be as equally effective at achieving weight loss as a dietary intervention group alone in interventions of 2 years duration.

There was ***Level D evidence*** (i.e. body of evidence is weak and recommendation must be applied with caution) for the following statements:

- In overweight and obese adults, recommending a lower GI ad libitum diet is not different to recommending a higher GI ad libitum diet in achieving weight loss over a 5 to 12 week period.
- Recommending a higher calcium intake (1100-1600mg/day) as part of an energy restricted diet is as equally as effective at achieving weight loss in overweight and obese adults as lower calcium intakes (400-900mg/day) over 12 and 24-weeks.

Part Two: Survey of dietetic intervention in overweight and obesity

An online survey of financial members of the DAA was undertaken from January to April 2011. The aims of the survey were to:

1. To describe dietitians use of the "2002 DAA Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults".
2. To describe current dietetic services and intervention strategies in obesity management.

Members responding to the 2011 survey (n=396, 10% response rate) currently spend a large proportion of their time in the provision of weight management services. Therefore, as a key domain of dietetic practice, it is important DAA supports best practice in this area and exerts strong leadership in this area to ensure its members are able to deliver the best available, evidence informed treatments.

The survey results highlight that while the majority of respondents had accessed the 2005 guidelines, less than one half had read them in full, while approximately a third has partly read the guidelines. This was to be expected, given the guidelines were the first set endorsed by DAA and as such, no implementation strategy had been developed at that time. Members with a greater number of years of experience reported higher levels of confidence and skill in provision of evidence based treatment and had higher best practice score. Overall since 2002 there have been no changes in the reported best practice weight management scores, despite the release of the Best Practice Guidelines in 2005.

Important themes emerging from the survey included barriers to implementing the guidelines within an APD's workplace were related to resource issues rather than perceived knowledge. However key weaknesses identified was related to skills in behavioural treatment to support clients in making dietary change and this was the main request made for continuing professional development opportunities through DAA.

Part Three: Scoping of existing guidelines regarding the management of overweight and obesity in children

The aim of part three was to locate and assess existing best practice guidelines and systematic reviews regarding the management of overweight and obesity in children. The best practice guidelines and systematic reviews were identified using a three step search strategy. Four best practice guidelines and six systematic reviews were located. Therefore, there are a number of existing guidelines and reviews that could potentially be used as a basis of DAA Best Practice Guidelines for the management of overweight and obesity in children.

Recommendations

There are a number of recommendations arising from this report. Weight management continues to be a dominate area of practice for APDs. Therefore, as a key domain of dietetic practice, it is important DAA exerts strong leadership in this area. DAA needs to support best practice ensuring members are able to

deliver the best available, evidence informed dietetic treatments. Therefore it is essential that both DAA members and DAA as the professional body representing members, work together to ensure APDs can provide the evidence that they are the key experts in the nutrition and dietetic management of overweight and obesity and are seen and valued for their expertise in this area.

Recommendations for APDs

APDs should consider the revised evidence statements, along with those previously developed in the DAA 2005 Best Practice Guidelines, and the new NHMRC guidelines that will be released in 2012.

Members should access and use the guidelines to create local CPD opportunities within current workplaces and teams.

Recent graduate APDs should be encouraged to join the Obesity IG and to seek mentoring from colleagues more experienced in weight management.

Members should be encouraged to participate in CPD opportunities provided by DAA related to implementation of Best Practice Weight Management Guidelines.

Recommendations for DAA

DAA needs to have a specific implementation plan that promotes accessible guidelines for implementation or adaptation into varying Dietetic services context to their workplace.

DAA should develop a strategy to increase the number of members who are aware of the content and key evidence based statements within the guidelines.

DAA should develop an easy to use brief implementation step-by-step guide for APDs to use at the point of care with clients to guide individual management.

DAA should prioritise efforts to support implementation of best practice weight management advice by developing practical web-based applications and / or e-tools that could allow access to resources, practice evaluation tools and /or further information.

Given the main barrier to implementing the guidelines for APDs was related to resource issues rather than perceived knowledge, DAA should commit to develop resources both for members and specific evidence informed, practical resources that APDs can use with clients.

Given members with a greater number of years of experience reported higher levels of confidence and skill in provision of evidence based treatment and greater best practice scores, a formal approach to mentoring of new graduates to enhance their weight management skills should be resourced and implemented via the Obesity Interest Group.

Members identified a key area of weakness related to skills in behavioural treatment to support clients in making dietary change and members requested continuing professional development opportunities in this area, therefore DAA should develop a range of opportunities related to this.

Given resources and time are reported as the biggest barriers to implementing best practice, high priority should be given to developing professional resources for APDs, client education resources and investigating innovative technological approaches to ensure more efficient treatment and follow up. These strategies will not only facilitate uptake of guidelines, but enhance the impact APDs make in treatment and ensure DAA is recognized as the leader in provision of effective obesity management in Australia.

1. Part One: Systematic review of the literature

1.1 Background

In 2003 a DAA working party was established to develop evidence based guidelines on the dietetic management of overweight and obesity in adults. These were the first clinical practice guidelines for dietitians that were submitted for endorsement by DAA and these were launched in May 2005.

In 2011, a series of systematic reviews, and literature reviews were undertaken to inform the revision of the evidence based guidelines.

1.2 Methodology

1.2.1 Systematic reviews

The overall aim of the systematic reviews was to identify the effectiveness of different dietary interventions for overweight and obese adults. More specifically the following types of dietary interventions were evaluated:

- Energy restriction /varying the levels of energy restriction, as well as approaches to achieving energy restrictions (e.g. meal replacements, macronutrient manipulation, popular diets)
- Modification of fat composition
- Modification of carbohydrate composition including glycaemic index/glycaemic load and vegetarian diets.
- Modification of calcium/dairy intake
- Behavioural/psychological approaches to support dietary interventions.

Each systematic review was undertaken as per the Dietitians Association of Australia Systematic Review Process Manual (3).

The inclusion criteria for the systematic reviews were as follows:

Types of studies: Systematic reviews of randomised controlled trials, or randomised controlled trials

Types of participants: Overweight and obese adults, however studies that focused exclusively on groups with pre-existing chronic disease such as Type 2 Diabetes were excluded.

Types of outcomes: The primary outcome measures considered were weight (kg), BMI, weight change, waist (cm), waist to hip ratio, waist to height ratio.

Types of interventions: All interventions had the primary aim of achieving weight loss. Studies primarily evaluating a weight loss maintenance intervention were excluded.

An expert medical librarian was employed to develop the detailed search strategies and conduct the searches. The following databases were searched Biosis Previews, Cinahl, Cochrane, Dissertations and Theses, Embase, Informit Health Collection, Medline, PsycEXTRA, PsycINFO , Scopus and Web of Science. All searches were limited to the English language and were conducted from 2003 to December 2010. The keywords used are outline in Table 1.1

Table 1.1: Summary of search strategies for systematic reviews

Obese, overweight, Limit to adults aged 19+	All reviews
Body weight changes, weight loss	All reviews
caloric restriction, diet, reducing (&the terms Very Low Calorie Diet / VLCD; or Very Low Energy Diet or VLED; or Meal Replacement; or Protein Sparing Modified Fast)	Energy restriction only
Diet, Mediterranean, Mediterranean diet	Modification of fat composition only
Glycemic index, glycemic load, vegetarian, plant based diet, fibre, dietary fibre.	Modification of glycaemic index/glycaemic load only
Calcium, Dietary, high calcium, Linoleic Acids, Conjugated.	Modification of calcium/dairy intake only
Behavior therapy, cognitive therapy, relaxation therapy, health behaviour, behaviour change, stages of change, motivational interviewing, social cognitive theory, dietary restraint, emotional eating	Behavioural/psychological approaches to dietary interventions.

All studies identified from the database searches were assessed for relevance from the title, abstract and keywords. Studies meeting all inclusion criteria, or it was uncertain if they met the inclusion criteria, were retrieved. Full articles were reviewed to determine inclusion or exclusion from the systematic review. Each article excluded from the reviews was assigned reason(s) for exclusion. The reasons were categorised as:

- Not a study (e.g. editorial)
- Not a relevant population (e.g. animal study, particular disease group)
- Not a relevant outcome (i.e. the study does not report any of the defined outcomes e.g. weight loss)

The methodological quality of all included studies was assessed using the American Dietetic Association's Quality Assessment Checklist (3). Data related to the characteristics of each study and the results were extracted, using a standardised data extraction form.

Body of evidence statements were generated as per the National Health and Medical Research Council's process for assessing the body of evidence and formulating recommendations(3), which included evaluation of:

- The evidence base, in terms of the number of studies, level of evidence and quality of studies (risk of bias).
- The consistency of the study results.
- The potential clinical impact of the proposed recommendation.
- The generalisability of the body of evidence to the target population for the guideline.
- The applicability of the body of evidence to the Australian healthcare context.

In order to generate body of evidence statements, studies with similar study designs (e.g. the type of interventions/comparators and intervention duration) were grouped together. Body of evidence statements were generated if an appropriate volume of evidence was available for the topic sub-groups (i.e. at least 1 level I study, at least 3 level II studies with a positive quality rating, or at least 5 level II studies (i.e. RCTs) of mixed quality).

If the volume of evidence was not sufficient to warrant a body of evidence statement, the evidence was summarised in narrative form.

1.2.2 Literature reviews

In addition to the systematic reviews a number of literature reviews were undertaken, utilising studies identified in the above mentioned systematic reviews. The interventions were identified opportunistically based on key themes emerging from studies that were not specific to the systematic reviews above, but were recognised as additional topics of interest, pertinent to APDs. This included meal frequency, nutragenetics and drug therapy.

1.3 Results

1.3.1 Energy restriction systematic review

The initial search of the databases located 1309 articles (Figure 1.1). Overall 82 articles, reporting results from 68 studies, met the inclusion criteria. Four of these studies met the inclusion criteria, but were excluded from further data extraction due to their inclusion in an included systematic review. The studies were divided into four distinct research categories: energy restriction (n=12), meal replacements and very low calorie diets (n=22), alterations to macronutrient composition (n=27), and popular diets (n=3).

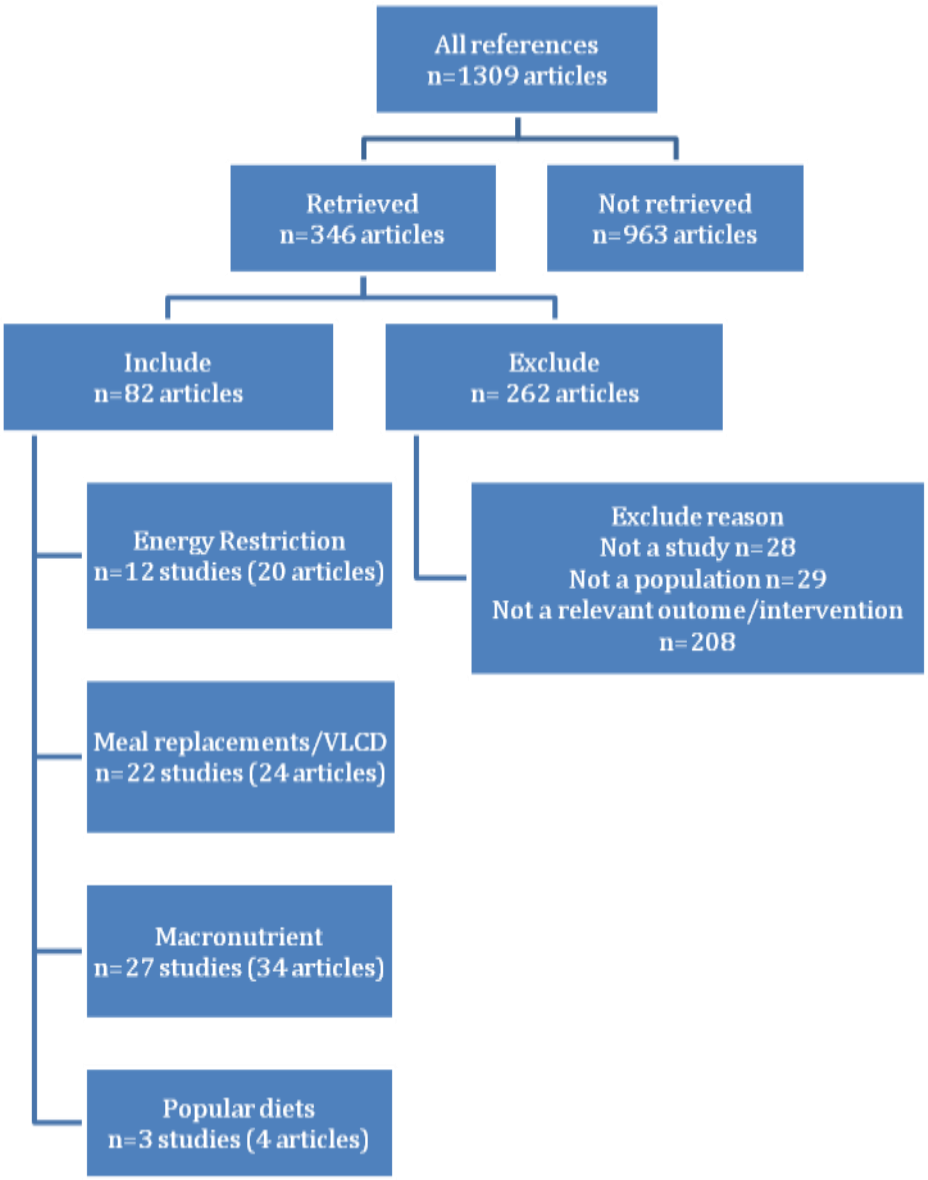

Figure 1.1: Flow diagram of included studies for energy restriction review

1.3.1.1 Energy restriction

For studies related to energy restriction, 12 had data extracted and 12 were used to make two body of evidence statements. Sufficient evidence was found to make statements for an energy restriction compared to no treatment (Table 1.2), and an energy restriction compared to very low carbohydrate diet (Table 1.3).

Table 1.2: Is an energy restriction more effective in achieving weight loss in overweight and obese adults, than no treatment?

Component	Rating	Notes
Evidence Base	Good	6 level II studies with low to moderate risk of bias (4-9). 5 studies had small sample sizes (n<20).
Consistency	Satisfactory	Three studies demonstrated significantly greater weight loss in the energy restriction group (-2.1 to -3.2MJ or 25% reduction) compared to no treatment, after 12 weeks to 6-months. Two RCTs did not present weight loss results as a comparison between two groups (energy restriction vs. control) therefore the effectiveness was unclear. One RCT showed no significant difference in weight loss between an energy restriction (-2.1MJ) and no treatment for 6-months.
Clinical impact	Good	The three studies that demonstrated significantly greater weight loss in the energy restriction group compared to no treatment reported results inconsistently (i.e. 6kg, 9% and unclear)
Generalisability	Good	Of the 3 studies reporting greater weight loss, 1 was in females only.
Applicability	Excellent	Most RCTs provided behavioural/dietetic consultation, one provided food to participants
Recommendation		***In overweight and obese adults, recommending an energy restriction of a minimum of 2MJ/day below the current intake or estimated weight maintenance energy requirements is effective in achieving greater weight loss compared to no treatment in durations of 3 to 6-months.***
Grade of recommendation		**C**

Table 1.3: Is an energy restriction or very low carbohydrate diet more effective in achieving weight loss in overweight and obese adults?

Component	Rating	Notes
Evidence Base	Excellent	1 Level I study (10) and 5 Level II studies with low risk of bias (11-15).
Consistency	Excellent (long-term) Satisfactory (short-term)	A systematic review showed no difference between very low CHO (≤40g/day) with no energy restriction and energy restricted (4.2-6.7MJ) diets in the long-term, from 1 to 5 years. Two additional RCTs showed no long-term (12/24months) difference in weight loss between very low CHO (20g CHO with gradual increase) and energy restriction. Three RCTs showed greater weight loss for very low CHO diet (range from ≤20g/day to <30g/day, with gradual increases in CHO) in the short term (after 6 weeks or 3 and/or 6 months). Two studies showed no difference in weight loss between very low CHO diet (≤20g CHO, with gradual increase in CHO in one study) and energy restriction after 6 weeks or 3 and 6 months of treatment.
Clinical impact	Good	The very low CHO groups achieved an average 2 to 4 kilogram greater weight loss compared to the energy restricted group over the short term (6 weeks up to 6 months), with no significant difference in weight loss between very low CHO and energy restriction after 1 to 5 years.
Generalisability	Excellent	Populations in body of evidence can be contextualised to overweight and obese adult Australians.
Applicability	Satisfactory	Majority of RCTs provide moderate to extensive behavioural/dietetic consultation
Recommendation		***In overweight and obese adults, recommending a very low carbohydrate diet (20 to ≤40g/day with no energy restriction) is not more effective than recommending an energy restricted diet in achieving weight loss in durations of 1 to 5 years.***
Grade of recommendation		**A**
Recommendation		***In overweight and obese adults, recommending a very low carbohydrate diet (≤20 to <30g/day with gradual increase, and no energy restriction) achieves greater weight loss (average in the range of 2 to 4kg) than recommending an energy restricted diet in durations of 6-weeks up to 6-months.***
Grade of recommendation		**C**

1.3.1.2 Meal replacements and VLCDs

For studies related to meal replacements and very low energy diets (VLEDs), 22 had data extracted and 14 were used to make three body of evidence statements. Sufficient evidence was found to make statements regarding: low energy diets with meal replacements compared to low energy diets (Table 1.4), a VLED with meal replacements compared to a low energy diet (Table 1.5), and reducing energy intake with meal replacements compared to general dietary advice (Table 1.6).

Table 1.4: Does a low energy diet (~4.2-5MJ/d) that incorporates meal replacements achieve greater weight loss in overweight and obese adults compared to a low energy diet (~4.2-5MJ/d) without meal replacements?

Component	Rating	Notes
Evidence Base	Satisfactory	1 level I study (neutral) (16) and 4 level II studies with moderate to low risk of bias (1 positive, 3 neutral) (17-21).
Consistency	Poor	The level I study showed significantly greater mean weight loss (2.6kg) in meal replacement group (partial) after 3 months, and 2.43kg greater weight loss after 1 year. 4 RCTs compared low energy diets using meal replacements (1 RCT had full use of meal replacements, with 3 RCTs having partial use) with low energy diets without use of meal replacements. 1 RCT showed significantly greater weight loss in meal replacement group (MR (partial) -13.5kg, n=28 vs. diet only -6.5kg, n=20) at 16 weeks, but no difference post-intervention at 40 weeks (MR -8.9kg vs. diet only -5.7kg). No differences in weight were observed between groups for remaining 3 RCTs with duration of 1 to 12 months (-2.7kg to -9.2kg), in sample sizes of 23-25. No trials showed greater weight loss in diet only group.
Clinical impact	Satisfactory	The systematic review showed 2.6kg greater weight loss with meal replacements at 3 months and 2.43kg after 1 year. Only 1/4 RCTs showed differences in weight between the intervention arms and found 7kg greater weight loss in MR group at 16 weeks. However 3 remaining RCTs found no differences between groups.
Generalisability	Excellent	Population in body of evidence can be contextualised to overweight and obese Adult Australians
Applicability	Satisfactory	The evidence base is relevant to the Australian health care setting generally. 3 RCTs were conducted in the US, and the remaining 1 in Australia. No RCTs held weekly meetings with participants and all 4 RCTs provided meal replacements or the equivalent financial compensation to the diet only group, to participants during intervention.
Recommendation		***A low energy diet (~4.2-5MJ/d) that incorporates meal replacements that are monitored by health professionals is as equally as effective in achieving weight loss[#] in overweight and obese adults as a low energy diet (~4.2-5MJ/d) without meal replacements for durations of 1 to 12 months.***
Grade of recommendation		**C**
[#] Amount of weight lost not provided due to large variations in study durations used in RCTs.		

Table 1.5: Does a very low energy diet (<4.2MJ/d)* that incorporates meal replacements achieve greater weight loss in overweight and obese adults than a low energy diet (~4.2-7.5MJ/d) without meal replacements?

Component	Rating	Notes
Evidence Base	Good	2 level I studies with moderate to low risk of bias (1 positive, 1 neutral). (10, 22)
Consistency	Poor	2 systematic reviews compared very low energy diets that incorporate meal replacements with low energy diets without meal replacements. 1 review showed significantly greater mean weight loss (6.4%) in meal replacement group (MR (partial) -16.1% vs. diet -9.7%) when prescribed for an average duration of 13 weeks, but no difference post-intervention (1-5 years follow up) (MR -6.3% vs. diet -5%). No trials showed greater weight loss in diet only group. However the other review showed no significant difference in weight change between groups after 12-months (-0.15kg (95% CI: -2.73 to 2.43kg, MR: -7% vs. diet -4%) and after 18-months (-1.13kg (95% CI: -5.32 to 3.06kg), MR: -7-8% vs. diet 3-7%).
Clinical impact	Poor	1 systematic review found that a very low energy diet that uses meal replacements leads to 66% greater weight loss than low energy diets without meal replacements, however another review found no differences between groups.
Generalisability	Excellent	Population in body of evidence can be contextualised to overweight and obese Adult Australians
Applicability	Good	The evidence base is relevant to the Australian health care setting generally.
Recommendation		***A very low energy diet (<4.2MJ/d)* that incorporates meal replacements that are monitored by health professionals is as equally as effective in achieving weight loss# in overweight and obese adults as a low energy diet (~4.2-7.5MJ/d) without meal replacements for periods of time varying from 3 months to 5 years.***
Grade of recommendation		**C**
# Amount of weight lost not provided due to large variations in study durations used in articles.		
* <4.2MJ was defined by review studies		

Table 1.6: Does reducing energy intake and incorporating meal replacements achieve greater weight loss in overweight and obese adults than general dietary advice?

Component	Rating	Notes
Evidence Base	Excellent	7 level II studies with moderate to low risk of bias (4 positive, 3 neutral) (23-29).
Consistency	Excellent	7 RCTs compared energy reduction diets using meal replacements (3 RCTs had full use of meal replacements, with 4 RCTs having partial use, 2 VLED, 3 LED, 2 RED) with general dietary advice. All 7 RCTs showed significantly greater weight loss in meal replacement group (MR -2.8kg to -18.5kg vs. general advice -3kg to +0.54kg) with duration of 1 to 12 months in sample sizes of 5-46. 4/6 RCTs also measured body fat. 3 RCTs had greater fat mass loss (MR: -4.3kg to -4.6kg n=37-44, and -0.28-0.95%, n=45 vs. general advice: -1.4kg to +1.3kg, n=37-42, and +0.41%, n=91) with duration of 1 to 6 months, and 1 RCT found no differences in % body fat (MR: -0.28 to -0.95% vs. general advice: +0.41%, n=97 vs. 36) over 1 month.
Clinical impact	Excellent	All 7 RCTs showed greater weight loss with energy reduction diets that use meal replacements compared with general dietary advice.
Generalisability	Excellent	Population in body of evidence can be contextualised to overweight and obese Adult Australians
Applicability	Good	The evidence base is relevant to the Australian health care setting generally. 4 RCTs were conducted in the US, and the remaining 3 in Europe.
Recommendation		***Achieving a reduction in energy intake, by incorporating meal replacements that are monitored by health professionals, provides greater weight loss[#] in overweight and obese adults than general dietary advice for periods of time varying from 1 to 12 months.***
Grade of recommendation		**A**
[#] Amount of weight lost not provided due to large variations in study durations and energy deficits used in RCTs.		

An additional 11 RCTs could not be or were not aggregated into a body of evidence statement related to meal replacements. One RCT compared a very low energy diet using meal replacements to laparscopic adjustable gastric band (LAGB) and found weight loss was similar in the short term but LAGB was able to maintain weight lost in the longer term (30). Five RCTs (29, 31-34), compared energy reduction diets using two different meal replacements with different macronutrient proportions (macronutrient profiles varied greatly between studies). 2 RCTs found a difference in weight loss between groups. 1 observed that higher protein MRs achieved greater weight loss (32) and the other study found greater body fat loss in the lower CHO group (29). The remainder of RCTs showed no differences in weight and fat weight lost.

Four RCTs (28, 35-37)compared two different meal replacements with similar macronutrient profiles. Meal replacement (MR) products compared included: casein vs. soy MR shake; cereal substitution and nutrient bar vs. cereal and waffle substitution and nutrient bar vs. cereal substitution alone; GMP-enriched whey protein isolate MR (Natrapep) vs. skim milk powder MR; and Allevo MR (milk & soy protein) vs. Nutrilett MR (soy protein). All 4 RCTs found no differences in weight or fat loss between groups.

One RCT (38) compared two different meal replacements both with different levels of energy restriction. No difference was observed in weight lost between groups.

1.3.1.3 Macronutrient composition

For studies related to manipulating macronutrient composition, 24 had data extracted and 19 were used to make 2 body of evidence statements. Sufficient evidence was found to make statements on the manipulation of protein and carbohydrate (Table 1.7) and fat and carbohydrate (Table 1.8).

Table 1.7: Does a higher protein / lower carbohydrate diet achieve greater weight loss in overweight and obese adults compared to a higher carbohydrate / lower protein diet, when fat intake and the level of energy intake are held constant?

Component	Rating	Notes
Evidence Base	Good	1 level I study (neutral)(39) and 10 level II studies with low to moderate risk of bias (9 positive, 1 neutral) (40-49)
Consistency	Poor	The systematic reviews results were inconclusive. Of the 8 RCTs that manipulated protein and carbohydrate in the review, 3/8 longer term studies found greater weight loss on a higher protein diet (12-21%P vs. 25-49%P, 6-45%CHO vs. 32-75%CHO; 2.8-5.5kg over 6 months) and the remaining 5/8 studies found no difference between groups (15-20%P vs. 27-45%P, 32-45%CHO vs. 53-60%CHO, 1-16 weeks, 2.1-8kg wt loss). No studies found greater wt loss on lower protein diets. 6/8 studies in the review also measured body fat. 1/6 studies found a 3.3kg greater fat wt loss on higher protein diet (12%P vs. 25%P, 45%CHO vs. 58%CHO) over 6 months, and remaining 5/6 studies found no differences in weight (2.8-6.9kg) between higher and lower protein groups (15-20%P vs. 27-40%P, 25-45%CHO vs. 57-75%CHO) over 1-16 weeks. No studies found greater fat weight loss on lower protein diets. 10 RCTs measured weight. 2 RCTs found a 2.8% and a 2.5kg greater improvement in weight with higher protein diets (30-45%P, 40-42%CHO) than with lower protein diets (15-23%P, 55-64%CHO) over a 2-3 month duration, with an additional RCT showing a trend for 2.2kg greater improvement to weight with a higher protein diet (30%P, 40%CHO) when compared with a lower protein diet (15%P, 55%CHO) over 4 months. The remaining 8/10 studies found no differences in weight between groups (1-4 mth duration (plus 1 RCT with 24 month duration), 25-32%P vs. 14-18%P, 35-45%CHO vs. 50-66%CHO, ~3-10kg over 4-12 weeks with 1 RCT of 52 weeks and another RCT of 104 weeks duration), and no studies found that higher CHO intakes achieved greater weight loss than higher protein intakes. 5 RCTs measured body fat. 3 studies with 1.5 - 3 months duration found no differences between high and low protein diets (30-34%P vs. 14-17%P, 40-46%CHO vs. 55-66%CHO, -0.4 to -18.4% body fat change). 1 found 1kg and 1.7kg greater body fat loss on a higher protein diet (30 vs.15%P, 40 vs. 55%CHO) at 4 and 12 months. Another found a 3% greater reduction in body fat with higher protein diets (30 vs. 15%P, 40 vs. 55% CHO) over 4 months. 1 RCT found no differences to waist circumference over 24 months.
Clinical impact	Poor	No pooled results from systematic review. The RCTs that did find differences had greater weight and fat losses by 19-74% and 22-77% respectively than the lower protein group. No studies found greater weight or fat loss in lower protein diet group.
Generalisability	Excellent	Can be contextualised to overweight and obese Adult Australians
Applicability	Good	The evidence base is relevant to the Australian health care setting generally. 1 RCT was conducted in Australia, 1 in Spain, 1 in Canada and the remaining 7 in the US. However, 9/10 studies held weekly meetings with participants and 3/10 studies provided food to participants during intervention.
Recommendation		***A higher protein / lower carbohydrate diet (25-49%P, 6-45%CHO) is as equally as effective in achieving weight loss in overweight and obese adults as a higher carbohydrate / lower protein diet (12-23%P, 32-75%CHO) for periods of time varying from 1 to 4 months, when fat intake and the level of energy intake are held constant.***

Grade of recommendation	C

Table 1.8: Does a higher fat / lower carbohydrate diet achieve greater weight loss in overweight and obese adults compared to a higher carbohydrate / lower fat diet, when protein intake and the level of energy intake are held constant?

Component	Rating	Notes
Evidence Base	Good	1 level I study (positive)(50), and 7 level II studies with low to moderate risk of bias (5 positive, 2 neutral)(48, 51-56).
Consistency	Excellent	A systematic review found no difference in weight loss between low fat (20-21%F, <30g/d) and high fat diets (30-35% of E from fat, <50g CHO/d) at 6 months (weighted sum of weight loss: -6.5kg (95%CI -7.3 to -5.7kg) vs. -5.08kg (95%CI -5.9 to -4.3kg)) and 12 months (weighted sum of weight loss: -3.4kg (95%CI -4.2 to -2.6kg) vs. -2.3kg (95%CI -3.2 to -1.4kg). 7 RCTs compared high fat/ low CHO diets (40-75%F, 5-45%CHO) with low fat/high CHO diets (20-25%F, 50-65% CHO). No differences in weight were observed between groups for all 7 RCTs with duration of 6-16 weeks (-4.35kg to -11.6kg), plus one study of 24 months (~-3kg), in sample sizes of 4-30, with 2 RCTs having sample sizes in each intervention arm of n=201-204 and n=382-9.
Clinical impact	Good	Pooled results from systematic review did not always contain relevant studies but when data was extracted generally found no differences between high fat/low carbohydrate and low fat/high carbohydrate diets. No differences in weight loss were observed in the RCTs.
Generalisability	Excellent	Population in body of evidence can be contextualised to overweight and obese Adult Australians
Applicability	Good	The evidence base is relevant to the Australian health care setting generally. 5 RCTs were conducted in the US, and the remaining 2 in Europe. However, 6/7 studies held weekly meetings with participants and 3/7 studies provided food to participants during intervention.
Recommendation		***A higher fat / lower carbohydrate diet (30-75%F, 4-45%CHO) is as equally as effective in achieving weight loss[#] in overweight and obese adults as a higher carbohydrate / lower fat diet (20-25%F, 50-65%CHO) for periods of time varying from 6 to 16 weeks, when protein intake and the level of energy intake are held constant.***
Grade of recommendation		**A**
[#] Amount of weight lost not provided due to large variations in study durations and energy deficits used in RCTs.		
One study suggested low fat diets may be more appropriate for insulin sensitive people and low carbohydrate diets for insulin resistant people.		

Two level I studies (39, 57)and 9 level II studies (58-65) manipulated all three macronutrients, however the macronutrient profiles of the diets varied greatly between studies such that they could not be aggregated into a body of evidence statement. The two level I studies concluded evidence was insufficient to determine whether greater weight loss was achieved with a particular macronutrient composition when all three macronutrients were manipulated. All RCTs found similar weight loss between groups with a 1-6 month duration, with 1 RCT having duration of 2 years.

1.3.1.4 Popular diets

Three RCTs comparing popular press or commercially available weight loss programs have been evaluated. No body of evidence statement could be formed due to the difference study aims and interventions.

The first by Truby et al (66)compared the Atkins Diet (n=57), Weight Watchers (WW) (n= 58), Slim-Fast (SF) meal replacement program (n=59), Rosemary Conley (RC) low fat dietary program (n=61) versus a control group (n=61) over a 6 month intervention in overweight and obese, but relatively healthy adults. The participants were then followed up till 12 months. The mean (SD) reductions in total body weight (TBW) and body fat (Fat) from baseline to 12 months were Atkins [TBW 6.0 (6.4) kg, Fat 4.6 (4.8kg)]; WW [TBW 6.6(5.4) kg, Fat 5.0 (4.3) kg]; SF [TBW 4.8 (5.6) kg, Fat 3.4(4.3) kg]; RC [TBW 4.86 (5.6) kg, Fat 3.4(4.3) kg]. Monthly weight loss was initially high in all groups but then slowed with the mean weight loss during the first four weeks significantly higher in the Atkins group ($p<0.001$). However, at other time points mean weight loss did not differ significantly between the diet groups. Between baseline and 6 months fat loss did not differ between diet groups but fat loss in all diet groups was significantly greater than in the control group. The absolute weight loss after 6 months from all the dietary approaches was clinically important, but there were no significant differences between them. Every dietary approach was more successful than the control group, who gained weight (0.95%). The proportion of individuals in each group who completed the trial, and lost at least 10% body weight at 6 months were 46% for RC, 45% for Atkins, 36% for WW and 21% for SF.

The second by Gardner et al (67)compared four popular approaches for a duration of 12 months. This trial was only in pre-menopausal women (aged 25-50 yrs) who were overweight or obese but relatively healthy. The diets compared were Atkins (n=77), ZONE (n=79), Ornish (n=76) and the LEARN (n=79) diets with no control group. Atkins used a ≤ 20g/day CHO intake during an induction phase and ≤ 50g/day during the weight loss phase. The Ornish diet was a <10% energy from saturated fat diet. LEARN was a 55-60% energy from CHO with <10% saturated fat plus increased physical activity plus an energy restriction. ZONE was a 40% CHO, 30% protein, 30% fat diet, plus an energy restriction. Weight change (mean, 95%CI) over 12 months was Atkins -4.7kg (95% CI -6.3 to -3.1); Zone -1.6 kg (95% CI -2.8 to - 0.4); LEARN -2.2 kg (95% CI -3.6 To-0.8kg); and ORNISH -2.6kg (95%CI -3.8 to -1.3). The 12 month weight change was significantly greater in the Atkins versus the ZONE diet but the weight change among the ZONE, LEARN and Ornish groups was not significantly different at any time point. There were no significant differences in body composition between the four groups at 12 months.

The third study by Dansinger et al (68)compared the impact of the Atkins, Ornish, Weight Watchers, and ZONE diets on both weight loss and heart disease risk over 12 months. The participants were overweight or obese men and women of any age and had to have at least one cardiac metabolic risk factor, but without a chronic condition. There were 40 participants allocated to each group and there was no control group.

Atkins used a ≤ 20g/day CHO intake during an induction phase and up to 50g/day during the weight loss phase. The Ornish diet was a vegetarian diet with <10% energy from saturated fat diet. ZONE was a 40% CHO, 30% protein, 30% fat diet and the Weight Watchers (WW) followed a 24 to 32 points daily plan which as the approach to achieving an energy restriction.

The 12 month weight change (mean ± SD) was Atkins -2.1 ± 4.8kg; Zone -3.2± 6.0kg; WW -3.0 ± 4.9kg; ORNISH -3.3 ± 7.3 kg. All diets resulted in statistically significant weight loss at one year but there were no significant differences between them ($p=0.40$). Approximately 25% of the initial participants from each diet group sustained a one year weight loss of >5% of initial body weight and 10% lost >10% body weight.

Taken together, these three trials highlight popular press or commercial approaches to weight loss can be successful in achieving modest weight loss, although this is variable, in the short to medium term. If

individuals express an interest in following these approaches it is recommended additional support from an APD may assist individual in achieving optimal weight and health outcomes. This area requires further study.

1.3.2 Modification of fat composition systematic review

The initial search of the data bases located 1082 articles (Figure 1.2). Of these articles, 107 were retrieved, 19 studies met the inclusion criteria and were divided into three distinct research areas: Monounsaturated fatty acids (MUFA) (n=6), Omega 3 Fatty Acids (n=8), and Mediterranean Diet (n=5).

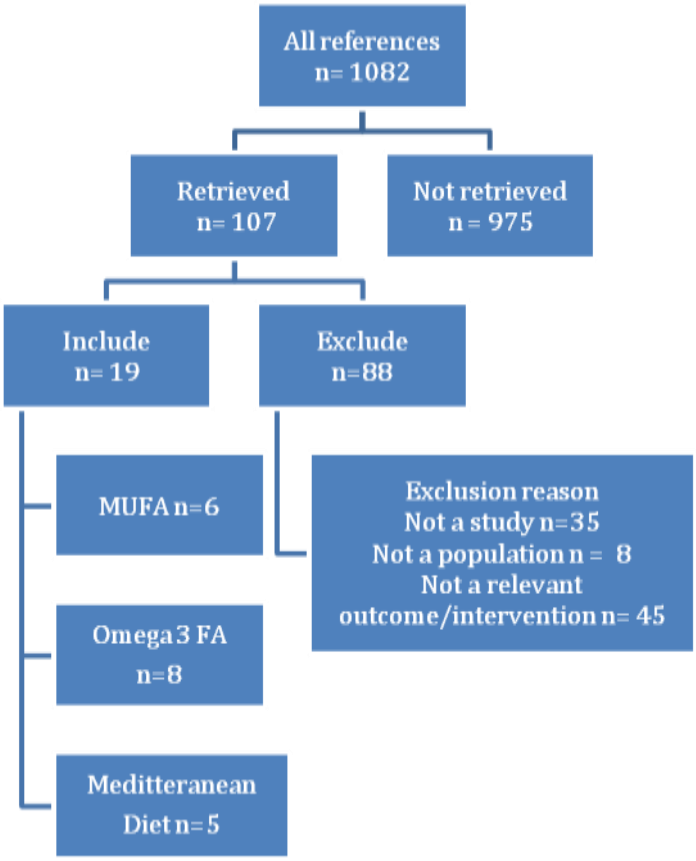

Figure 1.2: Flow diagram of included studies for Fat composition review

1.3.2.1 Monounsaturated fatty acids

For studies related to manipulating MUFA composition, 6 had data extracted and 4 were used in the body of evidence statement (Table 1.9).

Table 1.9: Does recommending a relatively higher intake of Monounsaturated Fatty Acids (MUFA) achieve greater weight loss in overweight or obese adults than a lower MUFA diet?

Component	Rating	Notes
Evidence Base	Satisfactory	4 level II studies with low to moderate risk of bias (3 positive, 1 neutral,) (69-72) . 3/4 RCTs had sample sizes of <30 in each group.
Consistency	Excellent	4 RCTs compared higher MUFA diets (n=83) to lower MUFA diets (n=80) (14 vs. 7%; 23 vs. 13%; 23 vs. 8-9%; >20 vs. <20% of energy as MUFA) with proportion of fat ranging from 18-45% of energy. All 4 RCTs found that weight change did not significantly differ between groups in durations of 4 to 26 weeks.
Clinical impact	Satisfactory	None of the RCTs showed differences in weight between the groups and found weight losses of 1.9-7.2kg over durations of 4 to 26 weeks.
Generalisability	Good	Population in body of evidence can be contextualised to overweight and obese Adult Australians.
Applicability	Good	The evidence base is relevant to the Australian health care setting generally. 2 RCTs were conducted in Europe, 1 in the US and 1 in Canada.
Recommendation		***Recommending a relatively higher intake of MUFAs (up to 23% of total energy) is equally as effective in achieving weight loss as a lower MUFA diet in overweight or obese adults over durations of 4 to 26 weeks.***
Grade of recommendation		**B**

An additional 2 level II studies (73, 74)were not able to be combined into a BOE statement. St-Onge et al 2008 compared 18-24g/d of MCT oil to 18-24g/d of olive oil and found no differences in body weight between groups over 16 weeks but weight changed significantly within the MCT oil group (3.2kg weight loss, $p<0.0001$) and did not in the olive oil group (1.4kg weight loss, $p=0.117$). Flynn 2010 compared a National Cancer Institute diet (with 15-30% fat, type of fat not specified in manuscript) to at least 3tb of olive oil per day over duration of 8 weeks and found the plant-based olive oil diet had a 1.9kg greater weight loss than the Cancer Institute group ($p<0.01$).

1.3.2.2 Omega-3 Fatty Acids

For studies related to the manipulation of omega 3 fatty acid composition, 8 had data extracted, and 8 were used in the body of evidence statements (Table 1.10).

Table 1.10: Does recommending a relatively higher intake of omega 3 fatty acids achieve greater weight loss in overweight or obese adults than other isoenergetic diets providing lower amounts of omega 3 fatty acids?

Component	Rating	Notes
Evidence Base	Good	8 level II studies with moderate to low risk of bias (4 neutral, positive quality)(75-82). n=11-244 intervention group; n=9-80 control group.
Consistency	Good	Evidence base mostly consistent in studies with durations of 3 to 12 weeks. 4 RCTs used omega 3 supplements. 6/8 RCTs (both arms had energy restriction) resulted in similar weight losses (4.5-10.9kg) for both groups; 1 RCT (both arms had 5.5MJ/d energy intakes) had 1.9kg greater weight loss in the comparator (no omega-3 supplement, n=19) when compared to omega-3 yoghurt supplement intervention (n=20) over 3 weeks; 1 RCT showed 1.7kg greater weight loss at 8 weeks with 5 fish meals (n=35) compared to no fish meals per week (n=35) using a linear trend analysis, but no differences between 3 fish meals (n=35) and no fish meals per week; and one-way ANOVA also showed no differences between all groups.
Clinical impact	Good	6/8 RCTs resulted in weight loss but same for both groups (4.5-10.9kg). Short duration studies (3 to 12 weeks), in small sample sizes.
Generalisability	Satisfactory	Two studies used very specific populations (obese insulin resistance; overweight on hypertensive medication). Other studies had participant numbers ranging from n= 11 - 244. Clinical research centres and food providers.
Applicability	Good	All studies included were applicable to the treatment of overweight or obesity in the Australian setting.
Recommendation		***Recommending diets that include between 790-2800mg/day of omega three fatty acids (both docosahexaenoic acid and eicosapentaenoic acids) during energy restriction is as equally as effective in achieving 4.5 – 10.9kg weight loss in overweight and obese adults in comparison to other energy restriction diets that provide lower amounts of omega 3 fatty acids over durations of 3 to 12 weeks.***
Grade of recommendation		C

Notably, diets including omega 3 fatty acids (790mg-2.8g per day) may have a concomitant benefit to lipid profiles and insulin resistance in overweight and obese adults as other dietary strategies in the short term (3 - 12 week duration).

1.3.2.3 Mediterranean diet

For studies related to the Mediterranean style diet 5 studies had data extracted, and 4 were included in the body of evidence statement (Table 1.11).

Table 1.11: Does recommending a Mediterranean diet achieve greater weight loss in overweight or obese adults than other diets?

Component	Rating	Notes
Evidence Base	Satisfactory	4 level II studies with low to moderate risk of bias (1 neutral; 3 positive quality)(83-86).
Consistency	Poor	No systematic reviews were located. 4 RCTs compared Mediterranean diets to other diets (n=1 prudent diet, n=2 low fat, n=1 Atkins, n=1 low carbohydrate). 2 RCTs used energy reduction diets (6.3MJ F, 7.6MJ M, 80kJ/kg BW) and the remainder appeared to be ad libitum. 2/4 RCTs found 1.5-2.8kg significantly greater weight loss in Mediterranean diet groups (-4.4 (6.0)kg n=109; -4(1.1)kg n=90) than a low fat (-2.9 (4.2)kg n=104) or prudent diet (-1.2(0.6)kg, n=194) over 2 years. 1RCT found that the Atkins group lost 2.7kg significantly more weight (n=10; -7.6(0.8)kg) over 2 months than the Mediterranean diet group (n=10; -4.9(0.6)kg). An additional 2RCTs found no differences in weight loss between Mediterranean diet (-0.19 to -0.26kg; n=514) and low fat diet (-0.24kg; n=255) over 3 months and between the Mediterranean diet (-4.4 (6.0)kg; n=109) and the low carbohydrate diet over 2 years (-4.7(6.5)kg; n=109).
Clinical impact	Poor	Weight loss was generally not clinically significantly different between groups and was not consistently different between Mediterranean and other diets.
Generalisability	Satisfactory	Population in body of evidence can be contextualised to overweight and obese adult Australians.
Applicability	Satisfactory	The evidence base is relevant to the Australian health care setting generally. 2RCTs were conducted in Italy, 1 in Spain and the other in Israel.
Recommendation		***The use of a Mediterranean diet is as equally as effective in achieving weight loss as a range of other dietary interventions with or without energy restrictions in overweight or obese adults*.***
Grade of recommendation		C
* weight lost during this time was not specified due to varying intervention durations (2-3 months or 2 years duration) and also because not all studies restricted energy.		

Some of the studies recognised the Mediterranean eating pattern having benefits outside of weight loss alone. These benefits include improved insulin resistance, improved cholesterol and triglyceride profile and decreased inflammatory markers (in particular the systemic inflammatory marker CRP), likely due to the concentration of LC n-3 PUFA in the eating pattern. As a result the Mediterranean diet style may be of greater use in metabolic syndrome than in weight loss alone.

An additional RCT (87)was not able to be incorporated into a BOE statement. This study compared a modified Mediterranean style, low glycaemic load diet to a Mediterranean, phytochemical enriched diet (focusing on soy protein and plant sterols) and were equally as effective at achieving weight loss after 12 weeks.

1.3.3 Modification of carbohydrate composition systematic review

The initial search of the databases located 440 articles related to manipulation of carbohydrates.

Of these articles, 51 were retrieved and data extracted from 15 RCT that met the inclusion criteria (Figure 1.3). The included studies were divided into two distinct research categories: glycaemic index/glycaemic load (n=11) and vegetarian (n=4).

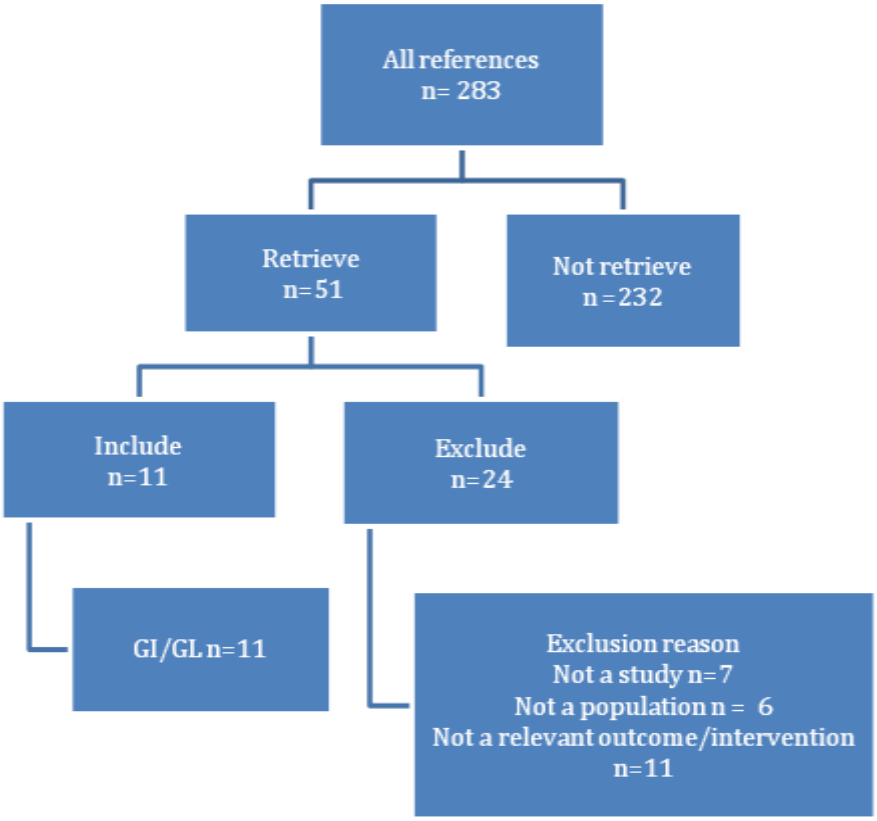

Figure 1.3: Flow diagram of included studies for Glycaemic Index /Glycaemic Load review

1.3.3.1 Glycaemic index/glycaemic load

For glycaemic index, 11 studies had data extracted, and 9 were used to make two body of evidence statements (Table 1.12 and Table 1.13).

Table 1.12: Is an energy restricted diet of low glycaemic index/glycaemic load more effective in achieving weight loss in overweight and obese adults, than an energy restricted diet of moderate to high glycaemic index/glycaemic load over a two to six month period?

Component	Rating	Notes
Evidence Base	Good	6 Level II studies with low risk of bias (6 positive)(20, 88-92); 5 studies of small sample sizes (n<20) in each dietary arm.
Consistency	Satisfactory	6 RCTs compared low glycaemic index/ glycaemic load energy restricted diets to moderate to high glycaemic index/glycaemic load diets (low GI n=128 vs. high GI n=126, intervention duration 8 weeks to 6 months). Energy restricted diets included 30% energy restriction, and 2.1 - 3.1MJ/day reduction. 4/6 RCTS reported that similar amounts of weight was lost in both groups (low GI -4.4 to -9.9kg vs. high GI -3.7 to -9.3kg at 12 weeks, low GI -7.2 to -10.4kg vs. high GI -7.7 to -9.1kg at 6 months). The remaining 2 RCTs found that weight loss was greater in the low GI group (-7.1kg at 8 wks, -4kg at 12 wks) than in the moderate to high GI group (-5kg at 8 wks, -1.5kg at 12 wks) in sample sizes of 22-23. None of the RCTs found significantly greater weight loss in the higher GI group.
Clinical impact	Good	Clinically significant weight loss often occurred regardless of whether intervention was low or high GI. The two RCTs that found differences between low and high GI groups did not find clinically significant differences between the two groups; however all studies were short term (8-26 wks duration) in small sample sizes.
Generalisability	Good	Population in body of evidence can be contextualised to overweight and obese Adult Australians.
Applicability	Satisfactory	The evidence base is relevant to the Australian health care setting generally. 3 RCTs were conducted in the US, 1 in Australia, and the remaining 2 in Europe. However, 3/6 studies provided food to the participants. Most RCTs provided behavioural/dietetic consultation.
Recommendation		***In overweight and obese adults, recommending a low GI/GL energy restricted diet of a minimum of 2.1MJ/day reduction (or 30% E restriction) is as equally as effective in achieving weight loss when compared to a moderate or high GI/GL energy restricted diet of a minimum reduction of 2.1MJs/day (or 30% E restriction) diet over a two to six month period.***
Grade of recommendation		**C**

Table 1.13: Is an ad libitum diet of lower glycaemic index more effective in achieving weight loss in overweight and obese adults, than an ad libitum diet of higher glycaemic index?

Component	Rating	Notes
Evidence Base	Good	3 Level II studies with low risk of bias (all positive)(93-95). All studies of small sample sizes (n<25) in each dietary arm per study.
Consistency	Satisfactory	3 RCTs compared lower glycaemic index to higher glycaemic index ad libitum diets for 5, 10 and 12 weeks. Two RCTs found no difference in weight change between treatment groups. One study found a significantly greater weight loss in the low GI (-1.1kg) compared to the high GI group (-0.3kg) after 5-weeks.
Clinical impact	Poor	Clinical impact is not clear. One study demonstrated significant increases in weight in both groups, one study demonstrated significant change in both groups irrespective of treatment, and the third study found significant weight loss in low GI group only.
Generalisability	Poor	2 of the 3 studies included all women; the 1 effective study included both men and women.
Applicability	Satisfactory	1 RCT conducted in the US, 1 in Denmark and 1 in France. All studies provided food to the participants.
Recommendation		***In overweight and obese adults, recommending a lower GI ad libitum diet is not different to recommending a higher GI ad libitum diet over a 5 to 12 week period.***
Grade of recommendation		**D**

An additional two included RCTs were not aggregated into a body of evidence statement. They (Maki 2007, Ebbeling 2005) (96, 97) compared low GI ad libitum energy diets to low carbohydrate or low fat energy restricted diets. One RCT found improvements in the lower GI diet during an initial weight loss period; however the other study found no differences in weight between groups.

1.3.4 Modification of calcium or dairy composition systematic review

The initial search of the data bases revealed 1125 articles (Figure 1.4). Overall 15 studies met the inclusion criteria, and were divided into five broad research areas: Conjugated linoleic acid (CLA) supplementation compared to placebo (n=2), calcium and vitamin D supplementation compared to placebo (n=2), calcium supplementation compared to placebo (n=4), studies comparing different amounts of calcium intake (n=4), studies comparing different sources of calcium (n=5).

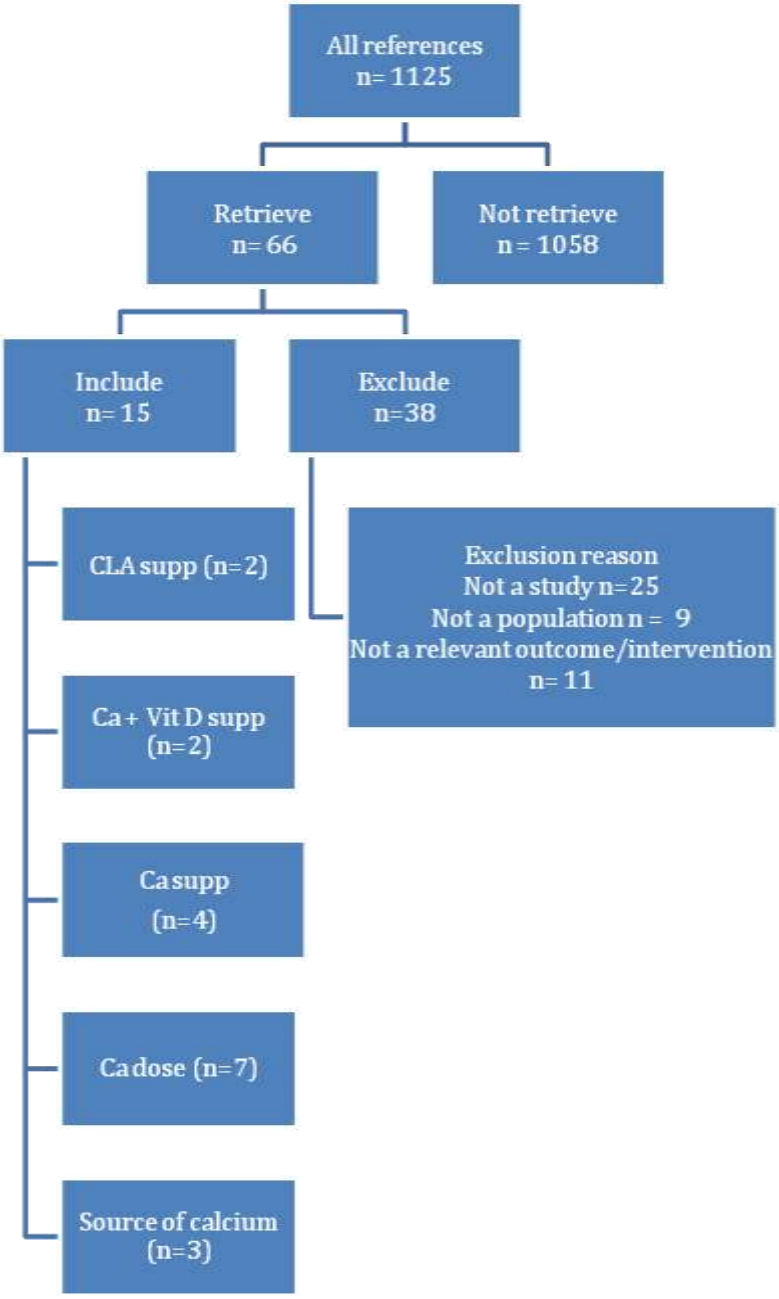

Figure 1.4: Flow diagram of included studies for calcium/dairy review

1.3.4.1 CLA supplementation

For CLA supplementation no body of evidence statement was generated, but data was extracted for two level II studies. The evidence regarding the use of CLA supplementation for weight loss in overweight and obese adults is currently inconclusive.

One RCT compared 3.2g/day of active CLA supplementation to placebo for 6-months with no caloric restriction, and found the CLA group achieved significantly greater reductions in weight (-0.6kg vs. 1.1kg, p=0.04)) after 6-months, compared to the placebo group (Watras 2007). The other RCT compared 3.4g/day of active CLA supplementation to placebo for 6-months with no caloric restriction, and found there was no significant difference in weight change between groups after 6-months.

1.3.4.2 Calcium and Vitamin D supplementation

For calcium and vitamin D supplementation no body of evidence statement was generated, but data was extracted for two level II studies. Both studies found no difference in the weight loss achieved by the calcium and vitamin D supplement group when compared to the placebo group. The supplementation level was 1200mg calcium and 200IU Vitamin D per day for 15-weeks (major 2007), and 2000mg calcium carbonate and 0.25µg Vitamin D per day for 3-months. All participants in both studies were prescribed a calorie restriction, and included only women.

1.3.4.3 Calcium supplementation

For calcium supplementation data was extracted for four level II studies (Table 1.14), and three were used to make a body of evidence statement.

Table 1.14: Does providing calcium supplements achieve great weight loss in overweight or obese adults, than a placebo?

Component	**Rating**	
Evidence Base	Good	3 level II studies of positive quality (98-100)with low risk of bias. Two RCTs sample sizes ~20 participants per group
Consistency	Excellent	3 RCTs compared provision of 1000mg of calcium in supplement form to a placebo over 6 months, with both groups also following an energy restricted diet. All RCTs found no difference in weight change post intervention between the calcium and placebo groups.
Clinical impact	Satisfactory	None of the RCTs showed differences in weight between groups, and found significant weight losses of 1.4 to 7.5kg after 6-months irrespective of calcium supplementation.
Generalisability	Satisfactory	Two RCTs conducted in women only, one of which was postmenopausal women only.
Applicability	Good	Generally applicable to the Australian health care setting, however calcium supplements provided in all studies. 2 RCTs conducted in USA, 1 in Iran.
Recommendation		**Providing calcium supplements (Ca 1000mg/day) as part of an energy restricted diet is as effective in achieving weight loss as a placebo in overweight and obese adults at 6 months.**
Grade of recommendation		**B**

An additional RCT (101) examined the effect of providing 1500mg of calcium /day in supplement form on weight change over 2 years, compared to providing a placebo. They found no significant difference in change in weight, BMI or fat mass between the two groups after 2 years.

1.3.4.4 Amount of calcium

For studies evaluating the impact of recommending different amounts of calcium, seven level II studies had data extracted. Therefore, sufficient evidence was available to make an evidence statement (Table 1.15).

Table 1.15: Does recommending a higher calcium intake achieve great weight loss in overweight or obese adults, than a lower calcium intake?

Component	**Rating**	
Evidence Base	Good	7 level II studies of positive quality(98, 102-107), with low risk of bias. Sample sizes ranging from 39 to 136.
Consistency	Poor	The 7 RCTs compared recommending higher intakes of Ca (1000 to 2400mg/day) to lower intakes of Ca (200 to 900mg/day) over 12 weeks to 6 month periods. 6 of the studies recommended an energy restriction to both groups. Three of the studies provided Ca supplements to meet the desired intake of calcium. Four RCTs encouraged participants to meet Ca recommendations using food sources high in Ca. One RCT compared supplements in two groups, and milk in another to increase Ca intake, compared to a standardized intake of Ca. Four of the RCTs found no difference in weight change between groups. These studies involved comparing higher intake ('high', 1000, 1550, 2400mg/day) to lower intake ('low', 200, 750, 500mg/day) for 16-weeks to 6 months. Three studies demonstrated greater weight loss in groups randomised to higher calcium intake, compared to lower calcium intake. Eftekari et al compared two 1600 calorie diets, the first was high calcium (1600mg), the second a high fibre (55g/day), moderate calcium (900mg). The high calcium group achieved significantly greater weight loss (-15kg vs. -9kg) than the high fibre group after 12-weeks. Zemel et al (2004) compared two 2.1MJ deficit diets, one included 0 to 1 servings of dairy/day (400-500mg of calcium per day), and the other 3 serves of dairy/day (1200 to 1300mg/day). Participants in the higher dairy group lost significantly more weight after 24 weeks (-11.1kg vs. -6.6kg). Zemel et al (2005) compared to energy deficit diet (-2.1MJ/day), one with low calcium intake (400-500mg Ca/day) the other a yoghurt group (1100mg Ca/day). The yoghurt group lost significantly more weight after 12-weeks than the control group (-4.4 vs -2.8kg)
Clinical impact	Satisfactory	The 3 RCTs with significant results found on average weight loss was 2 to 6kg more with higher Ca intake after 12 to 24 weeks.
Generalisability	Good	1 RCT conducted in males only, 1 RCT in postmenopausal women only, 1 RCT in premenopausal women only.
Applicability	Good	Generally applicable to the Australian health care setting, however calcium supplements/food provided in 3 studies. 4 RCTs conducted in USA, 1 in Iran, 1 in Norway, 1 in Australia.
Recommendation		**Recommending a higher calcium intake (1100-1600mg/day) as part of an energy restricted diet is as equally as effective at achieving weight loss in overweight and obese adults as lower calcium intakes (400-900mg/day) over 12 and 24-weeks.**
Grade of recommendation		**D**

1.4.4.5 Source of calcium

Three studies compared the difference in weight loss achieved when a standardised amount of calcium was consumed from different sources. No body of evidence statement was generated due to the diverse nature of the three studies, but data was extracted.

Zemel *et al* (2004)(107) compared two 500kcal deficit diets over a 24-week period. One group included 400-500mg of calcium from dietary sources, and 800-900mg from supplements, the other group consumed 3 serves of dairy/day, to equate to 1200 to 1300mg/day of calcium. The high calcium diet from food sources achieved significantly greater weight loss than the calcium supplement group (-11.1 vs. -8.6kg)

Wagner et al (105) prescribed a 500kcal restriction with ~750mg Ca/day and randomised participants to receive a calcium lactate supplement (+800mg Ca/day), calcium phosphate supplement (+800mg Ca/day) or low fat milk (+800mg Ca/day) for 12-weeks. There was no significant difference in weight loss between groups after 12-weeks.

Lukaszuk et al (108)prescribed a 500kcal deficit diet, and randomised women to 720mL of soy milk/ day or 720mL of skim milk / day for 8 weeks. There no significant difference in the weight loss achieved by the two groups after 8-weeks.

1.3.5 Behavioural/psychological approaches to dietary interventions systematic review

The initial search of the data bases located 777 articles (Figure 1.5). Overall 19 articles, reporting results from 18 studies, met the inclusion criteria. None of the studies meeting the inclusion criteria were also included in a systematic review. Sufficient evidence was found to make statements for a behavioural therapy and/or psychological intervention combined with diet therapy compared to diet therapy only for intervention durations of: 0 to <6 months (Table 1.16), 6 months to <2 years (Table 1.17), and 2 years (Table 1.18).

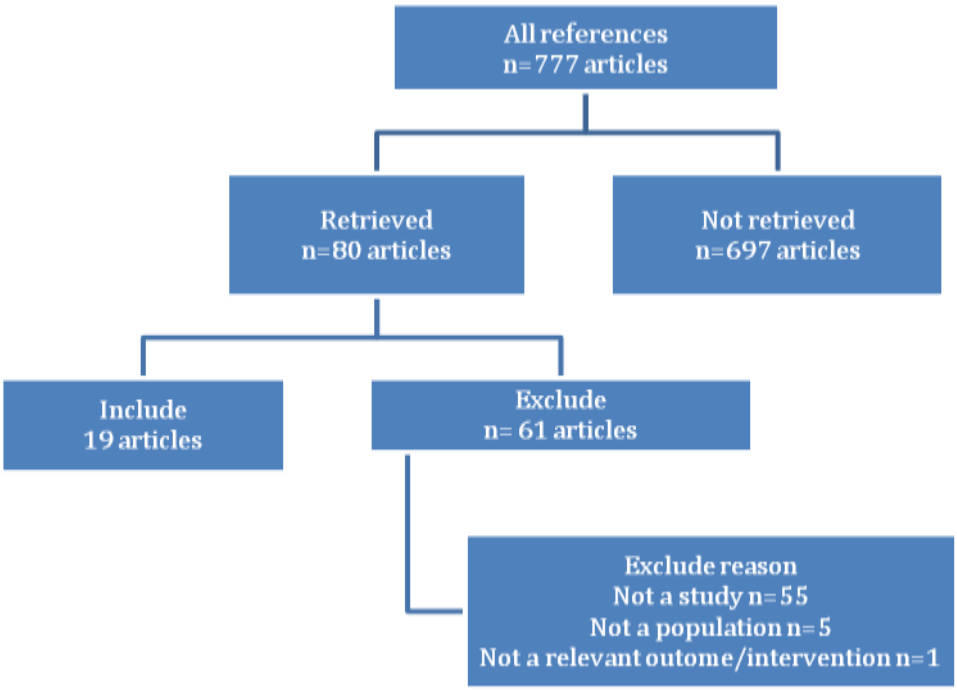

Figure 1.5: Flow diagram of included studies for behavioural/psychological approaches

Table 1.16: Does a combination of behavioural and psychological therapy and dietary intervention achieve greater weight loss in overweight and obese adults compared to a dietary intervention group only in interventions of less than 6 months duration?

Component	**Rating**	
Evidence Base	Excellent	1 level I study (positive)(109), and 10 level II studies with low to moderate risk of bias (6 positive, 4 neutral)(110-119)
Consistency	Poor	A systematic review found that Behaviour Therapy (BT) in combination with diet (and physical activity) lost 4.71kg more weight (95%CI -4.97 to -4.45) than diet (and physical activity) group alone (BT n=235 vs. control n=232, intervention duration median 12 weeks (1-26wks)). Five studies favoured BT in combination with diet and physical activity and one study favoured diet and physical activity alone for weight loss. An additional two studies in the systematic review found that Cognitive Behaviour Therapy (CBT) in combination with diet (and physical activity) lost 4.9kg more weight (95%CI -7.3 to -2.4kg) than diet (and physical activity) group alone (CBT n=37 vs. control n=26; intervention durations were 10 wks& 4 mths). 10 RCTs compared behaviour therapies (4 BT, 1 motivational interviewing, 1 mindfulness, 3 cognitive therapy (CT), 1 cognitive behaviour therapy, 1 self-determination theory (SDT)) in combination with diet (and physical activity) against diet (and physical activity) alone (therapy n=525 vs. control n=472; intervention duration 6-16 weeks). 4/10 RCTs found that the combination of therapy (1CT, 2BT, 1SDT) and diet (and physical activity) led to greater weight loss (3.4 kg over 16 wks, 6.3kg* over 10 wks, 1.4kg over 12 weeks (completers analysis only), ~2.9kg over 16 weeks) than diet (and physical activity) alone. Groups lost a similar amount of weight in the remaining 6 RCTs (-0.7kg to -10kg), in sample sizes of 9-104.
Clinical impact	Good	Pooled results from the systematic review found that 4.71kg (95%CI -4.97 to -4.45) more weight was lost when therapies were added to diet. While one RCT found a greater weight loss of 6.3kg after 10 wks when therapies were added to diet, the energy restriction was greater in the therapy intervention arm which could also explain this greater weight loss and the remaining studies had 1.4-3.4kg greater weight loss over 12-16 weeks. Most (4/6) RCTs that did not find differences in weight lost between groups had weight losses of <3kg in both groups.
Generalisability	Good	Population in body of evidence can be contextualised to overweight and obese Adult Australians, however 2 studies recruited only females (1 of these recruited people with a BMI>40), and another 2 recruited a low proportion of males.
Applicability	Good	The evidence base is relevant to the Australian health care setting generally. 3 RCTs were conducted in the US, 1 in Australia, and the remaining 6 in Europe. However, 7/10 studies held weekly meetings with participants.
Recommendation		***A combination of behavioural and psychological therapy and dietary intervention may achieve between 1.4kg to 4.7kg greater weight loss than a dietary intervention group alone in interventions of less than 6 months duration.***
Grade of recommendation		**C**
* In this RCT, an E restricted diet (5-5.5MJ/d) was suggested to the intervention group, but not stipulated in the control group		

Table 1.17: Does a combination of behavioural and psychological therapy and dietary intervention achieve greater weight loss in overweight and obese adults compared to a dietary intervention group only in interventions of at least 6 months duration but less than 2 years?

Component	Rating	
Evidence Base	Good	1 level I study (positive)(120, 121), and 7 level II studies with low to moderate risk of bias (5 positive, 2 neutral) (114, 116, 118, 122-125).
Consistency	Good	A systematic review found that the addition of Behaviour Therapy (BT) to diet (and physical activity) lost 7.67kg more weight (95%CI -11.97 to -3.36) than diet (and physical activity) group alone (n=192-277, weight change assessed at 12 months[#]), and lost 4.18kg more weight (-8.32 to -0.04kg) than diet alone at 18 months[#]. 7 RCTs compared the addition of behaviour therapies (5 BT, 1 cognitive behaviour therapy, 1 self-determination therapy, 1 psychological treatment) to diet (and physical activity) against diet (and physical activity) alone (therapy n=1497 vs. control n=852; intervention duration 26-52 weeks). 6/7 RCTs found that the addition of therapy (4 BT, 1 cognitive behaviour therapy, 1 self-determination therapy, 1 psychological treatment) to diet (and physical activity) led to greater weight loss (0.6-6.4kg over 26 wks, 2.4-4.4kg over 52 wks) than diet (and physical activity) alone. No differences in weight were observed between groups for the remaining 1 RCT (Melin 2003) however both groups lost weight (therapy: -10.6(0.6kg at 6mths, -7.6(1)kg at 12 mths, vs. control: -12.3(0.7)kg at 6mths, -6.4(1.2kg at 12 mths), in sample sizes of 17-22.
Clinical impact	Good	Pooled results from the systematic review found that 7.67kg (95%CI -11.97 to -3.36) more weight was lost at 12 months and 4.18kg more at 18 months when behavioural therapies were added to diet. The addition of therapy to diet (and physical activity) led to 0.6-6.4kg greater weight loss at 24 weeks and 2.4-4.4kg over 52 weeks. Only 1 RCT did not find differences in weight lost between groups however both groups lost weight.
Generalisability	Good	Population in body of evidence can be contextualised to overweight and obese Adult Australians, however 2 studies, 1 of these recruited only females with a BMI>40, 1 study recruited only males, another recruited a low proportion of males and two additional studies recruited some participants with diabetes mellitus.
Applicability	Good	The evidence base is relevant to the Australian health care setting generally. 2 RCTs were conducted in the US, 1 in Australia, 1 in Mexico and the remaining 3 in Europe. However, 3/7 studies held weekly meetings with participants.
[#] This systematic review included weight change at any time point, and this weight change assessed here was generally at follow up, not during an intervention.		
Recommendation		***A combination of behavioural and psychological therapy and dietary intervention may achieve an additional 2.4-7.7kg greater weight loss than a dietary intervention group alone in interventions of at least 6 months duration but less than 2 years.***
Grade of recommendation		**B**
NOTE: 4 RCTs made it clear as to which discipline conducted the behavioural therapy and psychological interventions, and the remaining 3 did not.		

Table 1.18: Does a combination of behavioural and psychological therapy and dietary intervention achieve greater weight loss in overweight and obese adults compared to a dietary intervention group only in interventions of 2 years duration?

Component	**Rating**	
Evidence Base	Satisfactory	3 level II studies with low risk of bias (3 positive) (114, 126, 127).
Consistency	Poor	3 RCTs compared behaviour therapies (2 BT, 1 stage of change (SOC)) in combination with diet (and physical activity) against diet (and physical activity) alone (therapy n=551 vs. control n=543). 1/3 RCTs found that the combination of behavioural therapy (1BT) and diet (and physical activity) led to greater weight loss (~5.9kg using intention to treat analysis, ~9.3kg using completers analysis, dropouts at 2 years were 46-51%) than diet (and physical activity) alone (BT n=200 vs. control n=190, meal replacements used in this study). No differences in the amount of weight lost were observed between groups for the remaining 2 RCTs (RCT1: therapy -0.39 (0.38)kg n=329 vs. control -0.16 (0.42)kg n=336; RCT2: therapy -6.8 (1.4)kg n=21 vs. control -8.6(1.6)kg n=22, RCT2 used meal replacements).
Clinical impact	Good	While one RCT found a greater weight loss of ~5.9kg after 2 years when therapies were added to diet, the remaining 2/3 RCTs did not find differences in weight lost between groups. However these weight losses, while not different between groups, were statistically different over time.
Generalisability	Good	Population in body of evidence can be contextualised to overweight and obese Adult Australians, however 1 study included people with diabetes mellitus and inclusion criteria was a BMI 40-60, and another recruited a low proportion of males.
Applicability	Good	The evidence base is relevant to the Australian health care setting generally. 2 RCTs were conducted in the US, and the remaining study in Sweden. However, 1 study held weekly meetings with participants, 1 study paid participants $25 for completing each post-baseline assessment, and 2 studies used meal replacements.
Recommendation		***A combination of behavioural and psychological therapy and dietary intervention may be as equally effective at achieving weight loss* as a dietary intervention group alone in interventions of 2 years duration.***
Grade of recommendation		**C**
* As 2 RCTs used meal replacements, weight losses were not reported here as they differed greatly from the remaining study that did not use meal replacements.		
NOTE: None of the 3 RCTs made it clear as to which discipline conducted the behavioural therapy and psychological interventions.		

1.3.6 Meal frequency literature review

One neutral quality systematic review and 1 positive quality RCT (128, 129) compared different eating frequencies during weight loss. The systematic review showed no difference in weight loss post-intervention for manipulations of eating frequency during weight loss trials (2-9 weeks -2.1 to -6.1kg (3 meals, 6 meals, 3 meals & 1 or 2 snacks); 24 - 52 weeks -2.1 to -5.3 kg (3 meals vs. 3 meals and 3 snacks)). The RCT showed no difference in weight loss between a higher meal frequency (3 meals/3 snacks: -4.6kg) and a lower meal frequency (3 meals/day: -5.3kg) after 8-weeks. However, there is no standardised definition of meals and snacks in the international literature and can be dependent on many factors including culture, time, kJ content consumed, and socio-economic status.

There is limited evidence comparing 3 meals/day to lower eating frequencies. Within the systematic review, 2 RCTs placed participants on energy restricted diets and compared 2 meals/day to 3 meals/day. Weight losses ranged between 4.1kg-8.9kg over 4-12 weeks, but this was not significantly different between groups.

1.3.7 Nutragenetics literature review

Evidence suggests that the genetic phenotype plays a part in the aetiology of obesity (130). Many genes have been implicated in the development of obesity, but our knowledge of the genes responsible for individual differences in weight loss secondary to treatment remains poor (131).

Genetic polymorphisms (a DNA sequence variation) associated with obesity may become relevant only under specific conditions such as macronutrient composition (132). Although opportunities exist to modify the risk of chronic disease based upon an individual's genetic profile, the scientific evidence informing such decisions has not yet reached a level of confidence to allow for efficacious personalised nutrition recommendations at this time.

1.3.8 Drug therapy literature review

The suggested use for weight loss drugs are as adjunct therapies to enhance weight loss from dietary energy restriction and increased physical activity. Weight loss drugs may be used for both obesity and overweight. Those considering pharmacologic treatment for obesity should understand these drugs can lead to modestly enhanced weight loss; usually< 5 kg at 1 year as a mean difference to those receiving the control intervention.(133)Data on the long-term effectiveness and safety of drugs for weight loss are lacking,(133) attrition rates tend to be high,(134) out of pocket expenses are high(135) and there are potential adverse effects as a result of treatment.(133)

The following provides an overview of the drugs Orlistat and phentermine, which are the only pharmacologic agents currently available for obesity treatment in Australia. Sibutramine (commercial name: Reductil, by Abbott) was withdrawn from the Australian market in October 2010 due to safety concerns).(136) The regulatory actions followed the release of results from the Sibutramine Cardiovascular OUTcomes (SCOUT) study, which showed a higher rate of cardiovascular events in obese and overweight patients using Sibutramine than in patients managing their weight through diet and exercise alone.(137)

1.3.8.1 Orlistat

Orlistat is commercially available in Australia as Xenical, and is produced by Roche. Orlistat is an inhibitor of gastrointestinal lipases, required for the systemic absorption of dietary triglycerides.(138)Orlistat prevents the absorption of about 30% of dietary fat, thereby promoting weight loss.(138) Based on faecal fat measurements, the effect of Orlistat is seen within 24 to 48 hours after a dose.(138) Discontinuation of Orlistat therapy results in a returns to pre-treatment faecal fat levels within 48 to 72 hours.(138)

The target group for Orlistat is individuals with a BMI ≥ 30 or BMI ≥ 27 with co-morbidity. In Australia, Orlistat does not require a prescription for most people, and is available from pharmacies. Medical doctors can issue an authority prescription to Veterans provided certain criteria are met.(139)
There is no recommended duration of use for Orlistat, and can be taken for years.(134)

There are several contraindications for use:

- Hypersensitivity to Orlistat or to any of the excipients (inactive drug additives) in the capsule.(138)
- Pancreatic enzyme deficiency or chronic pancreatitis and major gastrointestinal surgery.(138)
- Chronic malabsorption syndrome.(138)
- Cholestasis.(138)

Hutton and Fergusson (2004) conducted a systematic review, which included 28 randomised controlled trials on weight loss in obese patients treated with the standard dosage of Orlistat.(134) The treatment or placebo was administered for as little as 4 weeks in one study,(140) up to 4 years in another).(141) Seventeen of the 28 trials administered either 3 x 120 mg Orlistat per day or a placebo for ≥ 48 weeks.(134) People with no co-morbidity, type 2 diabetes, and cardiovascular co-morbidity were represented in the review and subgroup analyses were performed.(134)

Results indicated 3 x 120 mg Orlistat per day was effective for enhancing weight loss and lowering serum lipids.(134) Those treated with Orlistat for 1 year were on average 2.8 kg lighter than the controls (95% confidence interval (CI) -3.5, -2.1 kg).(134) Individuals who received Orlistat for 1 year were also twice as likely to lose ≥ 10% of their initial body weight (relative risk (RR) 2.0, 95% CI 1.7, 2.2).(134)

Treatment with Orlistat can cause gastrointestinal disturbances (RR 1.5; 95% CI 1.4, 1.6), mostly reported during the early treatment period, and described as mild to moderate in intensity, transient and spontaneously resolving.(134)Concentrations of fat-soluble vitamins should also be monitored in those taking Orlistat, as greater reductions in vitamins A, D and E and β-carotene have been observed with Orlistat use compared to placebo.(134)

The safety of Orlistat for use during pregnancy has not been confirmed. It has been"…taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage."(142)

Orlistat is not on the Pharmaceutical Benefits Scheme (PBS), but on the Repatriation Pharmaceutical Benefits Scheme (RPBS) for Veterans if the treatment criteria[139] are met. No recommended retail price is available. However, consumer group CHOICE (2007) found that the average price of Xenical from 30 pharmacies in the Sydney metropolitan area was $68 for a 2 week supply.[135]

1.3.8.2 Phentermine

Phentermine is commercially available in Australia as Duromine or Metermine, and is produced by iNova. Phentermine is a sympathomimetic amine with its appetite suppressant effect generally considered to be exerted through the hypothalamus.(143, 144)Phentermine primarily increases the neurotransmitter noradrenaline, and but may have some effect on dopamine.(145, 146)The half-life of phentermine is about 25 hours.[143]

The intended target group for Phentermine is adults with a BMI≥ 25.(146) In Australia, Phentermine is a prescription only medication. It is intended for short term use; generally ≤ 12 weeks(147) but one trial had a duration of 36 weeks.(148) The recommended starting dose is 30 mg per day but 40 mg per day may be required for those with very high BMIs.(146)

There are several contraindications for use:

- Pulmonary artery hypertension.(143, 144)
- Existing heart valve abnormalities or heart murmurs.(143, 144)
- Moderate to severe arterial hypertension.(143, 144)
- Cerebrovascular disease.(143, 144)
- Severe cardiac disease including arrhythmias and advanced arteriosclerosis.(143, 144)
- Known hypersensitivity to sympathomimetic drugs.(143, 144)
- Hyperthyroidism.(143, 144)
- Agitated states or a history of psychiatric illnesses including anorexia nervosa and depression.[143, 144]
- Glaucoma.(143, 144)
- History of drug/alcohol abuse or dependence.(143, 144)
- Concomitant treatment with monoamine oxidase inhibitors (MAOIs) or within 14 days following their administration.(143, 144)

There are significantly fewer trials evaluating the efficacy of phentermine monotherapy than Orlistat, despite the fact this product was first approved in 1959. However, Haddock *et al.* (2002) compiled a meta-analysis of randomised controlled trial of all pharmacotherapies for treating obesity, which included trials using phentermine.(149)The treatment or placebo was administered for as little as 2 weeks in one study, up to 24 weeks in another.(149) For 6 trials, the average was 13 weeks of treatment with 30 mg phentermine per day, and this resulted in an enhanced weight loss of 3.6 kg (range 0.6-6.0 kg) compared to the placebo control.(149) However, it is important to note withdrawal rates in phentermine-treated groups tend to be high.(148, 150)

The most common adverse reactions include palpitations, tachycardia, elevated blood pressure, precordial (chest) pain.(146) Other reactions include restlessness, insomnia, nausea, and dry mouth. [(146)]More serious but rare adverse events include psychotic episodes, hallucinations, cardiovascular and cerebrovascular events.(146)

It has been "…taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage."(142)

Phentermine is not on the PBS or RPBS. Prices vary depending on the pharmacy, but approximate costs per 30 capsules are:

	Strength	*Cost*		*Strength*	*Cost*
Duromine	15 mg	= $90	*Metermine*	15 mg	= $85
	30 mg	= $100		30 mg	= $96
	40 mg	= $120		40 mg	= $110

In summary, in Australia Orlistat is the only weight loss medication for long term obesity treatment. Phentermine should only be used as a short term treatment for overweight and obesity. Sibutramine has been withdrawn from the Australian market due to safety concerns. Weight loss medications can modestly enhance weight loss, when used as part of a weight management plan including energy restriction with or without increased physical activity. Adverse events, cost and compliance are factors that need to be discussed with each individual, prior to commencing any treatment. APDs are able to assist with weight loss when commencing drug treatments, by providing nutritionally adequate low energy diets and tailoring nutritional advice to the needs of the individual.

1.3.9 Comparisons between 2005 DAA weight management guidelines and current findings

Comparisons between the 2005 DAA weight management guidelines evidence statements and the current recommendations are listed in Table 1.19. As this review focussed on nutritional weight loss interventions, research on the best approaches for assessment, goal setting, evidence-based optimal treatment features, weight maintenance, physical activity, weight loss surgery and documentation sections from the 2005 guidelines were not examined in this report and therefore were not compared.

The 2005 and 2011 statements were difficult to compare for a number of reasons. Firstly, different methods were used to evaluate the strength of the recommendations made in 2005 and 2011, which means the evidence categories used in 2005 were not directly comparable to the grades of recommendation used in 2011. As the methods suggests in section 1.2, recommendations were only developed in 2011 if at least one systematic review or three positive quality RCTs or at least five RCTs of varying quality were located. The grading assigned to the 2011 recommendations was then determined based on the amount and quality of the literature available, consistency in findings, clinical impact of the results, generalizability to Australian adults, and applicability to the Australian healthcare context. However, the 2005 recommendations included studies that were not randomised controlled trials (including pseudo or non-randomised controlled trials, observational studies and expert opinion), and 2005 evidence categories may have been based on only one study without consideration for the quality of the study, consistency in findings, clinical impact of the results, generalisability to Australians, or applicability to the Australian healthcare context. As such, the strength of the statements made in 2005 and 2011 was not comparable.

Secondly, as the development of statements in the 2011 review was contingent upon sufficient evidence being available to form a statement, this often meant very different questions were answered in 2005 and 2011, and was often the reason for differences occurring between the two reviews. Other statements examined in the 2005 review could not be answered in the 2011 review as they did not lend well to being answered by RCT weight loss interventions, which was the method used in the 2011 review. The lack of availability of longer term evidence was also a challenge acknowledged in both 2005 and 2011 statements. Longer term research remains an avenue for further research, as 2011 statements were often based on short-term durations of less than 1 year.

1.4 Discussion

This review was designed to examine the recent evidence, published since 2003, on the efficacy of dietetic interventions for weight management in adults. It has been able to present a number of evidence statements for specific dietary approaches, on which previously there was insufficient evidence. Importantly, the NHMRC guidelines are currently under review and this report will need to be aligned with the revised NHMRC guidelines once the final version and the implementation approach is released by the NHMRC.

Study strengths and limitations

A limitation of the current review is it has only examined the literature since 2003. This limited time frame means the evidence statements reflect only the recent research and therefore caution should be taken when interpreting these evidence statements. They should also be considered alongside the previous guidelines. Another limitation is the review has focused on dietary interventions for weight loss only.

Other limitations include physical activity is often not controlled for, blinding to dietary intervention group allocation can rarely be achieved, and these reduce the overall quality ratings of the studies. Another major limitation is dietary intake and dietary adherence are rarely measured; making it a challenge to know how the intervention program has impacted on participants' eating habits and which aspects of the dietary intervention they have been able to adhere to.

Current Dietetic practice

We have summarised the key aspects of the review that have implications for selecting dietary approaches for clients who are overweight or obese. The overriding feature of successful approaches is they include a strategy specifically targeting reduction in total kilojoules.

While some "unrestricted" dietary approaches are more likely to lead to a reduction in total kilojoules in the short-term, for example recommending a low carbohydrate diet, in the long-term weight loss outcomes do not differ, unless a kilojoule reduction is achieved.

Many macronutrient manipulations do not lead to greater weight reduction in overweight or obese adults. This includes the proportion of total fat or type of fat versus carbohydrate; the glycemic load or glycemic index of the carbohydrate; the proportion of protein versus carbohydrate; providing calcium supplements; or recommending a higher calcium diet.

The evidence base for use of VLEDs that incorporates use of a meal replacement program to achieve an energy restriction of <4.2MJ/d indicate this is just as effective in achieving weight loss as using a low energy diet ~4.2-7.5MJ/d without meal replacements in both the short and long-term. However, when compared to providing general dietary advice only, the use of meal replacements to achieve a reduction in energy intake leads to greater weight loss over time periods of one to 12 months in overweight or obese adults. An extremely important caveat in this research is these approaches, i.e. using VLEDs and meal replacements, were monitored by health professionals and/or the researchers.

Using a combination of behavioural and psychological therapy along with a dietary intervention leads to greater weight loss up to two years compared to using a dietary intervention alone, whereas they appear to be equally effective at two years. Some of the loss of differences between approaches were more effective in the short-term can be explained by the fact most interventions do no extend beyond eighteen months, and many are considerably shorter than this. This suggests without a maintenance intervention the effect of a short-term weight loss intervention is lost over the longer-term.

Future practice and research directions

Most of the BOEs were based on studies of less than one year duration and many were very short term. Therefore more studies with a longer follow-up period are required.

Further research could explore whether lower carbohydrate approaches to diet facilitate greater weight loss in those who are also insulin resistant and whether low fat approaches are more appropriate for insulin sensitive overweight/ obese people.

Motivational interviewing and a range of other behavioural and psychological techniques have not regularly been added to dietary therapy, nor compared to the effect of providing diet therapy alone. More research in this area is needed as there was not enough evidence to make BOEs on specific behaviour change strategies, for example, motivational interviewing alone.

Higher protein / low fat diets compared with lower protein / high fat diets have not recently been manipulated within iso-caloric energy reduction diets.

Emerging areas of research appears to be the use of intermittent fasting. Approaches using a lower eating frequency, i.e. consuming just three or less meals per day with no snacks, could also be more closely examined in future guideline updates.

1.5 References

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Table 1.19: Comparisons between 2011 recommendations and 2005 DAA guidelines.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
DIET THERAPY				
• The over-riding aim of diet therapy is to establish a long term eating patterns that support optimal health guided by the Dietary Guidelines for Australian Adults (DGA) (2). When planning short and long term diet therapy, care needs to be taken to ensure micronutrient needs are met and non-nutritive benefits of foods are considered. (3)	*C*	No amendment	-	This statement has not been revised and is still current. Micronutrients, except calcium, not specifically considered in 2011 review. See Calcium section for calcium-related statements.
• The main requirement of a dietary approach to weight loss is a reduction in total energy intake. (1,4) • A "reduced-energy diet" (RED) aims to create a 2000 to 4000 KJ/day deficit in daily energy intake, using initial energy intake as baseline. Studies performed under controlled and 'real life' conditions indicate this approach can be expected to produce a gradual reduction in weight of 0.5 to 1.0 kg/week (1).	*A* *A*	***In overweight and obese adults, recommending an energy restriction of a minimum of 2MJ/day below the current intake or estimated maintenance energy requirements is effective in achieving greater weight loss compared to no treatment in durations of 3 to 6-months.***	**C**	Findings were similar but specific rates of weight loss were not able to be determined due to high variability of study durations and level of weight lost in 2011.
• Stabilisation of, or reduction in total energy intake can be achieved in a number of ways. The approach chosen will be in consultation with the client, with consideration of their needs, background, preferences and lifestyle. The approach chosen may change depending on whether the individual is currently in a weight loss or weight maintenance phase of treatment or if other circumstances have changed for the client. (1) • Actual rate and duration of weight loss varies between individuals and re-establishing an energy deficit is required for continued weight loss once weight stabilises or slows for further weight loss to occur (1).	*D* *D*	No amendment	-	This statement has not been revised and is still current. Studies on the tailoring of treatment to individual preferences and tailoring energy restriction based on rate of weight loss were not located but this remains a key component of dietetic medical nutrition therapy.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
LEVELS OF ENERGY RESTRICTION				
• A RED provides a flexible dietary approach to achieve gradual change and when monitored to lower kJ intake is likely to be more effective in maintaining weight loss than more prescriptive energy levels or restrictive diets (1, 3, 6).	*B*	***In overweight and obese adults, recommending an energy restriction of a minimum of 2MJ/day below the current intake or estimated maintenance energy requirements is effective in achieving greater weight loss compared to no treatment in durations of 3 to 6-months.***	**C**	These statements have not been revised and are still current and remain key components of dietetic medical nutrition therapy.
• Additional benefits of RED include focusing on promoting client's knowledge and skill in selecting and preparing appropriate food which may assist long term weight maintenance.	*B*			
• The effect of limiting alcohol intake is to lower kJ intake which can achieve weight loss over time. The majority (90-98%) of ingested alcohol is oxidized to carbon dioxide and water in the liver, with the remainder excreted through the lungs and kidneys. While alcohol is not converted to fat and stored in the human body, short-term studies show that consumption of alcohol in excess of energy needs can predispose to increased fat storage through preferential metabolism of alcohol and displacement of metabolism of protein, fat and carbohydrate and hence increased fat storage *de novo* (1, 3).	*C*	***In overweight and obese adults, recommending a very low carbohydrate diet (20 to ≤40g/day with no energy restriction) is not more effective than recommending an energy restricted diet in achieving weight loss in durations of 1 to 5 years***	A	The review did not locate studies with hypotheses that directly compared the effectiveness of providing varying levels of energy restriction.
• There is a risk of developing binge eating, for some individuals when following energy restricted diet therapy.	*D*	***In overweight and obese adults, recommending a very low carbohydrate diet (≤20 to <30g/day with gradual increase, and no energy restriction) achieves greater weight loss (average in the range of 2 to 4kg) than recommending an energy restricted diet in durations of 6-weeks up to 6-months.***	C	
• When discussing use of energy-restricted diets with clients it is important to convey the use of them as a structure to guide eating rather than absolute "rules" to adhere to. For any diet therapy, progression to a sustained eating pattern in line with the Dietary Guidelines for Australian Adults (2) is the ultimate aim as the client progresses towards the weight maintenance stage. (1).	*B*			

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
• A nutritionally-balanced "low energy diet" (LED) containing 4200 to 5000KJ/day can be expected to give an average weight loss of 0.3-0.5 kg/week over a period of 6 months, with significant loss of abdominal fat. However, unless combined with lifestyle changes that assist with long-term weight maintenance, this weight loss is unlikely to be sustained, with half of the weight lost regained after one to two years of treatment (1).	*A*	***In overweight and obese adults, recommending an energy restriction of a minimum of 2MJ/day below the current intake or estimated maintenance energy requirements is effective in achieving greater weight loss compared to no treatment in durations of 3 to 6-months.***	**C**	Findings were similar but specific rates of weight loss were not able to be determined due to high variability of study durations and level of weight lost in 2011.
• Very low energy diets (VLED), which use full meal replacements to limit energy intake to 1800 to 2500 KJ/day, are useful for initiating rapid weight loss of ~2kg/week over four weeks and ~1-1.5kg/week over 20 weeks (7). • VLED can be considered for use in the obese (BMI >30) or for those with a BMI >27 plus co-morbidities or rapid weight loss is required for surgery (1). • For people with disabilities VLED are not recommended, except in people with specific genetic conditions, such as Prader-Willi Syndrome. VLED would usually only be possible for those people living in supported accommodation or with supportive families or carers and requires comprehensive management and support.	*A* *B* *D*	***A very low energy diet (<4.2MJ/d) that incorporates meal replacements that are monitored by health professionals is as equally as effective in achieving weight loss# in overweight and obese adults , as a low energy diet (~4.2-7.5MJ/d) without meal replacements for periods of time varying from 3 months to 5 years.***	**C**	Several new research questions were answered based on the level of evidence available in the 2011 review. No specific VLED studies related to pre-surgery preparation or people with disabilities were located and met the inclusion criteria. Note that this review was not intended to address bariatric surgery approaches to weight management.
• Unless short-term treatments are followed by a weight management program, long-term (>1 yr) weight loss is not different from the results with a LED (7). Weight management therefore needs to include lifestyle interventions involving nutrition education, dietary change, behaviour therapy and/or increased physical activity.	*A*	No amendment	-	Very few BOEs were able to be created that examined time periods of >1yr or longer term as studies with long term follow-up are rare. Weight loss interventions with long-term follow-up are needed.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
CHANGING MACRO AND MICRO COMPOSITION				
• Reducing overall food intake, manipulating fat, carbohydrate, protein or alcohol intake, changing food patterns (e.g. portion sizes, eating in front of TV, skipping breakfast, increasing fruit and vegetable intake) can all achieve an energy deficit as part of a RED or LED (1,3). Combining these strategies may achieve improved results and allow diet therapy to be tailored to the client's needs and stage of management.	*D*	No amendment	-	The 2005 statement is very broad and encompasses a number of topics. Some of these particular topics are addressed individually as narrative statements in the 2011 report (e.g. eating frequency, vegetarianism) and others such as macronutrient manipulation are addressed below.
• Reducing dietary fat produces weight loss primarily through decreasing energy intake. Low-fat *ad libitum* energy diets, that reduce daily energy intake by 2000-4000KJ/day, can lead to weight loss of 2-6kg and a waist-circumference loss of 2-5cm after one year (6). • Reducing fat intake as part of a RED or LED is a common and practical way to reduce kilojoule intake and may be in the form of a low fat diet (20-25% energy intake) or reduced fat diet (25-30% energy intake). However, reducing dietary fat alone without reducing kilojoules is not sufficient for weight loss (5, 6).	*A* *A*	***A higher fat / lower carbohydrate diet (30-75%F, 4-45%CHO) is as equally as effective in achieving weight loss in overweight and obese adults as a higher carbohydrate / lower fat diet (20-25%F, 50-65%CHO) for periods of time varying from 6 to 16 weeks, when protein intake and the level of energy intake are held constant.***	**A**	The 2011 statement indicates that the manipulation of fat does not achieve greater weight loss in the short term than higher fat intakes on energy restricted diets. Reducing fat alone without reducing total energy intake was evaluated and found to not be effective in the 2005 guidelines, but this comparison was not made in the studies in the 2011 review.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
• Meal replacements may be used as part of a RED or LED. They can either replace all meals and snacks (full meal replacements) or be used in conjunction with low energy meals and snacks (partial meal replacements). Use of meal replacements for one to two years can produce weight losses of 3.0-9.5 kg, with significant improvements in co-morbidities in overweight and obese people (1).	*B*	***A low energy diet (~4.2-5MJ/d) that incorporates meal replacements that are monitored by health professionals is as equally as effective in achieving weight loss# in overweight and obese adults as a low energy diet (~4.2-5MJ/d) without meal replacements for periods of time varying from 1 to 12 months.*** ***Achieving a reduction in energy intake, by incorporating meal replacements that are monitored by health professionals, provides greater weight loss# in overweight and obese adults than general dietary advice for periods of time varying from 1 to 12 months.***	**C** **A**	Similar recommendations were made in both the e 2005 and 2011 guidelines. However weight losses are not reported in 2011 recommendations due to large variation in intervention durations.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
EMERGING RESEARCH AREAS				
Glycaemic Index • Use of low Glycaemic Index (GI), modified fat and modified protein diets have recently shown promise as effective dietary approaches to weight loss in short-term studies but at present no long-term evidence is available (1, 3). Long-term evidence is required to assess usefulness in long-term weight loss. • Low GI diets have been proposed to facilitate weight loss by increasing satiety and therefore facilitating the achievement of an energy-restricted diet. It is important to consider total energy intake, the GI of the included carbohydrate and the overall glycaemic load (the product of the foods' specific GI and the total carbohydrate content provided by the specific amount of the food) of the diet when using this dietary approach.	*D*	***In overweight and obese adults, recommending a low GI/GL energy restricted diet of a minimum of 2.1MJ/day reduction (or 30% E restriction) is as equally as effective in achieving weight loss when compared to a moderate or high GI/GL energy restricted diet of a minimum reduction of 2.1MJs/day (or 30% E restriction) diet over a two to six month period.*** ***In overweight and obese adults, recommending a lower GI ad libitum diet is not different to recommending a higher GI ad libitum diet in achieving weight loss over a 5 to 12 week period.***	**C** **D**	Longer-term evidence regarding GI not available in either 2005 or 2011. Evidence of short-term effects of GI on weight now provided in 2011.
Moderate protein low fat, moderate carbohydrate diets • Moderate protein (25-30%), low fat (25-30%), moderately low carbohydrate (40-45%) diets have been proposed as an effective dietary approach to achieve energy restriction, improved lipid and insulin profiles, satiety and client satisfaction. Long-term results using this approach are not yet available but remain promising.	*D*.	***A higher protein / lower carbohydrate diet (25-49%P, 6-45%CHO) is as equally as effective in achieving weight loss in overweight and obese adults as a higher carbohydrate / lower protein diet (12-23%P, 32-75%CHO) for periods of time varying from 1 to 4 months, when fat intake and the level of energy intake are held constant.***	**C**	Different questions were asked in 2011 to 2005 which means these statements are not comparable. Lipid and insulin profiles, satiety and client satisfaction mentioned in 2005 were not primary outcome variables in the 2011 review. Neither statement includes long term evidence – this is an avenue for further research.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
Mediterranean Diets • Modified fat diets, based on the Mediterranean approach and containing approximately 30-40% energy from fat, low saturated fat (~7%) and with preferential use of monounsaturated oil have been trialed under research conditions (5). This approach has been found to produce weight loss similar to that achieved with lower fat diets, with better lipid profiles after weight loss compared to other approaches (5). However, it is not known whether similar results would be seen if saturated fat was substituted with either mono- or polyunsaturated fat.	*D*	***The use of a Mediterranean diet is as equally as effective in achieving weight loss as a range of other dietary interventions with or without energy restrictions in overweight or obese adults.*** ***Recommending a relatively higher intake of MUFAs (up to 23% of total energy) is equally as effective in achieving weight loss as a lower MUFA diet in overweight or obese adults over durations of 4 to 26 weeks.*** ***Recommending diets that include between 790-2800mg/day of omega three fatty acids (both docosahexaenoic acid and eicosapentaenoic acids) are equally as effective in achieving weight loss in overweight and obese adults in comparison to other dietary strategies that provide lower amounts of omega 3 fatty acids over durations of 3 to 12 weeks.***	C B C	Similar statement to 2005 guidelines. 2011 has developed statements regarding the evidence on MUFAs or omega 3 fatty acids; however statements were not made on this in 2005.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
High Dairy and Calcium Diets • Epidemiological studies have demonstrated an association between dietary calcium intake and a reduction in risk of weight gain (9).	*C*	***Providing calcium supplements (Ca 1000mg/day) as part of an energy restricted diet is as effective in achieving weight loss as a placebo in overweight and obese adults at 6 months.***	B	In the previous guidelines, the majority of studies were cohorts, with a limited number of trials – so the 2011 recommendation is new and is based on randomised controlled trials.
• Recent evidence suggests that at least in the short-term, a high (1200-1300mg/day) dietary calcium (dairy product) intake is associated with greater loss of body weight and body fat (9).	*B*	***Recommending a higher calcium intake (1100-1600mg/day) as part of an energy restricted diet is as equally as effective at achieving weight loss in overweight and obese adults as lower calcium intakes (400-900mg/day) over 12 and 24-weeks.***	D	Calcium supplementation not examined in 2005.
• A recent study has highlighted that calcium absorption may be reduced in the presence of energy restriction (10) it therefore seems prudent to evaluate the clients dietary calcium intake as part of management, to ensure intakes are optimised.				Not enough evidence available in the 2011 update to suggest that increased calcium intakes lead to greater weight loss. Calcium absorption not specifically examined in 2011 review.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
Popular diets • There is currently no long-term evidence supporting the use of 'popular' diets, for example, low-carbohydrate and single-food diets over RED. • Assessment of 20 popular diet books ranked 11 of these books as *not recommended* when assessed against quality criteria, including nutritional adequacy, promises made for rate of weight loss, use of special supplements, ability to follow diet long term, physical activity recommendations and scientific evidence. Low scoring dietary regimes included no fat, low carbohydrate, high protein, blood type and liver cleansing diets (11).	*D*	Narrative statements only were made in 2011.	-	Insufficient evidence available to produce recommendations in 2011. This is consistent with the lack of evidence reported in 2005.
BEHAVIOURAL THERAPIES AND PSYCHOLOGICAL INTERVENTIONS				
• Behavioural therapies used in combination with other weight loss therapies have been found to induce a mean weight loss of about 3-5kg during treatment *(1, 2).*	*A*	***A combination of behavioural and psychological therapy and dietary intervention may achieve between 1.4 kg to 4.7kg greater weight loss than a dietary intervention group alone in interventions of less than 6 months duration.*** ***A combination of behavioural and psychological therapy and dietary intervention may achieve an additional 2.4-7.7kg greater weight loss than a dietary intervention group alone in interventions of at least 6 months duration but less than 2 years.***	**C** B	Compared to the 2005 guidelines, these evidence statements are informed by randomised controlled trials.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
• Three to five years after intervention ceases, weight loss from baseline falls to about 3kg (0-10kg) *(3)*.	*B*	***A combination of behavioural and psychological therapy and dietary intervention may be as equally effective at achieving weight loss as a dietary intervention group alone in interventions of 2 years duration.***	**C**	Not enough evidence available to form a statement over 3-5 years.
• Long-term (more than one year) behaviour therapy used in combination with other weight-loss interventions can be associated with improved dietary intake, physical activity levels and reduction in abdominal fat, even in the absence of weight loss *(4, 5)*.	*B*	No amendment		This statement has not been revised.
• Behavioural therapy can: ➢ improve compliance with dietary and physical activity requirements *(6).* ➢ reduce blood pressure *(7).* ➢ improve psychological function *(8).*	 *B* *B* *C*	No amendment	-	These outcomes were not amended in the 2011 review.
• No one behaviour therapy appears to be superior to any other in its effect on weight loss. Multi-modal strategies appeared to work best and those interventions with the greatest intensity appeared to be associated with the greatest weight loss *(9)*.	*B*	No amendment	-	Not enough studies located to compare particular behaviour therapies in a body of evidence statement. More research could be done on therapies such as motivational interviewing.
• Increased duration of treatment increases the likelihood of maintaining weight loss. Long-term follow-up of clients undergoing behaviour therapy shows a return to baseline weight in the great majority of subjects in the absence of continued behavioural intervention *(4, 10, 11)*.	*B*	No amendment	**-**	Weight maintenance interventions were not examined in the 2011 review.

Evidence statements from 2005 guidelines (1)	2005 Evidence Category	Evidence statements from 2011report	2011 Evidence Grade	Comparison between 2005 and 2011 Evidence Statements
DRUG THERAPY				
• Orlistat (Xenical™) combined with a low-energy, low-fat diet can lead to a weight loss of 6-13kg or 10%, and improve some co-morbid factors after 1-2 years of treatment. Two-thirds of this weight loss is the result of diet modification. The safety of prolonged (more than 2 years) therapeutic use of Orlistat has however, not been demonstrated (1,2). • Orlistat reduces absorption of some fat-soluble vitamins. Clients taking Orlistat are more likely to require vitamin supplements than those who are not (1,2). • Some adrenergic agents (such as Duromine™) can produce effective short-term weight losses of about 3-4 kg, but their potential for adverse side effects precludes long-term use (1,2). • Sibutramine (Reductil™) can lead to a weight-loss of between 4-8kg, or 6%, and improve some co-morbid factors within 1-2 years of treatment. If preceded by or combined with lifestyle and dietary modifications weight loss in some individuals can almost double to 5-17kg or > 10% (2,3). • The safety of prolonged (more than 2 years) therapeutic use of Sibutramine has however, not been demonstrated. Longer and more methodologically rigorous studies, that are empowered to examine end-points such as mortality and cardiovascular morbidity, are required (3, 4).	*A* *B* *B* *A* *A*	Narrative statements only created.	-	A systematic literature review was not done for Drug Therapy. Please see narrative statements in Drug Therapy literature review section of 2011 report.

1.6 Summary of evidence tables

Table 1.20: Studies used to make evidence statement for energy restriction compared to no treatment

Reference	Bouchard 2009(8)	Ross 2004(4)	Weiss 2007(5)	Heilbronn 2006(6)	Kirkwood 2007(7)	Nicklas 2004(9)
Type of study	RCT	RCT	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II	II	II
Intervention/ comparator	CR: -500kcal/day 55% CHO, 30% fat, 15% protein and 1 hour weekly group session/ Control: no intervention. 12 week intervention.	CR: -500kcal/d/ Control: no change to energy intake. Both groups 55%-60% of E CHO: 20% Protein: 30% fat 14 weeks duration	CR: 16% first 3 months, 20% next 9 months; total duration 12 months. Weekly consultations with dietitian/Control: No intervention	CR: 25% of baseline energy requirements/Control: Weight maintenance diet for 6-months. All food provided to week 12, and from week 22 to 24. Week 12 to 22 self-selected	CR: -500 -750kcal/day. 50-55% CHO: 30-35% fat, 10-20% protein. "System S Plan"/ Control: no intervention for 12-weeks.	CR: -500kcal/day . Three phases: intensive (months 1-4), transition (5-6) and maintenance (months 7-18). Included group sessions and one individual session. /Control: no intervention. 6-month results only reported here.
N	CR: 11/Control:12	CR: 15/Control:10	CR: 18/Control:10	CR: 12/Control 12	CR: 16/Control:18	CR: 71/Control:70
Population/ study information	0% Male, Age: 63 years. Retention rates: 100% No follow-up beyond intervention.	0% Male, Mean age 45 years, BMI 32. Retention rate: CR 54%, Control: 43%. No follow-up beyond intervention	39% Male, BMI:27, Age 56 years. Retention rate: 96%. No follow-up beyond intervention	46% Male, BMI: 28, Age: 38. Retention rate: CR: 100%, Control: 92%. No follow-up beyond intervention	0% Male, BMI: 31.6 Age: 41yrs. Retention rates: 63% overall. No follow-up beyond intervention.	~30% Male, Age ≥60 yrs, BMI≥28 with knee osteoarthritis. Retention rates: 80% at 18-months. No follow-up beyond intervention.
Quality	Neutral	Positive	Positive	Positive	Neutral	Positive
Results	Mean weight, BMI and fat mass at baseline and 12-weeks.Weight: CR 0:78.4±10.8, 12: 74.4±9.8. Control 0: 80.1±8.9, 12: 80.1±9.4. BMI: CR 0: 31.9±2.7 12: 30.4±2.3, Control 0: 32.3±2.4, 12: 32.6±2.4. Fat mass CR 0 36.1±7.4, 12: 32.9±7.3. Control: 0 36.9±5.7, 12: 36.9±5.8.	Mean ±SD weight, waist circumference and total fat at baseline to 14-weeks (Completers). CR: Weight 0: 86.6±10.9, 14: 80.2±11.2. Control: Weight 0:88.1±8.2, 14: 88.6±7.4 BMI: 0:32.4±2.8, 14: 32.7±2.9 Waist: 98.1±6.9, 14: 99.2±7.7	Mean ±SD wt loss: 8.2± 4.8 (kg), total body fat mass: -6.3± 3.8 (kg); (p<0.0001); fat free body mass -1.7kg (p<0.05) in CR group after 1 year. Control not reported.	Mean ±SD weight loss (%) from baseline to month 6 CR: -10.4% ±0.9%, Control: -1% ±1.1% wt loss . Significantly greater weight loss in CR group than control	Mean reduction in weight of 3.1kg or 3.7%, mean decrease in BMI of 1.1, and waist circumference of 4.9cm in CR group. No change data reported for control. Significantly greater reductions in weight and BMI in CR group compared to control.	Mean±SD weight change at 6-months CR: -10.6±14.0, Control: -0.15±6.7kg. (Completers) Mean±SD BMI change at 6-months. CR: -1.78±3.0, Control: -0.52±2.5. Unclear if difference between groups.

Reference	Bouchard 2009(8)	Ross 2004(4)	Weiss 2007(5)	Heilbronn 2006(6)	Kirkwood 2007(7)	Nicklas 2004(9)
	Significant change over time in CR group for all measurements, but no significant difference to control.	Fat: 0 40.4±5.4, 14: 41.2±5.2 BMI: 0:31.9±2.8, 14: 30.2±3.0 Waist: 0:97.9±8.0,14: 94.0±7.9 Fat 0:39.2±7.8, 14: 35.1±7.1. Significant difference in weight, BMI, waist circumference and fat free mass between groups. Significantly lower in CR group compared to control.				
Effect on risk (Increase/None/Protect)	None	Protect	Unclear	Protect	Protect	Unclear
Clinical importance	3	1	Unclear	1	1	Unclear
Clinical relevance	1	1	1	1	1	
Generalisable	Older women only	Y	Y	N- Food provided	Y	Older with knee osteoarthritis
Applicable	Y	Y	Y	Y	Y	Y

Table 1.21: Studies used to make evidence statements for energy restriction compared to low carbohydrate

Reference	Avenell 2004(10)	Foster 2010(11)	Foster 2003(12)	Hernandez 2010(13)	Nickols-Richardson 2005 (14)	Samaha 2003(15)
Type of study	Systematic review	RCT	RCT	RCT	RCT	RCT
Level of evidence	I	II	II	II	II	II
Intervention/ comparator	Low CHO/Protein sparing modified fast: ≤40g/day CHO irrespective of energy intake Low calorie diets: 4.2-6.7MJ	CR:1200-1500kcal F, 1500-1800kcal M , 55% CHO, 30% fat, 15% protein. Low CHO: 1st 12-weeks=20g/day CHO, increased by 5g/day/ week until stable body weight. Both groups received comprehensive group behavioural treatment program weekly for 20 weeks, every 2nd week for next 20-weeks and then monthly for remainder of 2-year period.	CR: 1200-1500kcal F 1500-1800kcal M. 60% CHO: 25% Fat: 15% Protein. LEARN/ CHO 20g/day increased gradually until desired weight is achieved. Dr Atkin's New Diet Revolution. 12-month intervention. Both groups Dietitian consultation at 0, 3, 6, and 12 months	CR: 1200-1500Kcal F 1500-1800 M. 55% CHO:15% protein:30%fat/<20g CHO/day, unlimited protein and fat for 6-weeks.	CR: 1500-1700kcal. 60% CHO:15% protein:25%fat/ CHO: <20g CHO/day 2-weeks, increased by 5g/week to 40g/day by 6-weeks. 6-week intervention. Both groups attended weekly group sessions for Dietitian.	CR: -500kcal/day 30% E Fat. CHO: <30g CHO/day for 6-months. Both groups attended weekly group sessions for 4-weeks, then monthly sessions for 5-months.
N	480	CR: 154/CHO: 153	CR: 30/CHO:33	CR:16/CHO:16	CR: 15/CHO:13.	CR: 68/CHO:64
Population/study information	Mean age >18 years, mean BMI>28. Up to 60-months follow-up	32% Male. Mean age 46yrs. BMI: 36. Retention rates: CR:68%, CHO: 58%. No follow-up beyond intervention.	32% Male, Mean age 44yrs. Mean BMI: 34. Retention rates: 57% CR, 61% CHO. No follow-up beyond intervention	31% Male, Mean age:43yrs. Retention rates 100%. No follow-up beyond intervention.	0% Male, Mean age: 39 yrs, Mean BMI 31. Retention rate: CR: 73%, CHO:92%. No follow-up beyond intervention.	83% Male. Mean age: 54yrs. BMI: 43. Retention rate: CR: 52% CHO:67%. No follow-up beyond intervention
Quality	Positive	Positive	Positive	Positive	Positive	Positive

Reference	Avenell 2004(10)	Foster 2010(11)	Foster 2003(12)	Hernandez 2010(13)	Nickols-Richardson 2005 (14)	Samaha 2003(15)
Results	Difference in weight change between groups: 12-months: -3.57kg (-7.36 to 0.22kg) 18-months: 0.69kg (-1.58 to 2.96kg) 24 months: -2.17 (-4.88 to 0.54kg) 36 months: -1.51kg (95% CI: -5.43 to 2.41) 60 months: 0.20kg (-5.68kg to 6.0kg) No difference at any time point. Heterogeneity not reported.	Mean (95% CI) weight change from baseline to 3, 6, 12 and 24-months. CR 3: -8.37 (-9.04 to -7.71), 6: -11.34 (-12.4 to -10.3), 12: -10.81 (-12.4 to 9.28), 24: -7.37 (-9.10 to -5.63).CHO: 3: -12.18 (-13.1 to -11.2), 6: -10.87 (-12.1 to -9.67),12:-10.81 (-12.4 to 9.28), 24: -6.34 (-8.06 to -4.63). No significant difference between groups at 3- (p=0.019), 6- (p=0.25), 12- (p=0.95) or 24- (p=0.41) months. Trend at 3-months, but p-value set at <0.01 due to multiple comparisons.	Mean±SD % weight change from baseline to 3, 6, & 12-months. CR: 3:-3.8±3.9 6: -5.3±6.4 12:-4.5±7.9. Low CHO 3: -8.1±4.4, 6: -9.7± 5.7, 12: -7.3±7.3. Both groups significant changes since baseline (p<0.05). Significant difference in change in percentage weight change greater in CHO group at 3- (p=0.002) & 6-months (p=0.03), but not 12-months (0.27).	Mean±SD change in weight (kg) from baseline to 6-weeks. CR: -6.0±3.5. CHO: -6.2±4.8. Both groups significant change over time (p<0.0001). No significant difference in weight loss between groups at 6-weeks (p=0.57)	Mean±SD weight (kg) at 0 & 6-weeks. CR: (Completers)0: 79.8±12.1kg, 6-wks 75.6± 15.4kg, CHO 0: 84.6±12.7kg, 6-weeks 78.2± 15.9kg, Both group significantly different from baseline p<0.05. Significant difference in weight and percentage weight change between groups at 6-weeks (p<0.05)	Mean ±SE change in weight 0 to 6-months CR: -1.8kg±3.9, CHO: -5.7kg±8.6 . CR: 2 and CH0: 9 achieved ≥10% weight loss. Significant greater weight change in CHO (p=0.002) and greater number in CHO gp achieved ≥10% weight loss (p=0.02).
Effect on risk (Increase/None/ Protect)	None (Calorie restriction not more effective than unrestricted low CHO or VLED)	None (both effective, trend at 3mth (p=0.019)	Protect (6-months) None (12-months)	None (both effective at 6 weeks)	Protect (6 weeks only)	Protect (6months)
Clinical importance	3	3	1 up to 6mth; 3 for 12 months	3	1 (6 weeks)	1 (6 months)
Clinical relevance	1	1	1	1	1 (only 6 weeks)	1
Generalisable	Y	Y	Y	Y	N- Women only	Y
Applicable	Y	Y	Y	Y	Y	Y

Table 1.22: Studies used to make evidence statement for low energy diets with meal replacements compared to low energy diets

Reference	Heymesfield 2003(16)	Rohrer 2008(21)	Ashley, 2006(17)	Noakes, 2004(19)	Davis, 2010(18)
Type of study	Systematic Review	RCT	RCT	RCT	RCT
Level of evidence	I	II	II	II	II
Intervention/ comparator	Partial meal replacement program (1-2 MR/day with CR meals/snacks) VS low calorie diet >800 but <1600kcal/day.	Pre-packaged foods / heart-healthy diet (both 1200kJ with unlimited fresh fruit/veg and 30 min motivational interview), follow up 1 month later.	MR (1-2 MR drinks or bars/day) / traditional food group. (both groups energy restricted goal of 5400kJ/d. attended 18 classes (bimonthly for first 12 months, monthly classes for 6 months), instruction materials developed by dietitian, LEARN program manual for weight control), provided MR or food vouchers to diet only group.	Slim-fast MRx2+ low fat evening meal and ≥5 serves of F&V/d (1800kJ + 3500kJ). vs. low-kJ/low-fat diet (equivalent amount of written/oral info), fortnightly visits, MR provided, financial compensation provided to diet only group.	Medifast 5&1 plan (5 MR, 90-110kcal each, 5-7oz lean protein, 1/5C non-starchy veg, up to 2 fat;. ~1000kcal/day.) / self-selected isocaloric food based meal plan using guidelines from the USDA Food guide pyramid (3 oz grains, 1C veg,1C fruit, 2 cups milk, 5-7 oz lean protein, 3 ts fat+ multivitamin+ calcium supp).(16 week intervention, 24 week maintenance), MR & cash provided to diet only group, fortnightly visits.
N	6 studies/487 participants	32/23	35/35	26/29	28/20
Population/study information	Mean age 46.1, Mean BMI31.0. 75% Female. 3 to 51 months follow-up	BMI≥25; mean (median): age 46.2(48)/48.7(48) BMI 35.1(34.4)/ 37.9(36.6) weight 98.3 (95.5)/104.4 (100.8); female 81.3%/78.3%	females, 25-50 years, BMI 25-35, generally healthy; age 39.79(6.1), weight 78.9(10.6), BMI 29.5(3.1), body fat % 47.9(7.9), waist 90.1(6.6) vs. age 36.7(6.3), weight 79.2(7.4), BMI 29.1(2.4), body fat % 44.6(5.8), waist 89.7(7.2)	20-65y; BMI 27-40; fasting TG >2.0mmol/L, no metabolic disease; male 17, female 9; age 49.3(8.8), BMI 31.8(2.8), TG 3.0(1.0) vs. male 15, female 14; age 47.1(10.3), BMI 33.2(3.1), TG 3.2(1.1)	BMI 30-50, 18-65 years, interested in weight loss but not actively involved in weight loss program/losing weight; 43(10.2) years, male 66.7% vs. 45(11.6) years, male 24.4%
Quality	Neutral	Positive	Neutral	Neutral	Neutral

Reference	Heymesfield 2003(16)	Rohrer 2008(21)	Ashley, 2006(17)	Noakes, 2004(19)	Davis, 2010(18)
Results	Weight change after 3-months difference between groups: Random effect meta-analysis -2.6 (se 0.96) p=0.006. Favours Meal replacement. Difference in weight change between groups after 1 year: Random effect meta-analysis -2.43 (se 1.65) p=1.42	mean -3.3/ -2.7, median -3.4/ -2.6, sad 2.56/2.25, min -8.1/ -7.0, max 2.3/1.7	MR: baseline to 6 months/ baseline to 1 year: weight -5.2(4.0)/ -5.0(4.9), BMI -1.9(1.4)/ -1.9(1.9), body fat -4.3(4.0)/ -4.5(6.5), waist -4.8(3.22)/ -4.9(4.6) vs. traditional food group: weight -5.4(5.4)/ -6.1(6.7), BMI -2.1(2.2)/ -2.6(2.9), body fat -5.4(6.5)/ -5.7(8.1), waist -6.1(5.5)/ -6.1(7.0)	baseline to 3 months/ baseline to 6 year: MR: weight -6.0(4.2)/ -9.0(3.4); 6.3%(0.8) loss at 3 months/ 9.4%(1.5) loss at 6 months vs. low kJ: weight -6.6(3.4)/ -9.2(5.1); 6.6%(3.4) loss at 3 months/ 9.3%(1.0) loss at 6 months	changes 0-16 weeks: weight loss 13.5(5.9) (12.3%)/ 6.5(6.8) (6.7%); 26/28 lost ≥5% of initial body weight at 16 weeks vs. 11/20, 21/28 ≥10% vs. 5/20 ; BMI -12.3%/-6.7%, body fat % -5.6% (13.6% reduction)/ -1.5% (2.7% reduction); waist -13.0 (11.2%). Changes 0-40 weeks: -8.9(8.9) (-7.8%)/-5.7(8.6) (-5.9%); 16/26 maintained ≥5% vs. 6/20 ,10/26 ≥10% vs. 4/20; BMI -7.8%/ -5.9%,body fat % -2.9%/ -1.8%
Effect on risk (Increase/None/ Protect)	Protect - MR achieved 2.6kg greater weight loss after 3 months, and 2.43kg weight loss after 1 year.	30d weight loss in MR diet comparable to that achieved by a low fat, calorie controlled diet. Not clinically significant loss	Significant weight loss by 6 months and maintained by 12 months in both groups. No significant difference between groups for weight/fat/waist. MR group had better nutrient composition.	Clinically significant weight loss in both groups at 3 and 6 months. Not significant between groups	At 16 weeks both groups achieved significant decrease in weight, BMI, waist, lean muscle. MR was significantly better than Food based for all but lean muscle mass
Clinical importance	1	1	1	1	1
Clinical relevance	1	1	1	1	1
Generalisable	Y	Y	Y	Y	N
Applicable	Y	Y	Y	Y	Y

Table 1.23: Studies used to make evidence statement for a VLED with meal replacements compared to a low energy diet

Reference	**Avenell 2004(10)**	**Tsai 2006(22)**
Type of study	Systematic Review	Systematic Review
Level of evidence	I	I
Intervention/ comparator	Low calorie diet : 4.2-6.7MJ/day VLCD<4.2MJ/day	VLCD: <800calories/day for 8 to 24 weeks LCD: 800 to 1800 calories
N	4 studies, n participants not reported	6 studies, 314 participants
Population/study information	Mean BMI: 37.3-40.5, 2 studies included only women.	Mean age 46.1, Mean BMI31.0. 75% Female
Quality	Positive	Neutral
Results	Weights change after 12-months no significant difference between groups. -0.15kg (95% CI: -2.73 to 2.43kg). Weight change after 18-months no significant difference between groups -1.13kg (95% CI: -5.32 to 3.06kg)	Difference in Weight change between groups (short term 8 to 50 weeks) -6.4% (2.7%)p =0.0001 in favour of VLCD. Short term = m 8-50 weeks, difference in Weight change (long-term: 18-66 months) -1.3 (5.1%) p>0.2 therefore no difference between groups
Effect on risk (Increase/None/ Protect)	None - significant weight loss in both groups but not different.	Protect - VLED achieved 6.4% greater weight loss in short term (8-50weeks) but not in the longer term (18-66 months).
Clinical importance	1	1
Clinical relevance	1	1
Generalisable	Y	Y
Applicable	Y	Y

Table 1.24: Studies used to make evidence statement for reducing energy intake with meal replacements, compared to general dietary advice

Reference	Tuomilehto, 2009(27)	Kemppainen, 2008(24)	Allison, 2003(23)	Miller, 2010(25)	Nerfeldt, 2008(151)	Vander Wal, 2007a(29)	Vander Wal, 2007b(28)
Type of study	RCT	RCT	RCT	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II	II	II	II
Intervention/ comparator	1 year lifestyle intervention including an initial weight reduction program with a 12 week VLCD/ general dietary and exercise counselling	VLCD with supervised lifestyle intervention (fortnightly with nutritionist)/ routine lifestyle counselling by physician and study nurse	Scan Diet MR (1200kcal/d;5 shakes, 4 exchanges of fruit, 4 veg, 1 fat)/ control (both received single dietary counselling session and pamphlet describing weight loss practices)	intensive weight loss (WL) daily energy deficit of 1000 cal/d; 2 MR (slimfast) + meal from menu plan + snacks (F&V)/ weight stable control (WS) (encouraged to maintain their weight throughout the study); WL group also had 60 min nutrition sessions and structured exercise training program 3d/week for 60 mins	LCD MR (Nutrilett) (~800kcal/day) + group meetings. For the first 7 weeks MR only, 1 week gradual introduction of low-calorie meals / control group (received LCD and group meetings after initial 8 weeks)	low-carb, high fat MR/ mod carb, low fat MR/ control (normal daily routines)	cereal substitution + Nutrient bar (CB)/ cereal and waffle substitution + nutrient bar (CWB)/ cereal substitution no nutrient bar (CR)/ control (followed normal dietary routines)
N	35/37	26/26	37/37 (50/50 enrolled - ITT used)	44 / 42(39/ 39 completed)	6/5.	enrolled 45/46/46; completed 42/40/44	30/34/33/36

Reference	Tuomilehto, 2009(27)	Kemppainen, 2008(24)	Allison, 2003(23)	Miller, 2010(25)	Nerfeldt, 2008(151)	Vander Wal, 2007a(29)	Vander Wal, 2007b(28)
Population/study information	age 18-65, BMI 28-40, apnea-hypopnea index 5-15 events; male/female 26/9, age 51.8(9) weight 101.2(11.9) BMI 33.4(2.8) waist 112.5(8.7) vs. male/female 27/10, age 50.9(8.6) weight 92.3(11.3) BMI 31.4(2.7) waist 105.3(8.3)	BMI 28-40; mild obstructive sleep apnoea; age 51(8.3); male/female 21/5; weight 103(14); BMI 33(3.3); waist 113(10) vs. age 49(8.9); male/female 20/6; weight 94(12); BMI 32(3.1); waist 105(9.5)	BMI 28-41, age 35-65, no, recent weight loss/attempts; age 50.4(8.9), weight 92.1kg(14.8), BMI 35.1 (7.9), total body fat mass 42.1%(6.3) fat mass 38.9kg(9.1) waist 101.2(10.7) vs. age 50.0(8.0), weight 91.4kg(14.0), BMI 33.5 (3.5), total body fat mass 43.1%(5.7) fat mass 39.5kg(8.7) waist 101.1(9.6)	BMI≥30.0, ≥60 years, symptomatic knee OA, self-reported difficulty in performing at least one certain activity. 65% female; weight: 97.4(2.6); BMI 34.9(2.5); body fat kg 41.0(6.2) vs. weight: 97.9(2.7); BMI 34.0(0.6); body fat kg 39.7(1.2)	20-69 years; males, BMI≥30, apnoea-hypnoea index≥10 and or oxygen desaturation index ≥6; age 50(35-60), weight 120 (100-180), BMI 38(33-54). Overall completers were older and lighter vs. age 48(28-57), weight 106 (98-126), BMI 34(30-36)	18-65years, BMI≥25, <6.82kg weight loss in previous 3 months; low carb: female/male 34/7; age 50.46(9.58); BMI 33.13(5.85); weight 90.51(17.88); % body fat 45.06(7.94); waist 100.84(12.34); hips 116.87(13.08). Mod carb: female/male 31/9; age 49.58(9.86); BMI 37.26(7.99); weight 105.15 (27.54); % body fat 47.03(7.67); waist 110.01(16.13); hips 126.47(0.2). control: female/male 37/7; age 49.57(8.78); BMI 34.97(7.72); weight 97.05(23.15); % body fat 45.27(8.84); waist 103.99(17.42); hips 119.86(14.15)	18-65 years, BMI≥25, <4.54kg weight loss in previous 3 months and no formal weight loss attempts in previous 10 weeks; women 115, men 18, age 46.74 (9.47)(21-62); BMI 37.04(6.74)(26.2-64.9)
Quality	neutral	neutral	positive	positive	neutral	positive	positive

Reference	Tuomilehto, 2009(27)	Kemppainen, 2008(24)	Allison, 2003(23)	Miller, 2010(25)	Nerfeldt, 2008(151)	Vander Wal, 2007a(29)	Vander Wal, 2007b(28)
Results	change in weight: -10.7(6.5)/ -2.4(5.6); BMI -3.5(2.1)/ -0.8(2.0); waist -11.6 (6.6)/ -3.0(6.0) (all <0.001)	Change 0-3 months: BMI -5.4 / -0.49. mean difference between groups BMI 4.9(4.1-5.7) p<0.001	(ITT) MR: 4 weeks/8 weeks/ 12 weeks: weight -3.5(3.8)/-5.5(5.7)/ -7.0(4.6), total body fat mass (%) -0.5(3.0)/-0.6 (3.5)/-1.5 (3.6), fat mass (kg) -1.8(3.3)/ -3.0 (4.1)/ -4.3(4.0), waist -3.2(4.0)/ -5.4(4.5)/ -6.0(4.2) VS. control 4 weeks/8 weeks/ 12 weeks: weight -2.7(4.5)/-3.0(4.9)/ -2.9(3.3), total body fat mass (%) -0.3(2.0)/-0.5 (4.2)/-1.5 (3.0), fat mass (kg) -1.5(3.0)/ -1.7 (3.9)/ -1.4(4.8), waist -2.9(4.0)/ -3.9(8.3)/ -2.9(3.7)	weight change 0-6 months: -8.8(0.7%)/ -0.1(0.7%); BMI baseline/6m 34.9(2.5)/ 31.8(0.8) vs. 34.0(0.6) (no change); kg body fat and lean body mass significantly lower in WL group then WS control	baseline/after LCD (median(range)) LCD: weight 115(100-124)/ 96.5(90-110); BMI 37 (33-40)/ 32.2(27.8-35.2) vs. control: 105(98-126)/102(100-127)/ 92(87-114); BMI 33.1 (30.2-36.4)/ 32.6(30.9-36.7)/ 29.4(26.9-33);	change 0-4 weeks: low carb: weight -2.94(2.25)/ -2.6(2.39)/ -0.61(1.33), BMI -1.02(0.84)/-0.94(0.85)/ -0.47(1.9), % body fat -1.22(1.21)/ -0.76(1.13)/ -0.47(1.9), waist -4.24(2.49)/ -4.32(2.95)/ 0.15(1.7), hips -3.43(2.24)/ -3.30(1.93)/ 0.08(1.27)	change baseline-4 weeks: CB/CWB/CR/control: weight -3.27(2.5)/-2.8(1.98)/ - 3.45(1.92)/ 0.54(1.57); BMI -1.18(0.9)/ -1.08(0.79)/ -1.30(0.75)/ 0.22(0.57); body fat % -0.95(1.21)/-0.28(1/35)/ -0.77(1.39)/ 0.41(1.5); waist -6.05(3.16)/-5.23(2.65)/ -5.93(2.72)/ 0.4(2.0); hips -5.37(2.64)/-4.22(2.88)/ -5.5(4.93)/ -0.46(1.10); thighs -1.92(1.88)/ -2.09(1.74)/-2.08(1.93)/ 0.32(1.19)
Effect on risk (Increase/None/ Protect)	Clinically significant 1 year weight/waist loss in intervention group (10.6% of initial weight vs. 2.6% in control) p<0.001	Clinically significant drop in VLCD group during the 3 months but not the routine lifestyle counselling group. Significant diff between groups	clinically significant weight loss in MR group after 12 weeks compared to control	Incorporating a MR into a weight loss program resulted in significant weight loss at 6 months, which was not seen in the weight stable control group.	The LCD resulted in significant weight loss both in the intervention group and the control group after LCD.	Protect - both MR diets produced significant weight loss in the 4 weeks however the low carb produced greater decline in % body fat. Significant difference between both diets and control except for BMI	Significant difference between meal replacements and control except for % body fat and CWB. Meal replacements did not differ
Clinical importance	1	1	1	1	1	2	2
Clinical relevance	1	1	1	1	1	1	1
Generalisable	N	N	Y	N	N	Y	Y
Applicable	Y	Y	Y	N	Y	Y	Y

Table 1.25: Studies used to make evidence statement for manipulation of protein and carbohydrate intake

Reference	Halton 2004(39)	Walker Lasker 2008(44)	Kleiner 2006(43)	Layman 2009(45)	Johnston 2004(42)	Stamets 2004(49)
Type of study	Systematic review of RCT	RCT	RCT	RCT	RCT	RCT
Level of evidence	I	II	II	II	II	II
Intervention/ comparator	High protein (22 to 49% of energy) compared to high carbohydrate (32 to 50% of energy from CHO), only 4/15 studies also manipulated fat. Weight loss studies. Intervention duration for studies that manipulated all macronutrients was: 10 weeks, 3 RCTs had 6 months duration and 1 RCT had 12 months. Intervention duration for RCTs that manipulated only P&CHO were 1 - 24 weeks.	Protein: %PCF: 30,40,30 vs. CHO: %PCF: 15,55,30. 7100kJ/d, fibre ~14g/1000kcal/d, 4 months duration, 1 hr meeting each week, food not provided.	HCLF: %PCF: 14,59,27 (<7% sat fat), 25g/d fibre vs HPLF: %PCF: 32,41,27 (<7% sat fat), 25g/d fibre, assigned either 1200, 1500, 1700 or 2000kcal on basis of RMR, 8 weeks duration, all foods provided to participants, hot lunches were served to participants every weekday.	Pro: %PCF: ~30,~40,30 vs. CHO: %PCF: 15,55,30, 7.1-7.9MJ, 17g/4.2MJ fibre, 1 hr meeting each week, food not provided, 12 months	HPLF: %PCF: 32,41,<30 vs. HCLF: %PCF: 15,66,<30, <10% refined sugar, >20g/d fibre, <10% refined sugar, >20g/d fibre, ~70-75% E needed for wt maintenance, 6 weeks duration, weekly meetings held, all foods provided to participants, hot lunches were served to participants every weekday	HP: %PCF: 30,40,30 vs. HC: %PCF: 15,55,30, 1000kcal deficit/day, 4 week duration, spoke with dietitian weekly, food not provided
N	n=249 for 8 RCTs that manipulated P&CHO, and maintained proportion of fat, n = 391 for 5 RCTs that manipulated all three macronutrients.	Pro: n=25, CHO n=25	High Cho Low fat (HCLF) n=7, High Pro low fat (HPLF) n=9	Pro n=64, CHO n=66	High P low F: n=10 (n=9 remained), high CHO low fat n=10 (n=7 remained)	HP n=13, HC n=13, 26% dropout rate.

Reference	Halton 2004(39)	Walker Lasker 2008(44)	Kleiner 2006(43)	Layman 2009(45)	Johnston 2004(42)	Stamets 2004(49)
Population/study information	Human, adults, 5 studies all women, 1 all men. 8 include obese individuals, 6 overweight, 1 glucose intolerant, 2 hyperinsulemic.	Human, adults (40-56yrs), BMI>26, wt< 140kg, non-smoker, no existing illnesses that required meds impacting on study outcomes, no oral steroids or anti-depressants,	Human, adults, BMI>25, non-smoker, no renal or hepatic disease or T2DM or heart disease or alcohol or drug dependence, no HT, no thyroid disease, no meds affecting metabolism, no food allergies or extreme food prefs, no serious medical ailment, ability to adhere to study protocol.	Human, adults (40-56yrs), BMI>26, wt< 140kg, non-smoker, no existing illnesses that required meds impacting on study outcomes, no oral steroids or anti-depressants,	Human, adults (19-546yrs), non-smoker, weighed at least 5kg over target ht-appropriate body wt, no renal or hepatic disease, no DM, no heart dx, no HT, and not taking prescriptive meds.	Human, adults (21-37yrs), females, PCOS, at least BMI 25, in good health, not taking meds known to affect sex hormone levels, CHO metabolism or appetite, non-smokers, exercise <4 times/week.
Quality	Neutral	Positive	Positive	Positive	Positive	Positive
Results	Of the 8 RCTs that manipulated P&CHO, 3/8 studies found greater weight loss on higher protein diet (12-21%P vs. 25-49%P, 6-45%CHO vs. 32-75%CHO; 2.8-5.5kg over 6 months) and the remaining 5/8 studies found no difference between groups (15-20%P vs. 27-45%P, 32-45%CHO vs. 53-60%CHO, 1-16 weeks, 2.1-8kg wt loss). No studies found greater wt loss on lower protein diets. 6/8 studies measured body fat. 1/6 studies found a 3.3kg greater fat wt loss on higher protein diet over 6 months, and remaining 5/6 studies found no	"A weight loss diet with moderate carbohydrate, moderate protein results in more favourable changes in body composition, dyslipidemia, and post-prandial insulin response compared to a high carbohydrate, low protein diet suggesting an additional benefit beyond weight management to include augmented risk reduction for metabolic disease." Trend for 3kg more weight loss and 3% body fat loss in higher protein group. Small sample size + short duration +	Both diets promoted at least 5% loss in body weight and significantly reduced percent body fat. Changes in body weight, fat mass, and percent body fat did not differ significantly between diet groups at any time point during the study, although a significant time effect on these parameters was noted. From baseline to week 8, body weight changed by −4.1 ± 0.6 kg and −4.9 ± 0.7 kg in the HPLF and HCLF diet groups, respectively. Total percent body fat	"The findings of the current study demonstrate that although energy deficit is the major factor for body weight loss, the macronutrient composition affects body composition, blood lipids, and long term compliance." Pro (4 mth intervention): -8.7±0.5% wt, -5.6±0.4kg fat mass; 12mths ITT -9.6±0.9% wt, 6.6±0.7kg fat mass; Completers 12 mths -10.7±1.1% wt, 7.3±0.9kg fat mass. CHO (4 mth intervention): -7.6±0.5% wt, -4.6±0.3kg fat mass; 12mths ITT -8.0±0.7% wt, 4.9±0.4kg fat mass;	"In conclusion, under tightly controlled experimental conditions, energy-restricted, low fat diets of varying protein content (15 or 30% energy) were equally effective at promoting steady weight loss over a 6 week period. However, subjects adhering to the high protein diet reported less hunger and a greater degree of diet satisfaction than their counterparts consuming the lower protein diet."	"Our study provides evidence that a short term hypocaloric diet, with appropriate supervision and monitoring, has a reasonably high compliance rate in a study setting (75%). Those who complete a hypocaloric intervention can expect a significant weight loss and significant improvement in their reproductive and metabolic abnormalities, but these data demonstrated that no statistically significant

Reference	Halton 2004(39)	Walker Lasker 2008(44)	Kleiner 2006(43)	Layman 2009(45)	Johnston 2004(42)	Stamets 2004(49)
	differences in weight (2.8-6.9kg) between higher and lower protein groups (15-20%P vs. 27-40%P, 25-45%CHO vs. 57-75%CHO) over 1-16 weeks. No studies found greater fat weight loss on lower protein diets. Of the 5 RCTs that manipulated all three macros, 3/5 RCTs found greater weight loss with higher protein intakes (3.9-5.5kg wt loss diff over 6 months). The remaining 2/5 studies found no difference in weight loss between groups (2.5-6.4kg wt loss over 10 weeks & 1 year). No studies found higher weight loss in lower protein groups. 2/5 studies also measured body fat, with 1 study finding higher protein diets had a 2.8kg greater fat loss over 6 months, and the remaining study finding no different in fat loss over 10 weeks (HP 4.5kg vs. LP 2.8kg).	findings not clinically significant.	(as measured using DEXA) differed significantly from baseline to week 8 in participants of both diet groups (HPLF: −1.5 ± 0.4%; HCLF: −0.4 ± 0.0%).	Completers 12 mths - 9.1±0.9% wt, 5.3±0.6kg fat mass. No significance between groups for weight loss at both time points. But significant difference in body fat loss.		increased benefit was associated with a high protein diet."
Effect on risk (Increase/None/Protect)	Inconclusive	None (trend for higher protein superior improvements in wt), Protect (3% reduction in body fat on high protein diet)	None	None (weight loss). Protect (body fat)	None.	None.
Clinical importance	4	2	3	2	3	3
Clinical relevance	1	1	1	1	1	1
Generalisable	Y	Y	Y	Y	Y	Y

Reference	Halton 2004(39)	Walker Lasker 2008(44)	Kleiner 2006(43)	Layman 2009(45)	Johnston 2004(42)	Stamets 2004(49)
Applicable	Y	Y	Y	Y	Y	Y

Reference	Moran 2003(47)	Campbell 2010(41)	Abete 2009(40)	Meckling 2007(46)	Sacks 2009(48)
Type of study	RCT	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II	II
Intervention/ comparator	HP: %PCF: 30,40,30, 6000kJ/d vs. LP: %PCF: 15,55,30, 12 weeks duration, food not provided, participants met with dietitian fortnightly	HP: %PCF: 30,45,25 (40% of this protein from lean pork), vs. LP: %PCF: 18,57,25 (lacto-ovo-vegetarian sources), 750kcal/day less than estimated energy requirement, 12 weeks, meat provided to higher protein group	HP: %PCF: 30,40,30 vs. Control: %PCF: 15,55,30, controlled balanced diet without legume and fatty fish consumption, 30% reduction in calories from total energy expenditure, 8 week duration, foods not provided, weight loss monitored weekly by dietitian	HP: %PCF: ~45,42,30 (1gP:1gCHO, no more than 30%F) vs. Control: %PCF: ~23,64,30, (1gP:3gCHO, no more than 30%F), 500kcal deficit/d, 12 weeks duration, food not provided, weekly counselling sessions held to improve dietary compliance.	low fat, high protein (%PCF: 25,55,20) ; high fat, average P (%PCF: 15,45,40); high fat high P (%PCF: 25, 35,40), low fat, average protein (%PCF: 15, 65,20), ≤8%sat fat, 20g fibre, ≤150mg chol/1000kCal, 750kCal deficit/day from REE and usual activity, 2 years duration, weekly sessions until 6 months and then fortnightly sessions until 24 months, food not provided.
N	HP n = 14, LP n = 14	HP n = 13, LP n=15	HP: 9/ C: 10	HP n=15 (dropouts = 7); Control n=15 (dropouts = 5)	LFHP n=202; HFAP n=204; HFHP n=201; LFAP n=204
Population/study information	Human, adults, females, PCOS, wt< 140kg, non-smoker, not using OCPs/hormone tx/insulin-sensitising agents. able to comply with requirements, no hyperprolactinemia, thyriod abnormalities, non-classic adrenal hyperplasia.	Human, adults (>19 years), females, BMI 25-37, clinically abnormal kidney, liver or heart function or protein or haematological status, no DM, no insulin therapy, non-smoker.	Human, males, mean age 38 ± 7 yrs, obese, no DM, no HT, no liver/ renal/haematological dx or other clinical disorders, maintained weight in last 3 months, no meds for chronic dx, no surgical or obesity tx, no alcohol or drug abuse.	Human, BMI 25-30, 25-30 yrs, non-smoker, premenopausal status, no major clinical dx requiring tx with drugs known to affect BP, protein metabolism, CVD, or DM.	Human, adults (30-70 yrs), aimed for 40% M, BMI 25-40, no diabetes or unstable CVD, no meds affecting body weight, sufficient motivation levels as assessed by interview and questionnaire.
Quality	Positive	Neutral	Positive	Positive	Positive

Reference	Moran 2003(47)	Campbell 2010(41)	Abete 2009(40)	Meckling 2007(46)	Sacks 2009(48)
Results	"This unique study confirmed the effect of weight loss on improving metabolic, endocrine, and clinical parameters in overweight women with PCOS. Improvements occurred maximally in energy restriction and were maintained or reversed in weight maintenance, in some cases to pre-baseline levels. Replacing protein for CHO resulted in minor cardiovascular and reproductive improvements that did not appear to be mediated through difference in weight or abdominal fat loss or insulin sensitivity..."	No differences in wt or body composition between high and low protein groups over short time frame and in small sample size.	"Thus, moderate HP diets appear as a valid strategy to improve weight loss and fat mass loss during an energy restriction period, potentially avoiding the resting energy expenditure reduction by the activation of mitochondrial oxidation pathway, which may be also associated with a better body weight regulation after the nutritional intervention period." Significantly greater reductions in weight (-8.3 vs. -5.5%), and BMI (-9.3% vs. -4.9%) in high protein group. (p=0.042) No difference in change in fat mass	"In conclusion, a high protein, moderate fat, moderate CHO diet proved superior to a low protein, moderate fat, high CHO diet in promoting weight loss in overweight and obese women. In fact, the 1:1 ratio need not be achieved; rather, 1 protein:1.5CHO was sufficient in promoting additional weight loss. .. Long term follow up studies should confirm whether these benefits are maintained once counselling ceases." 2.5kg diff between groups.	"Reduced-calorie diets result in clinically meaningful weight loss regardless of which macronutrients they emphasize." "Changes from baseline difference among the groups by <0.5kg weight and 0.5cm waist at each time point (6, 12, 18, 24 months) P>0.05." "In conclusion, diets that are successful in causing weight loss can emphasize a range of fat, protein, and carbohydrate compositions that have beneficial effects on risk factors for cardiovascular disease and diabetes. Such diets can also be tailored to individual patients on the basis of their personal and cultural preferences and may therefore have the best chance for long-term success."
Effect on risk (Increase/None/Protect)	None	None	Protect (higher protein led to small improvements in weight/BMI) , None (Fat mass)	Protect (higher protein may lead to small greater improvements in weight by 12 weeks)	None
Clinical importance	3	3	1	2	3
Clinical relevance	1	1	1	1	1
Generalisable	Y	Y	Y	Y	Y
Applicable	n	Y	Y	Y	Y

Table 1.26: Studies used to make evidence statement for manipulation of fat and carbohydrate intake

Reference	Pirozzo 2003(50)	Segal-Isaacson 2004(56)	Arvidsson 2004(51)	McLaughlin 2006(54)
Type of study	Systematic review of RCT	RCT	RCT	RCT
Level of evidence	1	II	II	II
Intervention/ comparator	Low fat (<30g/d or 20-21% of E) vs. Higher fat (<50g CHO/d or 35% of E from fat), 1000-1500kCal, 3-18months duration.	VLCHO: %PCF: 30,5,65, 22%SF:21%PUFA:22%MUFA vs. HPLF: %PCF: 30,50,20, 6%SF:6%PUFA:8%MUFA, REE-200kcal/d, 12 week cross-over controlled feeding study, 6 weeks each intervention arm, food was provided, measures taken every 6 weeks	Low fat: %PCF: 15-20, 60-65, 20-25, vs. Modfat: %PCF: 15-20, 40-45, 40-45, 600kcal/d reduction, 10 week duration, dietitian had weekly face to face or telephone contact with participant, food not provided.	HCHO: %PCF: 15,60,25 vs. MCHO: %PCF: 15,40,45, 7% sat fat, 200mg cholesterol/d, 750kcal/d deficit, 16 week duration, food not provided, weekly meeting with dietitian.
N	3 relevant RCTs from 6 RCTs in total, 346 participants	n=4, cross-over trial	Lowfat: n=20, modfat n=20	HCHO: n=30; MCHO: n=27
Population/study information	Human, adults (18-66 yrs), 85-100% women, overweight or obese, free from serious medical conditions, USA or UK residents, intervention duration 3 - 18 months	Human, overweight or obese postmenopausal women, WHR ≥0.8, BMI 28-40, <114kg, no hx CVD, no DM, no meds affecting wt or insulin sensitivity, no hx of eating disorders, trigs<400mg/dl, weight stable past 3 months, no low CHO wt loss diet undertaken past 6/12, no claustrophobia, no ferromagnetic foreign bodies, easy access to veins for venipuncture.	Human, obese women, 21-49yrs, BMi30.9-47.7, otherwise healthy, no regular meds,	BMI 29-36, stable recent wt hx, no use of wt loss drugs, no hx of major organ dx, no anaemia, no kidney or liver dx, no DM.
Quality	Positive	Neutral	Positive	Neutral

Reference	Pirozzo 2003(50)	Segal-Isaacson 2004(56)	Arvidsson 2004(51)	McLaughlin 2006(54)
Results	At 6 and 12 months, weight loss was similar for both the low fat and low CHO groups (6mths: LF -5.08kg (95%CI -5.9 to -4.3kg) vs. control -6.5kg (95%CI -7.3 to -5.7kg) (12mths: LF -2.3kg (95%CI -3.2 to -1.4kg) vs. control -3.4kg (95%CI -4.2 to -2.6kg). Only 1 relevant study measured weight at 18 months therefore 18 months timeframe not examined further. Significant losses to follow up reported, paucity of longer term studies. 2/3 of eligible studies provided weekly meetings. No studies provided foods.	No difference in weight change between intervention arms, sample size very small. "In conclusion, additional controlled feeding studies are needed to determine whether protein and gluconeogenesis contribute toward greater weight loss on VLC diets. Such studies may want to compare VLC diets against both iso-nitrogenous and lower protein LF diets to determine whether, if there is greater energy expenditure, it is protein per se or protein in the context of CHO restriction that is the operative mechanism. Additional studies are also needed to determine whether the consistent pattern of greater short-term weight loss with LVC diets under 'natural conditions' (where calories are not strictly controlled) is caused by increased energy expenditure, restriction of food choices, greater satiety, or some combination of all three."	No difference in weight and body comp between groups (~7.5% wt decrease achieved in both groups).	No difference in weight between groups. ".. Our results suggest that a calorie-restricted diet that is moderately greater in unsaturated fat and lower in carbohydrate resulted in amounts of weight loss comparable to those seen with the diet currently recommended by the ADA, AHA, and NHLBI and led to perhaps greater reductions in CVD risk than did the recommended diet. Finally, because the 40% CHO diet does not require major changes in the average US diet, and because compliance, rather than macronutrient content, appears to be the major contributor to effective weight loss, a calorie-restricted diet containing 40% CHO may represent an attractive alternative to either a high fat, very low CHO diet or the low fat, 60% CHO diet currently recommended by national organizations."
Effect on risk (Increase/None/Protect)	None	None	None	None
Clinical importance	4	2	3	2
Clinical relevance	1	1	1	1
Generalisable	Y	Y	Y	Y
Applicable	N	Y	Y	Y

Reference	Cornier 2005(52)	Kirk 2009(53)	Petersen 2006(152)	Sacks 2009(48)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	HCLF: %PCF: 20,60,20 vs. LCHF: %PCF: 20,40,40, 400kcal deficit, 16 week duration, all food was provided, weekly meeting with dietitian	HC: %PCF: 15,65,20 (at least 180gCHO/d) vs. LC: %PCF: 15,10,75 (no more than 50gCHO/d), 1000kcal/day deficit, ~11 week duration, food was provided, weekly meeting with dietitian	HF: %PCF: 15,40-45,40-45 vs. LF: %PCF: 15,60-65,20-25, 600kcal/d less than individually estimated energy requirements (RMR*1.3), 10 week duration, food was not provided, weekly meeting with dietitian	low fat, high protein (%PCF: 25,55,20) ; high fat, average P (%PCF: 15,45,40); high fat high P (%PCF: 25, 35,40), low fat, average protein (%PCF: 15, 65,20), ≤8%sat fat, 20g fibre, ≤150mg chol/1000kCal, 750kCal deficit/day from REE and usual activity, 2 years duration, weekly sessions until 6 months and then fortnightly sessions until 24 months, food not provided.
N	Insulin sensitive HCLF: n=6; Insulin resistant HCLF: n=4; Insulin sensitive LCHF: n=6; Insulin resistant LCHF: n=5	HC n=11, LC n=11	HF: n=382 (dropouts n=70); LF: n=389 (dropouts n=53)	LFHP n=202; HFAP n=204; HFHP n=201; LFAP n=204
Population/study information	Human, obese (BMI 30-35), fasting insulin <10uU/mL or >15uU/mL.	Human, obese, insulin resistant (HOMA >3), no DM, no excessive alcohol consumption, no liver dx, no other serious illnesses or organ dysfunction, non-smokers, no meds altering glucose metabolism, weight stable, sedentary (<1 hr / week) for at least 3 months prior	Human, at least BMI 30, 20-50 yrs, wt stable prior 3/12, no HT, no DM, no meds treating hyperlipidemia, no untreated thyriod dx, no surgically or drug treated obesity, not pregnant, no participation in other trials, no alcohol or drug abuse.	Human, adults (30-70 yrs), aimed for 40% M, BMI 25-40, no diabetes or unstable CVD, no meds affecting body weight, sufficient motivation levels as assessed by interview and questionnaire.
Quality	Positive	Positive	Positive	Positive

Reference	Cornier 2005(52)	Kirk 2009(53)	Petersen 2006(152)	Sacks 2009(48)
Results	"In conclusion, the state is insulin sensitivity determined the effectiveness of macronutrient composition of hypocaloric diets in obese women. Clearly, to lose weight, patients must be on a hypocaloric diet. To obtain maximal benefits, the macronutrient composition of a hypocaloric diet may need to be adjusted to fit the state of insulin sensitivity. Insulin sensitive individuals (fasting insulin <10 uU/mL) should be recommended to consume an HCLF hypocaloric diet (60% CHO and 20%F) (~7% wt loss diff). Insulin resistant individuals (>15uU/ml) should be recommended a diet containing 40% CHO and 40%F (LCHF) (~5% wt loss diff). The short term changes seen in this study have not been demonstrated to be durable over longer periods of time as seen in longer term studies lasting up to a year."	No difference in weight loss and body composition between groups.	No difference in weight loss and body composition between groups.	"Reduced-calorie diets result in clinically meaningful weight loss regardless of which macronutrients they emphasize." "Changes from baseline difference among the groups by <0.5kg weight and 0.5cm waist at each time point (6, 12, 18, 24 months) P>0.05." "In conclusion, diets that are successful in causing weight loss can emphasize a range of fat, protein, and carbohydrate compositions that have beneficial effects on risk factors for cardiovascular disease and diabetes. Such diets can also be tailored to individual patients on the basis of their personal and cultural preferences and may therefore have the best chance for long-term success."
Effect on risk (Increase/None/Protect)	Protect (high CHO low fat with insulin sensitive ppl, low CHO high fat with insulin resistant people)	None	None	None
Clinical importance	1	3	3	3
Clinical relevance	1	1	1	1
Generalisable	Y	Y	Y	Y
Applicable	Y	Y	Y	Y

Table 1.27: Studies used to make narrative statement for manipulation of fat, protein and carbohydrate intake

Reference	Halton 2004(39)	Bravata 2003(57)	Jenkins 2009(153)	Tay 2008(154)
Type of study	Systematic review of RCT	Systematic review of RCT	RCT	RCT
Level of evidence	I	I	II	II
Intervention/ comparator	High protein (22 to 49% of energy) compared to high carbohydrate (32 to 50% of energy from CHO), only 4/15 studies also manipulated fat. Weight loss studies. Intervention duration for studies that manipulated all macronutrients was: 10 weeks, 3 RCTs had 6 months duration and 1 RCT had 12 months. Intervention duration for RCTs that manipulated only P&CHO were 1 - 24 weeks.	Low (<60g/d) compared to high (>60g/d) CHO (0-901g/d CHO), however all but 8 RCTs had manipulated all three macronutrients (P 0-189g/d, F 0-346g/d), intervention 6 - 365 days.	LC: %PCF: 31,26,43 vs. HC:%PCF: 16,58,25; food provided for 60% caloric requirements , 4 weeks duration, weekly meetings held, food provided.	VLCHF: %PCF: 35,4,61 (First 8 weeks CHO Intake restricted to <20g/day then option to increase to <40g/day for the remaining 16weeks) vs. HCLF: %PCF: 24,46,30 (<8% sat fat), isocaloric ~ 30%, 24 weeks duration, fortnightly meetings for first 8 week and monthly consultations thereafter, key food provided for first 8 weeks.
N	n=249 for 8 RCTs that manipulated P&CHO, and maintained proportion of fat , n = 391 for 5 RCTs that manipulated all three macronutrients.	43 RCT studies (however 17 of these studies had dietary energy content of at least 2000kCal); 3268 participants (1439 were from RCTs, remainder from case/control, sequential or pre-post studies)	LC:25/HC:25	VLC:55/HCLF:54
Population/study information	Human, adults, 5 studies all women, 1 all men. 8 include obese individuals, 6 overweight, 1 glucose intolerant, 2 hyperinsulemic.	Human, adults, 18-68 years (one study >16 years), 5 RCTs were all males, 12 RCTs were all females, remainder were13-83% male, studies did include participants with diabetes but results from all trials (diabetic and non-diabetic populations) were grouped(appears to be 6 RCTs from reference list), intervention > 4 days (6 - 365 days)	Healthy Males/postmenopausal females 21-70 yrs, with high LDL Cholesterol and TGs, BMI>27 and not in a wt loss program. No lipid lowering meds, hormone therapy, alcohol consumption of >2 drinks/day, tobacco use, DM, BP, Renal/liver disease ,cancer or food allergies	Males & Females 18-65yrs, abdominal obesity and presence of least 1 Additional metabolic syndrome risk factor, No hx of liver, CVD or PVD, respiratory, Gastro disease, DM or malignancy

Reference	Halton 2004(39)	Bravata 2003(57)	Jenkins 2009(153)	Tay 2008(154)
Quality	Neutral	Positive	Positive	Positive
Results	Of the 8 RCTs that manipulated P&CHO, 3/8 studies found greater weight loss on higher protein diet (12-21%P vs. 25-49%P, 6-45%CHO vs. 32-75%CHO; 2.8-5.5kg over 6 months) and the remaining 5/8 studies found no difference between groups (15-20%P vs. 27-45%P, 32-45%CHO vs. 53-60%CHO, 1-16 weeks, 2.1-8kg wt loss). No studies found greater wt loss on lower protein diets. 6/8 studies measured body fat. 1/6 studies found a 3.3kg greater fat wt loss on higher protein diet over 6 months, and remaining 5/6 studies found no differences in weight (2.8-6.9kg) between higher and lower protein groups (15-20%P vs. 27-40%P, 25-45%CHO vs. 57-75%CHO) over 1-16 weeks. No studies found greater fat weight loss on lower protein diets. Of the 5 RCTs that manipulated all three macros, 3/5 RCTs found greater weight loss with higher protein intakes (3.9-5.5kg wt loss diff over 6 months). The remaining 2/5 studies found no difference in weight loss between groups (2.5-6.4kg wt loss over 10 weeks & 1 year). No studies found higher weight loss in lower protein groups. 2/5 studies also measured body fat, with 1 study finding higher protein diets had a 2.8kg greater fat loss over 6 months, and the remaining study finding no different in fat loss over 10 weeks (HP 4.5kg vs. LP 2.8kg).	"There is insufficient evidence to make recommendations for or against the use of low-carbohydrate diets, particularly among participants older than age 50 years, for use longer than 90 days, or for diets of 20g/d or less of carbohydrates. Among the published studies, participant weight loss while using low-CHO diets were principally associated with decreased caloric intake and increased diet duration but not with reduced CHO content."	Mean wt loss from baseline to four weeks LC: 4.7% , -3.9± 0.4kg / HC: 4.9% , -4.2 ± 0.3kg. No difference in weight loss between groups (p=0.94)	Mean wt loss from baseline to 24 weeks: VLCHF: -11.9 ± 6.3kg/ -12.3± 5.5%/ HCLF: -10.1 ± 5.7kg/ -10.5 ± 5.%. No significant difference in wt loss between groups (p=0.17)
Effect on risk (Increase/None/Protect)	Inconclusive	Inconclusive	None	None
Clinical importance	4	2	3	3
Clinical relevance	1	1	1	1
Generalisable	Y	N, participants with T2DM included	Y	Y

Reference	Halton 2004(39)	Bravata 2003(57)	Jenkins 2009(153)	Tay 2008(154)
Applicable	Y	Y	Y	Y

Reference	Halyburton 2007(59)	Sharman 2004(64)	Sacks 2009(63)	Aude 2004(58)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	LCHF: %PCF: 35,4,61 (20% sat fat) vs. HCLF: %PCF: 24,46,30 (<8% sat fat); moderate energy restriction ~30% energy (6000kJ for women, 7000kJ for men) , 8 weeks duration, fortnightly meetings, food provided	VLCD: %PCF: 30,<10,60, vs. LF: %PCF: 20, 55, 25 (<10% saturated fat), -2.1MJ/day, 6 weeks duration, weekly meetings were held, shakes were provided to the low carbohydrate group	low fat, high protein (%PCF: 25,55,20) ; high fat, average P (%PCF: 15,45,40); high fat high P (%PCF: 25, 35,40), low fat, average protein (%PCF: 15, 65,20), ≤8%sat fat, 20g fibre, ≤150mg chol/1000kCal, 750kCal deficit/day from REE and usual activity, 2 years duration, weekly sessions until 6 months and then fortnightly sessions until 24 months, food not provided.	NCEP: %PCF: 15,55,30, Saturated fat <7%, MUFA 10-15%, Modified low carbohydrate (MLC)refer to table 1 (%PCF: 28-33,20-28, 39-62): 1300 calories for women, 1600 calories for men , duration 12 weeks, foods not provided, did not state whether weekly meetings were held.
N	LCHF:48 / HCLF:45	n=15 in total, not specified further into groups ,	LFHP n=202; HFAP n=204; HFHP n=201; LFAP n=204	MLC: 29/ NCEP: 25
Population/study information	Males & Females 24-64 yrs, BMI 26-43 and ≥ other metabolic risk factor. No hx of liver, CVD, PVD, respiratory, gastrointestinal disease, DM, Malignancy or psychological disorder	Overweight males: 33.2±11.3 yrs, body mass: 109.1 ±17.8kg, body fat: 34.9± 5.2%, BMI: 34.3± 5.6kg/m2. Sedentary or moderately active. Cross over design	Human, adults (30-70 yrs), aimed for 40% M, BMI 25-40, no diabetes or unstable CVD, no meds affecting body weight, sufficient motivation levels as assessed by interview and questionnaire.	Males & Females 18 yrs or older, BMI ≥27 willingness and ability to adhere to a prescribed diet for 3 mths and no alterations of physical activity. No hx of thyroid disease, IDDM, pregnancy, unstable medical conditions, current use of oral/parenteral medications known to affect weight or appetite. The use of lipid lowering agents was permitted if it had not been changed during the 3 months prior to participation.
Quality	Positive	Neutral	Positive	Positive

Reference	Halyburton 2007(59)	Sharman 2004(64)	Sacks 2009(63)	Aude 2004(58)
Results	Mean wt loss from baseline to 8 weeks: LCHF: 8.0 ± 0.3% / HCLF: 6.6 ± 0.4 %. Significant greater wt loss in the LCHF compared to HCLF p=0.005	Decrease in body mass VLCD: -6.5 ± 3.0kg (p<0.01)/ LF: -3.7 ± 3.3kg, (p<0.01)	"Reduced-calorie diets result in clinically meaningful weight loss regardless of which macronutrients they emphasize." "Changes from baseline difference among the groups by <0.5kg weight and 0.5cm waist at each time point (6, 12, 18, 24 months) P>0.05." "In conclusion, diets that are successful in causing weight loss can emphasize a range of fat, protein, and carbohydrate compositions that have beneficial effects on risk factors for cardiovascular disease and diabetes. Such diets can also be tailored to individual patients on the basis of their personal and cultural preferences and may therefore have the best chance for long-term success."	Mean wt loss: MLC:-13.6 ± 4.0 lb, NCEP:-7.5± 4.4 lb. Wt loss was significantly greater in the MLC than in the NCEP group (p=0.02)
Effect on risk (Increase/None/Protect)	None	None	None	None
Clinical importance	3	3	3	3
Clinical relevance	1	1	1	1
Generalisable	Y	N	Y	Y
Applicable	N	Y	Y	N

Reference	Noakes 2005(62)	Volek 2009(65)	Meckling 2004(61)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	HP: %PCF: 34,46,29 (<10% sat fat) vs. HC: %PCF: 17,64,20 (<10% sat fat), 5600kJ, 12 week duration, participants were interviewed by a dietitian every 4 weeks, food not provided.	CRD: %PCF: 28,12,59 vs. LFD: %PCF: 20,56,24, 1500 kcal hypocaloric diet, duration 12 weeks, weekly counseling session provided, food not provided.	LF: %PCF: 20, 62, 18, 5-6.7MJ F vs. LCHO: %PCF: 26,15,56 (50-70g CHO/d), 5.9-9.2MJ M, 10 weeks duration, food not provided, weekly meetings held.
N	High Protein (HP) n=52, High CHO (HC) n=48	CRD: 20 / LFD: 20	LF: n=20 (16F, 4M) (dropouts 4F); LCHO: n=20 (15F, 5M) (dropouts 5F)
Population/study information	Human, adults (20-65yrs), females, BMI 27-40, no hx of metabolic dx or T1 or T2DM.	Males & Females 18-55yrs, BMI> 25. No metabolic or endocrine disorders, glucose or lipid lowering meds, consumption of a CRD at baseline or wt loss > 5.0kg in the past 3 mths	Human, BMI >25, sufficient habitual EI (>4000kJ/d), strong personal motivation, no meds affecting blood glucose/ lipids or BP, no clinically diagnosed endocrine dx, no DM, no high trigs or high cholesterol.
Quality	Positive	Positive	Positive
Results	No difference in weight and fat loss between groups using completers analysis. When using one type of intention to treat analysis, the high protein diet had a 1.4kg greater weight loss on average than the high CHO group ($p<0.05$).	Mean wt loss : CRD: -10.1kg / LFD: -5.2kg . Wt loss in the CRD group was , on average 2-fold greater than that in the LFD group -no mention of significance	"In conclusion, hypo energetic diets of widely differing macronutrient concentration are feasible strategies for promoting short term weight loss and improvements in chronic disease risk markers in overweight and obese men and women. Either strategy promotes loss of fat weight... "
Effect on risk (Increase/None/Protect)	Protect (higher protein small improvements in weight - clinically insignificant diff)	None	None
Clinical importance	2	2	3
Clinical relevance	1	1	1
Generalisable	Yes	Yes	Yes
Applicable	Yes	Yes	Yes

TABLE 1.28 Studies used to make narrative statement for popular diets

Reference	Truby 2006(66)	Gardner 2007(67)	Dansinger 2005(68)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	Atkins Diet, Weight Watchers(WW), Slim-Fast (SF), Rosemary Conley (RC), Control group: maintain their current diet and exercise pattern, duration 6 months	Atkins:≤ 20g/d CHO for induction and ≤ 50g/d, for ongoing wt loss phase, Ornish: <10% energy from sat fat, Learn: 55-60% energy from CHO & <10% sat fat, ↑ PA, plus energy restriction Zone: 40% CHO, 30%P, 30%F plus energy restriction, duration 12 months	Atkins: ≤ 20g/d CHO gradual increase to 50g/d, for ongoing wt loss phase, Zone: 40% CHO, 30%P, 30%F, Weight Watchers (WW) 24 to 32 points daily Ornish: vegetarian diet ,<10% energy from sat fat, duration 12 months
N	Atkins:57/ WW: 58/ SF:59, RC:61/ Control: 61	Atkins: 77/ Zone: 79,/ Learn: 79/ Ornish: 76	Atkins: 40/ Zone: 40/ WW: 40/ Ornish:40
Population/study information	Males & Females 18-65 yrs, BMI 27-40. No CHD, DM, Renal, liver, respiratory failure, gout, obesity with known cause, prey gastric or wt loss surgery, clinical depression, eating disorders, drug or alcohol misuse, taking lipid/BP or weight loss drugs, cancer, breastfeeding or pregnant	Premenopausal women 25-50 yrs, BMI: 27-40, stable wt over previous 2 months. No SR BP or using BP meds, DM, heart, liver, renal disease, cancer, any meds to affect wt/energy expenditure, alcohol intake, pregnancy, lactating, no menstrual period in the last 12 months, or planning to become pregnant	Men & Women any age, OW or obese BMI: 27-42, have at least 1 metabolic cardiac risk factor. No unstable chronic illness, insulin therapy, urinary microalbumin of more than 2 times normal, abnormalities of liver or thyroid test results, on wt loss medication or pregnant
Quality	Positive	Positive	Positive

Reference	Truby 2006(66)	Gardner 2007(67)	Dansinger 2005(68)
Results	Mean change in weight and body composition from baseline to 12 months Atkins: 6.0 (6.4) kg, Fat loss: 4.6 (4.8kg) WW: 6.6(5.4) kg, Fat loss: 5.0 (4.3) kg SF: 4.8 (5.6) kg, Fat loss: 3.4(4.3) kg RC: 4.86 (5.6) kg, Fat loss: 3.4(4.3) kg Monthly wt loss was initially high in all groups but then slowed down. Mean wt loss was significantly higher in the Atkins group during first four weeks ($p<0.001$). At other time points mean wt loss did not significantly vary between the diet groups. No comparison between the diet groups and control. Greatest loss of body fat was seen in the Atkins group - it was significant between the Atkins and slim fast diet. Between baseline and 6 months fat loss did not differ between diet groups but fat loss in all diet groups was significantly greater than in the control group. Absolute wt loss: aster 6 months all diets resulted in clinically useful mean reduction in % bw- no significant differences were seen between the diets but all were more successful than the control as they gained wt 0.95% . The proportion of who completed the trial and lost 10% bw at 6 months 45% Atkins, 36% WW, 21% SF, 46%RC.	Mean 12 month weight change Atkins: -4.7kg (95% CI -6.3 to -3.1) , Zone: -1.6 kg (95% CI -2.8 to - 0.4), LEARN: -2.2 kg (95% CI -3.6 To-0.8kg), ORNISH -2.6kg (95%CI -3.8 to -1.3) Mean 12mth weight change was significantly different for Atkins vs. Zone. Wt change among the Zone, LEARN and Ornish groups did not differ significantly at any time point. Although wt loss in the Atkins group was greater than any other group, it was modest with a mean 12month wt loss of only 4.7kg. No significant differences in body composition between groups at 12 months	Mean 12 month weight change Atkins: -2.1 ± 4.8.kg Zone: -3.2± 6.0 kg WW: -3.0 ± 4.9kg ORNISH -3.3 ± 7.3 kg All diets resulted in statistically significant wt loss at one year however no significant differences between diets ($p=0.40$). Approximately 25% of the initial participants from each diet group sustained a 1 year weight loss of more than 5% of initial body wt and 10% lost more than 10% bw.
Effect on risk (Increase/None/Protect)	None	None	None
Clinical importance	3	3	3
Clinical relevance	1	1	1
Generalisable	Y	Y	Y
Applicable	Y	Y	Y

TABLE 1.29: Studies used to make evidence statements for comparing intakes of higher to lower levels of MUFA

Reference	Due 2008 (69)	Paniagua 2007(71)	Pelkman 2004 (72)	Desroches 2006 (70)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	Intervention: Two diet groups 1) MUFA diet: moderate in fat (35-45% of energy) and high in monounsaturated fatty acids (>20% of energy). 2) LF diet: low-fat diet (20-30% of energy). Comparator: Control diet- 35% of energy as fat (>15% of energy as saturated fat)	Crossover design: 1) diet high in saturated fat (SAT)-47% CHO, 15% PROT, 38%fat- (23%SAT, 9%MUFA, 6%PUFA) , 2) diet rich in monounsaturated fat (MUFA) -47% CHO, 38%fat (9%SAT, 23%MUFA, 25% extra virgin olive oil, 6%PUFA) 3) Diet rich in carbohydrate (CHO)- 65% CHO and 20%fat (6%SAT, 8%MUFA, 6%PUFA).	Intervention: Moderate-fat diet- 33% energy from fat (with 6.5% from saturated fat, 14% MUFA and 8% PUFA.) Comparator: low-fat diet - 18% energy from fat (with 6% saturated fat, 7% MUFA, 2.5% PUFA)	Intervention: High-fat diet rich in MUFA (40.1% of energy intake from fat: 8.2% saturated fat, 22.5% MUFA, 7.6% PUFA) Comparator: low-fat diet (25.8% of energy intake from fat: 6% saturated fat, 13% MUFA, 5% PUFA.)
N	34 (16 MUFA, 18 LF)/ 12(Control)	11 (total)	27 (Moderate-fat diet)/ 25 (Low-fat diet)	29 (High-MUFA diet)/ 32 (low-fat diet)
Population/study information	18-35yrs of age, BMI of 28-36, body weight fluctuations < 3kg over the previous 2mo, non-smokers, pre-menopausal women, non-diabetic/ Participants randomly assigned to diets after > or = 8% weight loss with an 8 week low calorie diet. This was a 6-month intervention period. MUFA diet also included more whole-grain foods, nuts, legumes.	Offspring of obese and type 2 diabetes patients, 35<75yrs of age, BMI > 25 Kg/m2, waist circumference (men/women) > 102/88, HBA1c < 6.5%, insulin-resistant. Participants randomly divided into 3 groups and underwent dietary periods each of 28 days (crossover) . 125% of subjects estimated energy requirements were provided during experimental protocol.	Overweight and obese (120-135% of ideal body weight), 20-67years, Healthy (determined by questionnaire and blood chemistry)/ A parallel-arm study design. Diets were followed for 6 wks to achieve weight loss, which was followed by 4 wk of weight maintenance. All foods were provided. Peanuts, peanut butter, and peanut oil were used to provide half of the fat in the moderate fat diet.	Age: 20-55yrs, Male, BMI 20-44, non-smoking, no large change in body weight for previous year, nil food aversions, no endocrine, cardiovascular, hepatic or renal disorders/ Diets followed for 6-7 wks. Weekday dinner and breakfast, and weekend lunches were provided. Participants received 150% of their habitual daily energy intake. Subjects instructed to eat all breakfast, but consume lunch and dinner meals ad libitum, until satiety was met.

Reference	Due 2008 (69)	Paniagua 2007(71)	Pelkman 2004 (72)	Desroches 2006 (70)
Quality	Neutral	Positive	Positive	Positive
Results	**MUFA-** Body weight (kg): Baseline: 81.3 (75.1, 87.4), 6 month: 83.2 (76.8, 89.6) BMI- Baseline: 27.4 (26.3, 28.5), 6 month: 28.0 (26.9, 29.1). **LF-** Body weight (kg)- Baseline: 85.7 (81.0, 90.5), 6 month: 87.2 (81.8, 92.6). BMI- Baseline: 27.6 (26.3, 29.0), 6 month: 28.8 (27.4, 30.2) **Control-** Body weight (kg): Baseline- 83.0 (75.7, 90.3), 6 month: 86.5 (78.5, 94.5) BMI- Baseline: 28.1 (27.0, 29.1), 6month: 87.2 (81.8, 92.6)	Body Weight (kg) at completion of each 28 day intervention (Mean ±SE) : SAT: 83.2 ± 4.7 , MUFA: 83.6±5.8, CHO: 81.8 ± 6.0	**Moderate Fat:** Rate of weight loss in first 6wks: 1.2 ± 0.05kg/wk, Weight loss at end of weight loss period (wk 6): 7.2±0.29kg **Low-fat:** Rate of weight loss in first 6wks: 1.09 ± 0.06kg/wk, Weight loss at end of weight loss period (wk 6): 6.5 ±0.34kg	**MUFA:** Body weight(kg): Baseline: 89.1 ± 16.5, 6-7wk: 86.7 ± 16.2 , p<0.001 BMI: Baseline: 29.3 ± 5.4, 6-7wk: 28.5 ± 5.3 , p<0.001 Waist circumference (cm): Baseline: 97.9 ± 16.1, 6-7wk: 95.5 ± 15.8, p<0.01 **Low fat:** Body weight(kg): Baseline: 87.6 ±, 14.7, 6-7wk: 85.4± 13.8, p<0.0001 BMI: Baseline: 28.7 ± 4.7, 6-7wk: 28.0 ± 4.5, p<0.0001 Waist circumference (cm): Baseline: 95.2 ± 13.5, 6-7wk: 92.6 ± 12.2, p<0.0001
Effect on risk (Increase/None/Protect)	None	None	None	None
Clinical importance	3	3	3	3
Clinical relevance	1	1	1	1
Generalisable	Y	Y	Y	Y
Applicable	Y	Y	Y	Y

TABLE 1.30: Studies used to make narrative statements for comparing intakes of higher to lower levels of MUFA

Reference	**St-Onge 2008 (74)**	**Flynn 2010(73)**
Type of study	RCT	RCT
Level of evidence	II	II
Intervention/ comparator	Intervention: MCT oil consumption group- consumed either 18g/d (women) or 24 g/d (men) of MCT oil Comparator: Olive oil consumption group- consumed either 18g/d (women) or 24 g/d (men) of olive oil.	Crossover design: Participants consumed a National Cancer Institute (NCI) diet (total fat >15% and <30%)and a plant-based olive oil (PBOO) diet (>= 3 tablespoons of olive oil/day). **Note:** Because of the significant period effect, and a near significant treatment-period effect (p=0.10), results from ONLY the first-administered diet for each subject was analysed.
N	16 (MCT oil)/ 15 (Olive oil)	15 (PBOO)/ 13 (NCI)
Population/study information	19-20yrs of age, BMI of 27-33, weight stable for >6mo and free of chronic diseases/ 16 wk intervention. Subjects received weekly group weight-loss counseling. All subjects received study muffins (contained 10g of MCT oil and 8 or 14g of liquid oil (for women and men respectively) to incorporate into their foods during cooking.	Diagnosis of invasive breast cancer after the age of 50 and within 4yrs of completing treatment. BMI 25-35, nonsmokers, non-diabetics/ NCI and PBOO diets consumed for 8 weeks each (crossover), with random assignment to the order. After completion of the two diet trials, each participant self-selected one of the diets for an additional 6 months of

Reference	St-Onge 2008 (74)	Flynn 2010(73)
		follow-up for weight management. This was a total of 44-week protocol.
Quality	Positive	Positive
Results	Change from wk 0 to wk 16 (Mean ±SEM) **MCT oil:** Body Weight (kg): -3.2 ± 0.49, Waist circumference (cm): -2.4±0.8 **Olive Oil:** Body Weight (kg): -1.4 ± 0.49, Waist circumference (cm): -2.5±0.8	Change from baseline to completion of two 8-week weight loss periods (Mean ± SD) **PBOO-** Body Weight (kg) : -3.6 ± 1.9, Body Weight (%): -4.9±2.4, Waist circumference (cm): -3.4±3.2, Body Fat (%): -1.9±1.8, Fat Free mass (%): +1.9±1.8 **NCI-** Body Weight (kg): -2.7 ± 1.4, Body Weight (%): -3.9±1.9, Waist circumference (cm): -2.6±1.7, Body Fat (%): -1.4±1.4, Fat Free mass (%): +1.1±1.7
Effect on risk (Increase/None/Protect)	Protect	Protect
Clinical importance	1	1
Clinical relevance	1	1
Generalisable	Y	N
Applicable	Y	N

TABLE 1.31: Studies used to make evidence statements for comparing intakes of levels of Omega 3 fatty acids

Reference	Hlavaty 2008 (77)	Mori 2004 (79)	Kunesova 2006 (155)	Ramel 2008 (156)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	Intervention: Low Calorie Diet with n-3 (n-3 LCD). Included supplemented yoghurt (790mg n-3 PUFA/day.) Control: Low Calorie Diet (LCD) without the yoghurt n-3 FA supplement	Intervention: Three groups: 1) daily fish meal (fish diet) 2) weight-reduction regimen (wt loss) 3) the two regimens combined (fish diet + wt loss). Comparator: weight maintenance dietary program.	Intervention: Very Low Calorie Diet (VLCD) with n-3 PUFA added (including Redita providing 2200kj/day and n-3 PUFA supplement providing 2.8g PUFA/day.) Comparator: VLCD only. Weight reducing regime (including Redita providing 2200kj/day).	Intervention: Three energy-restricted diets (-30E%). 1) lean fish (150 g cod three times/week,0.26g PUFA/day); 2) fatty fish (150 g salmon three times/week, 2.1g PUFA/day); 3) fish oil (daily DHA/EPA acid capsules, 01.3g PUFA/day). Comparator: energy-restricted diet (-30E%), no seafood (0g PUFA/day).
N	20 (LCD with n-3 FA)/ 19 (LCD)	47 (17 fish diet, 16 weight loss, 14 fish + weight loss)/ 16 (control)	11 (VLCD with n-3 FA)/ 9 (VLCD)	244 (80 lean fish, 84 fatty fish, 80 fish oil)/ 80 (control)
Population/study information	Female, moderately obese, no diabetes thyroid dysfunction, diuretics or hormone replacement therapy/Short-term in-patient weight-reducing regimen, including a weight maintenance diet for the first 3 days, followed by a weight reduction program for the following 18 days. All food provided. LCD was 5500kj/day (protein-22.7%, fat 28.7%, Carbohydrate- 48.6%). Included daily light to moderate exercise lasting 60min/day.	Overweight, non-smoking, postmenopausal, 40-70yrs of age, on hypertensive medication for at least 3 months/ This was a 16 week intervention. Subjects in weight loss group aimed to lose 5-8kg during the first 12 weeks. All groups were placed on a weight maintenance diet for last 4wks. Those on a fish diet consumed canned and filleted fish providing 3.65g of omega 3 fatty acids per day.	Women, severely obese/ A three-week inpatient weight reduction program. Both diets contained 40g protein, 70g carbohydrate, 9g fat. Both regimes included light to moderate daily physical activity lasting 60min/day. n-3 PUFA supplement contained EPA and DHA in a ratio of 2:1	20-40 years of age, BMI 27.5-32.5, waist circumference >94cm for men and >80cm for women, no use of supplements containing n-3 fatty acids, calcium or vitamin D during last 3 months, no diabetes, hyperlipidaemia or hypertension/ 8 week dietary intervention. All diets had identical macronutrient composition (30% fat, 50% CHO, 20% protein) but different LC n-3 PUFA content. Physical activity level remained unchanged. Subjects received detailed meal plans and recipe books.
Quality	Neutral	Neutral	Neutral	Neutral

Reference	Hlavaty 2008 (77)	Mori 2004 (79)	Kunesova 2006 (155)	Ramel 2008 (156)
Results	**n-3 LCD**: Baseline: Weight (kg): 87.6 (9.5), BMI: 33.1 (2.83), Fat mass(%): 42.2 (4.07), fat mass (kg): 37.2 (6.91), fat free mass (kg): 50.4 (4.52), Waist circumference (cm): 99.9 (10.5) After 21 days: Weight (kg): 85.2 (9.54), BMI: 32.1 (2.9), Fat mass(%): 41.6 (3.67), fat mass (kg): 35.6 (5.2), fat free mass (kg): 49.6 (4.57), Waist circumference (cm): 97.8 (10.1) **LCD:** Baseline: Weight (kg): 96.3 (13.9), BMI: 36.2 (4.11), Fat mass(%): 45 (3.9), fat mass (kg): 43.5 (9.04), fat free mass (kg): 52.9 (5.99), Waist circumference (cm): 111 (11.2) After 21 days: Weight (kg): 92 (13.8), BMI: 34.6 (4.14), Fat mass(%): 41.7 (3.9), fat mass (kg): 37.1 (2.59), fat free mass (kg): 55.7 (3.88), Waist circumference (cm): 107 (11)	Change (Mean ± SEM) from baseline to after 16wk intervention: Body Weight (kg): Fish Diet: 0.5 ± 0.5 , Wt loss Diet: -5.2 ± 1.0, Fish+ wt loss diet: -5.9 ± 1.3.	Mean ± SD decreases after 3 week weight-reducing regime: **VLCD with n-3 FA:** Weight (kg): 7.55 ± 1.77, BMI : 2.82 ± 0.62, Waist circumference (cm): 5.5± 1.71 **VLCD:** Weight (kg): 6.07± 2.16, BMI: 2.22 ± 0.74, Waist circumference (cm): 3.3± 2.51	Body weight (kg) change at 8wks (Mean): Lean fish: -5.4 , Fatty fish: -5.6, Fish oil: -5.2, Control: -4.5
Effect on risk (Increase/None/Protect)	Protect	Protect	Protect	Protect
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisable	Y	N	Y	Y
Applicable	Y	Y	Y	Y

Reference	Abete 2009 (76)	Abete 2008 (75)	Ramel 2009 (80)	Krebs 2006 (157)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	Intervention: Three hypocaloric diets (-30E%) 1) Balanced diet with high legume consumption (L-diet), 2) Balanced diet with fatty fish consumption (FF-diet), 3) high-protein energy restricted diet (HP-diet). Comparator: Hypocaloric diet (-30E%), balanced diet without legume and fatty fish consumption.	Intervention: Fish-based energy-restricted diet (-30E%, 3 days/week fish consumption. Fatty fish supplied approximately 13-14% of total energy intake.) Comparator: energy-restricted diet (-30E%, without fatty fish consumption).	Intervention: Two energy-restricted diets (-30E%) 1) 150 g cod 3 times a week (providing 0.26g LC n-3 PUFA and 11.4g fish protein); 2) 150 g cod 5 times a week(providing 0.43g LC n-3 PUFA and 19.1g fish protein). Comparator: energy-restricted diet (-30E%), No seafood (alternative protein source was lean meat)	Intervention: Two weight loss groups 1) Weight-loss programme, with LC n-3 PUFA (WLFO): received five 1g oil capsules per day with predominantly LC n-3 PUFA 2) Weight-loss programme with placebo oil (WLPO): received five 1g oil capsules per day (containing 2.8g linoleic acid and 1.4g oleic acid). Comparator: control group (no weight loss and placebo oil)
N	25 (8 legume diet. L-diet, 8 fatty fish diet.FF-diet, 9 high-protein diet. HP-diet)/ 10 (C-diet)	16/ 16	70 (35 cod three times/wk, 35 cod five times/wk)/ 35 (control)	67 (35 WLFO, 32 WLPO)/ 26 (control)
Population/study information	Men, BMI: 31.8 +/- 3.0 kg/m(2), Age: 38 +/- 7, no diabetes, hypertension, liver or renal disease/ This was an 8 week intervention. Macronutrient balanced diets (legume and fatty fish diets) provided 53% of energy from CHO, 17% proteins, 30% fat. The high protein diet provides 30% energy protein, 30% fat, 40% CHO. Protein source differed among diets. With HP diet, protein was supplied by eggs, meat and skimmed dairy. In the L-diet, animal protein intake was decreased and plant protein sources increased (had to eat legumes 4 days per week). In FF diet, protein source was mainly fatty fish (had to eat fatty fish 3 days per week and avoid legumes). Diet	18 men, BMI 31.6 +/- 3.5 kg m(2), aged 36 +/- 7 years, no diabetes, hypertension, liver or renal disease/ 8-week intervention period. Subjects instructed by dietitians. Required to maintain current habitual patterns of physical activity. Macronutrient composition of both diets: 30% fat, 53% CHO, 17% protein. Fatty fish included tuna, salmon, anchovies, sardines etc.	Age 20-40 years, BMI 27.5-32.5, waist circumference >94cm for men and >80cm for women, no use of supplements containing n-3 fatty acids, calcium or vitamin D during last 3 months, no diabetes, hyperlipidaemia or hypertension / 8 week dietary intervention. Diets had identical macronutrient composition (30% fat, 20% protein, 50% CHO) but different amounts of cod. Food frequency questionnaires were used to assess compliance to seafood intake. Subjects were provided with frozen cod fillets.	Female, BMI >27, hyperinsulinaemic, nonsmokers. No known diabetes, intercurrent infection, chronic inflammatory condition, treated dyslipidaemia, malignancy or liver disease/ 24-week intervention- Weight loss programs designed to achieve 10% weight loss in 12 weeks, followed by 12 week weight maintenance phase. Attended fortnightly group sessions to receive dietary advice . Subjects consumed energy-restricted diet of 800-900kcals/day for the first 5wks followed by a staged increase in calories.

Reference	Abete 2009 (76)	Abete 2008 (75)	Ramel 2009 (80)	Krebs 2006 (157)
	compliance was weekly assessed by a dietitian. Encouraged to maintain same habitual physical activity levels.			
Quality	Positive	Positive	Positive	Positive
Results	Percentage change after 8 week intervention: **L-diet:** Weight: -8.3 ± 2.9, Waist circumference: -7.0 ± 3.0, fat mass: -15.1±6.6 , fat free mass: -5.0 ± 2.6 **FF-diet:** Weight: -6.4 ± 2.6, Waist circumference: -5.1 ± 2.7, fat mass: -14.3±76.3 , fat free mass: -3.4 ± 2.5 **HP-diet:** Weight: -8.4 ± 1.2, Waist circumference: -9.8 ± 2.4, fat mass: -18.6 ±.3.6 , fat free mass: -4.9 ± 1.6 **Control:** Weight: -5.5 ± 2.5, Waist circumference: -6.1 ± 2.9, fat mass: -12.7 ± 7.2 , fat free mass: -2.7 ± 1.3 The HP-diet and L-diet achieved the greater body weight reduction (-8.4 +/- 1.2% and -8.3 +/- 2.9%, respectively), as compared to the C-diet (-5.5 +/- 2.5%; P = .042). Changes were statistically significant when compared to the C-diet (p=0.042). No diff in weight between fish groups compared to all other groups. HP diet lost 4.7cm more waist than FF diet. (p<0.05)	**Intervention (fish based)**: Baseline: BMI: 31.1 ± 2.3, Waist circumference (cm): 97.6 ± 9.5 , Fat Mass (%) 35.1 ± 8.1, fat mass (kg) 30.5 ± 7.2 8 wks: BMI: 29.5 ± 2.6, Waist circumference (cm): 93.2 ± 9.6 , Fat Mass (%) 34.2 ± 8.7, fat mass (kg) 27.1 ± 7.4 **Comparator:** Baseline: 32.2 ± 4.4, Waist circumference (cm): 102.3 ± 10.3 , Fat Mass (%) 32.4 ± 9.9, fat mass (kg) 31.6 ± 11.4 8 wks: BMI: 30.5 ± 4.5, Waist circumference (cm): 95.7 ± 9.9 , Fat Mass (%) 31.1 ± 8.7, fat mass (kg) 28.3 ± 10.9	Differences at 8 weeks relative to control group (Mean, p-value): **Cod 3 times/week:** Body Weight (kg): -0.666 (p=0.396), BMI: -0.161 (p=0.527) Waist circumference (cm): -0.994 (p=0.199), Fat mass (kg): -0.191 (p=0.793), Fat free mass (kg): -0.333 (p=0.533) **Cod 5 times/week:** Body Weight (kg): -1.729 (p=0.396), BMI: -0.161 (p=0.015) Waist circumference (cm): -0.555 (p=0.015), Fat mass (kg): -0.873 (p= 0.209), Fat free mass (kg): -0.529 (p=0.2554) Linear trend analysis showed a significant treatment effect between the groups, after adjusted for baseline weight. Differences were evident in body weight (1.7kg greater weight loss in 5/7 FF compared to control, no diffs between 3/7FF and control) (P<0.015). Body weight decreased in intervention groups after 8-weeks (5.0+/-2.9 kg, P<0.001), also waist circumference (5.0+/-3.2 cm, P<0.001), BMI (1.65+/-0.95 kg, P<0.001). The trend analysis supported a dose-response relationship between cod	**WLFO:** Baseline: Weight (kg): 92.5 (15.0), Waist circumference (cm): 98.7 (11.1), BMI 35.3 (5.6), DXA fat mass (kg): 43.1 (12.5), DXA Abdominal Fat: 6.16 (2.55); 12 weeks: Weight (kg): 82.6(14.3), Waist circumference (cm): 91.3 (11.9), BMI 31.5 (5.2), DXA fat mass (kg): 33.5 (10.9), DXA Abdominal Fat: 4.18 (2.10); 24 weeks: Weight (kg): 82.3(14.6), Waist circumference (cm): 91.1 (11.3), BMI 31.4 (5.4), DXA fat mass (kg): 33.3 (11.1), DXA Abdominal Fat: 4.22 (2.11); **WLPO:** Baseline: Weight (kg): 90.8 (15.0), Waist circumference (cm): 99.2 (11.6), BMI 34.6 (5.3), DXA fat mass (kg): 42.5 (12.4), DXA Abdominal Fat: 6.17 (3.09); 12 weeks: Weight (kg): 79.9(14.6), Waist circumference (cm): 90.7 (13.3), BMI 30.5 (5.3), DXA fat mass (kg): 32.2 (11.7), DXA Abdominal Fat: 4.18 (4.12); 24 weeks: Weight (kg): 79.9(15.1), Waist circumference (cm): 90.9 (13.1), BMI 30.3 (5.6), DXA fat mass (kg): 31.7 (12.3), DXA Abdominal Fat: 4.12 (2.73)

Reference	Abete 2009 (76)	Abete 2008 (75)	Ramel 2009 (80)	Krebs 2006 (157)
			consumption and weight loss (P=0.007).	
Effect on risk (Increase/None/Protect)	Protect	Protect	Protect	Protect
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisable	Y	Y	Y	Y
Applicable	Y	Y	Y	Y

TABLE 1.32: Studies used to make evidence statements for the use of Mediterranean diets

Reference	Buscemi 2009(85)	Estruch 2006(86)	Shai 2008 (84)	Esposito 2004(83)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	Mediterranean/ Atkins (endothelial function main outcome), both groups received 20kcal/kg body weight daily	Med + virgin olive oil/ Med + nuts/ low fat (reduced kcal by 34 to ~200kcal/day but no specific E restriction mentioned)	Med, restricted calorie (1500kcalF, 1800kcal M)/ low fat, restricted calorie (1500kcalF, 1800kcal M)/ low carb, non-restricted calorie	Med / prudent diet (no specific E restriction)
N	10/10	257/257/255	109/104/ 109	90/90
Population/study information	female, overweight/obese, 30-50 years, range of BMI 27-39.9 (exclusion: metabolic, CVD)	55-80 years, high risk for CVD but asymptomatic	40-65 years; moderately obese (BMI ≥27) or T2DM or CHD; male 86% (14% of sample had DM)	sedentary (<1h/week), weight stable, Met syndrome (could have DM but not specific criteria for it - impaired glucose tolerance (fasting BG >6.1mmol/L)
Quality	Positive	Positive	Neutral	Positive
Results	weight change -0.19(-0.45, 0.07)/ -0.26(-0.59, 0.08)/ -0.24(-0.48, 0.01) ; BMI change -0.12(-0.24, 0.06)/ -0.09(-0.24, 0.05)/ -0.21(-0.38, 0.05); waist change -0.82 (-1.8, 0.14)/-0.29 (-0.95, 0.37)/-0.37 (-1.2, 0.44)	weight change -0.19(-0.45, 0.07)/ -0.26(-0.59, 0.08)/ -0.24(-0.48, 0.01; BMI change -0.12(-0.24, 0.06)/ -0.09(-0.24, 0.05)/ -0.21(-0.38, 0.05) ; waist change -0.82 (-1.8, 0.14)/ -0.29 (-0.95, 0.37)/ -0.37 (-1.2, 0.44)	24 month weight change: -4.4 (6.0)/-2.9 (4.2)/-4,7(6.5); BMI change: -1.5(2.2)/-1.0(1.4)/-1.5(2.1); waist 3.5(5.1/-2.8(4.3)/3.8(5.2)	weight change -4(1.1)/ -1.2(0.6); BMI -1.2(0.3)/ -0.4(0.4); waist -2(0.5)/ -0(0.0) (for Mediterranean all signif, but prudent diet only weight signif). Difference between groups: weight: -2.8(-5.1 to -0.5); BMI: -0.8 (-1.4 to -0.2); waist -2(-3.5 to -0.5). both diets decreased calories signif after 2 years but med diet significantly more than control (-170 vs. -70kj)
Effect on risk (Increase/None/Protect)	Protect	None	Protect	Protect
Clinical importance	1	3	2	1
Clinical relevance	1	1	1	1
Generalisable	N	N	Y	N
Applicable	Y	Y	Y	Y

TABLE 1.33: Studies used to make narrative statements for the use of Mediterranean diets

Reference	**Lerman R, 2008(87)**
Type of study	RCT
Level of evidence	II
Intervention/ comparator	modified Mediterranean style, low glycaemic load diet (MED) / phytochemical enriched diet (MED + soy protein and plant sterols) (to improve cardiometabolic risk factors) (8wk EI were on average 6.1-6.7MJ)
N	*25/19*
Population/study information	*Met syndrome and hypercholesterolemia; 25-80yrs*
Quality	Positive
Results	*weight: -5.9(0.7)/ -5.7(1.0); waist reduced significantly*
Effect on risk (Increase/None/Protect)	Protect
Clinical importance	1
Clinical relevance	4
Generalisable	Y
Applicable	Y

TABLE 1.34: Studies used to make evidence statements for comparing the use of glycaemic index/ glycaemic load

Reference	Abete 2008(88)	Philippou 2008 (91)	Das 2007 (89)	Pittas 2006 (92)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	2 dietary treatments: 8 wk intervention of higher-GIndex + lower-GIndex. Energy-restricted (-30%). Both gps: 53% CHO, 17% PRO, 30% Fat. Fiber higher in LGI gp. LGI:40-45units, HGI:60-65units	2 dietary treatments: 12wk intervention of low GIndex and high diets. Energy-restricted (-30%). Both gps: Diets matched. 50–55% CHO, <30% Fat.	2 dietary treatments: 6mo intervention of High Glycemic Load and low Glycemic Load. Energy-restricted (-30%). Food provided for 6mo and 6mo self-selected foods. LOW GI DIET: 40% CHO, 30% fat, 30% protein. HIGH GI DIET: 60% CHO, 20% fat, 20% protein. HGIndex: 85.6 ±2.8/ LowGI Index diet GI 52.4 ±4.4* Glycemic load (g/1000 kcal) HGI: 118.3 /LGI: 4.1 45.4±4.6*. (*significantly different from HG diet, P <0.001).	2 dietary treatments: 6 mo intervention of High glycemic load (HGL) or low glycemic load (LGL). Energy-restricted (-30%). Low GLoad DIET (LGL): 40% CHO, 30% protein, 30% fat, GI: 53, GL: 45g/1000 kcal. High GLoad diet (HGL): 60% CHO, 20% protein, 20% fat, GI: 86, Gload: 116 g/1000 kcal.
N	LGI:16/HGI:16	LGI:7/HGI:6	LGL:14/HGL:15	LGL:16/HGL:16
Population/study information	32 obese subjects. (BMI: 32.5±4.3 kg/m2). 14 women & 18 men Age 36±7 yr.	18 subjects recruited. 13 completed study. LOW GI GROUP: n=7: 4F 3M, BMI: 28.6 (28.1–29.8) kg/m2, age: 54.0 (49.0–58.0) yr. HIGH GI GROUP: n=6: 4F 2M, BMI: 33.2 (28.2–34.2) kg/m2, age: 45.0 (39.0–50.0) yr	34 overweight men and women aged. BMI (kg/m2) 27.6±1.4. Age of 35±6 yr	34 adults aged 24 - 42 yrs. BMI 25 - 29.9kg/m2. HGL: n=16:13F,3M Age (yrs) 34.3 ±1.2; Wt (kg) 79.3±3.1; BMI (kg/m2) 27.6±0.4. LGL:n=16:12F 4M, Age (yrs)35.0±1.5 ; Wt (kg)78.8 ±2.3 ; BMI (kg/m2)27.6±0.3
Quality	Positive	Positive	Positive	Positive

Reference	Abete 2008(88)	Philippou 2008 (91)	Das 2007 (89)	Pittas 2006 (92)
Results	Intervention: Wt loss in both gps. Lower-GI diet significantly greater wt loss than HGI (-5.3±2.6% vs. -7.5±2.9%; p=.032). F/Up: 47% respondents. 1 yr after intervention wt regain in both gps. Wt regain statistically significant in the higher-GI group (p=0.033).	No differences in nutrients between gps at baseline or week 12. By week 12 there was a significant difference in diet GI (low GI: 51.3 (51.0–52.0) vs high GI: 59.3 (59.2–64.0) (P<0.05). The diet G Load did not differ between the gps (105.6 (76.9–110.1) vs 114.7 (98.5–134.9) (P=NS) By week 12, E intake significantly lower in HGI gp. By week 12 LGI gp lost significantly more wt (-4.0 (-4.4– -2.4)kg vs HGI gp wt-1.5 (-3.6– -0.8) kg	29 subjects completed study. HG diet: (n= 4 M, 13 F)/LG diet (n =4 M, 13 F). LG DIET: Baseline wt (kg) 78.0±9.3. Wt change at 6mo -10.4± 4.1. Wt change at 12mo -7.8±5.0. HGL DIET: Baseline wt (kg) 78.5±12.3. Wt change at 6mo -9.1±4.2%. Wt change at 12mo -8.0±4.1%.	Reported daily E intake at 6 months did not differ between the two groups (2017 kcal on the HGL diet vs. 1972 kcal on the LGL diet, p = 0.70). At 3 and 6 months, both groups achieved statistically significant (p <0.001) wt loss compared with baseline wt. Adjusted for baseline wt, weight loss was equivalent in both gps: -7.2 kg in HGL gp vs. -7.7 kg in the LGL gp at 6 months, p = 0.69.
Effect on risk (Increase/None/Protect)	Protect	Protect	None	None
Clinical importance	1	1	3	3
Clinical relevance	1	1	1	1
Generalisable	Y	Y	N	N
Applicable	Y	Y	Y	Y

Reference	Raatz 2005 (20)	McMillan-Price 2006 (90)
Type of study	RCT	RCT
Level of evidence	II	II
Intervention/ comparator	3 dietary treatments: 12wk intervention of LowG Index, High G Index and High Fat diet. Energy restricted. During 12wk of intervention: HGI diet ; LGI diet; HF diet: CHO, %= 60; 60; 45 Protein% =15; 15; 15 Fat% =25; 25; 40 Glycemic index =63; 33; 59	4 dietary treatments. 12wk intervention of High Carb AvePro LGI/High Carb Ave Pro HGI:/Low Carb HighPro LGI/Low Carb High Pro HGI. Energy restricted. High Carb: 55%/Low Carb: 45%. Ave Pro:15%/High Pro:25% DIET 1 and DIET 2 were high CHO with high and low GIs respectively; DIET

Reference	Raatz 2005 (20)	McMillan-Price 2006 (90)
	Glycemic load =272; 178 ;182 Intervention followed by 24wk free-living phase.	3 and DIET 4 were high protein with high and low GIs respectively. The glycemic load was highest in DIET 1 and lowest in DIET 4. Diet 1: GI=70, GL=129/Diet 2:GI=45, GL=89/Diet 3: GI=59, GL=75/Diet 4: GI=44, GL=59.
N	LGI: 10/HGI: 9/ HF: 10	Hcarb AvePro LGI:32/Hcarb Ave Pro HGI:32/Lcarb HPro LGI:33/Lcarb Hpro HGI:32
Population/study information	42 men and women, ages 18–70 y with a BMI of 30–40 kg/m2.	129 overwt or obese young adults assigned to one of 4 diets for 12 wks. Characteristics of participants at baseline in Diet 1(n = 32); Diet 2; (n = 32); Diet 3(n = 32); Diet 4(n = 33): Age, y =31.8 ± 1.7; 30.5 ± 1.4; 30.2 ± 1.5; 34.6 ± 1.5 Women, No. = 25 ; 23 ; 24 ; 26 Wt, kg= 86.0 ± 1.9; 87.1 ± 2.7; 87.7 ± 2.9 ;88.4 ± 3.0 Ht, m =1.68 ± 0.02; 1.67 ± 0.02; 1.66 ± 0.02; 1.66 ± 0.02 BMI= 30.9 ± 0.6; 30.6 ± 0.8; 31.3 ± 0.8; 32.1 ± 0.9 Waist, cm= 96.4 ± 2.0; 96.8 ± 2.2; 96.8 ± 2.2; 98.2 ± 2.4
Quality	Positive	Positive

Reference	Raatz 2005 (20)	McMillan-Price 2006 (90)
Results	29 subjects completed study. Change from baseline to end of 12wk intervention: LGI DIET: Wt kg=-9.95 ± 1.4; bmi=-3.91 ± 0.5; %body fat=-2.9 ± 0.4; fat mass kg=-6.9 ± 0.9; lean body mass kg=-3.04 ± 0.6. HGI DIET: Change from baseline to end of 12wk intervention in Wt kg= -9.3 ± 1.3; bmi= -3.0 ± 0.4; %body fat= -2.8 ± 0.7; fat mass kg= -4.5 ± 1.9; lean body mass kg= -4.8 ± 2.2. HIGH FAT DIET: Change from baseline to end of 12wk intervention in Wt kg= -8.4 ± 1.5; bmi= -3.0 ±0.5; %body fat= -2.5 ± 0.8 ; fat mass kg= -5.8 ± 1.0 ; lean body mass kg= -2.6 ± 1.0	Diet 1, high-carbohydrate (CHO)/high–glycemic index (GI); diet 2, high-CHO/low-GI; diet 3, high-protein/high-GI; and diet 4, high-protein/low-GI. All 4 gps lost a similar mean±SE percentage of wt (DIET 1, −4.2%±0.6%; DIET 2, −5.5%±0.5%; DIET 3, −6.2%±0.4%; and DIET 4, −4.8%±0.7%; P=.09). The proportion of subjects in each group who lost 5% or more of body wt varied significantly by diet (DIET 1, 31%; DIET 2, 56%; DIET 3, 66%; and DIET 4, 33%; P=.01). Women on DIET 2 and DIET 3 lost approximately 80% more fat mass (−4.5±0.5 [mean±SE] kg and −4.6±0.5 kg) than those on DIET 1 (−2.5±0.5 kg; P=.007).
Effect on risk (Increase/None/Protect)	None	None
Clinical importance	3	3
Clinical relevance	1	1
Generalisable	No	No
Applicable	Yes	Yes

TABLE 1.35: Studies used to make evidence statements on an ad libitum diet of lower glycaemic index compared to an ab libitum diet of higher glycaemic index

Reference	Aston 2008(93)	de Rougemont 2007(94)	Sloth 2004(95)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	Ad libitum diet for for 12 weeks with key carbohydrate foods provided to participants of Gp 1: Lower GI or Gp 2: Higher GI. These comprised of either lower or higher GI breads, breakfast cereals and rice, plus pasta on the lower GI diet and potatoes during the higher GI period. GI values of intervention foods differed significantly for all equivalent 'low' and 'high' GI foods, with a mean difference of 28.5 units	Ad libitum diet for 5 weeks. Gp 1: Low GI Starchy foods (<50) Gp 2: High GI starchy foods (>70). Some of the foods provided throughout the study, and guidance provided by dietitian on 2 occasions.	Ad libitum diet for 10 weeks Gp 1: Low GI Gp 2: High GI. High or low GI foods were given as replacements for the subjects' usual carbohydrate-rich foods, were equal in total energy, energy density, and nutrient composition. The study was performed as an ad libitum study of high CHO (55–60% of energy from CHO), low-fat (30% of energy from fat) diets that were rich in either LGI or HGI foods. Subjects received a certain amount of carbohydrate-rich test foods. The test foods given to subjects during the present study were well matched in composition.
N	Cross-over n=19	Low GI:19/High GI 19	Low GI: 23/High GI 22
Population/study information	All women, aged between 34-65 yrs at baseline (mean 51.9 (s.d. 7.6) years). All overwt or obese, BMI range 25.6-46.7 kgm2 (mean 33.1 (s.d. 4.9) kgm2), and body fat% 38.8-52.6 (mean 47.8 (s.d. 3.5) %).	Men and women, aged 20 to 60 years, BMI 25 to 30 (Mean 27.3)	Subjects were 45 healthy overweight [Mean BMI (kg/m2): 27.6±0.2] women aged 20–40 y.
Quality	Positive	Positive	Positive

Reference	Aston 2008(93)	de Rougemont 2007(94)	Sloth 2004(95)
Results	Weight increased during both intervention periods, but weight gain did not difference between treatments (1.1 (s.d. 1.5) kg on the low GI diet vs 1.4 (s.d. 1.7) kg on the higher GI diet; P=0.7).	Low GI: After a 5-week nutritional intervention, body wt and BMI were significantly decreased in the LGI group (-1·1 (SEM 0·3) kg, P=0·004 and -0·4 (SEM 0·1) kg/m2, P=0·005 respectively). Changes in fat mass from week 0 to week 5 were not significant within the LGI group (-0·7 (SEM 0·6) %, P=0·15). No change in WHR after 5 wks. High GI: No significant changes in wt and BMI were reported in the HGI group (-0·2 (SEM 0·2) kg, P=0·41 and -0·1 (SEM 0·1) kg/m2, P=0·39 respectively). Changes in fat mass from week 0 to week 5 were not significant within the LGI group (-0·2 (SEM 0·4)%, P=0·40). No change in WHR after 5 wks. Weight loss significantly different between groups.	There was no significant difference in body-wt changes between groups (LGI: -1.9± 0.5 kg; HGI: -1.3± 0.3 kg; P = 0.31), but body wt decreased significantly in both groups over time.
Effect on risk (Increase/None/Protect)	None	Protect	None
Clinical importance	3	1	3
Clinical relevance	1	1	1
Generalisable	Y	Y	Y
Applicable	Y	Y	Y

TABLE 1.36: Studies used to make narrative statements on an ad libitum diet of lower glycaemic index compared to an ad libitum diet of higher glycaemic index

Reference	**Maki 2007(97)**	**Ebbeling 2005(158)**
Type of study	RCT	RCT
Level of evidence	II	II
Intervention/ comparator	Ad libitum reduced-glycemic-load (RGL) or low fat portion-controlled (control) diet. Wks 0–12 were weight-loss treatment. At some point between wks 12 and 24, each subject transitioned to a wt-maintenance phase. From wk 24 on, all subjects were in the weight-maintenance phase. The RGL was intended to include a moderate intake of dietary CHO with emphasis on low-GI foods and lean sources of protein to replace some high-carbohydrate foods. Duration 36 weeks	ad libitum low-glycemic load diet (45–50% of energy from CHO, 30–35% of energy from fat) or conventional :energy restricted (250-500 kcal/d deficit) and <30% fat , 12 months duration
N	RGL: 42/ Control 42	LGL: 11/ Conventional:12
Population/study information	RGL : Women 29 (67.4%), Men 14 (32.6); Age (y) 47.9 ± 1.83; Weight (kg) 91.2± 2.0; BMI (kg/m2) 32.1± 0.6; Control: Women 29 (67.4), Men 14 (32.6); Age (y) 51.4± 1.5;Weight (kg) 88.7± 1.8; BMI (kg/m2)31.6 ± 0.5;309.8± 10.0	LGL: all female Age (y)= 29.8± 1.7. Weight (kg)= 93.3±5.3; Conventional: all female + 1 male subject. Age (y)= 27.2±1.3. Weight (kg)= 83.2±3.3;
Quality	Positive	Positive
Results	At the end of the initial 12-wk weight-loss period, the mean weight change was 4.9 ±0.5 kg in the RGL arm, 2.5 ±0.5 kg in the control arm. The RGL group lost significantly more wt than control group at week 12 P=0.002, but no significant difference at week 36	Mean wt loss did not differ significantly during the intensive 6-mo intervention (-8.4% and -7.8%, respectively), and there was no significant weight rebound during the follow-up.
Effect on risk (Increase/None/Protect)	None	None
Clinical importance	3	3
Clinical relevance	1	1
Generalisable	Y	Y
Applicable	Y	Y

TABLE 1.37: Studies used to make evidence statements for providing calcium supplements

Reference	Shapses 2004(100)	Shalileh 2010(99)	Riedt 2005(98)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	Int : 1000mg of Calcium citrate malate or calcium citrate or Placebo, two divided doses taken at breakfast and evening for 6 months. Caloric restriction and behavioural therapy with dietitian.	Int: 1000mg / day calcium carbonate taken as two tablets with dinner or placebo. All participants maintained on deficit diet of 500kcal / day. 24 weeks duration	group 1: 1000mg Calcium (HICAL) group 2: 200mg calcium (NOCAL - normal calcium) If subjects consumed an 800mg dietary intake and supplement compliance was 100% then calcium intakes would have been 2000mg and 1200mg accordingly or group 3 placebo. 6 months duration. Caloric restriction and weekly counseling with dietitian.
N	n= 165. 100 completed (n=46 Int, n=54 placebo)	n= 40 total. (n= 20 int, n= 20 placebo)	n= 66 total. (Hi CAL n= 23 , no CAL n=24 placebo n= 19)
Population/study information	All female. Obese, post and premenopausal. Int: age 61.6 ± 8.6/ 40.4 ±5.4 weight 84.1 ±9.4 /93.7 ±13.6 BMI 32.1 ±3.5/ 33.9 ±3.9. Placebo: 57 ±8.2/41.5 ±6.8 weight 89.4 ±10.3/93.5 ±14.3 BMI 32.8 ±4.2 / 34.7 ±5.9	Int: 20% male age: 36.6 ±7.8 weight 77.65±16.87 Waist 89.4±11.02 Placebo: 10% male age 36.6 ±8.0 weight 76.25 ±8.23 Waist 87.65 ±7.74	All female. Post-menopausal. Age 61 ±6, BMI 27.0 ± 1.8
Quality	Positive	Positive	Positive
Results	Mean changes in body weight and fat mass post meno/pre menopause weight -7.5/ -6.4 f at -6.4/-5.1. No statistical significance differences between the calcium and placebo conditions.	Mean changes at 12 and 24 weeks. All subjects lost body weight mean 2.65 ±0.13 due to the daily energy deficit by the 12th week but decreased to 1.4 ±0.3 in the calcium group at the 24th week and for the placebo 1.55 ±0.51kg and 1.5 ±0.44 in those taking the placebo at the 12th and 24th week. Each of the changes was significant within the two groups but not between the groups	Mean weight change %. Women in both groups lost 9.3 ±3.9% of initial body weight. There was no significant difference between those consuming the high calcium (-6.2 ±2.8kg) and those consuming normal calcium (-7.4 ±2.9).
Effect on risk (Increase/None/Protect)	None	None	None
Clinical importance	3	3	3
Clinical relevance	1	1	1

Reference	Shapses 2004(100)	Shalileh 2010(99)	Riedt 2005(98)
Generalisable	N	Y	N
Applicable	Y	Y	Y

TABLE 1.38: Studies used to make narrative statements for providing calcium supplements

Reference	Yanovksi 2009(101)
Type of study	RCT
Level of evidence	II
Intervention/ comparator	Int: 1500 mg calcium carbonate or placebo (2 divided doses) with meals for 2 years. No caloric restriction.
N	n= 340. 256 completed [n=132 (78%) int, n=124 (73%) placebo]
Population/study information	29% male. Int: Age: 38.9 ± 10.5 weight 94.5 ±20.5 BMI 33.2 ±6.8, Placebo: age 38.7 ±10.4 weight 94 ±20.5 BMI 33.6 ±6.8age .
Quality	Positive
Results	Mean change (95% CI) at 2 years: Int 0.54(0.70-1.79) fat mass (kg) 0.40(-0.61-1.41) BMI 0.18(-0.33-0.69). Placebo: weight 0.52(-0.82-1.86) fat mass 0.01(-1.15-1.16) BMI -0.14(0.73-0.45). ll changes non-significant and no clinical effects
Effect on risk (Increase/None/Protect)	None
Clinical importance	3
Clinical relevance	1
Generalisable	Y
Applicable	Y

TABLE 1.39: Studies used to make evidence statements for recommending a higher calcium intake than a lower calcium intake

Reference	Riedt 2005(98)	Eftekhari 2009(102)	Bowen 2005 (103)	Wennersberg 2009(104)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	group 1: 1000mg Calcium (HICAL) group 2: 200mg calcium (NOCAL - normal calcium) If subjects consumed an 800mg dietary intake and supplement compliance was 100% then calcium intakes would have been 2000mg and 1200mg accordingly or group 3 placebo. 6 months duration. Caloric restriction and weekly counseling with dietitian.	Group 1: low fat high calcium, 20% fat, 1600mg calcium, < 20g fibre. Group 2: low fat high fiber, 20% fat, 900mg calcium , 45g fibre. For both groups energy intake was 1600-2200kcal. 12 weeks duration	Group 1: high in dairy protein. (2400mg calcium/ day) Group 2: mixed protein sources (500mg calcium /day) for 12-weeks. All subjects attended individual consults with dietitian every 2 weeks throughout the study period, and were advised to reduced their energy intake.	Milk Group: 3-5 portions of dairy products daily or Control: instructed to consume their habitual diet without changing the intake of dairy products . 6 months duration with no energy restriction.
N	n= 66 total. (Hi CAL n= 23 , no CAL n=24 placebo n= 19)	n=136 total. 130 completed (n=60 Low fat/high cal, n=56 low fat, high fibre)	n=60 total. 50 completed (n= 25 dairy protein [n=10 male n=15 female] n=25 mixed protein [n=10 male n=15 female])	n= 121 total . 113 completed (n=54 control, n=55 milk group)
Population/study information	All female. Post menopausal. Age 61 ±6, BMI 27.0 ± 1.8	All Males, obese. Group 1: age 54.5 ± 3.5, weight 89.0 ±6.5 BMI 33.2 ±1.7 wc 101.3 ±3.6. Group 2: age 57 ±5.5 weight 92.0 ±3.5 BMI 34.4 ±1.5 wc 103.2 ±3.2	Overweight men and women BMI 27-10 aged 20-65, lactose intolerance or calcium supplements were excluded. DP Group: dairy protein group data presented for men and women not as total group men: age 49.4± 3.2 weight 107.7 ±3.6 BMI 34.6 ±7.3 Women age 46.5 ±2.4 weight 93.4 ±3.8 BMI 34.6 ±1.0. MP Group: Men age 48.7 ±4.4 weight 103.2 ±3.7 BMI 32.5 ±0.9 Women 46.1 ±2.7 weight 85.9 ±2.7 BMI 31.9 ±0.8	Healthy Males/ post-menopausal women. Had to be low consumers of dairy (<2 portions per day) and fulfill 2 criteria for metabolic syndrome (LDL, HDL, WC, triglycerides). 33 % males. Milk group : weight 86 ± 12.5 BMI 30.1 ±3.6waist 100.9 ±10.1. control weight 87.5 ±12.2 BMI 30 ±3.3 waist 101.6 ±9.2.

Reference	Riedt 2005(98)	Eftekhari 2009(102)	Bowen 2005 (103)	Wennersberg 2009(104)
Quality	Positive	Positive	Positive	Positive
Results	Mean weight change %. Women in both groups lost 9.3 ±3.9% of initial body weight. There was no significant difference between those consuming the high calcium (-6.2 ±2.8kg) and those consuming normal calcium (-7.4 ±2.9).	Mean change in body weight: -15 kg (95% CI -16.5 to -12.5 kg) in the low fat/high calcium group, -9 kg (95% CI -11.5 to 7.3 kg) in the low fat/ high fibre group. The low fat /high calcium group achieved significantly more weight loss when compared to the low fat /high fibre group.	DP group: week 12 / week 16 men weight 97.7 ± 4.3 / 97.6 4.6 total fat week 0 and 16 62.3 2.7m 60.2 2.7 Female weight 84.0 3.7 / 83.5 3.8 total fat (kg) 43.5 2.9, 34.3 2.8. MP group: males weight 89.4±3.1 / 89.2 ± 3.1 total fat week 0 and week 16 35.2 ±3.5, 26.4 ±3.4 females 76.0 ±2.6, 75.9 ±2.7 total fat (kg) 36.7 ±1.0 / 29.7 ±1.3	Mean changes in body weight from baseline to 6 months. Milk group: weight -0.1 ±2.8 BMI -0.1 ±1.7waist -0.9 ±3.1, Control: weight -0.1 ±2.6, BMI 0.0 ±0.9 waist -0.6 ±2.6. No significant difference from baseline to 6 months and between groups.
Effect on risk (Increase/None/Protect)	None	Protect	None	None
Clinical importance	3	1	3	3
Clinical relevance	1	1	1	1
Generalisable	post menopausal women only	Men only	Y	Y
Applicable	Y	Y	Y	Y

Reference	Zemel 2005(106)	Zemel 2004(107)	Wagner 2007(105)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	Group 1: a control diet providing a 500kcal deficit, 0-1 servings of dairy per day and 400-500mg calcium per day. the control diet was provided a sugar free gelatin based dessert Group 2: a yoghurt diet providing a 500kcal deficit and containing 3 daily 6 ounce servings of commercial fat free yoghurt to bring total calcium to 500-1100mg per day for 12-weeks.	Group 1: a control diet providing a 500kcal deficit with 0-1 servings of dairy, 400-500mg calcium with a daily placebo supplement Group 2: A calcium supplemented diet with a diet the same as the control group with the placebo replaced by calcium supplement to bring calcium intake up to 1300mg Group 3: a high dairy diet providing a 500kcal deficit, 3 daily serves of dairy products to bring calcium intake to 1200-1300mg / day for 24-weeks.	Group 1 : Calcium Lactate capsules 2/day , Group 2: Calcium Phosphate capsules 2/day , Group 3: Milk 10 oz of 1 % fat milk twice/day , Placebo . All subjects followed a diet with a 500kcal deficit. 12 weeks duration

Reference	Zemel 2005(106)	Zemel 2004(107)	Wagner 2007(105)
N	n= 39 total. n= 34 completed maintenance n=29 completed weight loss (F = 25 M = 4 completed)	n= 41. 32 completed F =27 M=5. (n=10 low Ca n=11 high Ca n=11 high dairy)	n= 58 completed (n=12 Ca Lactate, n= 16 Ca Phos, n=17 milk, n=13 placebo)
Population/study information	Obese healthy adults from 18-50yrs. yoghurt group age 39 ±10 BMI 32.1 ±0.4. control: age 42 ± 6 BMI 33.2 ±0.9	obese healthy adults age 18-60years for all groups age 46 ±8 BMI 35 ±4.1	All females, pre menopausal and overweight. Group 1: calcium lactate: age 40.2(25-47) weight(lbs)196.2(160-231) BMI 33.3(29.6-37.5) group 2: calcium phosphate age 41.6(25-48) weight 196.7(143-261)BMI 33.4(25-42.8 group 3: milk 37.6(19.53)weight 203.1(153-255) BMI 33.7(29-42.5)Placebo age 36(22-46) weight 190.7(148-298) BMI 32.4(26.4--44.8)
Quality	Positive	Positive	Positive
Results	All participants lost body weight due to the daily deficit. Participants on the low calcium control diet lost 4.99 ± 0.5kg while this was increased to 22% for those in the yoghurt group 6.63 ±0.6kg (P0.001), fat loss followed a similar trend in the control group 2.75 ±0.73 kg while yoghurt group 4.43 ±0.47 (P<0.05)	Weight change - All participants lost weight however body weight and fat mass were markedly increased on the high dairy diet with significant effects on the high calcium diet. Group 1: 6.60 ±2.58 group 2: 8.58 ±1.60 group 3: 11.07 ±1.63	Body weight changes presented in figures. All groups lost significant amount of weight, however this did not differ between groups. Group 1: calcium lactate -5kg, group 2: -5kg group 3: milk -3kg placebo-7kg
Effect on risk (Increase/None/Protect)	Protect	Protect	None
Clinical importance	1	1	3
Clinical relevance	1	1	1
Generalisable	Y	Y	Women only
Applicable	Y	Y	Y

TABLE 1.40: Studies used to make narrative statements for sources of calcium

Reference	Zemel 2004(107)	Wagner 2007(105)	Lukaaszuk 2007(108)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	Group 1: a control diet providing a 500kcal deficit with 0-1 servings of dairy , 400-500mg calcium with a daily placebo supplement Group 2: A calcium supplemented diet with a diet the same as the contra group with the placebo replaced by calcium supplement to bring calcium intake up to 1300mg Group 3: a high dairy diet providing a 500kcal deficit, 3 daily serves of dairy products to bring calcium intake to 1200-1300mg / day	Group 1 : Calcium Lactate capsules 2/day , Group 2: Calcium Phosphate capsules 2/day , Group 3: Milk 10 oz of 1 % fat milk twice/day , Placebo . All subjects followed a diet with a 500kcal deficit. 12 weeks duration	Group 1: 720ml per day soy milk group 2: 720 ml per day skim milk over 8 weeks. 500kcal/day deficit diet developed
N	n= 41. 32 completed F =27 M=5. (n=10 low Ca n=11 high Ca n=11 high dairy)	n= 58 completed (n=12 Ca Lactate, n= 16 Ca Phos, n=17 milk, n=13 placebo)	n= 18 total. 14 completed (n=7 soy n=7 skim)
Population/study information	obese healthy adults age 18-60years for all groups age 46 ±8 BMI 35 ±4.1	All females, pre menopausal and overweight. Group 1: calcium lactate: age 40.2(25-47) weigth(lbs)196.2(160-231) BMI 33.3(29.6-37.5) group 2: calcium phosphate age 41.6(25-48) weight 196.7(143-261)BMI 33.4(25-42.8 group 3: milk 37.6(19.53)weight 203.1(153-255) BMI 33.7(29-42.5)Placebo age 36(22-46) weight 190.7(148-298) BMI 32.4(26.4--44.8)	Healthy pre menopausal women, classified as overweight / obese age range 18-45. Group 1 - Age 33.71± 6.32, BMI 38.39 ± 10.02, weight 101.58 ±23.88. Group 2 - Age 29.43±11.03, BMI 33.93 ±10.55, weight 91.18
Quality	Positive	Positive	Positive
Results	Weight change - All participants lost weight however body weight and fat mass were markedly increased on the high dairy diet with significant effects on the high calcium diet. Group 1: 6.60 ±2.58 group 2: 8.58 ±1.60 group 3: 11.07 ±1.63	Body weight changes presented in figures. All groups lost significant amount of weight, however this did not differ between groups. Group 1: calcium lactate -5kg, group 2: -5kg group 3: milk -3kg placebo-7kg	Day 1 minus day 56 group 1 (soy milk) : Weight 4.27 ± 2.05 % body fat 1.30 ±1.37, fat mass 3.32±2.0 abdominal circumference 11.28 ±5.23 BMI 1.70 ±0.68 fat free mass 1.12 ±1.29. Group 2 (skim milk)weight 3.76±2.25, %body fat 1.87 ±1.45,fat mass3.27 ±2.77 abdominal circumference 8.66 ±2.51,BMI1.38 ±0.88fat free mass0.43 ±1.12

Reference	Zemel 2004(107)	Wagner 2007(105)	Lukaaszuk 2007(108)
Effect on risk (Increase/None/Protect)	Protect	None	None
Clinical importance	1	3	1
Clinical relevance	1	1	1
Generalisable	Y	N	Y
Applicable	Y	Y	Y

TABLE 1.41: Studies used to make evidence statements for a combination of behavioural and psychological therapy and dietary intervention of less than 6 months duration

Reference	Shaw 2005(159)	Stahre 2007(117)	Alberts 2010(110)	Ash 2006(111)
Type of study	Systematic Review	RCT	RCT	RCT
Level of evidence	I	II	II	II
Intervention/ comparator	8 RCTs compared **BT** in combination with diet/ exercise with diet/exercise alone (Black 1984, Calle-Pascual 1992, Gormally 1981, Jeffery 1985, Lindahl 1999, Stuart 1971, Wing 1984, Wing 1985). Two additional RCTs compared **CBT** + diet /PA with diet/PA alone. (Block 1980, Dennis 1999) **BT** included: self-control and therapist-controlled contingencies, stimulus control, reinforcement, self-monitoring, problem solving and goal setting, and behaviour modification. Concomitant interventions were low calorie diet, nutritious balanced diet, instructions to gradually increase levels of PA, daily low to mod PA for 2.5 hrs, and individualised aerobics exercise programme based upon walking further during daily activities. **CBT** interventions included rational emotive therapy, and concomitant therapies included low calorie diet, and exercise advice..	Cognitive gp:2 hours per week lessons for 10 weeks. Traditional weight reducing program of 1,200-1,300kcal/day. Aimed to inform participants of probable cause of dysfunctional eating and provide ways to change such eating behaviour. VERSUS Control: 2 hour per week lessons for 10 weeks. Lessons, group discussion and practical demonstrations in Behavioural changes in dieting, stress management and physical training.	Craving regulation + diet and PA - 7 week manual based training that aimed to teach regulation of cravings by means of acceptance. 10 weekly meetings (1.5 hrs each) - information on healthy food choices provided by dietitian, PA for 1 hr also. VS Diet & PA only: 10 weekly meetings (1.5 hrs each) - information on healthy food choices provided by dietitian, PA for 1 hr also.	Fat Boosters Inc (FBI) group: 10-12 participants/group. 1.5hrs lifestyle behaviour management/ week for 6 weeks, with follow up at 8 weeks; tri-phasic design involving knowledge and skill development, cognitive behaviour therapy and relapse prevention with a focus on improvement in self-concept, self-efficacy and skills mastery (emphasised empowerment, development of self-efficacy and skills, with a non-directive approach taken by facilitators.) Information available on diet and exercise, but up to individuals if they acted on this information in making changes to lifestyle. Nutrition resource booklet based on cognitive behaviour therapy principles was also purchased by each participant. VS IDT group: individualised weekly contact with a dietitian for 8 weeks (including an initial nutrition assessment, provision of individualised diet prescription (aiming to achieve a weight loss of 0.5-1kg/wk), and an exercise

Reference	Shaw 2005(159)	Stahre 2007(117)	Alberts 2010(110)	Ash 2006(111)
				prescription (20-30mins of accumulated exercise most days of the week). Nutrition resource booklet based on cognitive behaviour therapy principles was also purchased by each participant. There was also a control group but as they were provided with no further nutritional advice other than the resource booklet, data on this group was not extracted.
N	BT n=235 vs. Diet/PA only n=232; CBT n = 37 vs. Diet/PA only n= 26	Cognitive gp therapy: 27 (16 analysed ITT) / Control: 26 (26 analysed ITT)	10/ 9(2 men in total in study - male allocation not reported)	FBI 62 randomised/ 57 analysed; IDT 66/65.
Population/study information	Adult participants (>18yrs), overweight, obesity at baseline. BT duration intervention was median 12 weeks (1 to 26 wks) with a median frequency of fortnightly sessions lasting 60 mins - all 8 RCTs were <12 months duration. CBT - both RCTs < 12 months duration (10 wks with 4.5mths follow up, 4 mths with 6 mths follow up).	Sweden, 10 week intervention, 18 months f/up, child care providers (preschool teachers, children's nurses, cooks, family child care providers, cleaning personnel, and directors of child care centres) filled out a survey and 97 obese (at least BMI 30) F were identified and invited to participate,	Netherlands; 7 wk intervention, W&M (only 2M); 28-74yrs, BMI 25.3-40.9, 7 week intervention, no follow up, food not provided, 10 *1.5 hour weekly sessions	Australia; 6 wk intervention, 1 yr follow up, overweight & obese M&F; recruited from current hospital referrals and advertising in local community newspapers; BMI ≥27; ≥18yrs; English speaking and not requiring interpreter; no cognitive impairment
Quality	Positive	Positive	Neutral	Positive
Results	"5 studies favoured **BT** in combination with diet and exercise and one study favoured diet and exercise alone for wt loss. Significant heterogeneity between studies was present (p<0.01). These data come from multiple studies and different populations which may be the factors contributing to the significant	CGT: 10wks/ 18mths: wt loss -7.7(3.8)kg / -5.5(5.5)kg; Control: wt loss = -1.4(1.6)/ -0.6kg (5.5). Effect size = 1.0 for the cognitive program; wt change diff between groups highly significant (p<0.001) - t-tests used to test diffs.	NS diff between groups, change in weight over time only regardless of group. Change 0-7wks: Intervention - wt 1.9±1.7kg, control 1.1±1.4kg	NS diff between groups - FBI: Change 0-3months/ 0-6months/ 0-12 months - wt (kg): -1.9 (0.5) (n=40) /-2.8(0.7)(n=32) /-2.9(0.9)(n=29); body fat %: -0.2(0.7) (n=37) / 0 (0.5) (n=32) / -0.2 (0.8) (n=29); waist (cm): -3.5 (0.6) (n=36) / -4.3 (0.9) (n=30); -5.8 (1.2) (n=28) vs. IDT: Change

Reference	Shaw 2005(159)	Stahre 2007(117)	Alberts 2010(110)	Ash 2006(111)
	statistical heterogeneity present, and limit the reliability of the results." WMD -4.71kg (-4.97 to -4.45) **CBT:** "The two studies, involving 63 participants, included data regarding wt loss that were suitable for meta-analysis. Studies were homogenous for the outcome of interest (p=0.09). Participants in both groups lost wt overall. Participants in the CBT group lost 4.9kg more than participants in the comparison group (95%CI -7.3 to -2.4)"			0-3months/ 0-6months/ 0-12 months - wt: -2.6 (0.4) n=51) /-2.6(0.5)(n=47) /-1.8(0.8)(n=49); body fat %: -0.4(0.4) (n=51) / -1.6 (0.5) (n=47) / -1.3 (0.6) (n=48); waist (cm): -4.6 (0.9) (n=48) / -4.8 (1.1) (n=47); -4.5 (1.1) (n=48)
Effect on risk (Increase/None/Protect)	Protect	Protect	None	None
Clinical importance	1	1	3	3
Clinical relevance	1	1	1	1
Generalisable	Y	N	Y	Y
Applicable	Y	Y	N	N

Reference	DiMarco 2009(112)	Lutes 2008(113)	Riva 2006(115)	Werrij 2009(119)
Type of study	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II
Intervention/ comparator	GSH/MI: 1st & 5th sessions focussed on MI (decisional balance exercise - aimed at encouraging participants to explore ambivalence about making changes); 6 sessions based on LEARN manual (traditional guided self-help) vs GSH: 1st & 5th sessions: 2 traditional motivation focused sessions; active encouragement of participants to consider benefits of wt loss during sessions; 6 sessions based on LEARN manual (traditional guided self-help)	A4L: choice-approach (no pre-set goals) focused on small, cumulative changes in PA & nutrition, including the same centre-based resistance and aerobic training program, each 40-45min training session (2times/wk, ~24 hrs in total) conducted with personal trainer and included 10-12 min graded ex protocol using treadmill or cycle ergometer, 15-20minresistance training protocol, 5 mins stretching every session. Wkly one on one meeting with lifestyle coach (20mins, total 5hrs). Challenging, yet achievable goals set regarding nutrition, PA, EI goals individualised based on REE (ranged from 1500kcal-2200kcal/d F, 1900-2600kCal/d M), increasing F&V, decreasing high fat dairy and meat/soft drinks/ high E snacks/portion sizes. Weekly PA goals set to increase pedometer steps to reach 3000 more steps than baseline (or total of 10000 steps/d). VERSUS StdEd: educationally based, didactically	CBT: same as NT plus15 additional sessions over 6 wks, CBT approach described by Cooper, self-monitor food intake and eating patterns and thoughts and circumstances and environment surrounding eating, identify problems in eating, mood, thinking patterns, gradually develop alternative patterns, - 5 weekly group sessions aimed at addressing wt and primary goals, 10 biwkly individual sessions to establish and maintain wt loss, addressing barriers to wt loss, increasing PA, addressing body image concerns. VERSUS ExpCT (Experiential cognitive therapy): same as NT plus 15 additional sessions over 6 wks, 5 weekly group sessions aimed at improving motivation to change and assertiveness, 10 biwkly virtual reality sessions (virtual reality for eating disturbances modification - presents critical situations related to maintaining/relapse mechanisms) VERSUS NT(nutrition): 5 weekly nutritional groups held by dietitians based on LEARN material - provide practical guidelines for self-monitoring of eating and lessons on nutrition (stressing gradual wt loss), 1200kCal/d (reductions in fat intake), PA (30mins	CDT (Cognitive + Diet therapy): same diet therapy as ExDT, but 2nd half of each session aimed to ID, challenge and change dysfunctional cognitions concerning eating, control, wt, shape, self-esteem and interpersonal schemas. Automatic thoughts and beliefs were challenged, behavioural experiments set up, workbooks with cognitive interventions and homework assignments, including thought diaries. Performed by CBT therapists intensely trained by qualified CBT therapists. VERSUS ExDT: first part of each session was dietetic intervention carried out by dietitians - change unhealthy dietary patterns by providing nutrition education, monitoring food diaries, cooking classes, eating 3m/d, eating at regular place, mindful eating, change bad eating habits into healthy habits, learned when to stop eating, learned how to refuse food, learned how to find social support/ how to deal with parties and supermkt shopping etc.

Reference	DiMarco 2009(112)	Lutes 2008(113)	Riva 2006(115)	Werrij 2009(119)
		delivered US Dept Agriculture nutrition& PA program - weekly 20min session with nutritionist using education program 'Dietary Guidelines for Americans' - eat <1600kcal/ F, <2000kcal/d M (~5 hours with dietitian), also encouraged to exercise at least 30mins/d on most days of week, coupled with centre-based resistance and aerobic training program (same as A4L gp) [control gp: continue life as usual - not extracted]	walking 2/7 minimum.), Waitlist group - no intervention provided (no further data extraction done on this group)	Received guidelines for healthy diet but not a prescribed diet. Physical exercise was 2nd part of each session, performed by physiotherapists, engaged in 1hr low intensity exercise program (gym). Diet + exercise regimen considered std Dutch tx for obesity in this field setting.
N	GSH&MI: recruited/completers 20/15, GSH 19/11	A4L n=20, StdEd n=20 (waitlist control n=19 not included in this review)	Randomised/ analysed: CBT: 56/52, Exp CT: 58/56; NT: 54/50; Waiting list: 53/53	CDT:96; ExDT:104
Population/study information	US; 11 wk intervention, recruited through advertisement in email sent to faculty/staff of large university, aged 18-55yrs, BMI 27-40, not participating in another wt loss program, no hx wt loss surgery, no medical conditions affecting wt, ability to perform mod PA, not pregnant, no significant symptoms of depression, no drug/alcohol abuse, infrequent purging behaviours (≤1/6mths); 11 weeks duration, weekly for 5 weeks, then fortnightly for 3 sessions;	USA, 16 wk intervention, f/up 3 months after intervention, recruited through newspapers and radio, BMI 26-40, sedentary lifestyle (<30mins mod-vig PA/wk), no cardiopulmonary or metabolic disease, BP<160/100mmHg, no meds affecting wt or other metabolic parameters, active health insurance, no recent pregnancy.	Italy, women, 6 weeks for treatment, f/up at 6mths, 18-50yrs, BMI>40, no other concurrent severe psychiatric disturbances, no concurrent medical condition not related to the disorder, one or more failures in following an obesity treatment, written and informed consent to participate; Age 36(9)yrs, 110.7(14.8)kg, 1.6(0.1)m, BMI 42.2(5), 54% graduated from upper secondary school, 71% employed and not married	Netherlands, 10 wks treatment, 1 yr follow up after end of tx, recruited at dietetics dept of local health centre and by ads in newspapers, BMI >27, 18-65yrs, not participating in another wt loss tx, not treated for mental hlth condition, able to exercise, not pregnant.
Quality	Neutral	Positive	Neutral	Neutral

Reference	DiMarco 2009(112)	Lutes 2008(113)	Riva 2006(115)	Werrij 2009(119)
Results	Baseline/post-treatment: GSH&MI: 33.1 (3.2)/ 31.6(3.1) kg/m2 vs. GSH: 31.6 (2.8)/ 30.9(3.1) kg/m2. NS diff between MI&GSH and GSH groups.	A4L: Bline/ 16wks/ 3mths follow-up: wt: 90.3(16.1)kg, 85.8(15.9), 86.2(15.8); intra-abdom fat (%): 35.6(4.3), 32.9(5.1), 33.6(5.6); waist (cm): 104.6(12), 97.8(11.6), 97.4(11.6); StdEd: Bline/ 16wks/ 3mths followup: wt: 89.7(15.6)kg, 88.6(15.3), 88.4(15.3); intra-abdom fat (%): 36.5(5), 35.7(5.9), 36(5.7); waist (cm): 105.4(10.1), 105(9.2), 105.5(8.9); A4L lost greater weight (-3.4kg), intra-abdom fat (-2%) and waist circumference (-6.4cm) than StdEd ($p<0.02$) at 16 weeks; no diffs detected during follow-up but both groups managed to maintain weight loss.	Bline/6wkstx/6mthsfollowup: CBT: 108(12.1)/100.5(11.3)/99.7(14.5); ExpCT: 112.1(15.6)/105(14.3)/99.6(15.5) vs. NT: 110(15.2)/103.2(14.5)/104.3(14.7). NS between groups both during intervention and at follow up. When subjects were categorised into: lost 10% wt (Y/N), maintained/improved wt reduction after tx (Y/N), and equal or higher wt than baseline (Y/N), the experiential CT gp was the best condition and NT worse condition ($p=0.000$)	Bline/~10wks/1yraftertx: CDT: BMI 33.4(4.4)/32.1(4.4), BMI change -1.36/32.1(4.5), BMI change -1.35, wt loss not shown but article stated "wt loss was close to, but somewhat less than, the predicted and desired 5%" VERSUS EDT: 33.3(4.8)/31.9(4.6), BMI change 1.4/32.2(4.7), BMI change 1.1. Wt loss in both groups over time was significant, no diffs between groups after intervention finished. 1 year later, trend for wt lost to be maintained after CDT, but not after EDT. Being treated by EDT showed a trend for participants to regain 25% of initially lost wt, whereas being treated by CDT predicted no weight regain at all. Completer's results were similar.
Effect on risk (Increase/None/Protect)	None	Protect	None	None
Clinical importance	3	1	3	3
Clinical relevance	1	1	1	1
Generalisable	N	Y	N	Y
Applicable	N	N	N	N

Reference	Melin 2003(114)	Tate 2003(118)	Silva 2010(116)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	Gp1: continuous intensive tx with planned group meetings fortnightly during 1st year, and 6 meetings during 2nd year (43 meetings in total). These participants had the opportunity to repeat self-monitoring and obtain more info and education in nutrition, food habits and strategies to control the eating behaviour. During VLCD period (25 days, once a year) - decrease EI from 800kcal/d to 200kcal/d over 3 days and maintain this intake for 19days, EI then progressively increased to 800kcal/d during final 3 days, twice weekly group meetings supervised by dietitian & psychologist, meetings on nutrition education, behaviour modification. After VLCD period, ordinary food gradually introduced. Prescribed individualised hypocaloric diet aiming at E deficit of 600kcal/d. Food recommendations based on Nordic Nutritional Guidelines. Education in Nutrition & food habits given, and self-monitoring and strategies to control eating behaviour (hunger & cravings, relapse, monitoring PA, satisfaction-happiness also) discussed to support subjects moving from precontemplation through to maintenance. VERSUS Gp 2: planned group meetings held every 3rd month (less often than gp 1). 27	Int-BT: internet plus behavioural e-counselling program -provided a tutorial on weight loss, a new tip and link each week and a directory of selected internet weight loss resources PLUS they communicated via email with an assignment weight loss counsellor. Participants reported calorie, fat, exercise and any other comments or questions. Participants were instructed to submit daily diaries for the first months and then daily or weekly diaries for the next 11 months. Therapist sent 5 emails to participants each week for first months, then weekly for the following 11 months. Calorie restricted diet of 1200-1500kCal/d, fat intake of 20% or less of calories, 1000kCal/wk of physical activity. VERSUS Int:basic internet program- provided a tutorial on weight loss, a new tip and link each week and a directory of selected internet weight loss resources. Calorie restricted diet of 1200-1500kCal/d, fat intake of 20% or less of calories, 1000kCal/wk of physical activity.	SDT: 30 sessions, self-determinant theory basic tenants - PA (safety, skills, managing goals, monitoring PA, dealing with barriers to practice, encourage ppl to find activities they enjoyed the most), eating/nutrition (reducing energy intake by increasing knowledge, triggering weight loss/ improving diet, understanding energy balance, principles of gaining/losing weight, nutrition education), body image (concerns about body shape, promoting greater self-acceptance, establishing more realistic goals for weight/body), other cognitive/ behavioural contents (regular monitoring of weight, adoption of flexible guidelines regarding eating), addressing barriers, promoting self-regulation, developing autonomy, emotional eating, intrinsic motivation; weekly or bi-monthly, 120mins/session; promoting in each participant a sense of ownership over their behaviour (stem from internal perceived locus of causality); VERSUS Control: 29 sessions, delivered in thematic courses such as healthy/ preventive nutrition, stress management, self-care, effective communication skills, interpersonal climate promoted was similar to that commonly observed in std healthcare settings (choices, rationale, and explanations

Reference	Melin 2003(114)	Tate 2003(118)	Silva 2010(116)
	meetings in total. Same VLCD period and hypocaloric diet intervention.		were limited; specific behavioural goals were not set; minimal feedback provided), E restriction not mentioned
N	Gp1: n=22/ 12mths n=17/ 24 mths n=17; Gp2: n=21/ 12mths n=18/ 24 mths n=15	Int-BT:46 (39) / Int:46 (38)	SDT: allocated/ completed: 123/115; Control: 116/93
Population/study information	Sweden, 2 year intervention, referred to clinic, 3 people in less intensively treated group had T2DM (not on insulin), no inclusion criteria specified.	USA, 12 month intervention, recruited through newspaper ads and drawn from wait list at research centre, access to computer, BMI 27-40, at least 1 risk factor for T2DM, no major health or psych dx, not pregnant, no recent wt loss (<4.5kg).	Portugal, 1 year behaviour change intervention, recruited through newspaper, flyers and TV ads; Female, 25-50yrs, premenopausal, not pregnant, BMI 25-40, willing to attend weekly meetings (during 1 year), be tested regularly (over 3 years), free from major illnesses, not taking medication known to affect weight, not participating in any other weight loss program during first year of study (intervention group only)
Quality	Positive	Positive	Positive
Results	Gp1: Baseline/ 3mth/ 6mths/ 12 mths/ 24 mths: 99.8(5.5)kg/ -8.3(0.6)kg/ -10.6(0.6)/ -7.6(1)/ -6.8(1.4); Gp2: Baseline/ 3mth/ 6mths/ 12 mths/ 24 mths: 93.4(4.1)kg/ -10(0.7)kg/ -12.3(0.7)/ -6.4(1.2)/ -8.6(1.6); p>0.05 between groups, wt loss significant across time (p,0.0001) but not clinically significant	Int-BT:-4.4(6.2)kg weight change (p=0.04), -4.8% body weight loss (p=0.03), Completer's only: 3mths/6mths: -4.1(3.7)kg/-5.2(5.4)kg, BMI loss = -1.6 (2.2)kg/m^2 (p=0.03), wc=-7.2cm (p=0.05) VERSUS Int:-2.0 (5.7)kg weight loss, -2.2% body weight loss, Completer's only: 3mths/6mths: -2.7(3.3)kg (p=0.04)/-2.5(4.7)kg (p=0.007), BMI loss = -0.8 (2.1)kg/m^2, wc=-4.4cm. Behavioural e-counselling had greater reductions in wt (p=0.04), %wt loss (p=0.03), BMI (p=0.03) and waist circ (p=0.05) compared with basic internet group.	SDT: 12 mths: (4mths)-3.77%/ (12mths)-6.64% wt change, fat mass: (12 mths) -5.6(4.1)kg, -6.9(7.9)% body fat, BMI -2.3(1.9); Control: 12 mths: (4mths) 0.28%/ (12mths) -1.34% wt change, fat mass: (12 mths) -1.5(4.3)kg, Body fat % -2.5(7.5), BMI 0.7(1.9). Weight - significant time*group interaction at 4 & 12 months compared to baseline (p<0.001); P<0.001 between groups at 4 & 12 months for completers only and baseline observation carried forward analysis. Fat mass & % body fat & BMI - P<0.001 between groups @ 12 months.
Effect on risk (Increase/None/Protect)	None	Protect	Protect
Clinical importance	3	1	1
Clinical relevance	1	1	1
Generalisable	N	Y	N
Applicable	Y	Y	N

TABLE 1.42: Studies used to make evidence statements for a combination of behavioural and psychological therapy and dietary intervention of at least 6 months duration but less than 2 years

Reference	Avenell 2004a(120)	Avenell 2004b(121)	Tate 2003(118)	van Wier 2009(125)
Type of study	Systematic Review	Systematic Review	RCT	RCT
Level of evidence	I	I	II	II
Intervention/ comparator	4 RCTs assess the added effects of BT to diet and provided change in wt at 12 months or longer.	4 RCTs in total related to behaviour therapy (BT) in comparison to diet (without use of Sibutramine). 4 RCTs assessed the addition of BT to diet (however 1 RCT did not appear to be conducting BT in either intervention arm), 1 cluster RCT assessed additional of BT to diet and exercise (PA), PA & diet, and 2 RCTs assessed addition of BT and PA to diet. (other RCTs were included in systematic review but were unrelated to behavioural therapy topic)	Int-BT: internet plus behavioural e-counselling program -provided a tutorial on weight loss, a new tip and link each week and a directory of selected internet weight loss resources PLUS they communicated via email with an assignment weight loss counsellor. Participants reported calorie, fat, exercise and any other comments or questions. Participants were instructed to submit daily diaries for the first months and then daily or weekly diaries for the next 11 months. Therapist sent 5 emails to participants each week for first months, then weekly for the following 11 months. Calorie restricted diet of 1200-1500kCal/d, fat intake of 20% or less of calories, 1000kCal/wk of physical activity. VERSUS Int:basic internet program-provided a tutorial on weight loss, a new tip and link each week and a directory of selected internet weight loss resources. Calorie restricted diet of 1200-1500kCal/d, fat intake of 20% or less of calories, 1000kCal/wk of physical activity.	Phone BT (phone behavioural counselling group): self-help materials published by the Netherlands Heart Foundation dealing with overweight, healthy diet and physical activity + behavioural therapy including 10 modules (in a binder for the phone group; InternetBT - or through an interactive website for the internet group) on nutrition, physical activity and lifestyle modification strategies emphasising attainable lifestyle changes rather than weight loss. After completing each module, participants were contacted by phone or email (depending on group allocation) VERSUS Control: self-help materials published by the Netherlands Heart Foundation dealing with overweight, healthy diet and physical activity .

Reference	Avenell 2004a(120)	Avenell 2004b(121)	Tate 2003(118)	van Wier 2009(125)
N	n=~192	n=277	Int-BT:46 (39) / Int:46 (38)	phone BT = 462 (332 completed body weight), internet BT = 464(329 completed body weight). VS. control: 460 (321 completed body weight)
Population/study information	Not reported here but studies were similar to Avenell et al 2004b therefore demographics will be similar. 3/4 RCTs recruited women only.	Human, adult studies, 18 to ~70 yrs; mean BMI ~31.3-39.4, 1/4studies both genders, n=257 F only, 2 studies from US, 2 from Europe, 1 study conducted in people with DM.	USA, 12 month intervention, recruited through newspaper ads and drawn from wait list at research centre, access to computer, BMI 27-40, at least 1 risk factor for T2DM, no major health or psych dx, not pregnant, no recent wt loss (<4.5kg).	Netherlands, 6 mths intervention, HR depts or Occ Hlth depts of lge companies were approached (IT companies, hospitals, insurance company, bank, police force), BMI at least 25, paid employment for at least 8hrs/7, able to read and write Dutch, access to internet, skilled in using internet, at least 18yrs, not pregnant, no disorders making PA difficult.
Quality	Positive	Positive	Positive	Positive

Reference	Avenell 2004a(120)	Avenell 2004b(121)	Tate 2003(118)	van Wier 2009(125)
Results	"Additional effect of BT on diet was associated with an overall WMD wt change at 12 mths of -7.67kg (95%CI -11.97 to -3.36), at 18 mths of -4.18kg (-8.32 to -0.04), at 36 mths of -2.91kg (-8.6 to 2.78) and 60 mths 1.9kg (-3.75 to 7.55). Thus there was significant added effect of BT on wt change at 12 & 18 mths, but not at 36 or 60 mths. The number of participants contributing to the comparisons decreased over time and so the sustained effect of BT cannot really be assessed." "In the cluster RCT by Phenix,236 where meeting time was the unit of randomisation, mean body weight in the groups ranged from 76 to 86 kg. Phenix evaluated the added effects to diet of two forms of behaviour therapy, which were overt behaviour therapy and cognitive behaviour therapy. The added effect of overt behaviour therapy to an LCD was associated with a weight change at 12 months of –3.26 kg compared with –4.82 kg in the diet-only group. The added effect of cognitive behaviour therapy to an LCD was associated with a weight change at 12 months of –6.68 kg compared with –4.82 kg in the diet-only group. No deaths or serious adverse events were reported in any of the included studies."	Addition of BT to diet -12mths: wt change -7.67kg (95%CI -11.97 to -3.36), 18mths: -4.18 (-8.32 to -0.04)kg, 36mths -2.91kg (-8.6 to 2.78), 60 mths 1.9kg (-3.75 to 7.55). Addition of BT to diet - 12mths: wt change -6.68kg vs. -4.82kg in diet only group, overt BT to low calorie diet associated with mean wt change at 12 mths of -3.26kg vs. -4.82kg diet only gp. (cluster RCT reported separately). Addition of overt BT to diet & PA: 12mths: -5.19kg vs. -5.32kg (diet & PA gp only). CBT added to diet & PA: -1.13kg vs. -5.32kg (diet & PA gp only) at 12 mths. Adding BT & PA to diet (one RCT in DM participants) led to wt change as follows: 12 mths -0.67kg (-4.22 to 2.88kg), overt BT -5.19kg (vs. -4.82 in diet only), CBT -1.13kg (vs. -4.82kg diet only), both overt BT & CBT -4.97kg (vs. -4.82kg diet only), 18mths -1.40 (-5.57 to 1.45), 24 mths-1.40 (-5.01 to 2.21). "After 12 months the greatest wt loss was associated with the addition of BT to diet... but confidence intervals were wide." "Adding BT to diet was associated with improved wt loss for up to 18 mths."	Int-BT:-4.4(6.2)kg weight change (p=0.04), -4.8% body weight loss (p=0.03), Completer's only: 3mths/6mths: -4.1(3.7)kg/-5.2(5.4)kg, BMI loss = -1.6 (2.2)kg/m^2 (p=0.03), wc=-7.2cm (p=0.05) VERSUS Int:-2.0 (5.7)kg weight loss, -2.2% body weight loss, Completer's only: 3mths/6mths: -2.7(3.3)kg (p=0.04)/-2.5(4.7)kg (p=0.007), BMI loss = -0.8 (2.1)kg/m^2, wc=-4.4cm. Behavioural e-counselling had greater reductions in wt (p=0.04), %wt loss (p=0.03), BMI (p=0.03) and waist circ (p=0.05) compared with basic internet group.	Bline/ 6mths: PhoneBT: 93.4(14.1)/90.7(13.7)kg, waist, cm (completers) n=236, 102.6(10)cm/98.6(10.3); InternetBT: 92.8(14.3)/ 91.0(14.2); n=235 101.5(10.3)cm/ 98.2(10.2) VERSUS Control 92.9(13.6)/91.7(13.8)kg, n=231 101.5(9.8)/99.5(10)cm. phone (compared to control) (-1.5kg [-2.2, -0.8], -1.9cm[-2.7,-1.0]) and internet (compared to control) (-0.6kg [-1.3, -0.01], -1.2cm [-2.1, -0.4]). No diffs found between phone and internet BT groups.

Reference	Avenell 2004a(120)	Avenell 2004b(121)	Tate 2003(118)	van Wier 2009(125)
Effect on risk (Increase/None/Protect)	Protect	Protect	Protect	Protect
Clinical importance	2	2	1	3
Clinical relevance	1	1	1	1
Generalisable	Y	Y	Y	N
Applicable	Y	Y	Y	Y

Reference	Cooper 2010(122)	Rodriguez-Hernandez 2009(123)	Subak 2009(124)	Melin 2003(114)	Silva 2010(116)
Type of study	RCT	RCT	RCT	RCT	RCT
Level of evidence	II	II	II	II	II
Intervention/ comparator	CBT: address psychological processes that interfere with weight maintenance (lack of acceptance and value of more modest changes in weight and appearance that comes with decline in rate of weight lost + encourage acquisition and practice of weight maintenance skills) - 24 * 50min one to one sessions over 44 weeks, weekly first 7 wks, fortnightly thereafter, 1500kcal E restriction for first 24-30 weeks also. VS. Behaviour Therapy (BT): modern behaviour therapy and methods applied to help	CBT: received intervention that included behavioural strategies, cognitive skills, relapse prevention techniques to identify factors that trigger overeating and lack of PA and for promoting use of new responses to these triggers. Both groups: wkly psychological support for tx or prevention of depression and anxiety, plus weekly sessions of 1h for diet and exercise advice. Individual meetings. Recommendations for exercise were walking, dancing, cycling or swimming for 30mins/d	DEBT (Diet, Exercise, Behaviour therapy): weekly 1hr meetings for 6 months in groups of 10-15 participants. Led by experts in nutrition, exercise and behaviour change. Intervention protocol based on previous clinical trials (AHEAD and Diabetes Prevention Program). Standard reduced calorie diet of 1200kCal to 1500kCal per day with < 30% of calories from fat. Provided with sample meal plans, vouchers for meal replacement products (Slimfast) to be used 2/d during months 1-4 and 1/d	Gp1: continuous intensive tx with planned group meetings fortnightly during 1st year, and 6 meetings during 2nd year (43 meetings in total). These participants had the opportunity to repeat self-monitoring and obtain more info and education in nutrition, food habits and strategies to control the eating behaviour. During VLCD period (25 days, once a year) - decrease EI from 800kcal/d to 200kcal/d over 3 days and maintain this intake for 19days, EI then progressively increased to 800kcal/d	SDT: 30 sessions, self-determinant theory basic tenants - PA (safety, skills, managing goals, monitoring PA, dealing with barriers to practice, encourage ppl to find activities they enjoyed the most), eating/nutrition (reducing energy intake by increasing knowledge, triggering weight loss/ improving diet, understanding energy balance, principles of gaining/losing weight, nutrition education), body image (concerns about body shape, promoting greater self-acceptance, establishing more realistic

Reference	Cooper 2010(122)	Rodriguez-Hernandez 2009(123)	Subak 2009(124)	Melin 2003(114)	Silva 2010(116)
	participants change their eating habits and activity level, aim to restrict EI to 1200kCal/d, same no. and pattern of sessions as CBT, choice to pursue further weight loss at weeks 24,30 and 36 or to maintain weight. VS. Guided self-help (GSH/control): based on LEARN programme for wt control; focuses on lifestyle, exercise, attitudes, relationships and nutrition; EI restricted to 1200 kCal/d, make healthy food choices; gradual increase in PA level; limited guidance and support from therapist; two initial face to face sessions with therapist followed up by 15 20-min telephone sessions. 44 week study duration (11 months) for CBT & BT, 24 weeks for GSH, follow up for 3 years	5/7. EI 125kg/kg/d of IBW. LC diet 27P:28F:25CHO; LF diet 25P:21F(<10sf):54CHO, adherence to diet assessed weekly by personal interview. VERSUS Control: wkly psychological support for tx or prevention of depression and anxiety, plus weekly sessions of 1h for diet and exercise advice. Individual meetings. Recommendations for exercise were walking, dancing, cycling or swimming for 30mins/d 5/7. LC diet 27P:28F:25CHO; LF diet 25P:21F(<10sf):54CHO, adherence to diet assessed weekly by personal interview.	after 4 months. Gradually increase physical activity to 200min/d. Behavioural skills including self-monitoring, stimulus control and problem solving. Plus self-help behavioural treatment book on improving bladder control. vs. Control: 4 x 1hr group education sessions at months 1,2,3 and 4. 10-15 women in each group. Sessions included general information on weight loss, physical activity and healthful eating habits. Plus self-help behavioural treatment book on improving bladder control.	during final 3 days, twice weekly group meetings supervised by dietitian & psychologist, meetings on nutrition education, behaviour modification. After VLCD period, ordinary food gradually introduced. Prescribed individualised hypocaloric diet aiming at E deficit of 600kcal/d. Food recommendations based on Nordic Nutritional Guidelines. Education in Nutrition & food habits given, and self-monitoring and strategies to control eating behaviour (hunger & cravings, relapse, monitoring PA, satisfaction-happiness also) discussed to support subjects moving from precontemplation through to maintenance. VERSUS Gp 2: planned group meetings held every 3rd month (less often than gp 1). 27 meetings in total. Same VLCD period and hypocaloric diet intervention.	goals for weight/body), other cognitive/ behavioural contents (regular monitoring of weight, adoption of flexible guidelines regarding eating), addressing barriers, promoting self-regulation, developing autonomy, emotional eating, intrinsic motivation; weekly or bi-monthly, 120mins/session; promoting in each participant a sense of ownership over their behaviour (stem from internal perceived locus of causality); VERSUS Control: 29 sessions, delivered in thematic courses such as healthy/ preventive nutrition, stress management, self-care, effective communication skills, interpersonal climate promoted was similar to that commonly observed in std healthcare settings (choices, rationale, and explanations were limited; specific behavioural goals were not set; minimal feedback provided), E restriction not mentioned
N	CBT 49/ BT 50 /GSH	CBT n=55 (completed	DEBT: 226 (221) / Control:	Gp1: n=22/ 12mths n=17/	SDT: allocated/ completed:

Reference	Cooper 2010(122)	Rodriguez-Hernandez 2009(123)	Subak 2009(124)	Melin 2003(114)	Silva 2010(116)
	(control) 51	n=52) -> CBT-LF n=29 (28), CBT-LC n=26 (24); Control n=50 (completed n=52) -> Con-LF n=29 (29), Con-LC n=21 (21)	112 (97)	24 mths n=17; Gp2: n=21/ 12mths n=18/ 24 mths n=15	123/115; Control: 116/93
Population/study information	Australia; 24-44 wk intervention, 3 yr follow up, referred by family physician or responded to advertisements placed in physician's clinics and local hospitals; female, 20-60 years; BMI 30-39.9; available for treatment for 44 weeks, willing to participate, maintained wt within 10% of prior 6 months; no major medical or psychiatric illnesses, no disorders or tx known to affect eating, wt, metabolic rate.	Mexico, 6 month intervention, obese women from same neighbourhood and similar social and economic strata invited to participate, not pregnant, no: hypothyroidism, heart failure, or renal or hepatic dx	USA, 6 month intervention, at least 30yrs, F, BMI 25-50, reported at least 10 urinary incontinence episodes in wk, not undertaking new tx for incontinence or wt within month before and during trial, no current UTI or no more than three UTIs in previous year, no hx of incontinence of neurologic or functional origin, no previous surgery for incontinence or urethral surgery, no major medial or genitourinary tract conditions, not pregnant/ parturition in prior 6/12, no DM requiring medical therapy that increased risk of hypoglycemia, no uncontrolled HT.	Sweden, 2 year intervention, referred to clinic, 3 people in less intensively treated group had T2DM (not on insulin), no inclusion criteria specified.	Portugal, 1 year behaviour change intervention, recruited through newspaper, flyers and TV ads; Female, 25-50yrs, premenopausal, not pregnant, BMI 25-40, willing to attend weekly meetings (during 1 year), be tested regularly (over 3 years), free from major illnesses, not taking medication known to affect weight, not participating in any other weight loss program during first year of study (intervention group only)
Quality	Neutral	Neutral	Positive	Positive	Positive
Results	Change 0-6mths (end of GSH intervention)./ 0-11 mths (end of CBT & BT intervention) / 1 yr 11 mths f/up / 2 yrs 11 mths f/up/ 3 yrs 11 mths f/up: CBT: 83.2(10.4)kg, -10(6)% wt change/84.2(11.1), -	Baseline / 6mths: CBT - LC: wt: 90(12.3)kg (8.7% wt loss)/82.1(12.1), waist (cm) 104.4(12.3)/98.7(10.8), total body fat (%) 44.7(3.7)/43.3(4.9) VERSUS Cont - LC: wt:	Bline/ 6mths/ wt loss 6mths/ %ch 6mths: DEBT: 98(17)kg/90(17)/ -7.8kg (7.0, 9.0)/ -8%(95%CI -9to-7) VERSUS Control: wt loss = 95(16)/ 94(17)/ -1.5kg (-0.4, -2.7)/ -1.6(-2.7to-0.4). p<0.001 diff in wt loss	Gp1: Baseline/ 3mth/ 6mths/ 12 mths/ 24 mths: 99.8(5.5)kg/ -8.3(0.6)kg/ -10.6(0.6)/ -7.6(1)/ -6.8(1.4); Gp2: Baseline/ 3mth/ 6mths/ 12 mths/ 24 mths: 93.4(4.1)kg/ -10(0.7)kg/ -12.3(0.7)/ -	SDT: 12 mths: (4mths)-3.77%/ (12mths)-6.64% wt change, fat mass: (12 mths) -5.6(4.1)kg, -6.9(7.9)% body fat, BMI -2.3(1.9); Control: 12 mths: (4mths) 0.28%/ (12mths) -1.34% wt change, fat mass: (12

Reference	Cooper 2010(122)	Rodriguez-Hernandez 2009(123)	Subak 2009(124)	Melin 2003(114)	Silva 2010(116)
	8.9(6.8)%/89(11.5),-3.7(6.7)%/91.4(11.2), -1(6.5)%/91.9(10.7), -0.4(7); BT: 84.5(12.6)kg, -11.3(7)% wt change/83.6(14.6), -12.7(9.9)/88.2(14.3), -7.4(9.2)/90.9(12.9), -4.6(7.7)/92(13.4), -3.4(8.3). VS. Change 0-6mths (end of GSH intervention)./ 0-11 mths (end of CBT & BT intervention) / 1 yr 11 mths f/up / 2 yrs 11 mths f/up/ 3 yrs 11 mths f/up: GSH: 89.5(11.6)kg, -6.7(7.6)% wt change/90.7(11.7), -5.4(8.3)%/93.6(11),-2.4(7.5)%/95.1(11.6), -0.9(7.2)%/95.9(10.9), -0.1(7.3); 6mths: BT lost 4.6% > wt than GSH p=0.003; 11mths: BT lost 7.3% > wt than GSH p<0.001; no diff between CBT & BT. BT lost 2.8kg more adjusted mean wt during follow up than CBT (95%CI 0.13-5.45)	89.4(10)kg (4% wt loss)/85.8(9.8), waist (cm) 113(13.8)/108.8(11.8), total body fat (%) 42.2(11.2)/41.7(9.4) AND Baseline / 6mths: CBT - LF: wt: 87.9(11.4)kg (9.7% wt loss)/79.4(11.8), waist (cm) 104.3(11.7)/100.4(8.8), total body fat (%) 44.4(4.1)/40.8(5.3) VERSUS Cont - LF: wt: 88.8(14.5)kg (3.9% wt loss)/85.3(14.3), waist (cm) 104.4(14.8)/102.7(10.6), total body fat (%) 43.8(8.8)/40.9(7.4); % wt loss was different between CBT and control group for both LF and LC groups(p<0.05). NS diff between CBT-LC & Cont-LC groups for wt (kg), waist and body fat. CBT-LF gp had significantly lower wt (kg) and body fat (p<0.05) than C-LF gp (no diff in waist).	between groups (and for completers analysis also)	6.4(1.2)/ -8.6(1.6); p>0.05 between groups, wt loss significant across time (p,0.0001) but not clinically significant	mths) -1.5(4.3)kg, Body fat % -2.5(7.5), BMI 0.7(1.9). weight - significant time*group interaction at 4 & 12 months compared to baseline (p<0.001); P<0.001 between groups at 4 & 12 months for completers only and baseline observation carried forward analysis. Fat mass & % body fat & BMI - P<0.001 between groups @ 12 months.
Effect on risk (Increase/None/Protect)	Protect	Protect	Protect	None	Protect
Clinical importance	2	1	1	3	1
Clinical relevance	1	1	1	1	1
Generalisable	Y	N	N	N	N
Applicable	N	N	Y	Y	N

TABLE 1.43: Studies used to make evidence statements for a combination of behavioural and psychological therapy and dietary intervention of 2 years duration

Reference	Ryan 2010(127)	Logue 2005(126)	Melin 2003(114)
Type of study	RCT	RCT	RCT
Level of evidence	II	II	II
Intervention/ comparator	IMI-BT (intensive medical intervention): 3 phases: 1-low calorie liquid diet for 2-12 weeks (10g of added fat + 5 shakes per day at 890kCal/d, 75g protein, 15g fat, 110g carbohydrates). 2- Structured diet (1200kCal-1600kCal/d) and medication along with group behavioural therapy (held weekly for 4 weeks and then fortnightly for 3 months with physician visits monthly). 2 meal replacements + 2 portion controlled snacks and 1 structured meal per day + weight loss medications. Individual behavioural therapy focusing on weight management, physical activity, behavioural strategies (self-monitoring, stimulus control, social support, contingency management, problem solving, relapse prevention). 3-months 8-24 weight loss medications + 1 daily meal replacement continued with monthly group sessions conducted. Repeated low-calorie diet in 4-12 week episode as required, novel dietary approaches (high protein, low carbohydrate diet, DASH diet and low GI load diet) and physical activity. VERSUS UC (usual care): Use Mayo Clinic Weight Management Website + appointments for annual visits at 1 and 2 years.	TM-CD: 10 min session with dietitian every 6 months for 2 years, counselling based on USDA Food Guide Pyramid, or Soul Food Guide pyramid, given written dietary and exercise prescriptions based on info from diet and exercise recalls (e.g. reduce calories, increase F&V, reduce fat, increase activity and exercise), advised to discuss lipid & BP with primary care physician, paid $25 for completing each post baseline assessment. In addition, formally evaluated for anxiety, depression, BED and completed a Stage of Change assessment for target behaviours (increased exercise, increased usual activity, increased dietary portion control, decreased dietary fat, increased F&V) - patients were mailed stage and behaviour matched workbooks that corresponded to their most recent SOC profile. Plus brief monthly phone calls from weight loss advisor trained to apply processes of change corresponding to SOC profile. Other relevant materials (e.g. mall walking maps) were mailed to participants as requested. vs. AUC: 10 min session with dietitian every 6 months for 2 years, counselling based on USDA Food Guide Pyramid, or Soul Food Guide pyramid, given written dietary and exercise prescriptions based on info from det and exercise recalls, advised to discuss lipid & BP with primary care physician, paid $25 for completing each post baseline assessment, 6 monthly measures taken in both groups	Gp1: continuous intensive tx with planned group meetings fortnightly during 1st year, and 6 meetings during 2nd year (43 meetings in total). These participants had the opportunity to repeat self-monitoring and obtain more info and education in nutrition, food habits and strategies to control the eating behaviour. During VLCD period (25 days, once a year) - decrease EI from 800kcal/d to 200kcal/d over 3 days and maintain this intake for 19days, EI then progressively increased to 800kcal/d during final 3 days, twice weekly group meetings supervised by dietitian & psychologist, meetings on nutrition education, behaviour modification. After VLCD period, ordinary food gradually introduced. Prescribed individualised hypocaloric diet aiming at E deficit of 600kcal/d. Food recommendations based on Nordic Nutritional Guidelines. Education in Nutrition & food habits given, and self-monitoring and strategies to control eating behaviour (hunger & cravings, relapse, monitoring PA, satisfaction-happiness also) discussed to support subjects moving from precontemplating through to maintenance. VERSUS Gp 2: planned group meetings held every 3rd month (less often than gp 1). 27 meetings in total. Same VLCD period and

Reference	Ryan 2010(127)	Logue 2005(126)	Melin 2003(114)
			hypocaloric diet intervention.
N	IMI-BT:200 (101) / UC:190 (86)	TM-CD: n=329; AUC: n=336	Gp1: n=22/ 12mths n=17/ 24 mths n=17; Gp2: n=21/ 12mths n=18/ 24 mths n=15
Population/study information	USA, 2 yr intervention, aged 20-60yrs, BMI 40-60, enrolled in programs of Louisiana State Employees Group Benefits office, non-pregnant, no pregnancy throughout trial, blood counts within RR, uric acid <9mg/dl, no major depression/suicidal behaviour/eating disorder, not hospitalised for mental disorder or substance abuse in past yr, no active cancer, no CVD event in past 12/12, no current use of wt loss meds, BP<160/100 if untreated, Duke activity status at least 25.	US, 2 yr intervention, recruited when inquired about study after either talking to physician or reading study brochures/posters/letters mailed to potential participants ID'd by primary care physicians, required to be patients in primary care practices affiliated with study, M&F, aged 40-69yrs, BMI>27, WHR >0.95M, >0.8F, access to telephone, can understand 8th grade level English, not pregnancy/lactating, >6mths postpartum, not using wheelchair for mobility, no severe heart or lung disease.	Sweden, 2 year intervention, referred to clinic, 3 people in less intensively treated group had T2DM (not on insulin), no inclusion criteria specified.
Quality	Positive	Positive	Positive
Results	IMI-BT: 2yrs -4.9% ±0.8 (BOCF) vs. UC: 2 yrs: -0.2 ±0.3% (BOCF). Significantly diff between groups (p<0.01) at yr 2 for BOCF, LOCF, completers and mixed models analysis.	TM-CD: wt change 0-24 mths: -0.39 (0.38)kg; waist decreased (both groups combined) at 24 months by 1.7(0.4)cm but did not differ between groups vs. AUC: wt change 0-24mths: -0.16(0.42)kg; p>0.05 between groups, wt loss highly significant across time (p,0.0001) but not clinically significant	Gp1: Baseline/ 3mth/ 6mths/ 12 mths/ 24 mths: 99.8(5.5)kg/ -8.3(0.6)kg/ -10.6(0.6)/ -7.6(1)/ -6.8(1.4); Gp2: Baseline/ 3mth/ 6mths/ 12 mths/ 24 mths: 93.4(4.1)kg/ -10(0.7)kg/ -12.3(0.7)/ -6.4(1.2)/ -8.6(1.6); p>0.05 between groups, wt loss significant across time (p,0.0001) but not clinically significant
Effect on risk (Increase/None/Protect)	Protect	None	None
Clinical importance	1	3	1
Clinical relevance	1	1	1
Generalisable	N	Y	N
Applicable	N	N	Y

TABLE 1.44: Studies used to make evidence statements for meal frequency

Reference	Palmer 2009(128)	Cameron 2010(129)
Type of study	Systematic Review	RCT
Level of evidence	I	II
Intervention/ comparator	Majority of studies tested 3 meals. Wt loss RCTs: 3 meals vs. (either 3 meals and 3 snacks, 2 meals, or 6 meals), 3 meals 1 snack vs. (either 3 meals 2 snacks or 6 meals). Wt maintenance: 3 meals vs. (either 17 snacks, 9 meals or 1 - 4 snacks).	High meal frequency (3 meals + 3 snacks/d) vs. Low meal frequency (3 meals/d). Both groups prescribed -2.9MJ/d energy restriction for 8 weeks and had to follow a meal plan according to the recommendations from Canadian Diabetes Association, not stated if food was provided or how often meetings were held.
N	n=404 in total RCT weight loss studies, n=157 in total RCT weight maintenance studies	16
Population/study information	Human, adult studies (>20 years, <70 years), no known chronic diseases, English studies	Canada; W&M 19, 31; obese (30-<45kg/m2), non-diabetic, non-smokers, non-pregnant, sedentary, weight stable for at least 6 mths, aged 18-55 years. Subjects were free from illness, medications that could influence outcomes, 8 wk intervention, no follow up.
Quality	Neutral	Positive
Results	11 RCTs (weight loss and weight maintenance) were located. All of the studies measured weight. All studies showed no differences between groups. Wt loss studies: 2-9 weeks -2.1 to -6.1kg (3 meals, 6 meals, 3 meals & 1 or 2 snacks); 24 - 52 weeks -2.1 to -5.3 kg (3 meals vs. 3 meals and 3 snacks). Wt maintenance studies: 2-4 weeks: -0.1 to -0.9kg (3 meals vs. 9 meals, 17 snacks or 3 meals and 1-4 snacks). 7 RCTs measured body composition. One study (weight loss) showed an inverse association between nitrogen and EF. Remainder studies showed no differences between groups for an array of body composition measures.	No significant differences between groups for wt, fat mass or lean body mass (p>0.05).
Effect on risk (Increase/None/Protect)	None	None
Clinical importance	3	3
Clinical relevance	1	1
Generalisable	Y	Y

Reference	Palmer 2009(128)	Cameron 2010(129)
Applicable	Y	Y

2. Part Two: Survey of dietetic intervention in overweight and obesity

2.1 Objectives

1. To describe dietitians use of the "2002 DAA Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults"
2. To describe current dietetic services and intervention strategies in obesity management

2.2 Methods

2.2.1 Sample and recruitment

All 2011 financial members of the DAA were invited to complete an online survey (n=3943). Invitations were distributed via email, as part of a national weekly e-mail sent to all financial members in January 2011. A link to access the online survey was provided. Reminders to complete the online survey were included in two further national e-mails (February and March 2011). The survey was open for completed from 30th January to 5th April 2011.

2.2.2 Survey development

The 64-item survey was designed by the DAA Obesity Guidelines reference group. The survey content was based on a similar survey conducted on behalf of DAA in 2002 (160). Additional questions were included to evaluate the uptake and impact of the 2002 DAA Best Practice Guidelines for the Treatment of Overweight and Obesity. Changes were also made to the 2002 survey questions to facilitate implementation of the survey via a different mode (i.e. online rather than paper). The main change was the key themes arising from open-ended questions in the 2002 survey were presented as categorical response options using the 2002 themes. The survey was administered by DAA using an online survey software application (Survey Methods). The survey was pilot tested by members of the DAA Obesity Guidelines reference group and refined, prior to distribution.

2.2.3 Measures

2.2.3.1 Demographic and service profile

Questions were included on DAA branch, APD status, employment status, geographical location, years since graduation, years practicing as a dietitian, area of dietetic practice (overall and for overweight and obesity), membership of interest groups, proportion of time spent working in obesity, whether the service had clinical guidelines for obesity management, the categories of obesity service provision and proportion of caseload time spent in each and whether the service was associated with a specialist medical service.

2.2.3.2 DAA Best Practice Guidelines for the Treatment of Overweight and Obesity Evaluation

Questions were included on whether the DAA guidelines had been accessed and read, the usefulness of the guidelines, whether practice had been changed as a result of the guidelines, changes made to practice as a result of the guidelines and attendance at CPD events related to the guidelines.

2.2.3.3 Current dietetic practice

Demand

Questions were included on source and number of referrals, number of clients seen and / or referred to other services and what other services they refer to.

Models of Intervention

Questions were included on the types of obesity consultations provided, the focus of the services, philosophical and dietary approaches, selection of dietary strategies, effectiveness, involvement of other disciplines in therapy, frequency and length of follow-up consultations, outcome measures used to monitor progress and fee structures.

Management

Adult obesity management questions were drawn from a previous dietetic survey (161), with permission, in order to compare changes in dietetic management over time. Additional questions were added to determine current practice in management of paediatric overweight and obesity. Using a 6 point likert scale (1 = most important, 6 = least important), respondents were asked "In judging success in treatment / management of overweight / obesity how important do you consider the following outcomes?" Six statements about treatment outcomes were provided. The mean responses for each statement were ranked.

Using a 5 point likert scale (1= strongly disagree, 5 = strongly agree), respondents were asked to rate their success with treatment outcomes for both adults and children in the overweight and obese categories. For analysis purposes the responses were collapsed into three categories (disagree, neutral and agree). Using the same 5 point likert scale as above respondents were asked to rate how well prepared they felt they were to treat / manage both adults and children in the overweight and obese categories.

Using a 5 point likert scale (1= never, 5 = usually), respondents were asked how frequently they performed each of 19 weight management activities. Using the same 5 point likert scale respondents were also asked to rate how frequently they performed each of 14 weight management activities. A best practice weight management score was calculated, as previously reported (160, 161), by adding together the scores from the two questions above. The maximum possible score was 62. To have a valid score each participant had to respond to every question used to calculate the score. If all questions were not answered that person was excluded from the analysis

Evaluation of practice

Questions were also included on dietetic management standards and details of service audits.

Enablers and barriers to evidence based practice

Questions related to features that support effective dietetic treatment of obesity and barriers that prevent dietetic involvement in management were also asked. Using a 5 point likert scale (1= low, 5 = high), respondents were asked to rank their knowledge and skill in best practice obesity management. They were also asked to identify gaps that limit provision of effective dietetic treatment.

Continuing professional development

Questions were included on the type of CPD activities undertaken to enhance management skills, the types and delivery method for CPD activities that DAA could provide to improve provision of effective dietetic treatments.

Research

Respondents were asked to identify research questions they believed needed to be answered in terms of the role of the dietitian in obesity management.

2.2.4 Data analysis

The majority of data presented is categorical; therefore results are presented as frequencies with number of respondents for each category. Mean scores were presented for the questions related to *definitions of success* and *source of referral*, to allow a rank order of outcomes to be recorded. One way ANOVAs with Bonferoni post-hoc comparisons were used to test for differences in Best Practice Weight Management scores across sub-groups.

2.3 Results

2.3.1 Demographic and service profile

The survey was attempted by 396 dietitians, 299 of which completed the full survey. This equates to 10% of DAA members.

The most survey respondents were from the Victorian (28%), New South Wales (27%) and Queensland (22%) branches, which is consistent with DAA membership (Table 2.45).

Table 2.45: Proportion of respondents by DAA branch (Q1)

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA	Overseas
Survey completers	2.3%	27.3%	0.8%	21.7%	7.3%	1.0%	28.0%	9.7%	2.0%

All participants had dietetic qualifications, and the majority reported they were accredited practicing dietitians (96%, n=381 Q2). Most respondents reported working full-time (63%, n=249, Q3). Most respondents were from metropolitan or large urban areas (71%, n=281), while 17% were from regional areas (n=69), and 12% rural or remote areas (n=46, Q4).

Just over one third of respondents (38%) graduate more than 10 years ago, while a similar proportion (~20%) graduated < 3, 3 to 5 and 5 to 10 years ago (Figure 2.6: Number of years since graduation (Q5)

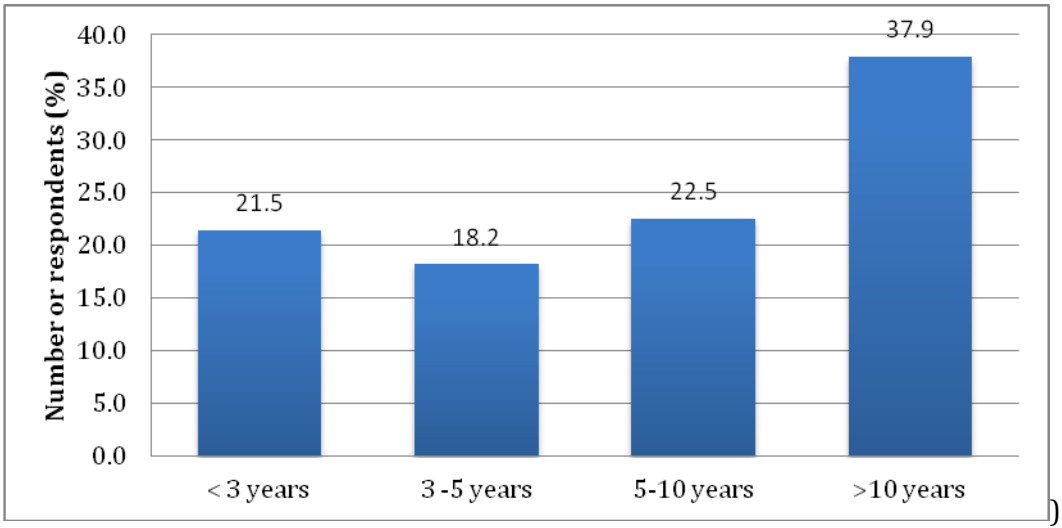
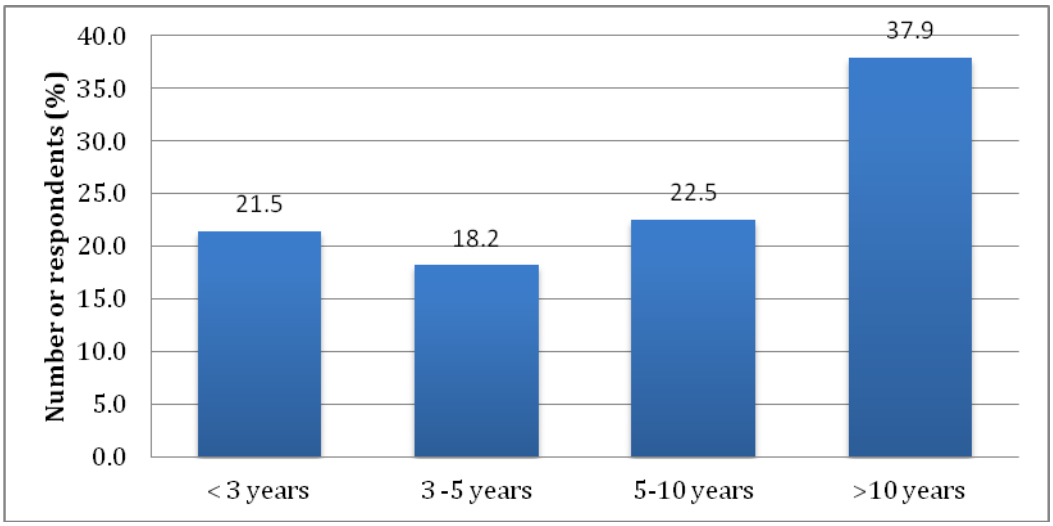

40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Number or respondents (%)
21.5
18.2
22.5
37.9
< 3 years
3 -5 years
5-10 years
>10 years
).

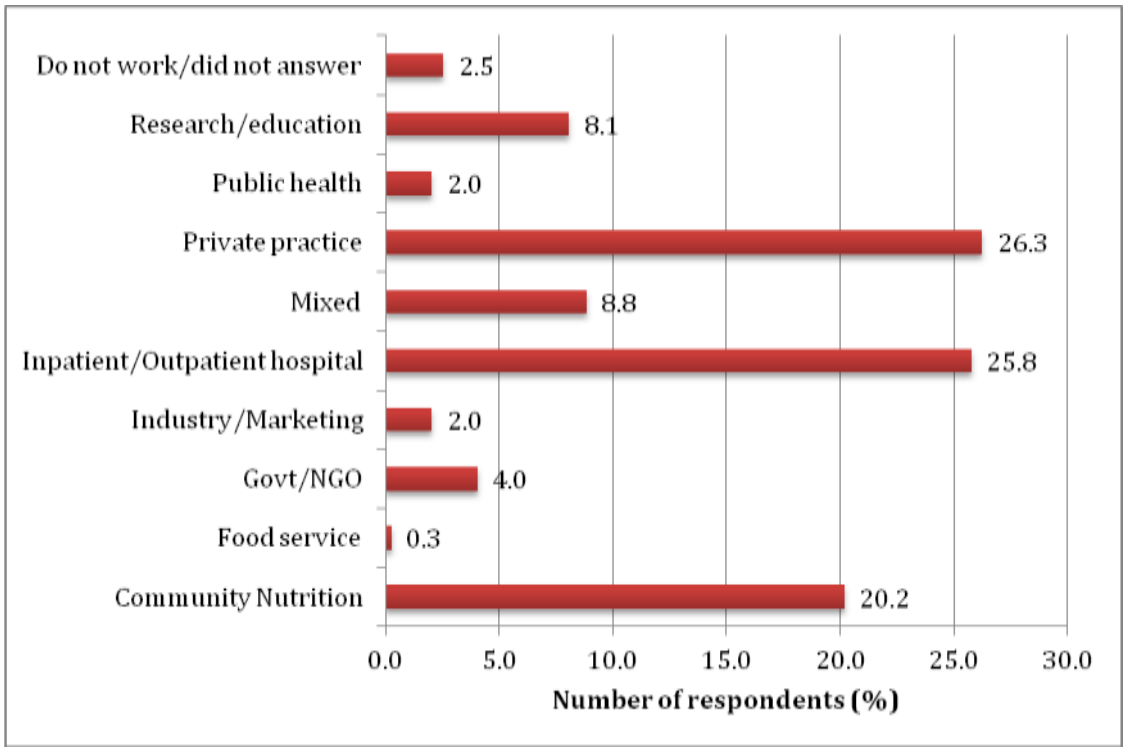
Figure 2.6: Number of years since graduation (Q5)



The number of years respondents had been practicing as a dietitian varied across the group. Most (41%) had been practicing for less than 5 years (n=163), 26% for 5 to 10 years (n=103), 20% for 11 to 25 years (n=48), and 12% for more than 25 years (n=50, Q6).

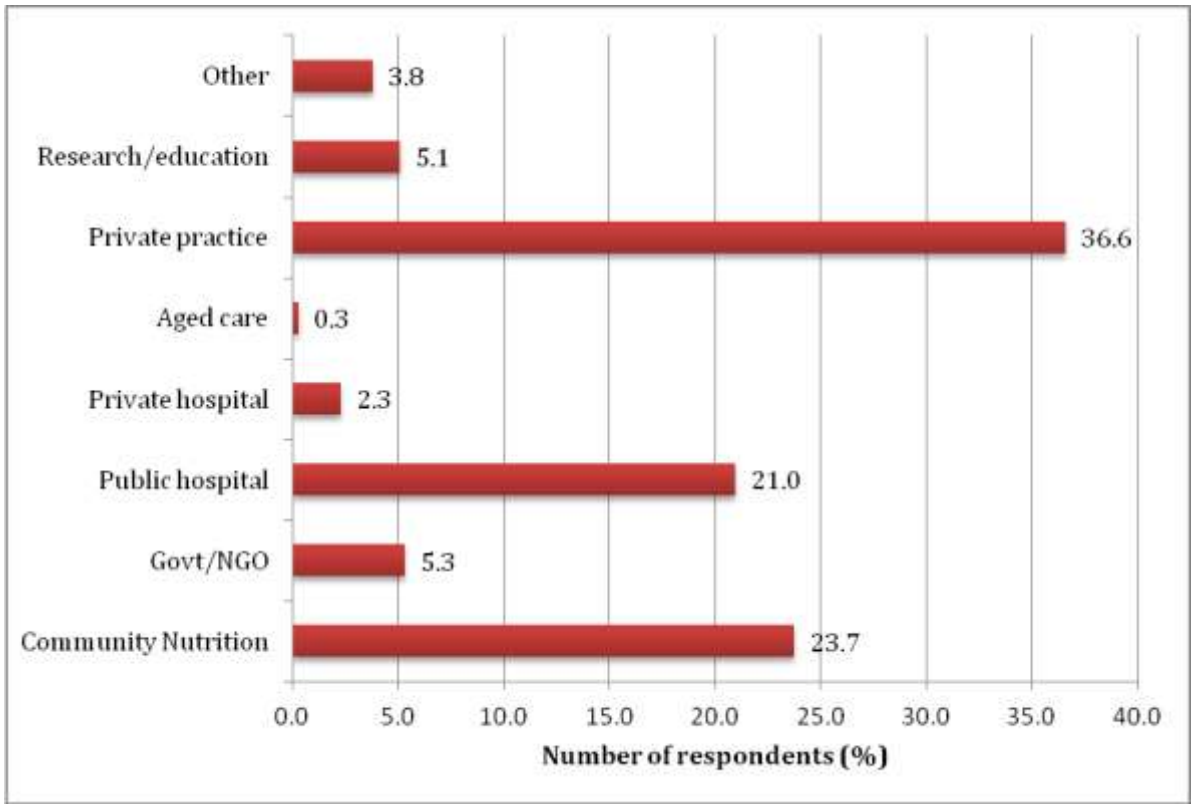
The majority (90%, n=355,) reported currently being employed in Australia as a dietitian (Q7, Figure 2.7). Respondent's major type of nutrition and dietetics practice varied (Q8). One quarter worked in the inpatient/outpatient hospital setting (n=102), and another 25% worked in private practice (n=104). Twenty percent of respondents worked in the community nutrition setting (n=80).

Figure 2.7: Major area of nutrition and dietetics practice (Q7)



The main area respondents managed overweight and obese clients was in private practice (37%, n=145), community nutrition (24%, n=94) and in public hospitals (21%, n=83) (Figure 2.8).

Figure 2.8: Work area respondents manage overweight and obese clients (Q9)



The amount of time spent working in the area of overweight and obesity also varied. Approximately half of the participants spent 50% or less of their time working in the area of overweight and obesity, while 20% spent 75% to 100% of their time working in the area (Table 2.46)

Table 2.46: Time spent working in the area of overweight and obesity (Q10)

<10%		10 to 25%		26 to 50%		51 to 75%		76 to 100%		Did not answer	
%	n	%	n	%	n	%	n	%	n	%	n
12.4	49	20.7	82	19.4	77	25.3	100	20.2	80	2.0	8

69% (n=272) of respondents reported being a member of an obesity interest group (Q11). The majority were members of the DAA National Obesity group (97%, n=262), while a small proportion were members of the Australia and New Zealand Obesity Society (7%, n=18), and the Obesity Surgery Society of Australia (10%, n=26)

23% (n=91) of respondents reported their service has clinical guidelines for obesity management, while 58% of services (n=228) did not have guidelines, and 16% were unsure (n=65) (Q13). Of the 23% who reported their service had clinical guidelines, most (40%, n=36) did not know what year the guidelines were implemented, while 35% of services implemented

clinical guidelines from 2006 to 2011 (n=32) and 17% were implemented from 2001 to 2005 (n=16, Q14).

Most respondents (70%) reported adult males made up ≤50% of their caseload (Figure 2.9), while adult females (Figure 2.10) appeared to make up a larger proportion of most respondents caseload. Paediatrics, adolescents and family weight management made up only a small or no proportion of respondents caseload (Figure 2.11,Figure 2.12, Figure 2.13).

Figure 2.9: Percentage of caseload adult males represent (Q22)

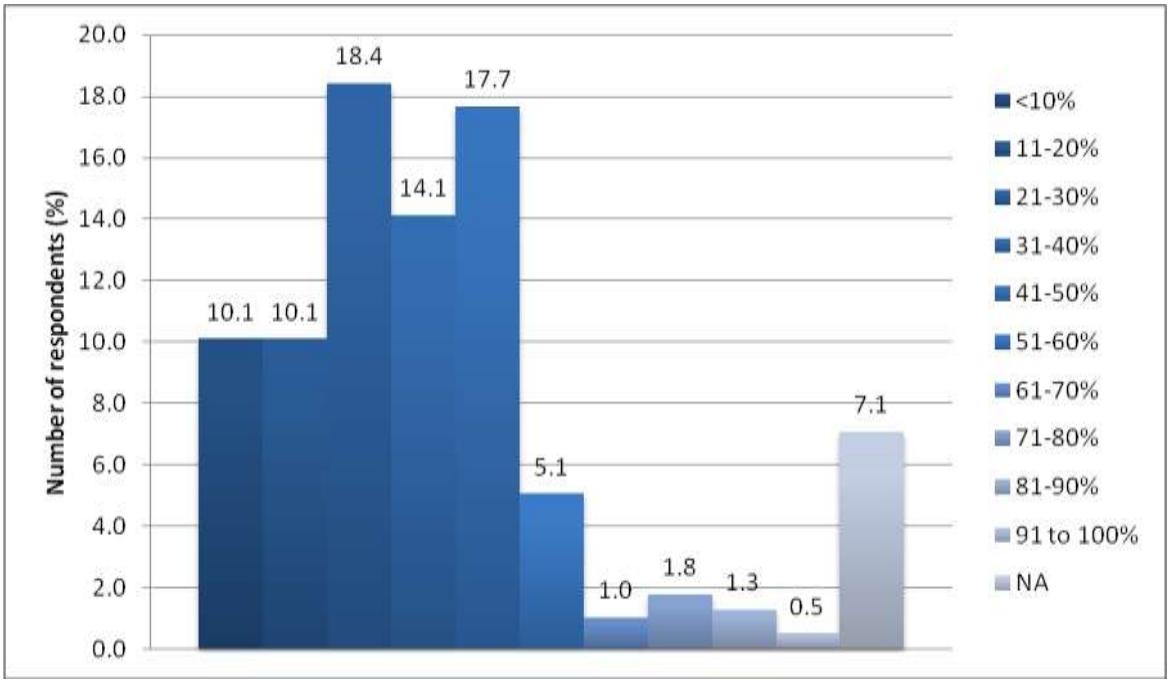


Figure 2.10: Percentage of caseload adult females represent (Q22)

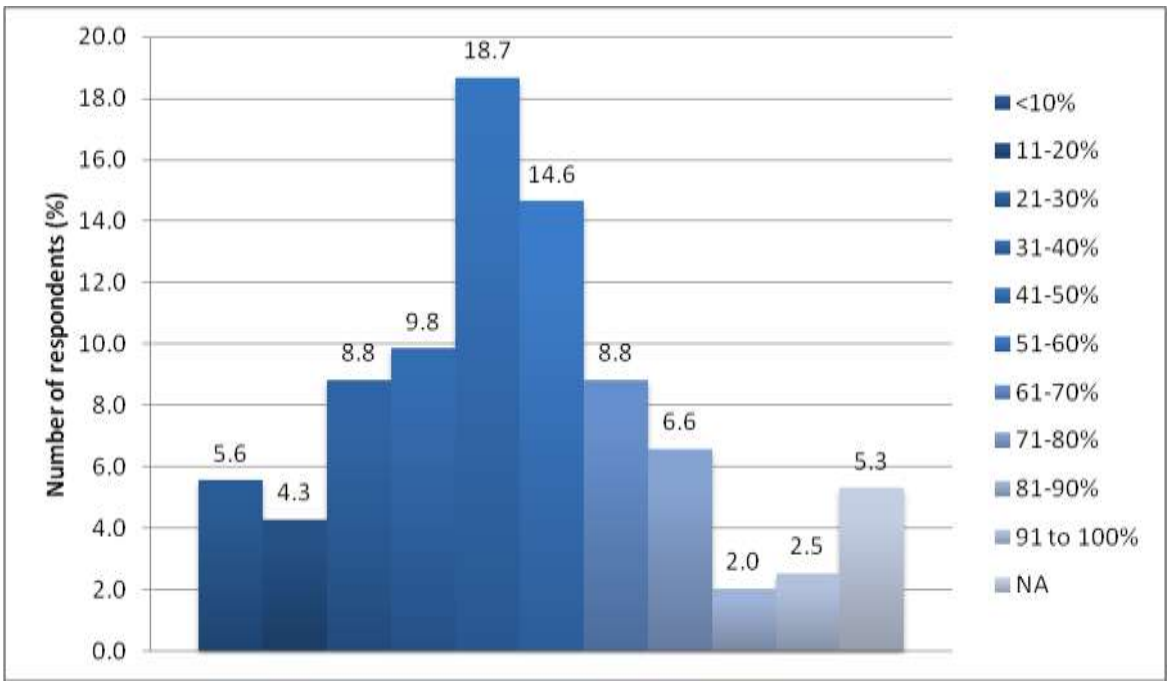


Figure 2.11:Percentage of caseload pediatrics (<13 years) represent (Q22)

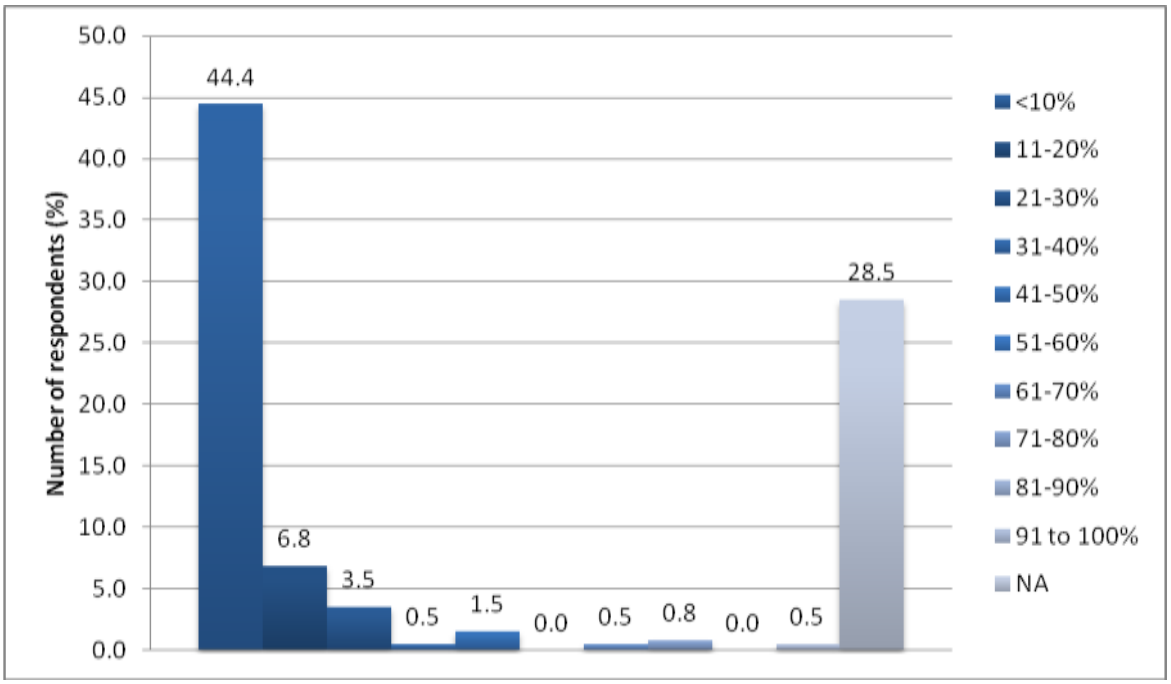


Figure 2.12: Percentage of caseload adolescents represent (Q22)

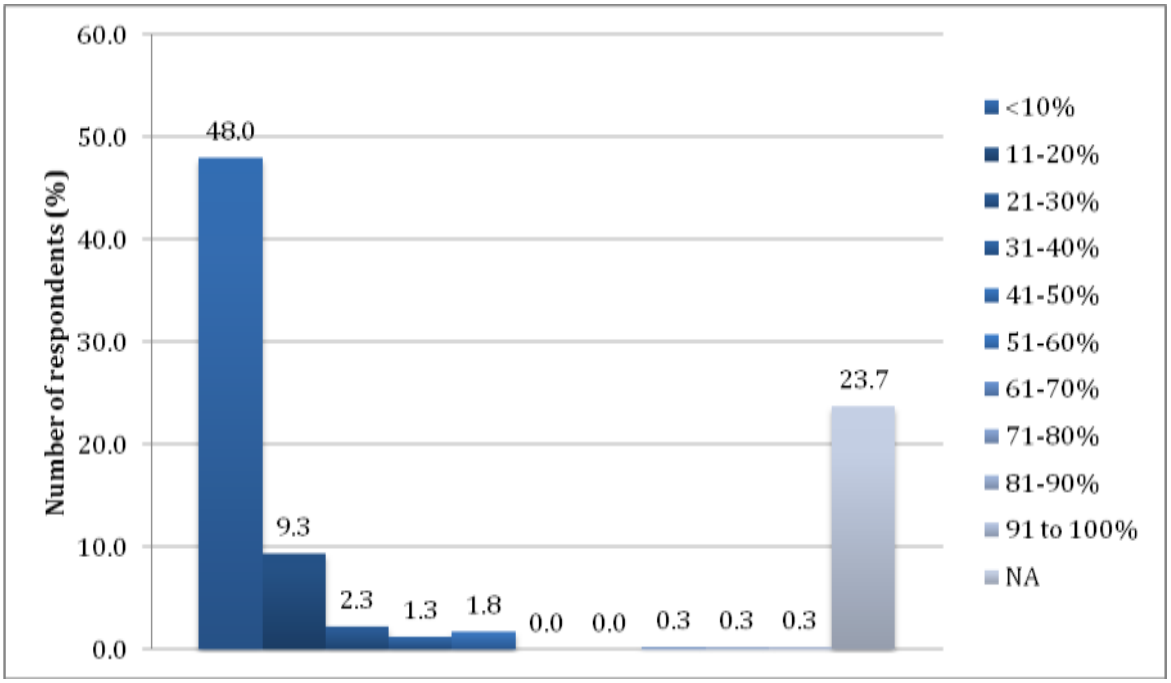
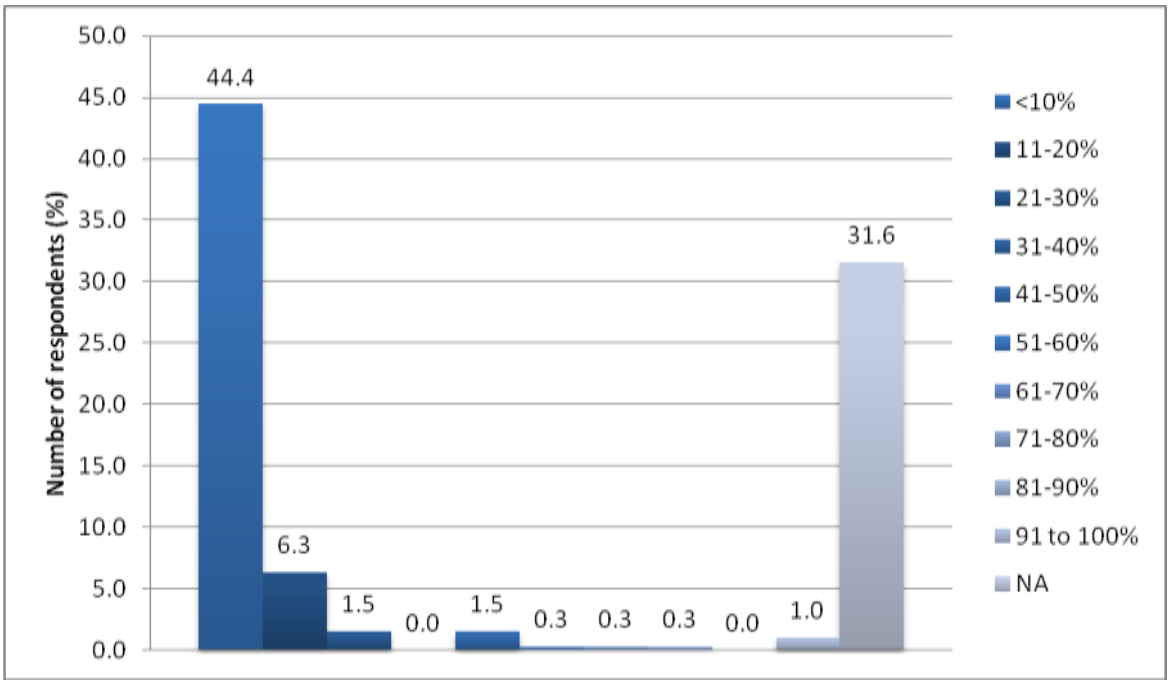


Figure 2.13: Percentage of caseload families represent (Q22)



20% of respondents (n=79) provide their obesity management service within a specialist medical service (Q23). Of this group, 27% provide a specialist obesity clinic (n=21), 39% services for Type 2 Diabetes (n=31), 19% services for Type 1 diabetes (n=15), 20% endocrine clinic (n=16), 14% hyperlipidaemia/coronary heart disease services (n=10), 5% services for sleep apnoea (n=4), and 44% bariatric surgery (n=35) (Q24).

21% of respondents (n=83) reported their service has a protocol, policy or clinical pathway for the dietetic management of overweight and obesity (Q45).

2.3.2 DAA Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults Evaluation

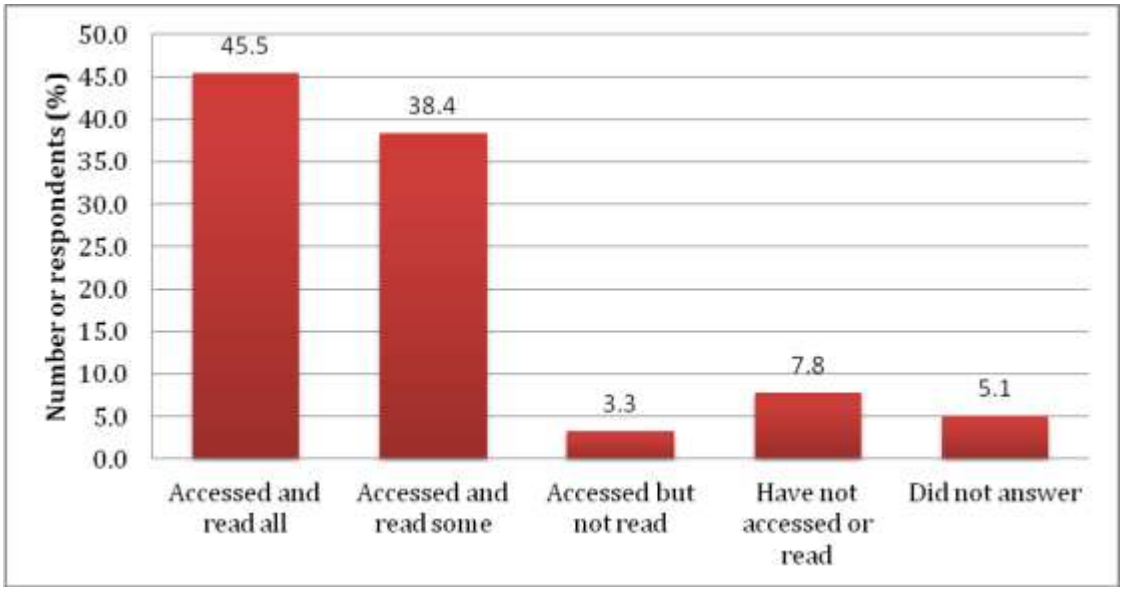
Less than half of respondents reported they have accessed and completely read (46%, n=180) while about a third had partially read (38%, n=152) the 2002 DAA Best Practice Guidelines for the Treatment of Overweight and obesity in adults (Figure 2.14)

Respondents who had read some or all of the guidelines were asked whether they found the DAA Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults and 10 point plan useful in their practice (Q16):

- 65% reported they found both useful (n=216)
- 15% reported they only found the guidelines useful (n=49)
- 5% reported they only found the 10 point plan useful (n=16)
- 13% reported they found neither useful (n=42)

Thirty-seven percent of respondents (n=148) said they have changed their practice as a result of the DAA guideline (Q17). Of the 214 respondents who reported they had not changed their practice as a result of the DAA guidelines, 67% reported this was because their practice was already aligned with the guidelines (n=143, Q18) .

Figure 2.14: Use of 2002 DAA Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults (Q15)



Of the 148 respondents who reported they had changed their practice as result of the DAA guidelines:

- 48% had changed their practice in the area of "assessment" (n=71)
- 74% had changed their practice in the area of "management or treatment strategies" (n=110)
- 54% had changed their practice in the area of "monitoring and follow-up" (n=80)
- 12% had changed their practice in the area of "evaluation" (n=18)
- 16% had changed their practice in the area of "documentation" (n=24, Q19)

Of the 148 respondents who reported they had changed their practice as a result of the DAA guidelines, 55% felt they had made the most improvement in the area of "management or treatment strategies" (n=82), 21% felt their greatest improvement was in the area of monitoring and follow-up (n=31), and 15% in the area of "assessment" (n=22, Q20).

Eight percent (n=32) of respondents reported they had attended a CPD event related to the DAA Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults.

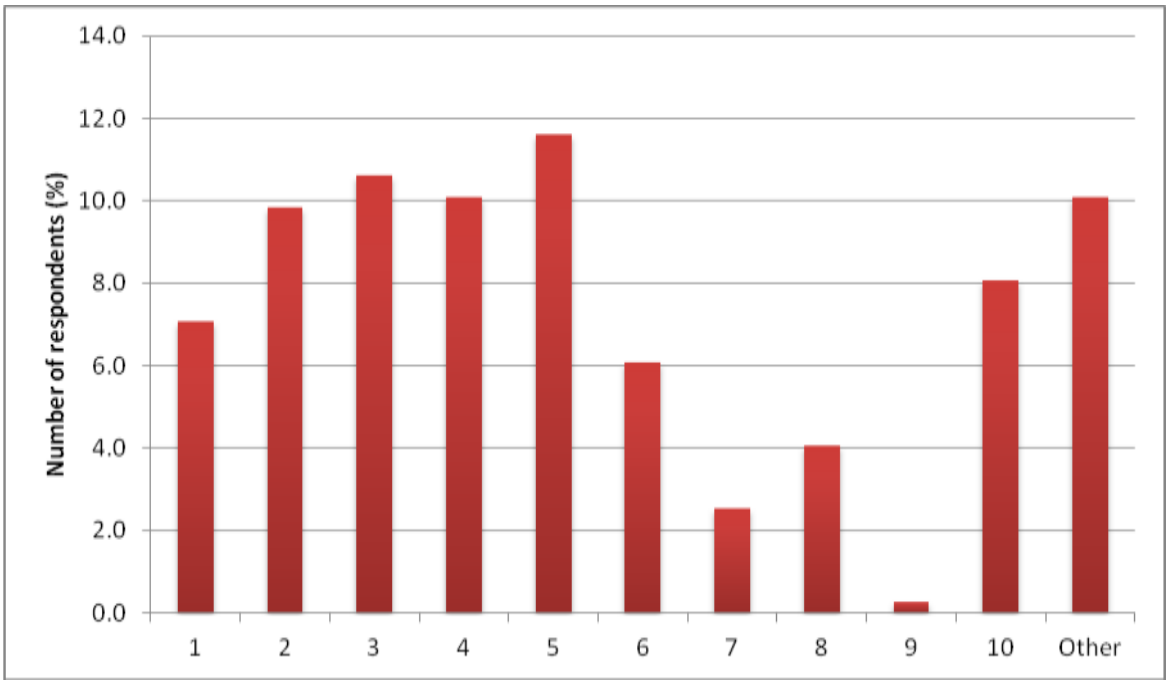
2.3.3 Current dietetic practice

Demand

Respondents were asked to rank the source of their referrals, from 1 to 5, with 1 being the source of most referrals. Eighty-two percent (n=324) of respondents answered the question. General practitioners were the highest referral source (mean ranking 1.81), following by self-referral (2.69), hospitals (3.36), specialist medical clinics (3.38) and community health centres (3.75) (Q25).

The number of referrals received per week by respondents varied considerably (Figure 2.15)

Figure 2.15: Number of referrals per week (Q28)



One third of respondents (n=132) reported their obesity service currently has a waiting list (Q26). Of this group, most reported a waiting list of 2 weeks to 2 months (63%, Q27).

Around 40% of respondents reported referring 1 to 2 clients per week to other services for treatment (Q30). Just over one fifth of respondents answered "other" to this question, with most reporting they do not refer clients on a weekly basis, or never refer clients.

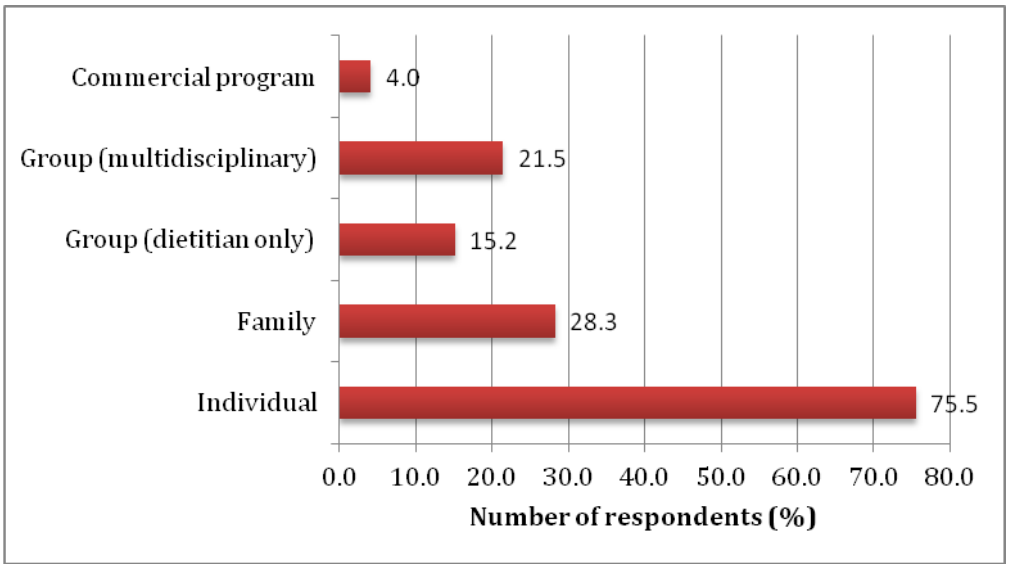
When asked what services they refer clients to who are not placed on a waiting list (Q31):

- 17% do not refer (n=64)
- 18% refer to private practice dietitian (n=70)
- 22% refer to a community group (n=88)
- 3% refer to a commercial program (n=12)
- 14% refer to their GP (n=57)
- 8% suggest self-management (n=35)
- 5% refer to a specialist medical clinic (n=18)
- 34% refer to exercise physiologists or physiotherapists (n=134)
- 33% refer to psychologists or psychiatrists (n=130)

Models of intervention

Most respondents provide individual obesity consultations (76%, n=299) (Figure 2.16), with fewer respondents providing family based (28%, n=112), group multidisciplinary (22%, n=85) or group based consultations with dietitians only (15%, n=60).

Figure 2.16: Type of obesity consultations provided (Q32)

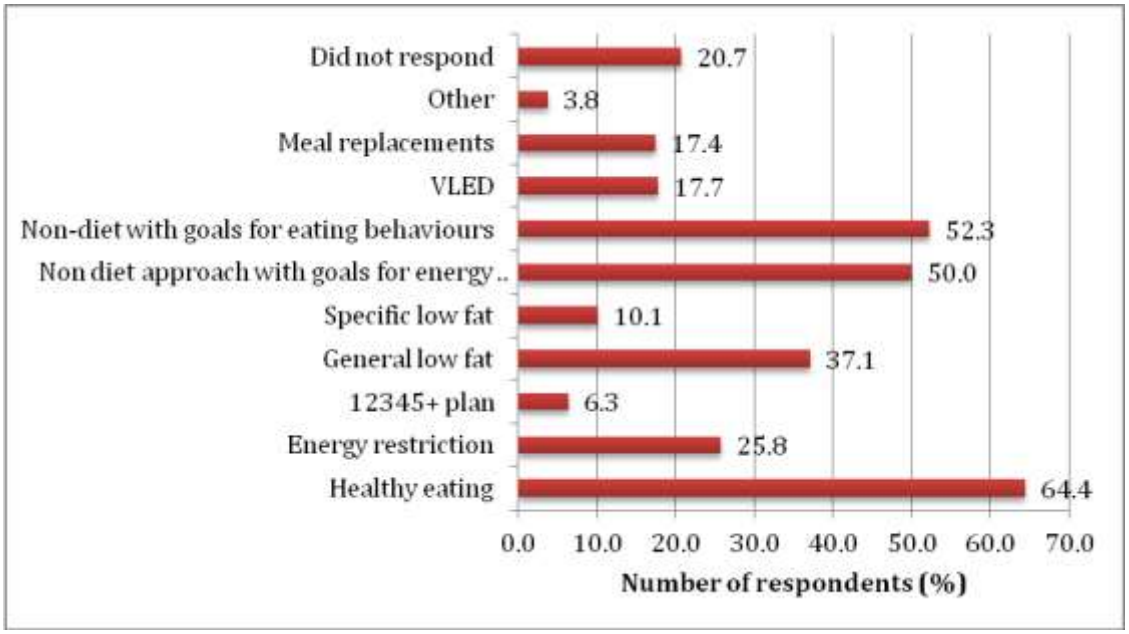


The majority of respondents reported the focus of their service is tertiary treatment (59%, n=234), with less focusing on secondary prevention (11%, n=44) or primary prevention (6%, n=22) (Q33).

The majority (72%, n=284) of respondents reported the philosophical approach of their service was a combination of diet, exercise and behaviour modification. Very few respondents focus on diet (n=6), diet and exercise (n=6) or behaviour modification (n=4) alone (Q34).

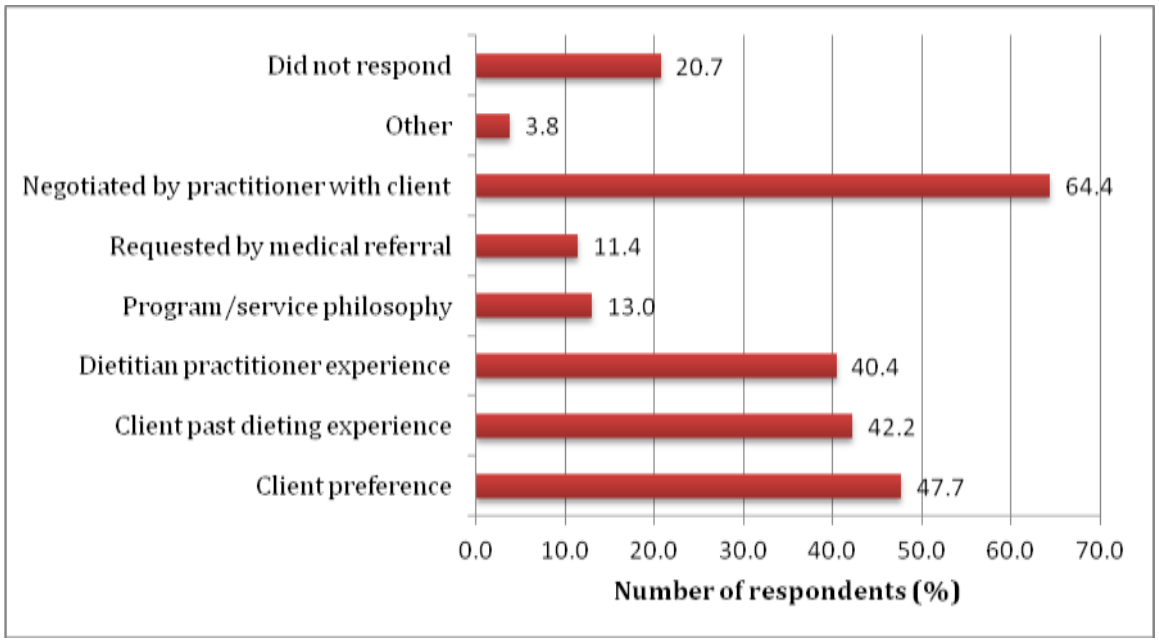
Respondents reported a number of different dietary approaches for weight loss (Figure 2.17). General healthy eating advice (64%, n=255) and non-dieting approaches by either identifying specific ways to reduce energy intake (50%, n=198) or eating behaviour goals (52%, n=207) were the most popular. The 12345+ plan (6%, n=25) and specific low fat eating plans (10%, n=40) were the least used dietary approaches.

Figure 2.17: Dietary approaches used by respondents (Q35)



The majority of respondents (64%, n=225) reported dietary strategies are selected for clients by negotiation (Figure 2.18). Almost half of respondents also reported strategies were selected based on client preference (48%, n=189), clients past dieting experiences (42%, n=167) or their own experience (40%, n=160).

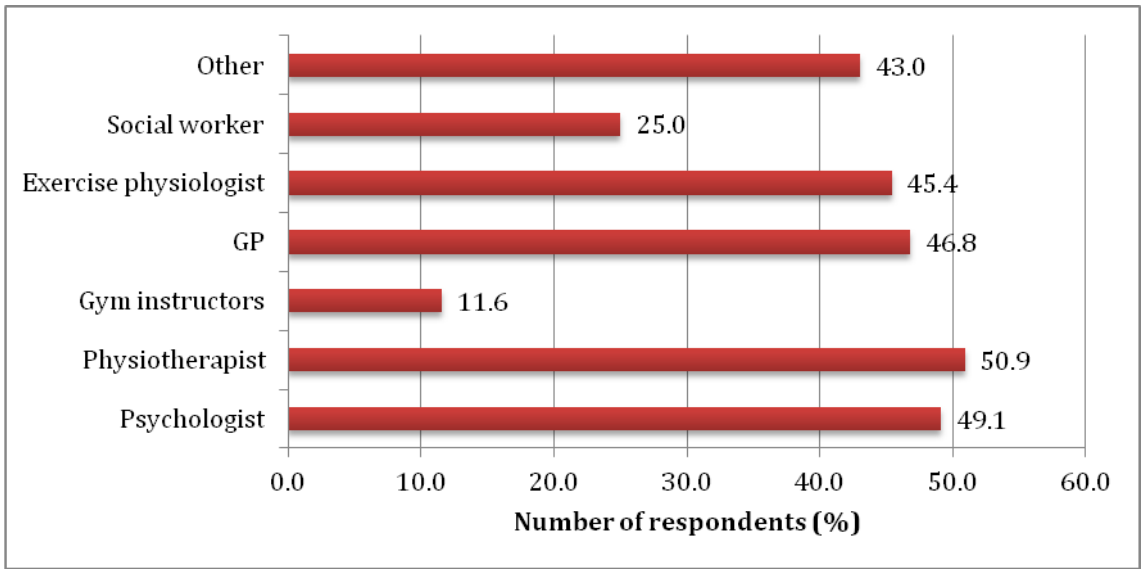
Figure 2.18: How dietary strategies or interventions are selected for clients (Q36)



Fifty-five percent of respondents (n=216) reported their weight management service to the average client usually included other members of a multidisciplinary team (Q39). Of these, psychologists, physiotherapists, general practitioners and exercise physiologists were most commonly reported members. (Figure 2.19) Other members of the multidisciplinary team reported by 43% of respondents, included surgeons, nurses, pediatricians, endocrinologists,

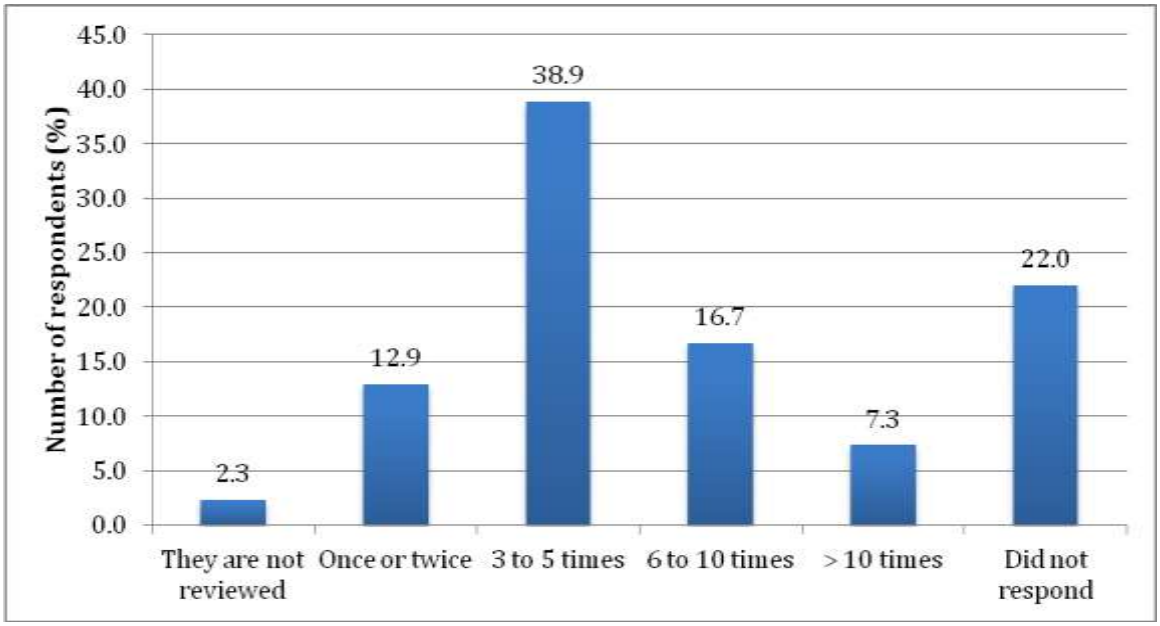
cardiologists, speech pathologists, occupational therapists, diabetes educators, pharmacists, podiatrists, health promotion officers, and allied health assistants.

Figure 2.19: Services within the multidisciplinary team (Q40)



The majority of respondents reported reviewing their clients 6 to 10 (17%, n=66) or 3 to 5 times (39%, n=154) (Figure 2.20) before discharge.

Figure 2.20: Number of times clients reviewed before discharge from service (Q41)



Respondents were asked after an initial consultation, over what period of time would clients be followed up or reviewed (Q42):

- 6% of respondents reported <2 weeks (n=22)
- 44% of respondents reported between 2 weeks and 1 month (n=176)
- 18% of respondents reported between 2 to 3 months (n=71)
- 8% of respondents reported between 4 to 6 months (n=32)
- 4% of respondents reported between 7 to 12 months (n=14)
- 6% of respondents reported >1 year (n=22)

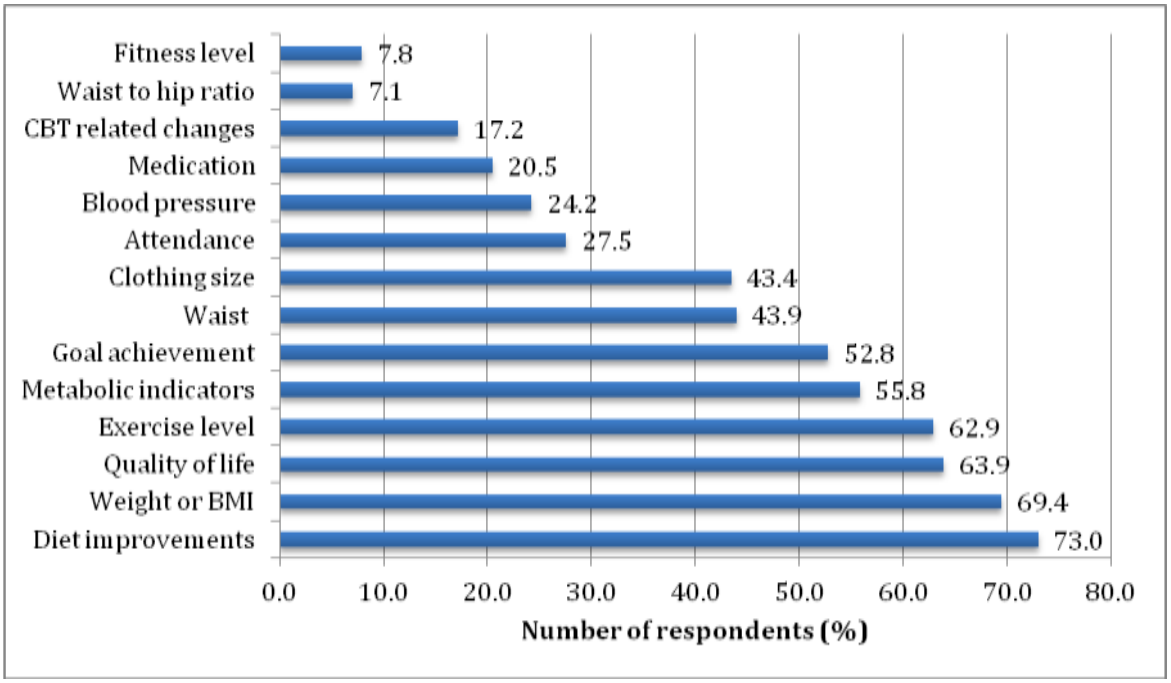
Notably, 23% of the group did not respond to this question.

Respondents reported using a variety of outcome measures to monitor their clients' progress. The most frequently reported outcome measures were improvements in diet, weight/BMI, quality of life and exercise levels (Figure 2.21).

Eleven percent of respondents (n=43) reported their department had a policy/strategy for formally reviewing the outcomes of weight management activities over time

Forty-one percent of respondents (n=162) reported there is a fee for their obesity services (Q44).

Figure 2.21: Outcome measures used to monitor clients progress (Q43)



Management

Respondents were asked to rank the importance of different outcomes in judging the success of treatment (Q57), on a 6 point scale (1 most important, 6 least important). From the 298 respondents who answered this question, the outcomes in order of importance were:

1. Adoption of improved food and exercise habits irrespective of weight loss (Mean 2.33)
2. Improvement in clinical indicators of health and disease (Mean 2.67)
3. Modest weight that is likely to be sustained over time (Mean 2.86)
4. Improved body image and self-confidence irrespective of weight loss (Mean 3.51)
5. Maintenance of body weight over time (Mean 4.06)
6. Modest weight loss to the normal weight range (Mean 5.58).

Table 2.47outlines participants' responses to a range of statements reflecting their experiences managing overweight and obese clients. Most respondents who felt the statements were applicable to their practice, agreed they achieved successful outcomes and were professionally well prepared to work with adults and/or children who are overweight an obese.

Table 2.47: Agreement/disagreement with statements related to treatment experiences (Q58)

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree	NA/Did not respond
I usually achieve successful outcomes with adult clients who are overweight (BMI 25 - 30kg/m2)	2.0%, 8	5.6%, 22	16.9% 67	39.9% ,158	5.8%, 23	29.8%, 118
I usually achieve successful outcomes with children at risk of overweight (BMI percentile >85th to <95th)	1.3%, 5	6.3%, 25	14.6%, 58	14.4%, 57	2.0%, 8	61.4%, 243
I usually achieve successful outcomes with clients who are obese (BMI>30kg/m2)	1.3%, 5	10.9%, 43	20.2%, 80	35.9%, 142	4.8%, 19	27.1%, 107
I usually achieve successful outcomes with overweight children (BMI percentile >95th)	1.0%, 4	6.6%, 26	16.4%, 65	12.9%, 51	2.3%, 9	60.9%, 241
I am professionally well prepared to treat/manage clients who are overweight	0.5%, 2	2.3%, 9	3.5%, 14	45.2%, 179	21.7%, 86	26.8%, 106
I am professionally well prepared to treat/manage children who are children at risk of overweight (BMI percentile >85th to < 95th)	4.0%, 16	13.4%, 53	7.6%, 30	25.8%, 102	4.8%, 19	44.4%, 176
I am professionally well prepared to treat/manage clients who are obese (BMI>30kg/m2)	0.5%, 2	5.3%, 21	6.8%, 27	41.7%, 165	19.2%, 76	26.5%, 105
I am professionally well prepared to treat/manage overweight children (BMI percentile >95th)	3.8%, 15	14.6%, 58	10.1%, 40	23.2%, 93	4.3%, 17	43.7%, 173

Table 2.48 outlines the frequency in which respondents reported performing key components of weight management in their practice. More than half of respondents reported frequently or always implementing several of the key components of weight management (e.g. assess weight history, exercise habits, readiness for change, home environment, weight loss expectations). Practices respondents were more likely to never or rarely conduct included assessing clients preferred style of consultation, anticipation of gaining weight and expectation of the number of consultation required. It was also rare for respondent to review a client's progress for more

than two years.

Table 2.48: Frequency of performing key components of weight management (Q59)

	Never		Rarely		Sometimes		Frequently		Always		Did not respond	
	%	n	%	n	%	n	%	n	%	n	%	n
Assess weight history	0.5	2	0.3	1	2.5	10	17.4	69	53.8	213	25.5	101
Assess weight history of the clients family	4.0	16	11.6	46	23.5	93	19.4	77	15.4	61	26.0	103
Assess the clients exercise habits	0.8	3	0.3	1	1.5	6	13.4	53	58.1	230	26.0	103
Assess the clients readiness for change at first contact	1.3	5	1.8	7	10.4	41	24.0	95	36.6	145	26.0	103
Assess the clients values and beliefs regarding his/her ability to lose weight	1.0	4	3.8	15	16.2	64	29.5	117	24.0	95	25.5	101
Assess the home environment for structures supportive of weight management/loss	2.3	9	3.0	12	14.6	58	29.5	117	25.0	99	25.5	101
Assess the clients expectations of weight loss	0.5	2	1.0	4	11.6	46	23.7	94	37.6	149	25.5	101
Assess the client's preferred style of consultation/method of intervention	3.3	13	9.3	37	14.9	59	26.3	104	19.7	78	26.5	105
Assess the client's definitions of successful outcomes in weight management	1.5	6	5.3	21	20.7	82	26.0	103	20.7	82	25.8	102
Assess the client's anticipation of regaining weight lost	3.3	13	15.4	61	24.7	98	20.2	80	9.6	38	26.8	106
Review your client's progress for more than two years	15.9	63	23.7	94	23.5	93	8.3	33	1.8	7	26.8	106
Assess the client's expectations of the number of consultations he or she will have with you	9.1	36	18.4	73	23.0	91	15.2	60	8.1	32	26.3	104
See clients on a one to one basis	1.0	4	1.3	5	4.0	16	23.5	93	44.2	175	26.0	103
See clients in a group format	27.3	108	13.4	53	21.0	83	9.1	36	2.5	10	26.8	106
See clients in a combined one to one counselling/group format	34.3	136	18.2	72	13.1	52	6.8	27	1.3	5	26.3	104
How often would your clients be accompanied by a significant other	2.3	9	8.1	32	37.9	150	24.7	98	1.3	5	25.8	102
Refer your clients to another member of the health care team	2.5	10	9.6	38	36.9	146	23.5	93	1.8	7	25.8	102
When a client does not lose weight using one weight management strategy how often another weight management strategy is offered	1.0	4	5.1	20	21.5	85	30.8	122	16.2	64	25.5	101
Review your client's progress for more than 6 months	3.0	12	8.6	34	23.2	92	33.8	134	5.8	23	25.5	101

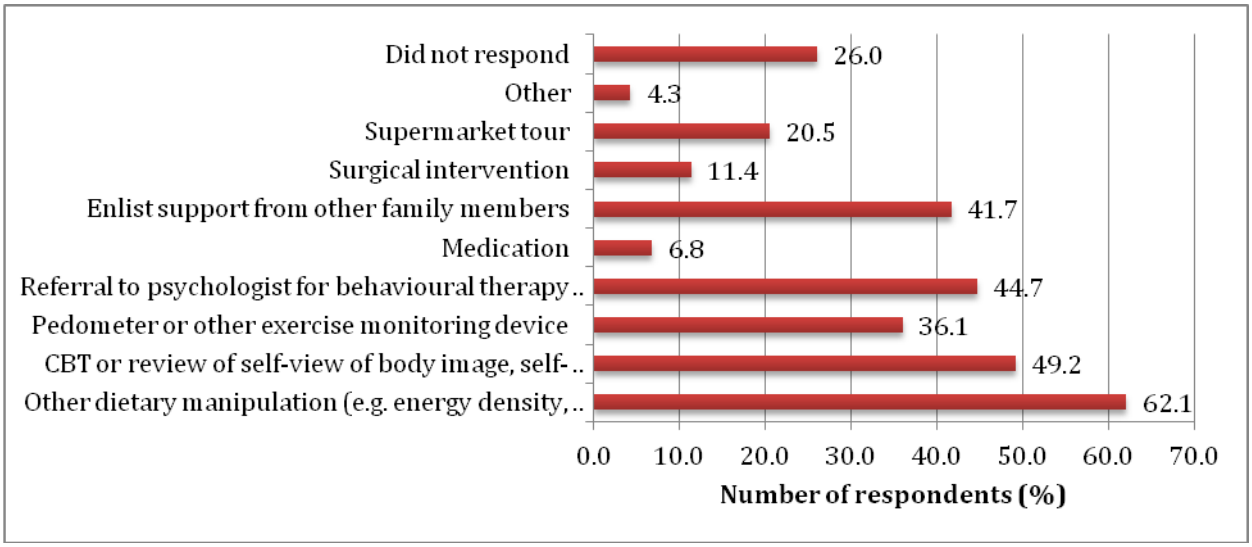
Respondents were also asked to indicate how frequently they undertake a number of other practices relevant to weight management (Table 2.49). Over 50% of respondents were likely to report frequently or always performing the practices, except for keeping a hunger awareness or food diary, planning for follow-up in the long-term and joining a commercial or community based 'slimming group".

Table 2.49: Frequency of performing other components of weight management (Q60)

	Never		Rarely		Sometimes		Frequently		Always		Did not respond	
	%	n	%	N	%	n	%	n	%	N	%	n
Specific advice to eat fewer kilojoules	1.5	6	5.8	23	13.9	55	33.3	132	19.7	78	25.8	102
Specific advice to reduce total fat intake	1.0	4	3.0	12	17.4	69	37.6	149	15.2	60	25.8	102
General advice to do more exercise	0.3	1	0.8	3	8.3	33	35.6	141	29.5	117	25.5	101
Specific advice regarding opportunities for increasing incidental daily activity	0.3	1	1.0	4	10.1	40	41.9	166	21.0	83	25.8	102
Specific advice re incorporating low intensity, long duration exercise such as walking into present lifestyle	0.5	2	4.0	16	18.2	72	36.1	143	15.4	61	25.8	102
Specific advice regarding ways of incorporating other forms of exercise into daily living	1.0	4	3.8	15	22.2	88	36.4	144	11.1	44	25.5	101
Practical advice regarding shopping and cooking to achieve dietary goals	0.5	2	1.8	7	12.1	48	37.6	149	22.0	87	26.0	103
Behaviour modification techniques	1.0	4	3.3	13	17.4	69	35.6	141	16.9	67	25.8	102
Keeping a hunger awareness diary	4.0	16	16.9	67	24.5	97	23.5	93	5.3	21	25.8	102
Keeping a food diary	1.0	4	5.8	23	28.0	111	30.3	120	9.1	36	25.8	102
Keeping a weight diary	20.5	81	25.5	101	17.4	69	7.6	30	3.0	12	26.0	103
Planning for follow-up in the short term	0.8	3	2.8	11	8.1	32	32.6	129	29.3	116	26.5	105
Planning for follow-up in the long-term	2.3	9	11.1	44	25.3	100	23.7	94	12.1	48	25.5	101
Joining of a commercial or community based "slimming group"	30.8	122	26.5	105	14.9	59	1.8	7	0.5	2	25.5	101

Other strategies commonly used by respondents (Figure 2.22: Other additional strategies used in weight management (Q61)) included other dietary manipulation such as meal spacing, low GI and VLCDs (62%, n=246), and CBT or review of self-view of body image, self- talk, personal goals and eating enjoyment (49%, n=195).

Figure 2.22: Other additional strategies used in weight management (Q61)



The median (IQR) best practice score was 42 (37-47). Dietitians with greater than 25 years of experience had significantly ($p<0.05$) greater best practice scores than those with 5 to 10 years of experience and those with less than 5 years of experience (median 47 versus 41 and 41 respectively). Those whose major nutrition and/or dietetic practice was in community nutrition had significantly greater ($p<0.05$) best practice scores than those whose major area of practice was in inpatient /outpatient hospitals (median 43 versus 40). Being a member of an obesity interest group or having clinical guidelines for obesity management had no significant effect on best practice score. Similarly, differences in the focus of dietitian's services and in the work time spent on overweight or obesity had no significant effect on best practice score.

Evaluation of practice

Twenty-three percent of respondents reported they have or are currently evaluating the effectiveness of different dietary interventions in their service (n=90, Q37)

Seven percent of respondents reported they had undertaken a recent audit of their obesity services for the purpose of quality assurance (Q46). Of the 28 respondents who reported undertaking audits:

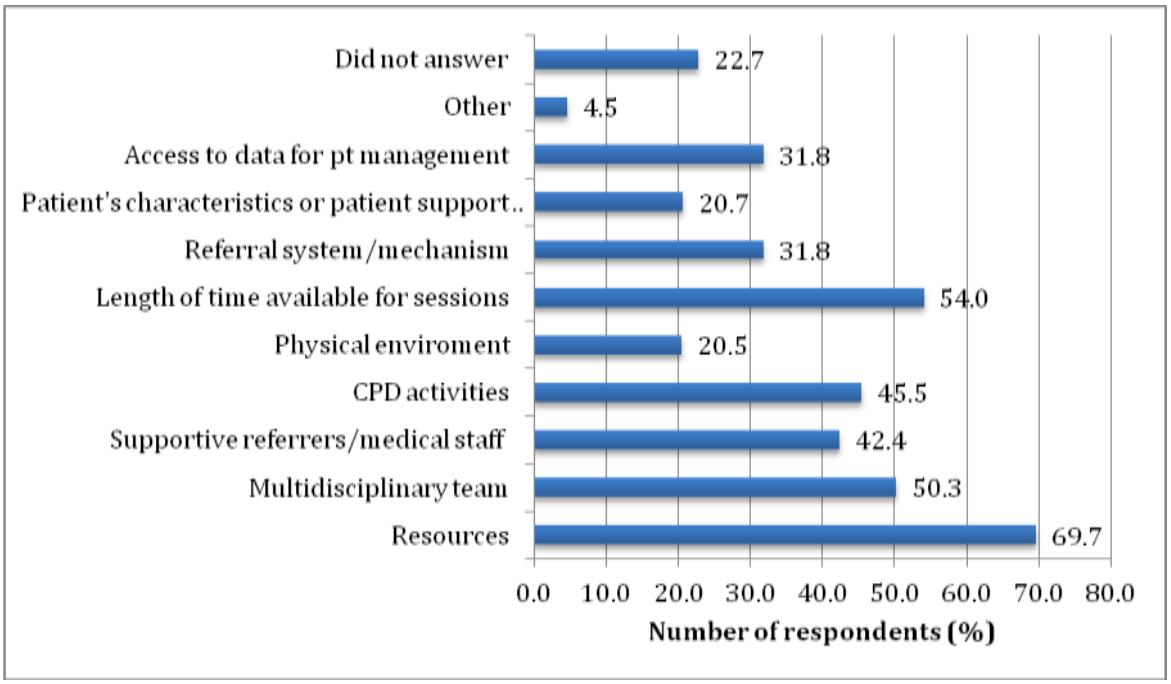
- 55% reported the audit evaluated the structure of the service (n=15)
- 79% reported the audit evaluated the services process (n=22)
- 89% reported the audit evaluated the services outcomes (n=25, Q47).

The results of the audit had been disseminated via reports (39%, n=11), workshop presentations (14%, n=4) or conference presentations (18%, n=5). Almost half had not published the results in any form (n=13), and 25% were in the process of publishing the results (n=7).

Enablers and barriers to evidence based practice

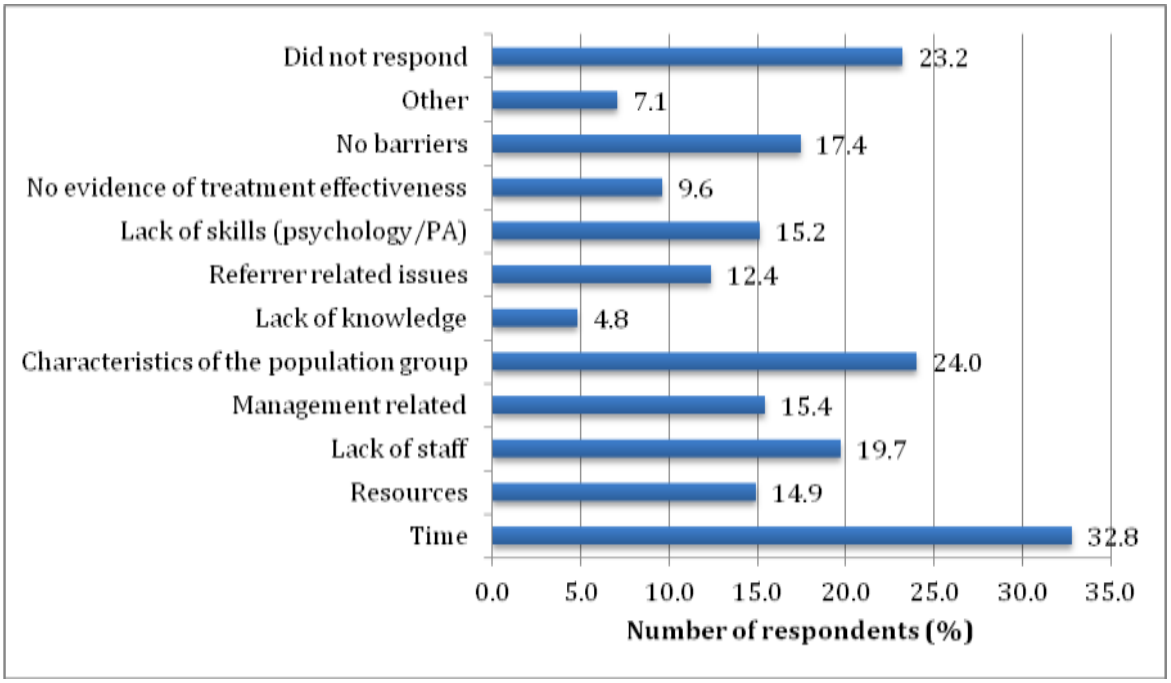
Respondents were asked what features are in their work environment to support their ability to provide effective dietetic treatment in obesity (Figure 2.23). Most reported having resources, such as scales and food models, available to them.

Figure 2.23: Features of work environment to support effective treatment (Q49)



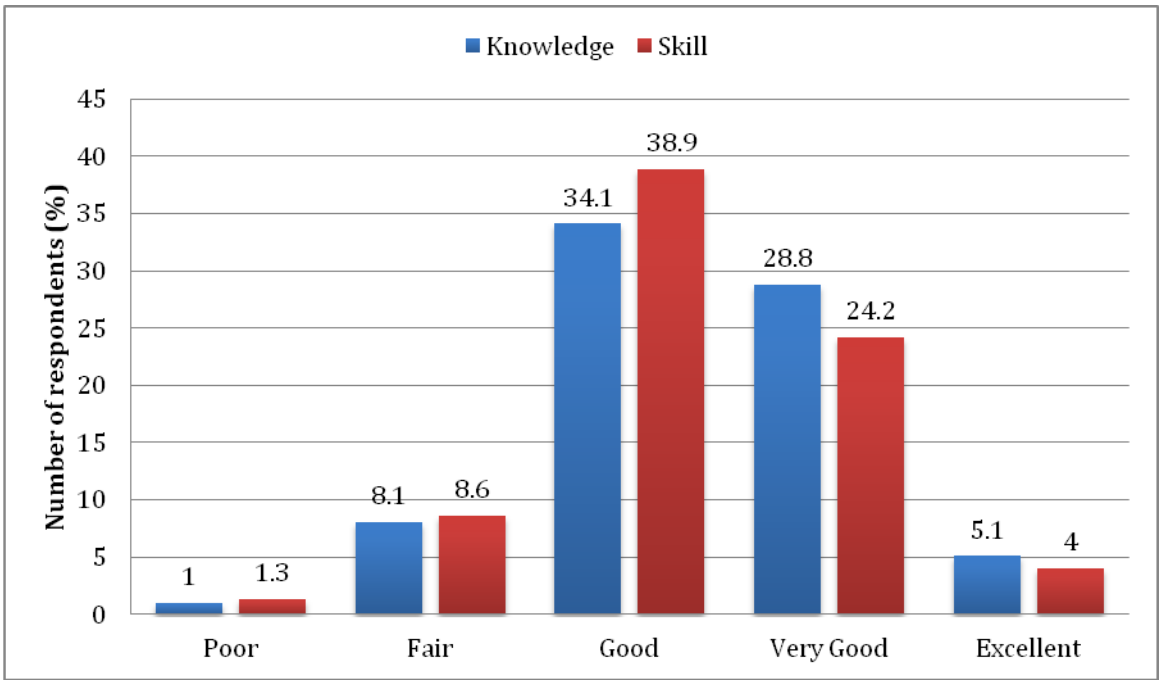
Respondents were asked about the barriers preventing them from becoming involved in obesity management (Figure 2.24). The main barrier reported was time (33%, n=130), followed by the characteristics of the population group (24%, n=95). Lack of knowledge was rarely reported as a barrier (5%, n=19).

Figure 2.24: Barriers in work environment that prevent becoming involved in obesity management (Q50)



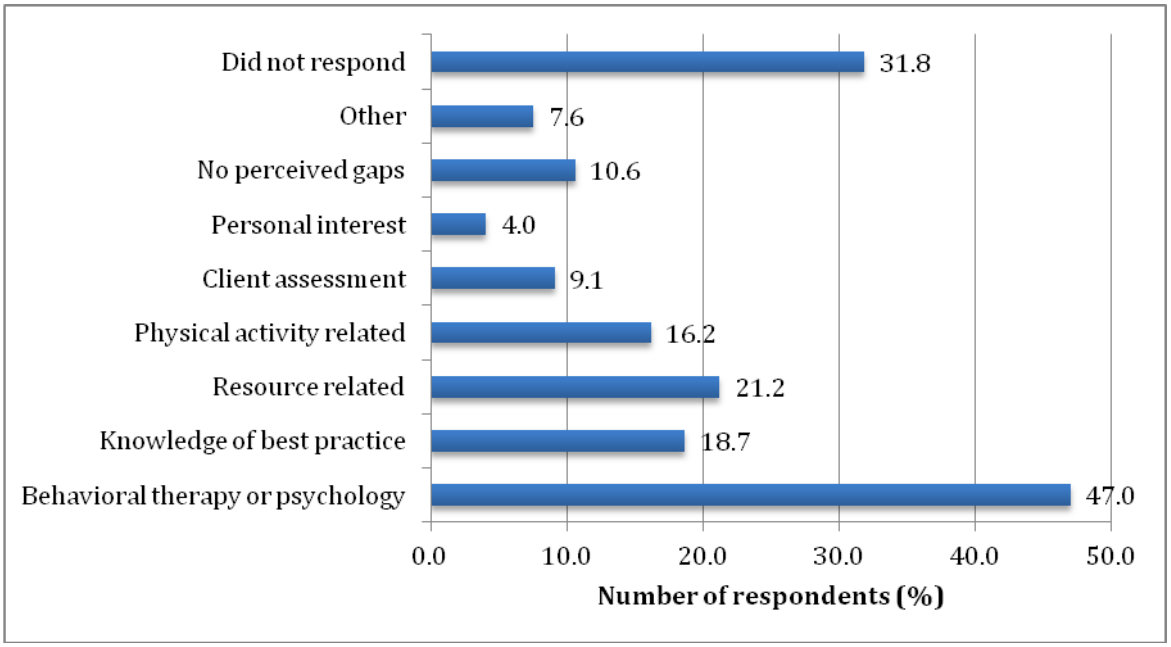
Most respondents rated their knowledge of and skill in best practice as good or very good (Figure 2.25). A lower proportion of participants rated their skill as excellent or good, compared to their knowledge.

Figure 2.25: Respondent's perceived knowledge and skills in providing best practice dietetic treatment (Q51)



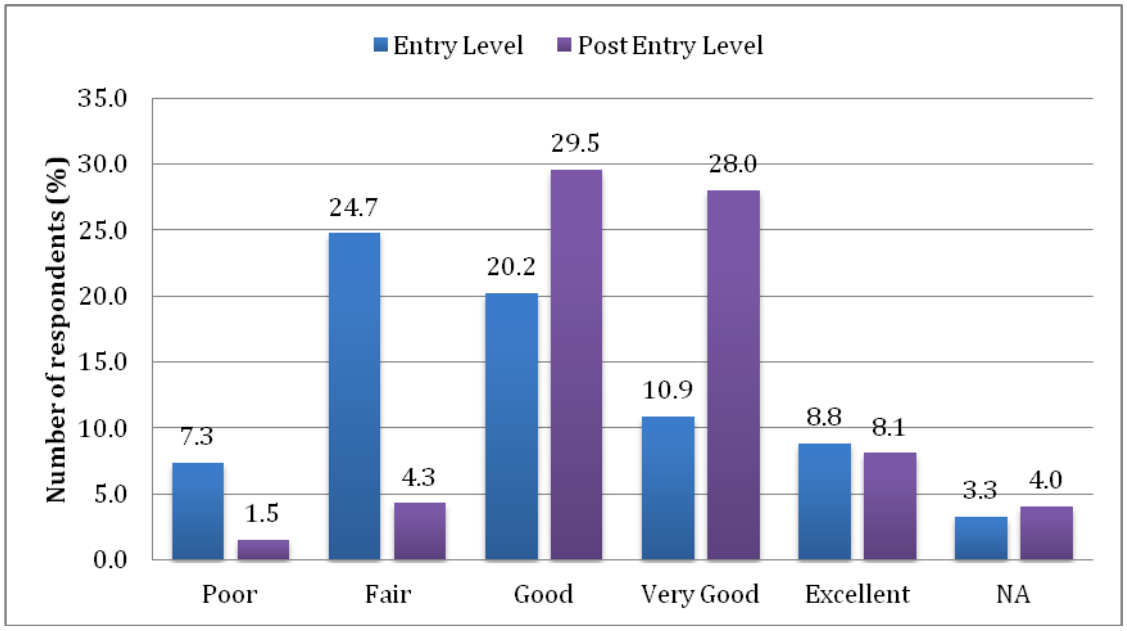
The most commonly reported gap in skills that limit respondents ability to provide effective dietetic treatment in obesity was "behavior therapy/modification or psychological assessment or behavior change or motivation or stages of change" (47%, n=186) (Figure 2.26).

Figure 2.26: Gaps in skills that limit ability to provide effective dietetic treatment in obesity (Q52)



Respondents reported higher levels of skill (good, very good and excellent) in managing overweight and obese clients at post entry level training, compared to entry level. The majority of respondents felt their skills were fair or good at entry level (Figure 2.27).

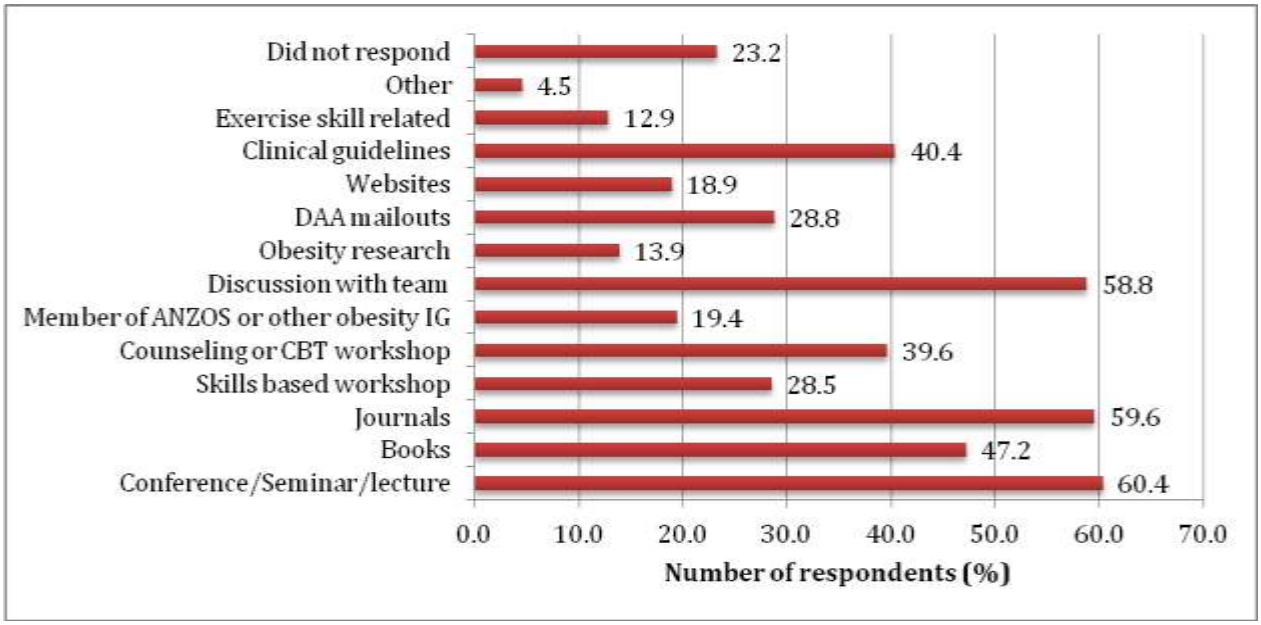
Figure 2.27: Rating of skills in managing overweight and obese clients by level of training (Q53)



Continuing professional development

Respondents reported a large variety of activities had been undertaken to enhance their skills in obesity management. The most commonly reported activities were conference/seminar attendance (60%, n=239), journal literature reviews (60%, n=236) and discussion with other dietitians or within their multidisciplinary team (59%, n=233) (Figure 2.28).

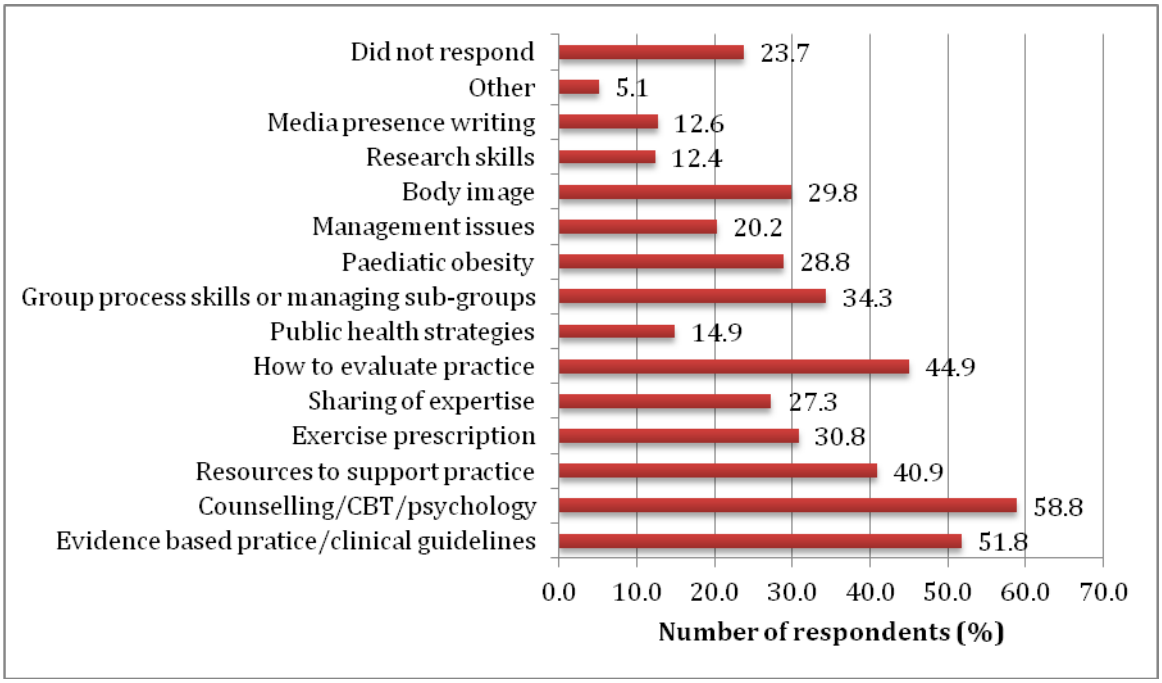
Figure 2.28: Activities undertaken to enhance skills in obesity management (Q54)



Respondents would like DAA to provide continuing education programs related to a variety of topics. The most popular response was for continuing education programs related to counseling skills for behavior change or motivation or barriers to change or CBT or stage of change/psychology (59%, n=233) (Figure 2.29). Respondents were less interested in continuing education programs related to media writing or research skills.

The preferred method of delivery of this CPD activity was a recommended reading list (mean 6.54), followed by a literature review report (mean 5.64). A workshop was the least preferred method (mean 2.98).

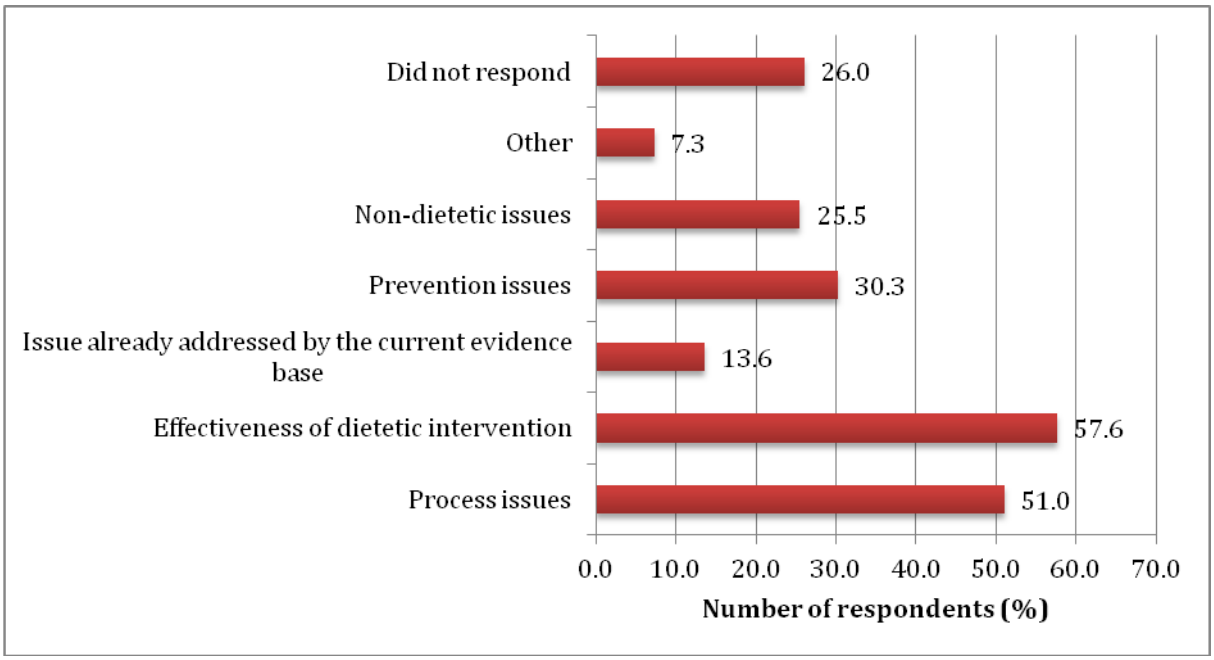
Figure 2.29: Preferred continuing education programs to help improve obesity treatment (Q55)



Research

Respondents were asked what research questions they felt need to be answered in terms of the role of the dietitian in obesity management (Figure 2.30). Just over half of respondents (58%, 228) would like research on the effectiveness of dietetic interventions to be undertaken. While 51% of respondents (n=202) would like research on process issues, such as frequency of client visits, to be undertaken.

Figure 2.30: Research questions to be answered in terms of the role of dietitians in obesity management (Q63)



2.4 Discussion

The current survey of dietetic practice in relation to weight management was conducted six years after the release of the 2005 DAA Dietetic Best Practice Weight Management Guidelines for Overweight and Obesity in Adults (1) and nine years since the previous dietetic practice survey (161).

Since 2005, less than half of the current survey respondents have read these DAA guidelines in full, while a further third reported they had read them in part. This is disappointing given working in the area of overweight and obesity is the domain of many APDs, with >65% of respondents spending more than 25% of their time working in the area of overweight and obesity and >45% reporting that they spend >50% of their time working in this area.

In addition, given the international emphasis on evidence based practice and the considerable time and resource implications for developing clinical guidelines for practitioners, ways in which they can be made more accessible and digestible is clearly warranted and would be an strategic investment of resources by DAA.For those who indicated they had accessed the guidelines, three quarters reported changing their practice in the area of "management or treatment strategies" and half in each of the areas of "assessment", "monitoring and follow-up". This highlights that even within existing resources, guidelines do help to target improvement in keys aspects of practice.

Less than one in ten respondents had attended a CPD event related to implementation of the previous Best Practice Guidelines. This was not unexpected considering there had not been an implementation strategy for these guidelines and only three seminars provided on them. However, respondents would like DAA to provide continuing education programs, with the majority of requests for programs related to counseling skills for behavior change or motivation

or barriers to change or CBT or stage of change/psychology. Respondents would prefer the CPD activities to be provided via a recommended reading list or a literature review report.

Lack of knowledge was rarely reported as a barrier to implementing best practice but time was cited by a third as a barrier and specific characteristics of the population group by a quarter of respondents. At the same time enablers were seen as having the right resources, including time.

Most respondents rated their knowledge and skills in regard to best practice as good or very good. Yet, despite having access to the DAA guidelines, the measured best practice score had not changed since the 2002 survey. Despite no change, there have been some changes in the dietary approaches used by APDs since 2002 that are in line with the guidelines. For example APDs report using both meal replacements and VLEDs more commonly and specific strategies to reduce total energy intake and less commonly give non-specific advise, although general healthy eating advice is a common dietary strategy. There were some aspects of best practise treatment that are currently not frequently used with clients, e.g. encouraging use of self-monitoring of adherence to the intervention, through self-monitoring weight or dietary intake. It is important that APDs are aware of the evidence for specific dietary strategies; given this is a key domain of practice.

This suggests further work is required by DAA to ensure members are informed of the content of the guidelines and that they are accessible. In particular, more recent graduates and those with less weight management experience may need opportunities specifically targeting their career stage and /or mentoring by more experienced members. This is important if APDs are to be valued as arbiters of knowledge related to the best available evidence for treatment of overweight and obesity.

2.5 Recommendations

DAA needs to develop a strategy to increase the number of members who are aware of the content and key evidence based statements within the guidelines. An executive summary and revised implementation guide will facilitate this and should align with the revised NHMRC guidelines. Furthermore, DAA needs to have a specific implementation plan that makes it easy to access the guidelines, incorporating a user friendly format that can be beadapted to varying Dietetic workplaces.

Members should be encouraged to use the guidelines to create local CPD opportunities within current workplaces and teams and to seek mentoring from more experienced colleagues in contextualising the guidelines.

DAA should provide CPD opportunities related to acknowledged skill gaps, e.g. behavior modification.

Given that resources and time are reported as the biggest barriers to implementing best practice, development of National level resources for APDs and for use with their clients, and technological approaches to making client treatment and follow-up resources efficient should be a high priority. These strategies will not only facilitate uptake of guidelines, but enhance the impact APDs make in treatment and ensure DAA is recognised as the leader in provision of effective obesity management in Australia.

3. Part Three: Scoping of existing guidelines regarding the management of overweight and obesity in children

3.1 Objective

To locate and assess existing best practice guidelines and systematic reviews regarding the management of overweight and obesity in children.

3.2 Methods

Recent evidence based guidelines and clinical practice guidelines and systematic reviews related to the management of overweight and obesity in children were located using a three step search strategy. Firstly, the Dietitians of Canada Practice-based evidence in Nutrition (PEN) tool was searched for reference to guidelines or systematic reviews relevant to the topic (obesity) and population group (children). Secondly, the websites of western dietetic associations were searched for mention of existing best practice guidelines in the area. Finally, a Pubmed search was undertaken. The keywords child, obesity, management were used, and the search was limited to the English language, systematic reviews, and publication from 2007 to 2011.

Current guidelines and systematic reviews identified were summarised in terms of their methodology/process, and the contents/components the guidelines or review covered.

3.3 Results

Four best practice guidelines and six systematic reviews were located. Details of their process and components are outlined in Table 3.1. To summarise, there are a number of existing guidelines and reviews that could potentially be used as a basis of DAA Best Practice Guidelines for the management of overweight and obesity in children.

Table 3.1 Summary of existing best practice guidelines related to the management of overweight and obesity in children

Name	Year	Process	Components	Reference/Link
			Practice guidelines	
Scottish Intercollegiate Guidelines Network Management of Obesity (includes adults and children)	2010	Systematic review of the literature with graded evidence statements	1. Diagnosis and screening 2. Prevention of overweight and obesity 3. Treatment of obesity (lifestyle interventions, planning treatment, pharmacological treatment , surgical treatment)	Scottish Intercollegiate Guidelines Network. Management of obesity. A national clinical guideline. 2010 SIGN, Edinburgh, Scotland. Available at: http://www.sign.ac.uk/pdf/sign115.pdf
Healthy weights/obesity: Pediatric- Knowledge pathway **(Dietitians of Canada)**	2010	Graded evidence statements	1. Intervention 2. Assessment 3. Counselling 4. Role of parent 5. Goals 6. Physical Activity 7. Dietary interventions 8. Follow-up care 9. Indicators of success 10. Risk for eating disorders	http://www.pennutrition.com/KnowledgePathway.aspx?kpid=8325
Canadian clinical practice guidelines on the management and prevention of obesity in adults and children	2006	Systematic review of the literature with graded evidence statements	1. Classification 2. Clinical evaluation 3. Dietary intervention 4. Physical activity and exercise therapy 5. Combined diet and exercise 6. Pharmacotherapy and bariatric surgery 7. Individual approaches to the prevention of paediatric obesity using physical activity 8. Prevention of childhood obesity through nutrition: review of effectiveness	Lau D et al. 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children. Canadian Medical Association Journal. 2007:176(8):S1-S13 Full guidelines: http://www.cmaj.ca/content/suppl/2007/09/04/176.8.S1.DC1/obesity-lau-onlineNEW.pdf

Name	Year	Process	Components	Reference/Link
Paediatric Weight Management Evidence-Based Nutrition Practice Guideline (American Dietetic Association)	2004	Systematic review of the literature with graded evidence statements	1. Assessment 2. Intervention (Nutrition prescription, nutrition education, counseling, coordination of care, physical activity, adjunct therapies) 3. Monitoring and evaluation	Available at: http://www.adaevidencelibrary.com/topic.cfm?cat=2721
			Systematic reviews	
Effectiveness of Weight Management Interventions in Children: A Targeted Systematic Review for the USPSTF	2010	Systematic review to examine the benefits and harms of behavioural and pharmacologic weight-management interventions for overweight and obese children and adolescents.	Meta-analyses Short term change in BMI after behavioural intervention, and maintenance of weight change.	Whitlock EP et al Paediatrics. 2010;125(2):e396-418.
Interventions for treating obesity in children- Cochrane review	2009	Systematic review of RCT of obesity treatment interventions for overweight and obese children (includes lifestyle and drug treatment) N=64 studies Lifestyle n=54 (6 diet specific)	8 meta-analyses in total: ▪ Lifestyle interventions children <12 years compared to standard care. Change in body mass index standard deviation score at 6-month follow-up (and repeated at 12-month follow-up) ▪ Lifestyle interventions children 12 years and older compared to standard care. Change in body mass index standard deviation score and BMI at 6-month follow-up (and repeated at 12-month follow-up) ▪ Drug interventions with Orlistat children 12 years or older compare to placebo. ▪ Drug interventions with sibutramine children 12 years or older compared to placebo.	Oude Luttikhuis et al Cochrane Database Syst Rev. Jan 21;(1):

Name	Year	Process	Components	Reference/Link
Effectiveness of Weight Management Programs in Children and Adolescents Prepared for: Agency for Healthcare Research and Quality U.S. Department of Health and Human Services 540 Gaither Road Rockville, MD 20850 www.ahrq.go	2008	Systematic review of systematic reviews and RCTs to examine available behavioral, pharmacological, and surgical weight management interventions for overweight (and/or obese children and adolescents in clinical and nonclinical community settings.	▪ Short-Term (6-12 month) Weight Outcomes With Behavioural Interventions ▪ Maintenance of Weight Changes After Behavioural Interventions ▪ Adverse Effects of Behavioural Interventions ▪ Other Beneficial Outcomes of Behavioural Interventions ▪ Important Components of Behavioural Interventions ▪ Factors Influencing the Effectiveness of Behavioural Interventions	Available at: http://www.ahrq.gov/downloads/pub/evidence/pdf/childweight/chweight.pdf
Treatment of paediatric obesity: A systematic review and meta-analysis of randomized trials	2008	Systematic review of RCT with non-surgical treatment for overweight and obese children.	4 meta-analyses (pharmacological (n=9), dietary (n=6), physical activity (n=17) and combined lifestyle interventions (n=23)	McGovern et al. J Clin Endocrinol Metab 2008. 93: 4600-4605
Expert committee recommendations regarding the prevention, assessment and treatment of child and adolescent overweight and obesity: Summary report	2007	Review of literature by expert committee and evidence ratings (consistent, mixed suggestive)	1. Assessment 2. Treatment (goals, outcomes, staged treatment,	Barlow S. Pediatrics 2007: 120 S164

Name	Year	Process	Components	Reference/Link
Measuring effectiveness of dietetic interventions in child obesity: a systematic review of randomized trials	2006 / 2007	Systematic review of RCT of obesity treatment interventions for overweight and obese children with a dietary component (and second publication including non-RCTs)	2 Meta-analysis of dietary intervention compared to no-treatment. Narrative summary of other studies. Summary of the dietary intervention components.	Collins et al A*rch Pediatr Adolesc Med.* 2006;160:906-922. Collins et al. *Int J Evid Based Healthc*. 2007 Mar; 5(1):2-53.