The effectiveness of diet, physical activity and behavioural interventions for weight loss among adults in primary care settings

A review of the literature



A literature review prepared for Dr Melissa Kerdemelidis, Planning & Funding, CDHB,

by the Information Team, Community & Public Health
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Executive summary

Introduction

The purpose of this report is to provide planners and decision makers with a synthesis of best evidence relating to non-environmental, non-surgical, non-pharmacological individual-level interventions for weight loss and weight loss management in overweight and obese adult populations, delivered (or at least suitable for delivery) in primary care settings or commercial settings. Consideration has been given to any factors that might be especially relevant to the New Zealand context, including any health system factors that may act to influence intervention effectiveness and/or equity of outcome.

Background

One of the major drivers of the increase in many chronic diseases (e.g. heart and lung disease, type 2 diabetes, lifestyle-related cancers) is the rising prevalence of obesity (Dobbs et al., 2014). Obesity is a complex, multi-causal problem and most people in Western societies are exposed to increasingly obesogenic environments (Egger & Swinburn, 1997). In New Zealand, almost one-third of adults are obese; a further third are overweight, and the prevalence has increased significantly over the last several years.

Over the last two decades, several large national and international organisations have published guidelines for managing patients who are overweight or obese. To generalise, most national guidelines (including New Zealand) recommend lifestyle interventions (e.g. behavioural therapies, and dietary and physical activity programming and support) as the first-line of treatment for most patients with overweight or obesity.

Methods

A literature search was undertaken to identify published secondary research (systematic reviews, economic analyses and meta-analyses) investigating diet, physical activity and behavioural interventions for weight loss and weight loss management among overweight and obese adults in the primary care setting. In addition, literature was sought specifically related to interventions conducted in New Zealand, and studies investigating the referral of primary care patients to commercial weight management programmes.

In interpreting the key findings of this review, several limitations imposed by the nature of the evidence warrant discussion. There was considerable variability in the level of information provided to describe intervention contexts, content, intensity, scheduling and delivery (often insufficient to permit replication or direct comparison of similar trials). Many studies were of mixed-weight populations (and typically subgroup analyses by BMI class were not possible due to small numbers). Many studies were of short duration and this limits the ability to demonstrate effectiveness over time, as behavioural regression cannot be captured by short-term studies. These limitations, and others, made it difficult to evaluate study findings exactly and to infer how studies might reflect the New Zealand context/setting: at the level of the participant-provider interaction. The local environment in which an intervention is delivered is likely to influence effectiveness.

Conclusions

Key findings

Effectiveness of inter-personal interventions

- Most structured weight loss programmes can reliably induce modest clinically significant weight loss
 (i.e. ≥5% of baseline body weight) in overweight and obese participants, over short time periods, but
 interventions are typically characterised by high attrition rates and relapse.
- No one intervention approach is strikingly more effective than any other in achieving short- to mediumterm weight loss.
- There is no universally agreed standard definition of 'success'. The basic parameters that might define
 'clinically significant weight loss' (i.e. the proportion of total body weight lost and the time period over
 which this must be sustained and/or measured) have not been universally agreed or applied to the
 main body of literature in this field.

Translational research

- Few studies have been conducted in the real-world settings without the support of external expertise and research funding.
- Translational trials typically induce only 30-50% of the weight loss found in clinical efficacy trials.

Weight loss maintenance

- The majority of individuals appear unable to maintain weight loss over the long term and therefore do
 not achieve the assumed benefits of improved morbidity and mortality.
- Many programmes are characterised by high attrition rates but little is known about participants who drop-out.
- While long-term weight loss (years not months) is sparsely reported, the available evidence suggests that weight loss generally persists with continued treatment, and higher treatment intensity does tend to be associated with greater weight loss and weight loss maintenance.
- A small proportion of weight loss programme participants do achieve life-long weight loss maintenance (possibly less than 10% of enrolees). However the predictive factors of 'success' are poorly understood.

Harm

- Overall, little is known about the longer term (life course) effects of unsuccessful and repeated weight loss and subsequent weight regain (weight cycling).
- Reported harms include loss of fat-free mass, increased risk of developing metabolic syndrome, and psychological distress associated with failure.

Predictors of attrition

- Few reliable predictors have been identified in pre-treatment patient characteristics between completers and non-completers.
- However, financial difficulties or the need to pay for the treatment appear to be associated with attrition.
- Baseline BMI does not appear to be related to attendance and completion outcomes.

Economics

- Out-of-pocket expenses were not included as a variable in the statistical analysis of any identified effectiveness trial. In practice, out-of-pocket expenses may lead to differential exposure to the intensity and duration of intervention on the basis of participants' ability to pay.
- The time, effort, and expense required for primary care practitioners to deliver intensive interventions would appear to be prohibitive for most practitioners, in the absence of adequate resources/reimbursement.
- Higher intervention costs (a proxy for intervention intensity) appear to be associated with more weight loss, however the association is non-linear. At higher costs, the additional weight loss associated with extra investments levels off dramatically.

Settings

- Routine healthcare provided by GPs or primary care clinics does not yet seem sufficient in the treatment of overweight and obese patients (however no other setting appears better).
- It is not clear if the apparently high intensity of intervention required is feasible/sustainable in general practice. Other specialist settings may be feasible.
- Few studies/interventions have focused on healthcare professionals' knowledge, skills, behaviour and systems and substantial understanding is still required of features such as the patient journey and funding pathways.

Internet- and mobile technology-based interventions

- Although the weight loss reported in most internet and self-directed studies is small, an internet delivered programme has the potential to be successful and cost-effective when applied on a large scale. However, it is not possible to infer which techniques or delivery modes are most strongly associated with increased weight loss, for whom, and in what contexts.
- Research in this specific field lags behind that of the more conventional intervention modes (e.g. face-to-face individual and group), and no translational studies were identified.

Commercial weight loss programmes

- Modest weight loss can be achieved using commercial weight loss programmes in the short to medium term
- Little published data exists regarding the effectiveness of specific weight loss programmes that are available in New Zealand.
- Evidence from the UK suggests that referral by primary care practitioners to commercial weight management programmes (at no additional cost to the patient) is a practical and modestly effective option, however programme attendance can be poor.
- The cost of commercial programmes is an important consideration, as those who need to use the services most may be the least likely to be able to afford them.

New Zealand context

• Findings from interventions conducted in New Zealand support international review literature, in particular that tailoring and regular continued contact enhance adherence and effectiveness.

• Findings highlight the need for programme content, setting and delivery that is individualised, the need to consider broader health and cultural beliefs, provide the opportunity for incorporating whānau support, and practices that are guided by Māori, Pacific, and other models of health.

Characteristics of effective interventions

- The effectiveness of interventions may be enhanced when both diet and physical activity behaviours are targeted, social support is engaged, and well-established behaviour change techniques are used.
- However, it is not possible to determine what combination or number of these characteristics would be the most effective. It is also important to note that the inclusion of any (or all) of the characteristics listed will not necessarily ensure the effectiveness of an intervention.
- As adherence to long-term physical activity and diet behaviour change is possibly the most crucial and
 difficult factor in intervention effectiveness, a practical strategy may be for health professionals to work
 alongside their patients to choose an evidence-based intervention that aligns with their personal values
 and can be tailored to their lifestyle and abilities.

Knowledge gaps

Further, review of the literature from a broader public health perspective highlights a number of significant gaps in knowledge and these gaps appear to be fundamental barriers or limiting factors to the development of more effective weight-loss and weight loss maintenance treatments. This literature review has highlighted an incomplete understanding of the:

- complexity of the energy balance model, including biological feedback mechanisms and other inputs
- role of specific nutrients and physical activity in weight loss and general health
- possible physical and psychological benefits and harms that might be associated with repeated weight-loss/weight-gain (relapse)
- optimal model of relapse prevention
- importance of population-level weight gain prevention and how this might be achieved
- influence that different funding models might have on weight loss outcomes
- real-world effectiveness of utilising commercial weight loss programmes in the context of the New Zealand primary care system, and
- acceptability and effectiveness of different types of interventions for Māori and Pacific groups, and appropriate ways to increase uptake and compliance.

Supplementary considerations

In recent years, at least in Western countries, the responsibility for addressing obesity has largely fallen on individuals, however many researchers attest that the likelihood of individual-level interventions achieving sustainable progress on the reduction of obesity is low, and *subconscious interventions* (e.g. environment, regulation, systems) offer more scope and potential impact (Acosta, Abu Dayyeh, Port, & Camilleri, 2014; Bartsch, Nuzzo, Alsford, & Morgan Stanley Research Group, 2015; Chan & Woo, 2010; Dobbs, et al., 2014; Hafekost, Lawrence, Mitrou, O'Sullivan, & Zubrick, 2013; Swinburn et al., 2011). Policy makers and healthcare practitioners should therefore consider the need for changes across a number of levels of influence.

Nevertheless, people who are already overweight or obese do need additional individual-level support from healthcare providers. Weight loss interventions need to be pro-equity, cost-effective and be readily available for providers to refer patients to. Based on the literature reviewed, three broad considerations or determinants of future programme success appear prominent: equity, funding models, and models of extended care. Questions around determinants of programme success (and success itself) appear to be in part philosophical, ethical and applied. It appears that the acceptability (access), engagement with, and long-term effectiveness of weight-loss interventions may be shaped, perhaps dramatically, by applying different emphases on these important domains (for example fully-funding vs cost sharing, culturally-tailored vs generic, pro-active vs passive). With these ideas in mind, key supplementary considerations are outlined below, with respect to future intervention design, implementation, and ownership.

- Pro-equity practices need to be guided appropriately by Māori, Pacific, and other models of health.
- A greater understanding is needed of the effects of different funding models on weight loss outcomes.
- Different methods of providing extended-care need to be trialled in fully developed programmes within healthcare systems, and these need to be rigorously evaluated, by funders, providers, researchers and economists.
- Obesity should be seen to be and acted upon as a chronic and relapsing condition (but not disease), by planners, decision makers, funders, educators, providers, researchers and patients.
- Further studies/interventions should focus on healthcare professionals' knowledge, skills, behaviour
 and systems, to substantially improve aspects of care such as the patient journey and funding
 pathways.

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Introduction

The purpose of this report is to provide planners and decision makers with a synthesis of best evidence relating to non-environmental, non-surgical, non-pharmacological individual-level interventions for weight loss and weight loss management in overweight and obese adult populations, delivered (or at least suitable for delivery) in primary healthcare settings or commercial settings.

This report is necessarily limited in scope and includes only systematic reviews and meta-analyses of interventions delivered at the level of the individual, group, family or whānau, and those that can be broadly categorised as *lifestyle change*, behavioural interventions (typically involving changes in physical activity and nutritional behaviours).

This report is a review-of-reviews and does not report on individual clinical trials, except for the purpose of example or in relation to interventions conducted specifically in a New Zealand setting. Intervention types identified within reviews included (singularly or in combination) education, individual or group counselling, physical activity on prescription and/or supervised physical activity, commercial weight loss programmes, short-term intensive weight management programmes, weight management around childbirth, ongoing pro-active follow-up and/or booster interventions, and personal technology-based interventions including internet-based and mobile devices to support healthy eating and physical activity¹.

Consideration has been given to any factors that might be especially relevant to the New Zealand context, to the extent that such information was provided in the original publications. This includes any health system factors that may act to influence intervention effectiveness and/or equity of outcome, compared to other high-income countries from which the evidence was sourced (potential moderators). With regard to generalisability, where possible, interventions were considered with regard to cultural appropriateness and equity, however note that few studies implemented and/or adequately described interventions that were specifically developed for indigenous populations and/or settings.

¹ Interventions based on the Internet and mobile devices have been summarised separately as these interventions are generally at a different (earlier) stage of development and translation compared to more traditional psychoeducational and counselling approaches.

Background

The obesity epidemic

No country can yet act as a public health exemplar for the reduction of obesity. All countries are searching for answers about how to reverse the rising tide of adult and childhood obesity (Swinburn, et al., 2011). One of the major drivers of the increase in many chronic diseases (e.g. heart and lung disease, type 2 diabetes, lifestyle-related cancers) is the rising prevalence of obesity (Dobbs, et al., 2014). Obesity is a complex, multi-causal problem and most people in Western societies are exposed to increasingly obesogenic environments (Egger & Swinburn, 1997). In the first half of the 20th century, increased mechanisation and motorisation reduced population-level physical activity dramatically. Along with declining population-level physical activity, changes in the global food system are seen to be the major drivers of the rise of the global obesity epidemic during the past three to four decades (Swinburn, et al., 2011). Cutler and colleagues (2003, p. 94) assert that there was "a revolution in the mass preparation of food that is roughly comparable to the mass production revolution in manufactured goods that happened a century ago," that "lowered the time price of food consumption". 2 Swinburn et al. (2011) point to "increasingly available, cheap, tasty, highly promoted obesogenic foods" as the food industry's contribution, in an era of mass-production and consumerism (Swinburn, et al., 2011, p. 807). Together, unhealthy behaviours relating to diet and physical activity are associated with weight gain³ and concomitant increases in morbidity and mortality (Rodgers, Ezzati, Vander Hoorn, Lopez, & Lin, 2004).

Diet and activity behaviours, at least in theory, are totally modifiable, yet health-related habits are generally very resistant to change. In New Zealand, almost one-third of New Zealand adults (30%) are obese⁴; a further third (35%) are overweight⁵ and the prevalence has increased significantly over the last several years (Ministry of Health, 2013). As obesity becomes more prevalent there is the danger that it is becoming accepted as the new norm in society (BPACNZ, 2014). It is broadly accepted that halting this epidemic requires wide-ranging social, economic and political change (Chan & Woo, 2010; Swinburn, et al., 2011). Obesity can be seen as the result of people responding normally to the obesogenic environments they find themselves in; nevertheless, people who are *already* obese require interventions and ongoing support from healthcare providers.

The prevalence of obesity is unequally distributed within populations, and in New Zealand, Māori and Pacific adults are significantly more likely to be obese than their non-Māori and non-Pacific

² Technological innovations—including vacuum packing, improved preservatives, deep freezing, artificial flavours and microwaves—have enabled food manufacturers to cook food centrally and ship it to consumers for rapid consumption (Cutler et al. 2003).

³ Only weight-related outcomes are considered in this review. Other potential health benefits such as cardiovascular outcomes (also important) are not considered here.

⁴ i.e. have a BMI of ≥30.

⁵ i.e. have a BMI of 25-29.9.

counterparts (Ministry of Health, 2013). Relatedly, people living in the most deprived communities in New Zealand are significantly more likely to be obese than people living in the least deprived communities (as is the case in most high-income countries) (Ministry of Health, 2013). A review by Drewnowski (2009) indicates that inequitable access to healthy foods (as determined by socioeconomic factors) means that energy-dense and nutrient-poor foods become the best way to provide daily calories at an affordable cost⁶ for low-income groups, whereas nutrient-rich foods and high-quality diets are consumed by more affluent groups. Physical activity is also influenced by socioeconomic position (SEP) and related factors such as a lack of leisure time, illness or disability, lack of money to access facilities and lack of transport (Chinn, White, Harland, Drinkwater, & Raybould, 1999). Therefore, weight loss interventions need to be both pro-equity and cost-effective and be readily available for providers to refer patients to.

Current recommendations and guidelines for managing patients who are overweight or obese

Over the last two decades, several large national and international organisations have published guidelines for managing patients who are overweight or obese (Canadian Task Force on Preventive Health Care, 2015; James D. Douketis, Paradis, Keller, & Martineau, 2005; Ministry of Health Clinical Trials Research Unit, 2009; National Institute for Health and Care Excellence, 2014; National Institute for Health and Clinical Excellence, 2006; National Institutes of Health/National Heart Lung and Blood Institute, 1998; NHMRC, 2013; Scottish Intercollegiate Guidelines Network, 2010; The Obesity Expert Panel, 2014; U.S. Preventive Services Task Force, 2012). Typically these guidelines have been revised and up-dated every two to five years as new evidence is evaluated. The objective of all such guidelines is to provide evidence-based clinical recommendations for structured behavioural interventions aimed at treating overweight and obesity (and in some cases preventing weight gain in adults of normal weight) and in most cases to also provide recommendations for pharmacologic interventions and specialised bariatric programs⁷. To generalise, most national guidelines recommend lifestyle interventions (e.g. behavioural therapies, and dietary and physical activity programming and support) as the first line of treatment for most patients with overweight or obesity (and pharmacotherapy and surgery are often recommended as options for more severe cases of obesity). Most national guidelines endorse a weight loss of 5% as being clinically important (as many cardiovascular risk factors are assumed to improve with weight loss of this magnitude). A brief summary of recommendations for the treatment of overweight and obesity from the main published national guidelines is provided below (Table 1).

⁶ Note that the energy cost differential (i.e. cost for the same amount of energy content) between added sugars and fats and fresh vegetables and fruit can be several thousand percent (Drewnowski, 2009).

⁷ Some guidelines do not apply to people with a BMI score of 40 or greater.

Table 1: Brief summary of recommendations on the treatment of overweight and obesity from published international guidelines

| Country | Treatment recommendations |
|--|---|
| Canada | Offer or refer to formal, structured behavioural interventions* aimed at decreasing weight in |
| Canadian Task Force on Preventive Health Care (2015) | overweight or obese adults. Do not recommend pharmacologic interventions (Canadian Task Force on Preventive Health Care, 2015). Recommend an energy-reduced diet, regular physical and comprehensive lifestyle intervention. |
| Obesity Canada (2007) | Pharmacotherapy for adults not attaining or unable to attain weight loss with diet and exercise therapy (Obesity Canada 2007). |
| Australia National Health and Medical Research Council (2013) USA U.S. Preventive Services Task Force (2012, 2014) | For adults who are overweight or obese, strongly recommend lifestyle change — including reduced-energy intake, increased physical activity, and measures to support behavioural change. For adults with a BMI ≥30, or adults with a BMI ≥27 and comorbidities, Orlistat may be considered as an adjunct to lifestyle interventions, taking into account the individual situation. Screen all adults for obesity; offer or refer patients with a BMI ≥30 to intensive, multicomponent behavioural interventions. Offer or refer adults who are overweight or obese and have additional cardiovascular disease risk factors to intensive behavioural counselling interventions to promote a healthful diet and physical activity for cardiovascular disease prevention. |
| UK National Institute for Health and Care Excellence (2014) | Multicomponent interventions are the treatment of choice. Weight management programmes should include behaviour change strategies [§] to increase physical activity or decrease inactivity, improve eating and diet quality and reduce energy intake. Pharmacologic treatment should be considered only after dietary, exercise and behavioural approaches have been started and evaluated. |
| Scotland Scottish Intercollegiate Guidelines Network (2010) | Weight-management programs should include physical activity, dietary change and behavioural components. Orlistat should be considered as an adjunct to lifestyle interventions in the management of weight loss following assessment of risk and benefits. |
| New Zealand Ministry of Health (2009) [†] | Screen all adults for obesity, focus on assessing risk (e.g. elevated blood pressure, lipids, smoking), and recommend comprehensive lifestyle approaches that incorporate diet, physical activity, and behavioural strategies (the FAB approach) [‡] . This should be the first treatment option for weight loss and sustained for weight maintenance. Providers should continue contact with advice to support patients to maintain initial weight loss using combined dietary change and increased physical activity. |

^{*}Formal, structured interventions are behavioural modification programmes that involve several sessions or interactions that take place over weeks to months. Interventions examined include behaviourally-based prevention interventions focused on diet, exercise, lifestyle changes or any combination of these.

New Zealand guideline development

In 2008, the Ministry of Health commissioned a consortium led by the Clinical Trials Research Unit at the University of Auckland to develop the Clinical Guidelines for Weight Management in New Zealand Adults, and the draft implementation and training considerations. The guideline development process involved the adaptation (with permission) of the United Kingdom's National Institute for Health and Clinical Excellence's (NICE) guidelines (National Institute for Health and Clinical Excellence, 2006) for the prevention, identification, assessment, and management of

⁹See Appendix A, Table 4 for a description of behaviour change strategies.

[†]The guideline development process involved the adaptation (with permission) of the UK's National Institute for Health and Clinical Excellence's 2006 guidelines for the prevention, identification, assessment, and management of overweight and obesity in adults and children (National Institute for Health and Clinical Excellence, 2006).

[‡]FAB = food, activity and behavioural-based approaches rather than single factor approaches to weight loss. BMI, body mass index; UK, United Kingdom; USA, United States of America.

overweight and obesity in adults and children (only the evidence pertaining to management was used in the NZ guideline) (Ministry of Health Clinical Trials Research Unit, 2009). The NICE guideline was selected for adaptation because it met a number of evidence criteria and permission was granted for the guideline's adaptation. The process of guideline development was informed by an internationally recognised tool for assessing the quality of practice guidelines⁸.

Lifestyle (FAB) approach

The New Zealand guidelines recommend 'lifestyle approaches' that involve combined (e.g. food, activity and behavioural based approaches – the FAB approach) rather than single factor approaches to weight loss. The FAB approach is integral in the treatment algorithm, key messages, and recommendations presented in the clinical guidelines and in the implementation and training manual (Ministry of Health, 2010). Recommended dietary changes involved either reduction in total energy intake through energy restriction or decreasing consumption of total and saturated fats, while increased physical activity involved moderate intensity exercise such as brisk walking three to five days per week. Identified behavioural strategies include the standard elements discussed in behavioural approaches (e.g. self-monitoring, stimulus control, problem-solving, see Appendix A, Table 4 for a further description) (Ministry of Health, 2010; Ministry of Health Clinical Trials Research Unit, 2009). These recommendations for comprehensive lifestyle approaches that incorporate diet, physical activity, and behavioural strategies are broadly in line with other international guidelines (see **Table 1**).

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⁸ The Appraisal of Guidelines for Research and Evaluation (AGREE) tool, The AGREE Collaboration. (2003). Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: The AGREE project. *Quality and Safety in Health Care*, *12*, 18-23..

Methods

Research question

The primary research question addressed by this review is: What is the effectiveness of individual-level or group-level physical activity, nutrition and behavioural/psycho-educational interventions that promote weight loss and/or weight loss management among overweight or obese adults (with or without comorbidities)?

The review question was defined according to the population, intervention, comparator, outcomes, and time (PICOT) criteria (as detailed in **Table 2**), and the types of studies and the exclusion criteria as detailed below. These criteria were developed *a priori*.

Table 2: Criteria for determining study eligibility

| PICOT | Inclusion criteria description |
|-------------------------|---|
| Participants/population | Adults (i.e. ≥18 years old), overweight (i.e. BMI ≥25) or obese (i.e. BMI ≥30) and/or stratified by |
| | BMI, with or without comorbidity (e.g. CVD, type 2 diabetes, musculoskeletal problems). |
| Intervention* | Any behavioural or psychoeducational intervention (or multi-component intervention) that is focused on lifestyle change (nutrition and/or physical activity), delivered at the individual level (in group or one-on-one settings or using web-based or other telehealth application), delivered within (or referred from) a primary or secondary-care setting, or community-based/commercial setting, or a specialist clinic. |
| Comparator | Usual care, no intervention. |
| Outcomes | Weight loss (absolute or relative), BMI, measures of energy balance, fat-free mass, ratio of waist and hip circumference. |
| Time | Short-term (0-6 months), medium-term (6-24 months), long-term (24+ months). |

| PICOT | Exclusion criteria description |
|-------------------------|---|
| Participants/population | Children or adolescents [†] , people with mental illness, people with BMI <25. |
| Intervention | Environmental-level interventions, legislative interventions. |
| Outcomes | Biochemical markers (e.g. blood lipid profiles, blood glucose profiles, blood pressure), cardiovascular fitness, etc. |
| Time | Less than 1 month follow-up. |

^{*}It is difficult to compare study contexts and settings exactly. Studies were selected on the basis that they reflected the New Zealand context/setting as much as possible: at the level of the participant-provider interaction.

Types of evidence

The types of studies considered as eligible were: studies published in the English-language, and secondary research (systematic reviews, economic analyses and meta-analyses) appearing in the published literature. Study types *not* eligible for this review include, individual RCTs (except in some special circumstances e.g. research conducted in New Zealand); pseudo-RCTs; non-randomised, experimental trials; cohort studies; case-control studies; and interrupted time series designs. Two exceptions were for literature specifically related to interventions conducted in New Zealand, and studies investigating the referral of primary care patients to commercial weight management

Also excludes studies of adults aged 65+ when studies include groups of only 65+ (in practice most study groups are of mixed age).

programmes. Due to the small body of research, all study types were considered for inclusion in these sections.

Literature search

A systematic method of literature searching and selection was employed in the preparation of this review. Searches were limited to English-language peer-reviewed review material published from 2008 onwards. This publication year range provides an overlap of the evidence base informing the most recent Clinical Guidelines for Weight Management in New Zealand Adults (Ministry of Health Clinical Trials Research Unit, 2009) and the specially commissioned augmented review relating to Māori perspectives (Kiro, 2009). The searches were completed in March 2015. Therefore, studies published after this date are not included in the review. The following databases were searched:

- a) bibliographic databases including PubMed, PsycINFO, and
- b) review databases including the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effectiveness, Health Technology Assessment database.

Search terms were used as keywords, expanded where possible, and as free text within the title and/or abstract, in the PubMed database. Variations on these terms were used for the Cochrane Library and other databases, and if required, modified to suit their keywords and descriptors. Key words/search terms included: Body Mass Index; obesity; overweight; weight loss; weight gain; exercise; lifestyle (limiters included: adult; review).

Further, reviews relating to commercial weight management programmes (e.g. Weight Watchers, Jenny Craig, Optifast) were also sought. Particular attention was paid to programmes available in New Zealand. Individual (i.e. not review) studies investigating the referral of primary care patients to commercial weight loss programmes were also pursued, as it was identified that this approach has been used in the UK as a strategy to address the growing prevalence of overweight and obesity in the population in recent years. Additional key words/search terms included: Commercial; popular diet; brand*; Weight Watchers; Jenny Craig; Optifast.

A search was also conducted specifically for reviews and individual interventions relating to weight loss interventions undertaken in Aotearoa New Zealand. Articles published prior to 2009 investigating the Green Prescription (GRx) were also included in acknowledgement that this programme is a widely-used nationwide programme currently in place. Additional key words/search terms included: New Zealand; Aotearoa; Maori; Green Prescription.

A broad search was also conducted using Google Scholar and nzresearch.org.nz⁹ using various combinations of the search terms listed above. The reference lists of included publications were scanned to identify any peer-reviewed evidence that may have been missed in the literature search. Grey literature and unpublished material such as conference abstracts were not included in the evidence review.

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⁹ http://nzresearch.org.nz/

Assessment of study eligibility

Broadly, studies were selected for inclusion in the review using a two-stage process. First, the titles and abstracts identified from the search were scanned and exclusions were made as appropriate. Second, the full-text articles were retrieved (where possible) for the remaining studies, and these were selected for inclusion in the review if they fulfilled the study selection criteria. EndNoteX6 ™ was used to manage citations (Thomson Reuters, 1988-2012 ®) with user-defined custom fields to tag all citations over the two appraisal passes (title/abstract and full-text). Internal searches were used to generate the final included study list.

Data synthesis

This review presents the statistical precision of the estimated effect size, together with a discussion of its clinical significance, to the extent that this information was reported by the original authors. A narrative synthesis summarises the overall findings.

Limitations of the evidence base

The review articles included in this report varied considerably with respect to their inclusion criteria and, in particular, the different types of study designs, publication year range, and the patient outcomes reported (all reviews needed to report change in body weight as a primary outcome). There was also considerable variability in the level of information provided to describe intervention contexts, content, intensity, scheduling and delivery. For example, the term 'behavioural counselling techniques' is commonly used, however the detail provided in published reports is often insufficient to replicate the intervention or to permit it to be compared exactly to other apparently similar trials. Further, there was a variety of professional backgrounds amongst the researchers and healthcare professionals who delivered the intervention components.

Many (or most) studies included in the reviews were of groups of participants of mixed weight (i.e., normal-weight, overweight and obese). In the case of overweight and obese individuals, the interventions may be considered *treatment*; however the inclusion of normal-weight participants in some studies blurs the distinction between treatment and prevention and possibly weakens the findings in some instances (typically sub-group analyses are not reported due to small numbers). Also, studies rarely reported comorbidities (the proportion of participants with comorbidities, what these conditions might be, and whether or not they posed barriers to participation).

Few studies have been conducted in real-world settings without the support of external expertise and research funding. Even when studies have been described as *translational* (i.e. translating the findings from clinical trials into everyday practice), few appear to achieve this. Almost all of the studies that attempted to trial programmes in real-world settings still included some 'expert' or 'researcher' input and/or funding (and participants' out-of-pocket expenses were not included as a variable in the statistical analysis of any identified effectiveness trial). Many programmes are characterised by high attrition rates and little is known about participants who drop-out¹⁰ (neither the predictive factors nor the outcomes). This represents a significant limitation of the evidence base

¹⁰ Although the statistical analyses are usually (but not always) based on the 'intention to treat' principle, this does not provide information on predictive factors or the 'lived experiences' (outcomes) of non-completers.

and this knowledge may be critical in determining ways to improve the overall effectiveness of weight loss programmes. Overall, little is known about the longer term (life course) effects of weight loss and weight loss maintenance programmes (both benefits and harms). Typically, weight loss intervention trials have short to medium follow-up periods (12-14 months) and weight loss maintenance trials seldom exceed 36-48 months.

In summary it is difficult to compare study contexts and settings exactly. Studies were selected on the basis that they reflected the New Zealand context/setting as much as possible: at the level of the participant-provider interaction.

Limitations of this review

While questions of generalisability are applicable to all clinical trials (and systematic reviews of these clinical trials), arguably, this may be more problematic when the intervention is intended to be incorporated into a community-based service (i.e. a programme of 'usual care', rather than a research-supported or other specialist activity). Intensive strategies that entail multiple follow-up visits may make unrealistic demands on limited clinical time and may simply be impractical in typical New Zealand primary care settings. The generalisability of findings to the New Zealand context should therefore be measured on a case-by-case basis and the potential cost-effectiveness should be considered carefully. Estimating resource utilisation and any possible cost off-sets and/or savings to the healthcare system is beyond the scope of this report.

The literature search was restricted to English language publications. Also, no attempt was made to identify unpublished studies. It is unlikely, therefore, that all the relevant research was identified. Publication bias was not assessed. This review is necessarily limited in scope and excludes environmental and legislative interventions but it should be noted that the local environment in which interventions are delivered is likely to influence an intervention's effectiveness. The *level* of intervention (i.e. individual/group/family/whānau) also needs to be considered as well as the *mode*, as from a public health perspective, even small changes in behaviours can be important when many people are affected (Fuchs, 1993, 1998). Further, consideration needs to be given to the specific New Zealand context and any factors that may act to influence intervention effectiveness/equity of outcome, compared to other high-income countries from which the evidence may be sourced.

In addition, only weight-related outcomes of interventions were considered in this review. However it is acknowledged that there are many non-weight related outcomes of diet, physical activity and behavioural interventions that are also important to health (e.g. blood glucose and lipid profiles, cardiovascular fitness, muscle strength, and quality of life).

This review only focusses on individual-level interventions and is provided to illustrate where the scope of this review fits within the wider range of possible interventions types. It is acknowledged that the greatest (potential) impacts of obesity interventions are exerted at the environmental level (Abraham & Michie, 2008; Dobbs, et al., 2014). The general relationship between population effect (impact) and political difficulty is also illustrated. Generally, intervention types that target systemic drivers have larger effects (interventions listed to the left of the diagram), but their political implementation is often more difficult than individual-level health promotion programmes and medical services (Abraham & Michie, 2008; Dobbs, et al., 2014; Swinburn, et al., 2011). This review is limited to individual-level behavioural interventions only.

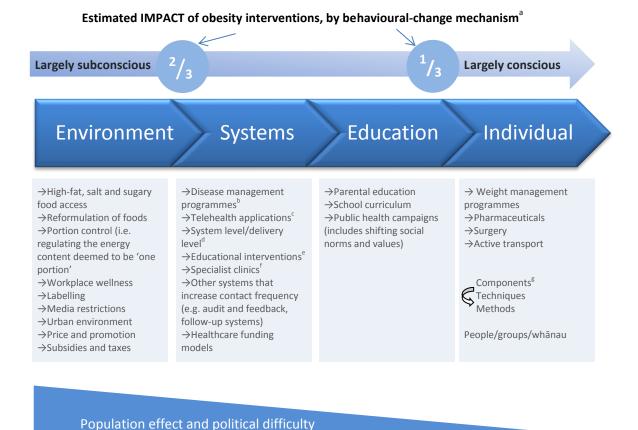


Figure 1: Intervention portfolio, relative proportion of impact across domains, population effect, political difficulty, and example intervention types

Created using concepts from: Abraham & Michie (Abraham & Michie, 2008); Dobbs et al. (Dobbs, et al., 2014); Norris et al. (Norris et al., 2002); Swinburn et al. (Swinburn, et al., 2011).

- ^a Case study modelled for the UK, full lifetime 2014 population (Dobbs, et al., 2014).
- ^b Organised Protective Population-based Integrated Interventions involve: healthcare delivery systems, providers, patients, populations. Adapted from (Norris, et al., 2002).
- ^cTelehealth applications involve distance communication and the transfer of biochemical data, specific advice and adjustment of medical management, counselling and often unlimited 24 hour access.
- ^d System level interventions when targeted at the level of healthcare delivery: involve critical care pathways, establishment of structures and programmes such as hospital-at-home and outreach programmes.
- ^e Educational interventions involving healthcare delivery systems, providers, patients, populations.
- ^f Specialist clinics deliver focused treatment in a clinic setting, a specific point of care, by a range of health professionals.
- ^g See (Abraham & Michie, 2008) for more detail.

Findings

Structure of this chapter

This chapter begins with a brief description of the search results (type, number and characteristics of the included studies) and a tabulated list (**Table 3**) is then provided to overview the included behaviour change intervention studies grouped by study *focus* and by publication date. In this way, **Table 3** serves to guide the reader in cross referencing all 41 reviews and 40 individual studies, and as an aid to navigation throughout the document. Elsewhere in the document, the more detailed individual study descriptions, tables and figures can be found in the relevant appendices, arranged alphabetically by first author (within topic groupings). This consistent ordering ensures that the most pertinent high-level summary findings are provided first (within this section) and then the more detailed information is located later in the document. The reader is also encouraged to consult the original publications for specific results from the primary research trials thus summarised, if still more detail is required.

Then, six main sections of findings are presented:

- 1. Overview of weight-loss interventions, including:
 - a. Introduction to measures of effectiveness, and
 - b. Definitions of success
- 2. Interpersonal-based interventions for weight loss and weight loss maintenance, including a focus on:
 - a. Primary care and real-world settings (translational research)
 - b. Weight loss maintenance (long-term care after an initial period of weight loss)
 - c. Harm
 - d. Predictors of programme attrition
 - e. Economics, and
 - f. Settings
- 3. Internet-based and self-directed interventions for weight loss and weight loss maintenance
- 4. Commercial weight management programmes for weight loss and weight loss maintenance
- Interventions for weight loss and weight loss maintenance conducted in Aotearoa New Zealand, and
- 6. Characteristics associated with increased effectiveness among interventions for weight loss and weight loss maintenance.

Literature included in this review

The publications varied considerably with respect to their inclusion criteria and in particular the different types of study designs included for review (e.g. clinical efficacy trials, pragmatic trials, translational research), the publication year range, and the patient outcomes reported (all reviews needed to report change in body weight as a primary outcome). The main study groupings (by focus) are outlined in **Table 3**.

Table 3: List of behaviour change intervention studies grouped by study focus and publication date

| First author | Year | Abbreviated title |
|---------------|------|---|
| Reviews focus | | mary care and real-world settings (translational research) |
| Booth | 2014 | Effectiveness of behavioural weight loss interventions delivered in a primary care setting. |
| Wadden | 2014 | Behavioural treatment of obesity in patients encountered in primary care settings. |
| Johnson | 2013 | Can type 2 diabetes prevention programmes be translated effectively into real-world settings and still deliver improved outcomes? |
| Yoong | 2013 | Review of behavioural weight-loss interventions involving PCPs in overweight and obese primary care patients. |
| Quigley | 2012 | Are nutrition and physical activity primary prevention interventions in the primary care setting effective at reducing biochemical and physical risk factors? |
| Cardona- | 2010 | Reduction of type 2 diabetes risk in routine clinical practice: are physical activity and nutrition |
| Morrell | | interventions feasible and are the outcomes from reference trials replicable? |
| Tsai | 2009 | Treatment of obesity in primary care practice in the USA. |
| | | ght loss maintenance (long-term care after an initial period of weight loss) |
| Kouvelioti | 2014 | Effects of exercise and diet on weight loss maintenance in overweight and obese adults. |
| Dombrowski | 2014 | Long term maintenance of weight loss with non-surgical interventions in obese adults. |
| Dunkley | 2014 | Effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations. |
| Johansson | 2014 | Effects of pharmaceutical weight loss agents, diet and exercise on weight loss maintenance after a VLCD or LCD. |
| Middleton | 2012 | The impact of extended care on the long-term maintenance of weight loss. |
| Loveman | 2011 | Clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults. |
| Barte | 2010 | Maintenance of weight loss after lifestyle interventions for overweight and obesity. |
| | | cacy (predominantly RCTs conducted in research settings) |
| Chen | 2015 | Effect of lifestyle intervention in patients with type 2 diabetes. |
| Nascimento | 2014 | The effect of physical exercise strategies on weight loss in postpartum women. |
| Peirson | 2014 | Prevention of overweight and obesity in adult populations. |
| Gallagher | 2013 | Multi-component weight-loss interventions for people with CVD and/or type 2 diabetes. |
| Kirk | 2013 | Effective weight management practice: a review of the lifestyle intervention evidence. |
| Young | 2012 | Effectiveness of male-only weight loss and weight loss maintenance interventions. |
| | | |
| | | er aspects of the research (by BMI class, tailoring & cost-effectiveness) |
| Moredich | 2014 | Physical activity and nutritional weight loss interventions in obese low-income women. |
| Barte | 2014 | Differences in weight loss across different BMI classes. |
| Bogers | 2010 | Relationship between costs of lifestyle interventions and weight loss in overweight adults. |
| | | ernet-based and self-directed interventions |
| Aguilar | 2014 | Use of mobile phones as a tool for weight loss. |
| Khokhar | 2014 | Effectiveness of mobile electronic devices in weight loss among overweight and obese populations. |
| Lyzwinski | 2014 | Mobile devices and weight loss with an intervention content analysis. |
| Tang | 2014 | Self-directed interventions to promote weight loss. |
| Vegting | 2014 | Internet programmes targeting multiple lifestyle interventions in primary and secondary care. |
| | | studies focused on commercial weight management programmes |
| Atallah | 2014 | Long-term effects of four popular diets on weight loss and CVD risk factors. |
| Finklestein | 2014 | Cost-effectiveness analysis of commercial weight management programmes. |
| Gudzune | 2014 | Efficacy of commercial weight management programmes. |
| Johnston | 2014 | Comparison of weight loss among branded diet programmes. |
| Madigan | 2014 | Comparing the effectiveness WW with other commercial weight management programmes. |
| Asher | 2013 | VLCDs for weight loss among adults. |
| Fuller | 2013 | Cost-effectiveness analysis of primary care referral to commercial weight management programmes, relative to standard care. |
| Dixon | 2012 | Weight loss from three commercial providers of NHS primary care. |
| Stubbs | 2012 | Attendance and weight outcomes among adults referred to a primary care/commercial weight |
| | 2012 | management programme partnership scheme. |
| Ahern | 2011 | Weight change among adults referred to WW by the NHS. |

| Jebb | 2011 | Primary care referral to a commercial weight management programme for weight loss treatment, |
|------------|------|---|
| | | relative to standard care. |
| Jolly | 2011 | Commercial or primary care led weight loss programmes versus minimal intervention. |
| Stubbs | 2011 | Weight outcomes for adults referred to a primary care/commercial weight management |
| | | programme partnership scheme. |
| | | ed on interventions conducted in Aotearoa New Zealand |
| Buckley | 2014 | Exercise self-efficacy intervention in overweight and obese women. |
| Claridge | 2014 | GP opinion of weight management interventions. |
| Ni Mhurchu | 2014 | Feasibility and effectiveness of a mobile health weight management programme for adults. |
| Marshall | 2013 | GRx support programmes in Canterbury. |
| Brooking | 2012 | Effects of diet macronutrient composition on body fat in Māori at high risk of type 2 diabetes. |
| Kolt | 2012 | Pedometer-based advice and physical activity for low-active older adults. |
| Krebs | 2012 | High-protein versus high-carbohydrate diets over 2 years in type 2 diabetes. |
| Leung | 2012 | Cost-effectiveness of pedometer-based versus time-based GRx. |
| Patel | 2012 | GPs' perceptions of barriers to the GRx for older adults. |
| Sukala | 2012 | Exercise intervention Māori and Pacific adults with type 2 diabetes. |
| Tava'e | 2012 | The experiences of Pacific women receiving the GRx. |
| Elley | 2011 | Cost-effectiveness of exercise on prescription with telephone support among women in general practice over 2 years. |
| Foley | 2011 | Comparison of two modes of delivery of an exercise prescription scheme. |
| Gorton | 2011 | Consumer views on the use of mobile phones for the delivery of weight-loss interventions. |
| Patel | 2011 | GPs' views and experiences of counselling for physical activity through the GRx. |
| Schluter | 2011 | Perceived barriers and incentives to increased physical activity for Pacific mothers. |
| Sukala | 2011 | Comparison of aerobic and resistance training for Māori and Pacific adults at risk of type 2 diabetes. |
| Coppell | 2010 | Diet intervention in patients with type 2 diabetes who are hyperglycaemic despite optimised pharmaceutical treatment. |
| Cutler | 2010 | Evaluation of the "Appetite for Life" primary care lifestyle programme. |
| Venn | 2010 | The effect of increasing consumption of pulses and wholegrains in obese people. |
| Dale | 2009 | Sustainability of lifestyle changes following an intensive lifestyle intervention. |
| Lawton | 2008 | Exercise on prescription for women aged 40-74 recruited through primary care. |
| Simmons | 2008 | Community health worker-based intervention for the prevention of type 2 diabetes among Māori. |
| Elley | 2007 | Patient attitudes to physical activity promotion in general practice. |
| Croteau | 2006 | Physical activity advice in the primary care setting. |
| Dalziel | 2006 | Cost utility analysis of physical activity counselling in general practice. |
| Kerse | 2005 | Physical activity counselling in primary care for older people. |
| Elley | 2004 | Cost-effectiveness of physical activity counselling in general practice. |
| Elley | 2003 | Effectiveness of counselling patients on physical activity in general practice. |
| Gribben | 2000 | Experience of GPs using GRx. |
| Swinburn | 1998 | Written exercise advice provided by GPs. |
| Swinburn | 1997 | Attitudes and perceptions of GPs towards prescribing exercise. |
| | | aracteristics associated with increased effectiveness among interventions |
| Ramage | 2014 | Healthy strategies for successful weight loss and weight maintenance. |
| Ali | 2012 | Effectiveness of lifestyle interventions in real-world settings based on the DPP. |
| Wieland | 2012 | Interactive computer-based interventions for weight loss or weight maintenance. |
| Armstrong | 2012 | Motivational interviewing to improve weight loss in overweight and/or obese patients. |
| Burke | 2011 | Self-monitoring in weight loss. |
| Greaves | 2011 | Intervention components associated with increased effectiveness. |
| LeBlanc | 2011 | Effectiveness of primary care-relevant treatments for obesity in adults. |
| Sweet | 2010 | Improving physical activity and dietary behaviours with single or multiple health behaviour |
| | | interventions. |

BMI, body mass index; CVD, Cardiovascular disease; DPP, Diabetes Prevention Programme; GRx, Green Prescription; GP, General Practitioner; LCD, Low-calorie diet; NHS, National Health Service; PCP, Primary care physician; RCT, randomised controlled trial; UK, United Kingdom, USA, United States of America, VLCD, Very low-calorie diet, WW, Weight Watchers.

A narrative and/or tabulated synthesis of each review including a description of the design, intervention, setting, providers, outcome measures, results and conclusions/clinical relevance for each study can be found in the relevant appendix: Appendix B for the interpersonal-based interventions, Appendix C for internet-based and self-directed interventions, and Appendix D for commercial weight management programmes for weight loss and weight loss maintenance.

Overview of weight-loss interventions

Introduction to measures of effectiveness

Lifestyle modification for obesity (consisting of a combination of diet, physical activity and behaviour change therapy) is considered the cornerstone of weight management for overweight and obese adults (National Heart Lung and Blood Institute and the North American Association for the Study of Obesity, 2000). Typically, participants in weight-management programmes¹¹ all achieve good weight loss in the first six months (**Figure 2**). However, initial success is often followed by a slow regain of the weight lost. Individuals often end up at the same (or greater than) the weight they were before the intervention (Dobbs, et al., 2014). Different approaches to weight loss produce notably different results in terms of the average amount of weight lost and the shape of the regain curve (**Figure 2**). Weight loss interventions that combine a healthy dietary pattern and regular physical activity tend to result in more favourable long-term weight-loss outcomes.

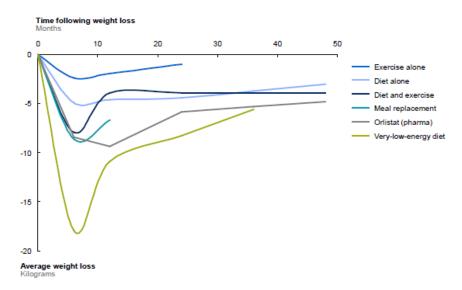


Figure 2: Average weight loss according to different strategies-an example meta-study of clinical trials

The figure illustrates that traditional targeted interventions struggle to sustain their impact, with weight regain ranging from 30-70% of the original loss. Reproduced from: Dobbs et al. (Dobbs, et al., 2014).

Still, more knowledge is required to guide the implementation of pro-equity and cost-effective ways to provide sustainable continuous healthy-lifestyle support beyond the initial intervention period. Currently it is not clear how best to achieve this behaviour maintenance.

Also relevant are the findings from a recent meta-analysis that evaluated the role of 'fitness' and 'fatness' together (Barry et al., 2014). This study found that compared to normal weight fit

 $^{^{\}rm 11}$ Including, dietary counselling, pharmaceutical treatment, bariatric surgery and others.

individuals, unfit individuals had twice the risk of mortality regardless of body mass index (BMI). Fit and overweight and obese individuals have similar mortality risk to their normal weight counterparts. The authors concluded that these findings have important public health implications, as researchers, clinicians, and public health officials should focus on physical activity-based interventions rather than weight loss driven approaches to reduce mortality risk. Barry et al. point out that fit individuals who are overweight or obese are not automatically at a higher risk for all-cause mortality and a higher cardio-respiratory fitness level independently reduces mortality risk regardless of BMI.

A further consideration relates to programme implementation. It is generally accepted that randomised controlled trials (RCTs) that are conducted in research settings are likely to demonstrate larger effect sizes than studies conducted in real-world settings. The more realistic 'pragmatic trials' and translational research studies seek to answer the question, "Does this intervention work under usual conditions?" (Thorpe et al., 2009). Even though pragmatic trials typically aim to approximate real-world conditions, they are still likely to be implemented with greater resourcing and expertise than is likely when the intervention is scaled up for introduction into a community-based service. When an intervention is introduced into a community-based service it typically becomes dependent (at least in part) on the attitudes, enthusiasm, competence and motivation of providers (and this can influence effectiveness). In primary care settings (e.g. the GP's office) there may be barriers to implementation including time, knowledge, and limited resources for follow-up and monitoring. System-level interventions may be needed to increase the delivery of effective weight-loss treatments in primary care settings. All of these themes are discussed more fully in the following sections of this report.

Definitions of success

An important framing question is "What might success look like?". Questions regarding the success (or not) of overweight and obesity treatments generally focus on the benefits derived from an observed degree of weight reduction, and its actual impact on morbidity and mortality and therefore its ability to make a difference in people's lives. Whether a treatment effect exists in the statistical sense has little to do with the clinical significance of the effect. Whether a treatment achieves a specified marker of success also depends on from whose perspective this is judged. For example, people who are overweight or obese, the health professionals involved in their care, and funders and decision makers may all differ in the degree of weight loss they see as 'significant'. Generally, the threshold of clinical significance is the effect size above which clinicians and patients would consider the benefit worthwhile (obtained from previous research, clinical experience and expert opinion). In the field of weight loss, most researchers consider a loss of 5% or greater (of baseline body weight) to be clinically significant and this figure appears to have been adopted by convention, although some consider 10% as a more appropriate and meaningful goal (Barte et al., 2010). However, it is still unclear if such weight loss (5%) improves risk factors in all obese persons or only in high-risk groups (Anderson, Konz, Frederich, & Wood, 2001; J. D. Douketis, Macie, Thabane, & Williamson, 2005). While most agree that a 5% weight loss is at least a useful threshold for comparison, there appears to be no consensus on the required length of time over which the weight loss should be maintained. Studies typically report weight loss outcomes at 6 months to 12 months, with few studies conducting follow-up beyond two to three years. This creates a methodological

problem whereby short-term and moderate-term studies cannot be compared directly, as well as a philosophical dilemma relating to differences in individual's perceptions and expectations.

One broad conceptualisation of clinically significant difference is that clinically significant change has something to do with the return to normal functioning (Jacobson et al., 1984). The most simple explanation of this idea being that the level of functioning following an intervention should place a person closer to the mean of the functional population (or homeostasis) than it does to the mean of the dysfunctional population (Jacobson, et al., 1984). Arguably, no currently available weight loss intervention consistently induces normal function (homeostasis) for more than a very few participants (Dobbs, et al., 2014), with the possible exception of bariatric surgery (Acosta, et al., 2014; Picot, Jones, Colquitt, Loveman, & Clegg, 2012). For patient-centred clinically-relevant outcomes, it is difficult to assign a threshold of clinical significance. Any improvement, however small, of patient-important outcomes may seem relevant. Nevertheless, the significance of the clinical benefit of weight loss interventions should be judged by also taking adverse effects and other costs of the interventions into consideration: a thorough overall assessment of the balance between beneficial and harmful effects (Jakobsen, Gluud, Winkel, Lange, & Wetterslev, 2014). Thresholds for statistical significance are almost always discussed in the context of making a valid assessment of results from randomised controlled trials, yet discussions of clinically significant change are often absent in the weight-loss literature.

Participants in weight-management programmes, dietary counselling, and pharmaceutical treatment, as well as bariatric surgery patients, generally achieve good weight loss in the first six months. But even in the case of surgery, initial 'success' is typically followed by a slow, creeping regain of the weight lost (Dobbs, et al., 2014; Johansson, Neovius, & Hemmingsson, 2014). Arguably, in other clinical contexts, this would be seen as late-stage intervention failure. Loveman et al. (Loveman et al., 2011) discussed this dilemma at length and precisely stated three perspectives from which the question of effectiveness, that is, the amount and duration of weight loss, might be viewed.

Loveman et al. (2011) first frame the debate by identifying several factors that need to be taken into account: trends in the weight change of the general population; the starting weight of individual participants; the time over which the weight loss is measured; the ease with which participants lose weight; their perceptions of the importance of losing weight; and their perceptions of meaningful weight loss. From these variables, the authors then formulated the following three viewpoints on clinically significant change:

- 1) adoption of the simple assumption that a 5% threshold for the degree of weight loss is meaningful (i.e. participants would be considered to have received clinical benefit from their 5% weight loss irrespective of the follow-up duration),
- 2) that for participants to benefit meaningfully from an intervention, any weight loss at the end of the intervention needs to be followed by longer-term weight stability (the amount and term would need to be specified), and
- 3) based on the natural tendency for weight gain over time in the general population, a result of zero weight regain beyond baseline might be judged as important.

If the goal is to reduce and to maintain weight at a clinically significantly lower level than preintervention, then satisfying the second criterion would appear to be necessary. Kirk et al. (Kirk, Penney, McHugh, & Sharma, 2012) expand this viewpoint and argue that obesity needs to be seen as a chronic and relapsing condition that requires ongoing continuous management. This viewpoint suggests that treatments might only be interpreted as effective if they provide for sustained follow-up contact and 'refresher' interventions that promote weight maintenance over time (because if treatment ends, relapse likely occurs) (Kirk, et al., 2012).

Further, weight-loss interventions need to be able to be delivered to people in real-world settings (and interventions need to be pro-equity). Failing to ensure translation or generalisability could be defined as a Type III error¹² (Schwartz & Carpenter, 1999). Thus, the results of the intervention trials seem to answer a specific 'effectiveness' question (i.e. are weight-loss interventions effective for the treatment and management of overweight and obesity, over the life-span, in primary care, community and/or commercial settings?), when in fact the results support a different question (i.e. are weight-loss interventions 'efficacious', as demonstrated by short-term clinical trials). In part, the difference to these questions is one of resources and scale.

If the tested interventions cannot (yet) be practically and sustainably implemented in real-world settings then they are arguably of little relevance to public health. Swinburn et al. (2011) argue that

"Sustainability and affordability are the two major continuing challenges, even for programmes with proven effectiveness" (Swinburn, et al., 2011, p.809).

If an individual-level behavioural intervention or programme or system cannot assist people to attain and maintain weight loss at a level that confers clinically significant health benefits, then its utility must fall into question. A number of researchers now voice this perspective explicitly, for example:

Hafekost et al. (2013) concluded that there is no single public health intervention for addressing overweight and obesity that is generally effective,

"Weight loss maintenance remains a major challenge in obesity treatment" (Johansson, et al., 2014, p.14),

"Traditional diets that restrict energy, or particular nutrients, to induce weight loss have achieved little long-term success" (Schaefer & Magnuson, 2014, p.734), and

"These programs have high attrition rates; participants rarely maintain weight loss and sometimes gain back even more weight than they lost during the program." (Schaefer & Magnuson, 2014, p.734).

All of the above conclusions suggest the tendency for one-point-in-time weight loss interventions to suffer from late-stage intervention failure. However, as Dombrowski et al. (2014) correctly state, the evidence base for weight loss maintenance is in its infancy. A number of recent systematic reviews specifically included a focus on weight loss maintenance (Dombrowski, Knittle, Avenell, Araujo-Soares, & Sniehotta, 2014; Johansson, et al., 2014; Kirk, et al., 2012; Kouvelioti, Vagenas, & Langley-Evans, 2014; Loveman, et al., 2011; Middleton, Patidar, & Perri, 2012; Yoong, Carey, Sanson-Fisher, & Grady, 2013) however most were limited in their ability to comment on outcomes beyond 24

¹² Whereby the results of an intervention trial appear to answer the pre-specified research question, but in fact the results support a different question.

months, due to a lack of evaluable studies. Arguably, this is a very short time scale in the context of the natural course of obesity (when weight gain typically spans decades). Therefore, discussions of effectiveness should acknowledge the different viewpoints and interpretations that can be applied and be specific about their implications.

Interpersonal-based interventions for weight loss and weight loss maintenance

This section summarises evidence from 23 recent reviews of weight loss interventions that have been trialled across a diverse range of settings (see Appendix B for details). There appears to be little doubt that short-term weight loss does result from the majority of behavioural interventions, particularly those that employ a combination of diet, exercise and behaviour modification techniques. Modest short-to-medium term weight loss is undoubtedly achievable for some people. Many different intervention types have, in one study or another, been shown to be effective over short to moderate time frames. However, even in positive studies, the differences in the outcomes among those who received the intervention and those who received the usual treatment (the effect sizes) were not high¹³ and it appears that the resultant weight loss is seldom maintained in the long term. Long-term weight loss maintenance (years not months) is sparsely reported. There are indications that weight loss does tend to persist with continued treatment (LeBlanc, O'Connor, Whitlock, Patnode, & Kapka, 2011), and when modest weight loss is achieved, the reduction can confer clinically important benefits with the potential to improve population health (Peirson et al., 2014). However, researchers raise concerns about a range of possible physical and psychological harms (and ethical disquiets) that might be associated with 'failure' or with recommending people to weight loss treatments that struggle to deliver favourable *long-term* outcomes.

Primary care and real-world settings (translational research)

Despite the many weight loss intervention studies, systematic reviews and meta-analyses published in the literature, there is still a scarcity of findings from *translational* studies (i.e. studies that translate the findings from clinical trials into everyday practice). Clearly there is a gap between evidence-based recommendations and current clinical practice. Kirk et al. (2012) conclude that currently, healthcare systems (in the Western World generally) do not provide adequate attention to obesity management services. Only three systematic reviews were identified (for inclusion in this report) that focused specifically on translational studies (Cardona-Morrell, Rychetnik, Morrell, Espinel, & Bauman, 2010; Johnson et al., 2013; Kirk, et al., 2012). Cardona-Morrell (2010) concluded that modification of RCT approaches (e.g. shorter duration, delivery of group sessions instead of individual face-to-face counselling) for adaptation to real life practice made the lifestyle interventions feasible, affordable and replicable in clinical care settings despite barriers to implementation. However, the 'real life practice' interventions typically performed at about 30%-50% of the effectiveness of the original controlled efficacy trials. Johnson et al., (2013) also found the translational studies to be feasible and replicable in clinical care settings, and to show a strong trend towards weight loss, however their findings were limited in that only one study provided

¹³ Therefore it is not possible to infer that a uniform or even single set of intervention components might be best suited for all or any sub-group of overweight or obese people. No head-to-head comparisons could be made.

results beyond 12-months. Kirk et al. (2012) found that very few studies approach true translational research.

Still, others argue that this situation is not surprising as typically within the healthcare setting the process of translating research into evidence-based practice may take 15 to 20 years to occur (Akers, Estabrooks, & Davy, 2010). Akers et al. (2010) concluded that it was still unknown how effective weight loss maintenance interventions could be in real-world situations, such as clinical or community practice settings. Almost all of the reviews included in this report recommend that future research should focus on translational studies with long-term follow-up, however issues of resources and scale appear to be almost insurmountable for most research groups (long-term follow-up is extremely resource intensive and plagued by high attrition rates). Glasgow et al. (2004) caution that often behavioural interventions (in real-world settings) do not reach those who could benefit most, show reduced effectiveness over time, and do not address setting-related issues necessary to ensure institutionalisation and sustainability of content delivery at the organisational level (Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004). Furthermore, there has been little research in other ethnic groups (non-Caucasians/non-European) or on related factors (e.g. socioeconomic position, acculturation) that may interact with the effect of ethnicity and response to interventions (Middleton, et al., 2012). Without this knowledge, the field risks creating programmes that are helpful to some with the exclusion of others (Middleton, et al., 2012).

Weight loss maintenance (long-term care)

Frequent contact during the first several months of intervention, followed by less frequent but regular therapeutic contact for a longer time period, appears necessary for weight loss programme participants to adopt and enact behavioural self-regulatory skills and the problem solving of barriers that hamper sustained weight loss (Kirk, et al., 2012; Loveman, et al., 2011; Middleton, et al., 2012). Regardless of intervention mode (e.g. in-person group or individual, internet based, self-help) the interactive process appears to be crucial for skill development and sustained weight loss. It appears that weight loss programme participants must ultimately transition to reduced session frequency and probably other modes of contact besides face-to-face (e.g. mail, telephone, or internet), probably based on provider and/or consumer cost concerns and other competing demands (Gallagher, Armari, White, & Hollams, 2013). Programmes of long duration (24 months and beyond) are rarely available outside of clinical research trials and little is known about how participants fare beyond the supervised period of research trials. No study included in this review reported on how participants achieved a state of independence (although a small percentage of participants undoubtedly do). Venditti and Kramer (2012) conclude that "clearly, there is value in determining ways to extend intervention contact, and the clinical accountability and support that this affords" (p. 143) yet there appears to be no clear agreement on the most cost-effective ways to set up the infrastructure for continued lifestyle contact and how best to engage participation over longer periods of time. Venditti and Kramer (2012) predict that future efforts to build recognised training and provider networks and (scalable) programs with evidence-based track records will require considerable infrastructure support.

Harm

The scope of this report and the available evidence did not afford an in-depth analysis of potential harms and other unintended consequences; however a brief outline of the main related issues

follows. As previously outlined, a quite common finding in clinical practice and in self-directed weight loss attempts is the tendency for dieters to swing between weight loss and weight regain, the well-known 'weight cycling syndrome' (Santarpia, Contaldo, & Pasanisi, 2013). However, little is known about the longer term effects of unsuccessful and repeated weight loss and regain (Elfhag & Rossner, 2005). The main documented concerns relate to the potentially negative influence of weight fluctuations on the development of metabolic syndrome¹⁴ (Vergnaud et al., 2008), the loss of fat-free mass (FFM) (Elfhag & Rossner, 2005; Lee et al., 2010)¹⁵ and the possible psychological distress associated with failure (Foster, Sarwer, & Wadden, 1997; Petroni et al., 2007). These effects (described more fully below) may impact negatively on future weight loss attempts and future health-related quality of life outcomes. Some researchers consider that people who are following current public health recommendations are being repeatedly set up for failure (Hafekost, et al., 2013). It is also unclear which benefits are derived directly from weight loss itself versus certain behavioural mediators, such as the physical activity and/or the dietary changes commonly prescribed as part of lifestyle change programmes. At a basic level, uncontrolled weight cycling means that individuals are less likely to receive meaningful health benefits, as their body weight loss is not likely to be clinically significant for any meaningful period of time.

The most commonly investigated (potential) complication of obesity treatment is that uncontrolled weight cycling may negatively influence body composition. Some research suggests that dieting (at least without physical activity) may result in net losses in FFM (i.e. muscle mass). Beavers et al. (2011) studied the before-and-after body composition of 78 obese postmenopausal women who participated in a weight-loss programme and found that for each 1 kg fat loss during the weight-loss intervention, 0.26 kg of FFM was also lost, as shown by dual X-ray absorptiometry (DXA). Then, for those participants who cycled back into weight regain, every 1 kg of fat regained over the following 12 months was only accompanied by 0.12 kg of FFM (i.e. fat mass was regained to a larger extent than fat-free mass) thus facilitating the development of sarcopenic obesity¹⁶. Lee et al. (2010) conducted a similar study with 147 older weight loss programme participants and again found that proportionally, more lean mass was lost during the weight-loss period than was gained during the weight-regain period, especially in men. Lee et al. (2010) concluded that the difference in body weight between the top of the weight cycle and the starting point (i.e. failure to completely regain total weight) was mostly explained by a deficit in lean mass after the weight cycle. It may be more beneficial for the participants' health to achieve and maintain a lower level of weight loss instead of losing more weight and then regaining a substantial part of it (even when total weight loss is more). In any case, the importance of physical activity should be emphasised as Nicklas et al. (2009) and others (Ballor, Katch, Becque, & Marks, 1988; Kerksick et al., 2010) have shown that body composition changes are generally more favourable after a weight loss programme of diet plus physical exercise, compared to diet alone (the additive/protective effect of physical activity).

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¹⁴ A disorder of energy utilisation and storage, diagnosed by a co-occurrence of three out of five of the following medical conditions: abdominal obesity, elevated blood pressure, elevated fasting plasma glucose, high serum triglycerides, and low high-density lipoprotein levels (ICD-10, E88.9).

¹⁵ Lee et al. (2010) defined a weight cycle as weight loss of 3% or more with regain of within +/-3% of baseline weight for a period of 2 years.

¹⁶ Skeletal muscle mass divided by body height squared in meters (muscle mass index) that is below certain reference values from young, healthy individuals.

Santarpia et al. (2013) concluded that uncontrolled weight cycling that significantly impairs body composition (i.e. with a marked imbalance between FFM and fat mass) should be considered harmful for the patient and carefully prevented and avoided.

Another potential complication of obesity treatment is that weight fluctuations may increase individuals' risk for metabolic syndrome. In one study, Vergnaud et al. (2008) followed up 3553 middle-aged weight loss participants longitudinally over seven years and concluded that weight fluctuations (adjusted for relative weight change) are an independent risk factor for the metabolic syndrome (those with the most weight fluctuation were over two times more likely to develop metabolic syndrome than those with the least weight fluctuation). Paradoxically, many subjects without repeated weight fluctuations were also found to be at increased risk for metabolic syndrome, due to having the highest weight gain during follow-up (i.e. those who lost significant weight then rebounded straight back to or above baseline levels also had elevated risk profiles). Vergnaud et al. (2008) concluded that the results clearly support the benefits of weight stability and emphasise the importance of weight gain prevention starting from early adulthood. In other words, if a person embarks on a weight loss programme then it is crucial that he or she finds a level that is sustainable and stable over time and sticks to it, because cycling up from a lower weight may be more detrimental than cycles of smaller magnitude (Elfhag & Rossner 2005).

Finally, it is suggested that regaining more weight and weight cycling may potentially negatively impact psychological factors, which may exacerbate further weight regain. For example, Petroni et al. (2007) studied the psychological distress and weight history (number of dieting attempts/year, BMI increase and cumulative BMI loss since age 20) in 632 treatment-seeking, morbidly obese participants. The results indicated that weight cycling was a risk factor for binge-eating, depression, interpersonal sensitivity and reduced health related quality of life. Further study is needed into the psychological consequences of weight regain following an intervention and its ultimate impact on future weight loss attempts (Barte et al., 2010; Foster et al., 1997; Petroni et al., 2007). Taken together, these studies support the benefits of weight stability and emphasise the importance of weight gain prevention.

Predictors of programme attrition

The majority of weight loss intervention research identified focused appropriately on weight loss outcomes (and the resolution of obesity-related comorbidities) but the reports often neglected to discuss attrition rates and/or predictors of success/failure. Weight loss intervention attendance and completion should also be viewed as important (essential) outcomes, at least from a public health perspective. The degrees to which programmes facilitate attendance and promote and enable completion have major implications for real-world programme effectiveness and efficiency.

Attendance and completion have been shown to be positively correlated with weight loss outcomes (e.g., Gallagher, et al., 2013; Johnson, et al., 2013; Kirk, et al., 2012; Middleton, et al., 2012). The number of studies that have specifically examined the reasons for attrition in weight loss interventions is still fairly limited and an in-depth review of this body of evidence does represent a separate review topic (to that of effectiveness per se, the focus of this report). However, Moroshko, Brennan and O'Brien (2011) provide a useful overview of 61 studies that addressed factors associated with weight loss and programme attrition and the key points from this comprehensive systematic review are presented below.

Moroshko et al. (2011) describe the current attrition literature examining predictors of attrition such as weight loss intervention types, settings, study designs, obesity level¹⁷ (BMI class) and participants' background characteristics and demographic data. Up front, Moroshko et al. (2011) discuss an important key finding and serious limitation of the research base, that is, research on attrition in weight loss interventions has primarily examined demographic data routinely collected prior to initiation of the intervention, rather than variables that have been carefully selected for inclusion due to their theoretical relevance. The routinely collected demographic factors often include age, gender, marital status, occupational status, level of education, SEP and ethnicity. Other variables that were examined in the systematic review included: patients' initial weight status; patients' weight loss expectations; maintenance expectations; patients' weight loss self-efficacy; weight loss motivation; initial treatment response (i.e. early weight loss); age of onset of obesity; family history of obesity; weight cycling; hip and waist circumferences; obesity related quality of life; reasons for losing weight; number of previous dieting attempts; disturbed eating behaviour; binge eating; anxiety, depression and a range of other potential psychological predictors; physical activity; smoking status; alcohol consumption; a range of personality factors; and a need to pay for the treatment.

An obvious challenge therefore is making sense of the sheer number of often loosely defined predictor variables when attempting to compare one study to another¹⁸. Another complication is that most studies of weight loss interventions involve mixed populations¹⁹. That is, the programme participants typically span a wide range of baseline BMI and ages, and programmes commonly mix individuals with comorbidity (typically established type 2 diabetes, for example) with those without, and may or may not represent gender and/or different ethnicity groups explicitly. While this can be considered helpful in terms of study generalisability, most study populations are too small for meaningful sub-group analyses, and this seriously restricts the conclusions that can be drawn with respect to factors predictive of attrition. Stubbs et al. (2011) estimated that current models of weight loss or maintenance explain only 20–30% of the variance (therefore most of the variance in predictors remains unexplained). Similarly, Moroshko et al. (2011) conclude that (with respect to attrition) "a consistent set of predictors has not yet been identified" (p. 912). In other words, few reliable differences in pre-treatment patient characteristics are known between completers and non-completers.

Notwithstanding the limitations described above, Moroshko et al. (2011) did report some general trends in the literature. Their analysis suggested that the following factors may contribute to attrition: greater body dissatisfaction; poorer body image; more past dieting attempts; lower levels of physical activity; poorer mental health; lower self-efficacy and lower social support. In addition, practical issues, such as greater travel distance to the clinic, financial difficulties or the need to pay for the treatment, were also associated with attrition. Baseline BMI did not appear to be related to attendance and completion outcomes.

¹⁷ Subsequently, Barte (2014) concluded that behavioural interventions are generally equally appropriate across BMI classes.

¹⁸ The different interventions, settings, follow-up periods, degree of overweight also make it difficult to compare across studies.

¹⁹ With recruited samples still tending to be overrepresented by white, female, and middle-aged individuals.

Economics

The scope of this report does not include a specific focus on economics. However, many of the published reviews provide comment on economic considerations with respect to study design²⁰, specifically external validity and the avoidance of Type III error. Type III error in this situation refers to finding favour for interventions that could not reasonably, practicably or sustainably be implemented in a healthcare system. By nature, lifestyle or behavioural interventions are contingent on participant engagement and adherence to certain routines and behaviours, all of which require motivation. Several authors point to health system funding structures as critical determinants of programme success, although levels of out-of-pocket spending is seldom if ever considered as an active intervention component per se. For example, Rock et al. (2010) illustrate this point with their analysis of a popular commercial programme provided free using a voucher system, free prepared meals and financially incentivised weight loss consultations to 442 participating women. Rock et al. (2010) demonstrated extraordinarily high long-term adherence (92.1% of the study sample at 24months) and weight loss (7.4kg or 7.9% of baseline weight at 24 months) with the free programme. This can be compared to a previous cohort study (Finley et al., 2007) involving 60 164 enrolees in the same commercial weight loss programme (but not free and incentivised). In the Finley et al. (2007) study only 7% of participants remained engaged in the programme at 52 weeks. An important question is whether an obese individual enrolling in a similar unfunded non-incentivised structured commercial weight loss programme will achieve similar results to those in the Rock et al. (2010) style free programme. Most likely, the answer is no.

This apparent interaction between cost and programme adherence is potentially a serious threat to the generalisability of these findings to the average patient population. In the above example, Rock et al. (2010) concluded that their results *were* influenced in part by the economic benefits provided to the participants (providing food as well as reimbursement for participating in clinic visits) and that the low dropout rate in their study contrasts sharply with the high attrition rates reported among weight loss programme cohorts generally (Rock, et al., 2010). This conclusion is also put forward by Cardona-Morrell et al. (2010) in their systematic review and meta-analysis of lifestyle interventions. They questioned the feasibility and replicability of interventions delivered to high-risk adult patients in routine clinical care settings. Cardona-Morrell et al. (2010) found that in 10 out of the 12 trials (83%) of intensive lifestyle interventions studied, *no* charges or out-of-pocket expenses were incurred by participants for each session (and the influence of such subsidisation was not accounted for in the studies). Cardona-Morrell et al. (2010) cautioned that in the real-world, out-of-pocket expenses may lead to differential exposure to the intensity and duration of intervention – on the basis of participants' ability to pay.

Ability to pay should be considered alongside other predictors of individual level motivation, within the context of individuals' life circumstances. It is well established that affordability is a strong predictor of health service utilisation, particularly in primary care (Wagstaff & van Doorslaer, 2000). Few translational studies of lifestyle interventions for weight loss have been conducted in primary care settings that have been completely divorced from expert supervision and external research funding (subsidisation) and this limits the applicability of the evidence to real-world settings. That is,

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²⁰ Specifically, the way individual's treatment is funded within the study.

a 'proven' programme (in an efficacy trial) might in practice show poor health outcomes and health inequalities if out-of-pocket payment policies discourage people from using the specific services: even if those services are high quality and appropriate (Smith, Mossialos, Papanicolas, & Sheila Leatherman, 2009).

Policy makers generally appear to be concerned about the effects of healthcare financing arrangements on the receipt of healthcare but one major challenge concerns how to take account of *how* people finance their medical outlays and *when* they incur the costs (Smith, et al., 2009). Nutritional interventions may set up conflicting goals for programme participants in that nutrient-rich foods are more expensive than nutrient-poor foods and some low-income households might already have a negative-estimated-ability-to-pay (based on what is considered to be the minimum acceptable level of expenditure on food and perhaps other necessities) (Xu et al., 2003).

Another potential threat to the generalisability of these research findings is the degree to which individuals' *motivation* for change might be influenced by economic influences beyond *ability-to-pay*. Individual's motivation for health behaviour change is typically tempered by their own assessment of related costs and benefits (including opportunity costs). Many models of health behaviour change include (along with other variables) some form of internalised cost-benefit analysis in which individuals weigh and decide on a range of possible actions (Fishbein, 1979; Rosenstock, 1974; Ryan, 2009). Simply, individuals' behaviour is influenced not only by whether or not they can *afford it* but rather by whether or not they think it is *worth it*. It is not known if programmes imposing significant out-of-pocket expenditures are generalisable to primary care settings but higher cost interventions (higher intensity and duration) are associated with greater weight loss (Bogers et al., 2010). Patient cost sharing (co-payments) may introduce ability-to-pay and motivational barriers, especially for poorer populations.

Finally, Bogers et al. (2010) suggest that policy makers, clinicians and other health professionals should assess their choice to implement certain lifestyle interventions based on a detailed understanding of cost-effectiveness, in particular, the relationship between the designed *intensity* of an intervention²¹ and the expected weight loss outcomes (including duration). Bogers et al. (2010) carried out a cost-effectiveness analysis of 19 studies describing 31 lifestyle interventions for weight loss, carried out in healthcare settings. Bogers et al. (2010) found that higher intervention costs (of the lifestyle interventions) were associated with more weight loss by the participants after one year, however they cautioned that the association was clearly non-linear (**Figure 3**). At higher costs, the additional weight loss associated with extra investments levelled off dramatically²².

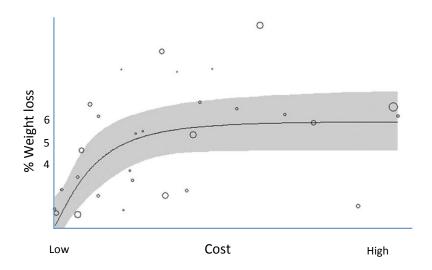
These findings may prove illustrative in highlighting interventions with either less or more weight loss after one year than may be expected by their costs: remarkable elements of the more (or less) cost-effective interventions may then be identified and perhaps replicated, modified or omitted in future interventions to improve their cost-effectiveness²³. However, the researchers stress that their study only considered weight loss after one year and the study provides no information on weight

²¹ And thus cost (cost can be regarded as a general measure of an intervention's intensity and vice versa).

²² A potential explanation for this finding may be that with increasing intensity, weight loss becomes more and more limited by physiological factors.

²³ See the original publication (Bogers et al., 2010) for a detailed analysis of the different interventions and their components.

loss maintenance beyond one year. Weight regain may occur, and although sustained weight loss might be possible, this likely entails additional costs and the relationship between cost and weight loss maintenance (long term) may be different (a different shape of the curve). Bogers et al. (2010) conclude that further research is recommended to establish the association between weight loss and costs in other population groups (e.g. those with comorbidities) to determine the optimal content of intervention programmes and the additional costs needed for the long-term maintenance of weight loss.



Adapted and simplified from Bogers et al. (2010)

Figure 3: Scatter plot between costs of interventions per person and the percentage of weight loss at 1-year

The above figure shows the scatter plot between cost of interventions per person and the percentage of weight loss 1-year after the start of the intervention, for an intention-to-treat analysis of 31 intervention groups in which the regression line with 95% confidence intervals is drawn (costs explained 47% of the variance in weight loss). The plot revealed that higher intervention costs were associated with more weight loss, but that with increasing costs the extra weight loss levelled off.

Note: costs are not directly shown here as these were calculated using Dutch reference prices expressed in 2007 Euros, and the estimated intervention costs likely differ from the actual costs incurred in other countries.

Settings

The studies included in this report were conducted across a range of settings variously described as: clinical research, primary care (GP's office), university out patient obesity clinics, hospital outpatient clinics or specialist medical clinics, supervised exercise facilities, gym-based, pharmacies, integrated healthcare organisations, public health clinics, community centres, church and YMCA, workplace, a shipboard setting, and commercial providers and programmes delivered within the home or via the internet.

It is a commonly-held belief that primary care physicians/practitioners are best placed to intervene in weight management (Booth, Prevost, Wright, & et al., 2014). Many national guidelines/recommendations (Ministry of Health Clinical Trials Research Unit, 2009; National Institutes of Health/National Heart Lung and Blood Institute, 1998; NHMRC, 2013; U.S. Preventive Services Task Force, 2012) identify primary care as central to the management and prevention of

obesity in the general population. Primary care practitioners are advised to screen all adults for obesity, and to spearhead individual and community-wide programmes to tackle overweight and obesity. In New Zealand, GPs or practice nurses are the intended provider-patient interface with primary care and the wider health system²⁴ (except in a medical emergency).

In the main, programmes have therefore been trialled in formats and settings that approximate those found in typical primary care settings. However, there have been relatively few studies of weight loss and weight loss management programmes that have been truly embedded sustainably within primary care practice (i.e. outcome evaluations of whole programmes rather than trials of interventions supported by researchers and research funding) even though this setting is the most commonly emulated. Also, some of the interventions that have been trialled have been particularly intensive and it could be argued that they moved beyond the primary care setting (or beyond what could be conceived as feasible within primary care such as home visiting and supervised exercise sessions) (Quigley, Brown, & Grant Schofield, 2012). Although general practice is the intended 'usual' portal to primary care in most health systems, unfortunately, it has been noted that conventional healthcare provided by GPs or primary care clinics does not yet seem sufficient in the proper treatment of overweight and obese patients, since many do not reach their treatment goals (Vegting, Schrijver, Otten, & Nanayakkara, 2014). Vegting et al. (2014) argue that it does not seem feasible to provide intensive coaching/treatment for the majority of patients at risk for overweight/obesity-related diseases within primary care (due to GPs already high workload, and the expected increase in chronic healthcare consumption generally).

Wadden et al. (2013) suggest that even though some studies have demonstrated that GPs and other trained health professionals, working together, can induce clinically meaningful weight loss in some patients, this finding does not necessarily mean that they can afford to provide such care. Other less expensive, equally effective weight loss interventions might be available (such as the option of having patients receive weight loss counselling via an internet programme or a face-to-face commercial provider). Wadden et al. (2014; 2013) assert that primary care practitioners' desire to offer lifestyle counselling in their practices would be a critical determinant of their adopting such a model. Yoong et al. (2013) suggest that interventions studied in primary care settings are often low intensity and in reality are reflective of real-world clinical practice, as primary care practitioners often face the need to deal with more acute issues and have less time to spend on delivery of lifestyle advice. Other researchers also question if the apparently high intensity of intervention required is sustainable in practice (Gallagher, et al., 2013; Johnson, et al., 2013).

The fact that interventions delivered in primary care have not been particularly effective to date does not necessary mean that primary care is the wrong setting to deliver weight loss interventions as routine care²⁵. Few interventions have targeted healthcare professionals' knowledge, skills, behaviour and systems, and substantial understanding is still required of features such as the patient journey, the funding pathways, patient/sector expectations and other links within the health sector

²⁵ Generally, there appears to be no logical argument put forward in the literature as to why primary care is not the right setting for the delivery of weight loss interventions.

²⁴ Funding of primary care services in New Zealand has a substantial private payment component (user charges or copayments) and a substantial government-funded component, depending on factors of the enrolled population, such as age, high-use, chronic condition, and geographical area.

(Quigley, et al., 2012). Barriers at the institutional level, health professional level and patient level must be known (Quigley, et al., 2012).

Everyone agrees that obesity is an important issue, and that there are major health consequences and costs associated with the growing prevalence of obesity, although popular views differ somewhat on issues of responsibility and the likely effectiveness of different interventions (Gendall et al., 2015). Nevertheless, most national guidelines (including NZ) identify primary care as central to the management and prevention of obesity in the general population. General practice appears to be the logical setting to deliver such care yet some suggest that such care appears to be beyond what could be conceived as feasible (Booth, et al., 2014; Cardona-Morrell, et al., 2010; Quigley, et al., 2012; Tsai & Wadden, 2009; Wadden, et al., 2014; Yoong, et al., 2013). Vegting et al. (2014) conclude that reorganisation of the healthcare system (in this area) with the aim of increasing efficiency using novel and innovative methods seems necessary. If there is a better care setting than general practice (for example, disease management clinics, specialist clinics, commercial settings) then the evidence base does not make clear exactly which setting this might be.

Section summary

This section provided an in-depth examination of the evidence by considering the broader aspects that relate to programme utility or generalisability, or applicability to the real-world problem of overweight and obesity treatment in primary care. The discussion summarised issues related to clinical significance, the challenges of translational research, long-term care, potential harms, predictors of attrition, economics, and settings. These aspects go beyond outcome and 'what' can be achieved, and endeavour to inform the debate around 'how' (how might current barriers be overcome). The above discussion section flags a number of significant issues yet to be resolved²⁶.

Internet-based, mobile phone and self-directed interventions for weight loss and weight loss maintenance

The evidence base

A large number of internet-based, self-directed weight-loss interventions have been evaluated and reported in the literature including a variety of weight loss and weight loss management tools delivered in various formats. While the searching and selection employed in the balance of this report covered publications from 2008-present, this sub-topic (i.e. internet-based interventions) was restricted to data published in the last five years only (2010-2015). This truncated date range was selected to improve the relevance of findings, due to the rapid advancement of technology in this field (in particular the rapid increase of smartphone and mobile device usage and capability and the rapidly increasing availability of health-related third-party applications, all contributing to a shift towards mobile connectivity for many people). As a guide to the evidence included in this report, the systematic reviews (all published in 2014), are listed below in chronological according to their respective search/publication date ranges (illustrated in **Figure 4**).

More than 20 systematic reviews were identified as relevant to this report including the large and comprehensive *review-of-reviews* by Tang, Abraham, Greaves and Yates (2014). Tang and colleagues

²⁶ In particular the system-level supports necessary for programme implementation.

employed a systematic method of literature searching and selection in the preparation of their review, and the inclusion criteria specified any behavioural or psychoeducational intervention using web-based or other telehealth applications, published in English between 2000 and 2012. The broad scope specified in Tang and colleagues' review resulted in the inclusion of a wide range of self-directed interventions, including interactive websites, smartphone applications, and SMS (text) messaging (**Figure 5** provides a brief evidence-based summary of the findings, and more detail is provided on p.102). Tang and colleagues' review summarised 20 identified systematic reviews covering 99 primary research studies (not all of which were relevant to this report). Given the comprehensiveness of Tang and colleagues' work, only the more recent reviews that further extend Tang and colleague's search/publication period have been included in this report. In addition to these five reviews, 13 earlier reviews (pre 2014) were also identified and have been briefly summarised in **Figure 10** (p.106) but they do not feature in the evidence synthesis below. This reporting strategy provides for concise and adequate coverage of the literature from 2000-June 2014.

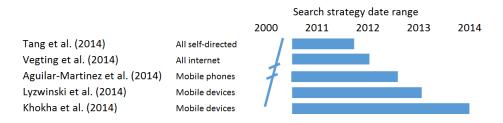


Figure 4: Search/publication date range of the five included reviews

Summary of the five systematic reviews of internet-based, mobile phone and selfdirected interventions for weight loss and weight loss maintenance

The use of mobile electronic devices has gained popularity in recent years as a delivery format to facilitate and maintain weight loss among overweight and obese populations. There is modest evidence for the effectiveness of mobile phone interventions, at least in short-term weight-loss programmes, but little is known about long-term outcomes. Mobile electronic devices have the potential to mimic traditional face-to-face healthcare provider interactions, providing a potentially cost-effective and convenient alternative. Mobile electronic devices may also be used to provide additional intervention components not possible within the limitations of the traditional in-person contact, such as real-time feedback, scheduled and random prompts/reminders and social networking. As mobile electronic devices continue to increase in popularity and the associated technology continues to advance, the potential for their use in weight loss interventions is enormous, but the extent to which mobile electronic devices are more effective than usual care methods is still being debated. The evidence suggests that mobile electronic interventions can independently promote weight loss and/or can augment interventions involving traditional inperson contact. However, when used as standalone interventions, mobile electronic interventions appear to be less effective than in-person treatment and the resultant weight loss may not reach clinical significance. Attrition rates are often high suggesting that these types of interventions may have diminishing appeal over time. Few, if any, trials have specifically set out to evaluate mobile electronic interventions for weight loss maintenance after an initial weight loss period. One of the

potential benefits of using mobile electronic interventions is that they may enhance or support the long-term effectiveness of multi-component interventions (via prompts and feedback for example) but this remains untested. The use of mobile phone-based interventions also gives rise to the possibility of efficient tailoring of interventions (intervention components) to different languages, settings, literacy levels, ethnic, or otherwise culturally specific groups across populations of varying socio-economic position. However, most studies to date have been conducted only in overweight/obese Caucasian/European populations and tailoring interventions to specific populations and sub-populations remains largely untested. No translational research was identified and from that perspective, mobile electronic intervention research is still in its infancy as most available evaluation studies are modest pilot or efficacy trials.

The use of mobile phone-based interventions and mobile communication technology is rapidly expanding in healthcare and the identified interventions utilised a wide range of intervention components (either singularly or in combination). Despite two recent systematic reviews specifically including a content analysis (Lyzwinski, 2014; Tang, et al., 2014), it is not possible to infer which techniques or delivery modes are most strongly associated with increased weight loss for whom and in what contexts. Further studies using large samples with long-term weight loss follow up and cost-effectiveness analyses are needed before recommendations for practice can be made.

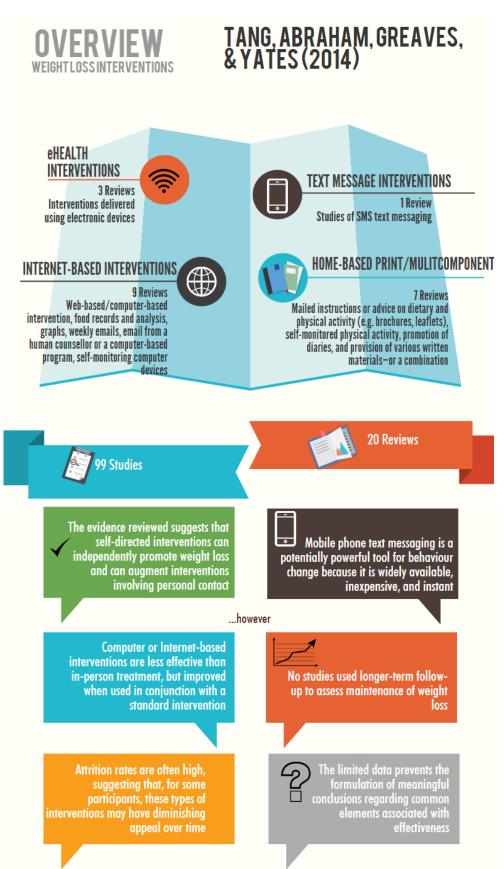


Figure 5: Overview of self-directed/internet weight loss interventions based on findings by Tang et al. (2014)

Commercial weight management programmes for weight loss and weight loss maintenance

The New Zealand Clinical Guidelines for weight management in New Zealand recommend "referral to professional and community providers" for overweight and obese patients ready to engage in interventions to promote weight loss (Ministry of Health Clinical Trials Research Unit, 2009). Due to the large number of overweight and obese adults in New Zealand, it is unlikely that there are a sufficient number of publicly-funded services able to provide these interventions to all who need them. One possible solution is to consider referring patients to commercial weight management programmes. However, it is important to first be confident that these services provide an effective intervention for participants.

Recent systematic reviews and meta-analyses that investigated the outcomes of a range of branded weight loss programmes have found that participation resulted in statistically significant weight loss after 6 and 12 months (Atallah et al., 2014; Gudzune et al., 2015; Johnston et al., 2014). Compared with overweight or obese participants in a control group, those attending Weight Watchers™ or Jenny Craig™ had a significantly greater mean weight loss (95% CI 3.5 to 6.4kg after 12 months) and/or percentage body weight loss (95% CI 2.6 to 4.9% after 12 months). No longer-term outcomes were reported. These reviews also included several other branded weight loss programmes, however these are not relevant to the current review as some were self-directed diets (e.g. Atkins, Zone), or programmes not commonly available in New Zealand (e.g. Nutrisystem, Rosemary Conley Diet and Fitness Club, Volumterics). Evidence from two systematic reviews including very low- (<800 kcal/day) or low-calorie (<1200kcal/day) meal replacements (e.g. Optifast) suggests that this type of dietary regime can be effective for significant short-term weight loss, however side effects may be more common among users of these products, and weight loss is not often sustained long-term (Asher, Burrows, & Collins, 2013; Gudzune, et al., 2015) (see Appendix D, **Table 7**, for more detail).

Due to the burden of overweight and obesity on the UK health system, the NHS has formed partnerships with commercial weight management organisations (e.g. Weight Watchers) to offer weight management services (Ahern, et al., 2011). Most often this has consisted of referrals from primary care practitioners to 12 free weekly programme sessions. These partnerships have been found to be a practical and modestly effective option (Ahern, et al., 2011; Dixon, Shcherba, & Kipping, 2012; Jebb et al., 2011; Jolly et al., 2011; Madigan, Daley, Lewis, Jolly, & Aveyard, 2014; R. J. Stubbs et al., 2012; R. J. Stubbs, Pallister, Whybrow, Avery, & Lavin, 2011) (see Appendix D, **Table 8** for more detail), and studies have shown that participants lose, on average, 3-5% of their initial bodyweight over 12 weeks (Ahern, et al., 2011; Dixon, et al., 2012; R. J. Stubbs, et al., 2011). Two RCTs investigated weight outcomes after 1 year and found that patients randomised to attend Weight Watchers for free for either 12 weeks (Jolly, et al., 2011) or 1 year (Jebb, et al., 2011) lost significantly more weight (≈2.4-2.8kg) than those receiving standard care.

In most of these studies, initial uptake and regular attendance was poor, with just over half of participants attending the majority or all of the sessions (Ahern, et al., 2011; Dixon, et al., 2012; Lavin et al., 2006; R. J. Stubbs, et al., 2011). However, session attendance appears to be a crucial factor, as many of these evaluations found that attendance was significantly associated with weight loss (Ahern, et al., 2011; Dixon, et al., 2012; R. J. Stubbs, et al., 2012; R. J. Stubbs, et al., 2011). Most studies do not provide any detail on why participants did not take up, attend, or complete the

programmes, however Lavin and colleagues (2006) found that participants who took up the referral to a commercial weight management programme were significantly more likely to be older, have higher income, and regard weight loss as important. In addition, those who attended more often (i.e. 10 of the 12 sessions) were significantly more likely to be Caucasian, aged between 50 and 60 years, and to report no financial worries in the few weeks prior to recruitment.

Furthermore, far fewer males than females took up these referrals to commercial weight management programmes (Ahern, et al., 2011; Dixon, et al., 2012; Jebb, et al., 2011; Jolly, et al., 2011; Lavin, et al., 2006; R. J. Stubbs, et al., 2012; R. J. Stubbs, et al., 2011). In order to ensure equity of access, further research is needed to increase referral rates for men and to establish why men do not engage with these types of programmes (Dixon, et al., 2012). These limitations are not unique to commercial weight management programmes however, and similar to those experienced in non-commercial programmes (Ahern, et al., 2011). The extent to which primary care practitioners typically play a role in monitoring patients participating in commercial programmes is not clear. Continued regular contact and discussion with the patient after the referral has been made may increase participation, and would provide the opportunity to assess the suitability of the programme for the individual.

An important consideration for referral to commercial weight management programmes is price for participants. In the research studies mentioned above, commercial services have been offered to participants free of charge. It could be assumed that uptake and participation would be lower if participants had to cover the programmes costs themselves, as some individuals may not be able to meet the continued costs of programme attendance. This then becomes an issue of equity, as those who need to use the services most may be the least likely to be able to afford them.

From a healthcare expenditure perspective, the economic feasibility of subsidised referrals to commercial weight management programmes has been investigated. Findings from an RCT comparing standard care (weight loss advice from a primary care practitioner, once a month, on average) with referral to a commercial weight management programme (i.e. Weight Watchers) in Australia, the UK, and Germany, indicated that the commercial programme was more cost effective over one year (Fuller et al., 2013). A meta- and cost-effective analysis comparing three commercial weight loss programmes (Weight Watchers, Jenny Craig, and Vtrim) and three weight loss medications found that despite less weight loss, Weight Watchers was the most cost-effective intervention (Finkelstein & Kruger, 2014). It also concluded that Jenny Craig was prohibitively expensive, due to the need to buy all pre-packaged meals.

There are a wide range of commercial weight management services available, however, only a small number have been formally evaluated. These tend to be programmes from large, (sometimes) multinational organisations, often based in the UK or USA. The effectiveness of the remaining majority has not been rigorously evaluated, and this is particularly true of services available in New Zealand, where services may have been developed locally, or are relatively new (e.g. commercial online weight management programmes). Therefore, it is difficult to recommend particular programmes. Where there are a range of services available, it may be possible to identify programmes which may be more likely to be effective by assessing the content and implementation of each programme (see later section discussing characteristics associated with increased effectiveness among interventions for weight loss and weight loss maintenance).

Due to the increasing need for weight loss interventions, and a lack of publicly-funded options available at present to meet this demand, it seems that it might be practical for primary care practitioners to recommend commercial weight loss programmes to patients in some circumstances, as has been done in the UK. However, this presents a challenge as many commercial programmes available in New Zealand have not been evaluated robustly, and those that have, have not been assessed over the long term. Therefore, the role of healthcare professionals may be to guide patients towards programmes that encompass best practice components and provide follow-up to patients to ensure the programme's suitability and effectiveness and patient's compliance at an individual level.

Interventions for weight loss and weight loss maintenance conducted in Aotearoa New Zealand

Most of the studies included in the reviews of weight loss interventions described previously were based in the USA, Canada or Europe. The broad characteristics of these interventions appear generalisable to a New Zealand setting²⁷, however the specific resources or activities within each intervention may require tailoring. To gain an understanding of interventions designed and undertaken specifically in the New Zealand context, findings of these interventions are discussed separately here²⁸. Primary care-based interventions which are currently available to patients in the Canterbury, West Coast and South Canterbury DHB regions (i.e. Appetite for Life and GRx) are described in greater detail. Overall, published New Zealand-specific research is sparse, including that of provider behaviours, programme design, implementation, and patient outcomes, especially over the long term.

Combined dietary, physical activity and behavioural interventions

Lifestyle programmes

Appetite for Life²⁹ is a 6-week weight management and healthy lifestyle programme that promotes lifestyle change, rather than dieting. The programme is delivered in the primary care setting by trained facilitators, and includes education sessions and food tastings. An evaluation of the programme found that after 12 months, while there were significant positive changes in self-reported dietary and exercise behaviours, there was no significant change in weight or waist circumference (L. Cutler, King, McCarthy, Hamilton, & Cook, 2010). The programme facilitators (practice nurses) felt that the positive outcomes of the programmes were due to the practical advice, food tastings, effective group dynamics, local delivery, and support from nutritionists. Initially, the programme was aimed at women, however there are now courses for men, as well as tastings including more culturally diverse foods, programmes presented in non-English languages, follow-up groups, and training for more Māori and Pacific facilitators.

In another programme, a pilot type 2 diabetes prevention intervention delivered by community health workers was trialled among Māori. The programme included tailored support for participants

²⁷ Some differences in funding models and system organisation may be relevant, including out-of-pocket charges/co-payments.

²⁸ This approach differs from that used in the balance of this report, whereby only review-level studies are described, and not individual studies.

²⁹ http://www.appetiteforlife.org.nz/

to achieve specific lifestyle goals (e.g. increase fibre intake, improve muscle strength) (Simmons, Rush, Crook, & Te Wai o Rona: Diabetes Prevention Strategy, 2008). Health workers kept in touch with participants using a personal digital assistant (PDA), goals and activities were built around community preferences, and family members were included. Participants took part in the study for approximately 6 months on average, and statistically significant weight loss (1.3kg, SD 3.6kg, p<0.001) occurred during the study period.

Mobile and web-based weight loss programmes

Gorton and colleagues (Gorton, Dixon, Maddison, Ni Mhurchu, & Jull, 2011) designed a tailored 8week weight loss intervention after first conducting a telephone survey of 306 randomly selected New Zealanders from a northern urban city and rural area. Three quarters of Māori and 65% of non-Māori participants stated that they would use a weight-loss intervention delivered by mobile telephone, particularly younger respondents, and those living in rural areas (Gorton, et al., 2011). These findings were also supported by data collected from focus groups with 54 purposively selected participants, who indicated that tailored interventions, and the opportunity for social interaction and support, were regarded as desirable features of an intervention (Gorton, et al., 2011). The 8week weight loss intervention was developed using behaviour change techniques that consisted of mobile telephone text messages, a hard-copy toolkit, use of a pedometer, and an interactive website (Ni Mhurchu et al., 2014). Sixty eight percent of the 53 overweight or obese participants (14 Māori, 18 Pacific) completed the non-randomised feasibility study, and there was a significant mean weight loss (1.0kg, SD 3.1, p=0.024), and decrease in BMI (-0.34kgm², SD 1.1, p=0.026) after 12 weeks. Feedback was largely positive, and the most liked features of the programme were goal setting, and step count recording. It was acknowledged that attrition was relatively high (particularly among younger, male and Pacific participants), and the engagement of some participants was low. Increased personalisation and additional features (for example, real-time feedback) were suggested as ways to increase engagement and retention.

Aspire for Life³⁰ is a commercial online healthy lifestyle programme developed by Plant & Food Research. It is a 12-week programme and includes personalised food plans, online support from dietitians and personal trainers, recipes and information, and self-awareness tools. Although research has been conducted on this programme, no published documents on this intervention could be sourced.

Weight maintenance programmes

Only one New Zealand study was identified that specifically evaluated the effectiveness of an intervention designed to prevent weight regain after initial weight loss (Dale, Mann, McAuley, Williams, & Farmer, 2009; Dale et al., 2009). Following self-directed weight loss (e.g. by dieting or using a commercial weight loss programme), 200 females were randomised to one of two diet regimes with either nurse-led follow-up consisting of fortnightly weigh-ins (5-10 minutes) and telephone support (\approx 10 minutes), and monthly support groups, or an intensive support programme based on the Finnish Diabetes Prevention Study (DPS) (11, 35-minute sessions with nutrition and activity specialists, and subsidised physical activity sessions, \$NZD2 per session, over a two year

³⁰ http://www.aspireforlife.com/PageContent.asp?PID=1

period. Although the focus was on weight maintenance, participants lost, on average, approximately 2kg over two years. There was no statistically significant difference in weight, BMI, waist circumference, FFM or fat mass between those randomised to the nurse-led support option and the intensive support programme after two years. While attendance at the subsidised supervised physical activity sessions in the intensive programme was poor (47% attended regularly in the first year and 28% in the second year), attendance at the support sessions was high (93% attended all sessions in the first year, and 87% attended all in the second year). In the nurse-led group, attendance at regular weigh-ins with nurse facilitators was also high (89% in the first year and 85% in the second year), though fewer took up the telephone calls (67% in the first, and 65% in the second year) or attended the support group (24% in the first, and 21% in the second year). Many participants reported that the success of these weigh-in sessions was due to the enthusiastic support of the nurse facilitator in person and over the telephone. This study indicates that women were able to maintain previous weight loss over 2 years with the support of a nurse-led support programme using frequent face-to-face contacts. It could be extrapolated that this relatively inexpensive approach to weight maintenance could be incorporated into the primary care setting with the support of some additional nursing resource.

Dietary interventions

Diet composition weight loss and weight loss maintenance programmes

The effectiveness of diets of differing macronutrient compositions at achieving weight loss has been assessed with New Zealand-based RCTs. In agreement with systematic reviews mentioned previously, an RCT of 419 participants with type 2 diabetes found an energy-reduced low-fat diet, with either increased protein or carbohydrate, resulted in similar modest losses in weight (2-3kg, p<0.001) and waist circumference (2-3cm, p<0.001) after the 1-year intervention and a further 1-year follow-up (Krebs et al., 2012).

Among Māori participants at risk of type 2 diabetes, those randomised to a high protein diet (n=28) for 8 weeks followed by an 8-week maintenance phase had significantly lower weight (-2.6kg, 95% CI -4.4 to -0.8kg, p=0.004), waist circumference (-3.0cm, 95% CI -5.7 to -0.2cm, p=0.034) and fat mass (-1.6kg, 95% CI -3.0 to -0.3kg, p=0.018) than the control group (n=25) over 6 months (Brooking, Williams, & Mann, 2012). Participants randomised to a high carbohydrate, high fibre diet (n=31) also showed significantly lower weight (-1.9kg, 95% CI -3.7 to -0.1kg, p=0.038) compared to the control group, however there was no significant difference for waist circumference (-0.5cm, 95% CI -3.0 to 1.9, p=0.668) or fat mass (-0.7kg, 95% CI -2.1 to 0.7cm, p=0.297). There was no significant difference between the BMI of those randomised to the control group and either the high protein diet (-0.7kgm², 95% CI -1.3 to 0.0kgm², p=0.065) or high carbohydrate, high fibre diet (-0.6kgm², 95% CI -1.2 to 0.0 kgm², p=0.069). Findings suggest that there were differences in adherence to each of the intervention diets. While participants in the high protein diet group reported significantly higher protein intakes during the intervention than at baseline, those in the high carbohydrate, high fibre diet group reported significantly higher carbohydrate, but not fibre intakes. Protein intake was also significantly higher than baseline among those in the high carbohydrate, high fibre diet group. Therefore, it may be that the high protein diet was more acceptable and easier to adhere to over an extended period for these participants. This study used a kaupapa Māori approach, including

community consultation, research conducted by a Māori researcher, and a focus on recommending traditional foods.

A further RCT with 113 obese participants found that a high fibre diet (from increased intake of pulses and low glycaemic index wholegrain products supplied for free) resulted in a statistically greater reduction in waist circumference compared to a control diet (standard New Zealand dietary guidelines) after 18 months (mean difference between groups -2.8cm, 95% CI -5.1 to -0.4cm) (Venn et al., 2010). However, there was no significant difference between groups in terms of weight (mean difference -2.2kg, 95% CI -4.8 to 0.4kg) or BMI (mean difference -0.8kgm², 95% CI -1.7 to 0.2kgm²) after 18 months.

In a weight loss maintenance study mentioned above (Dale, Mann, et al., 2009; Dale, McAuley, et al., 2009), female participants were randomised to either an individually prescribed high-carbohydrate or high monounsaturated fat diet with regular support over 2 years. Participants lost, on average, approximately 2kg, and there was no statistically significant difference between participants randomised to either diet regime after two years in terms of weight (0.7kg, 95% CI -1.1 to 2.4, p=0.46), BMI (0.2kgm², 95% CI -0.4 to 0.9kgm², p=0.51), waist circumference (0.3cm, 95% CI -1.5 to 2.1cm, p=0.77), FFM (0.4kg, 95% CI -0.3 to 1.1kg, p=0.31) or fat mass (0.5kg, 95% CI -0.9 to 2.0kg, p=0.47).

Intensive dietary advice and support

Participants with type 2 diabetes and persistent hyperglycaemia (despite optimised pharmaceutical treatment) were randomised to receive either individualised intensive dietary advice and monthly sessions with a dietitian (based on the Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes (Mann et al., 2004), (n=52) or usual care (n=52) over 6 months (Coppell et al., 2010). At the end of the intervention period, compared to usual care, those in the dietary intervention group had significantly lower weight (mean difference -1.3 kg, 95% CI -2.4 to -0.1kg, p=0.032), BMI (mean difference -0.5kg/m², 95% CI -0.9 to -0.1kg/m², p=0.026), and waist circumference (mean difference -1.6cm, 95% CI -2.7 to -0.5cm, p=0.005). Retention was high (90%), and the authors suggest this could be due to the tailored nature of the dietary advice, flexible dietary patterns possible within the recommended macronutrient guidelines, and motivation of participants.

Physical activity interventions

Some of the physical activity interventions included in this section are not necessarily weight loss programmes, however physical activity is an integral part of the multicomponent approach to weight loss, therefore these studies they have been discussed here with reference to the weight loss outcomes reported in the studies.

Green Prescription

GRx began in 1998 and is perhaps the longest running and most researched physical activity promotion intervention in New Zealand. The initiative was transferred from Sport and Recreation New Zealand to the Ministry of Health in 2009. GRx involves health professionals (GP or practice nurse) providing brief counselling using motivational interviewing techniques to patients who are physically inactive, to increase physical activity. While GRx is not specifically framed as a weight-loss

intervention, research suggests that over half of participants engage in the GRx programme for weight loss purposes (Research New Zealand, 2014). The details of the exercise advice are written or issued electronically, and if the patient wants ongoing support, the script is forwarded to the nearest GRx community-based Patient Support Person³¹ (Ministry of Health, 2014b). The Patient Support Person encourages the patient to become more active through monthly telephone calls for 3-4 months, face-to-face meetings for 3-4 months, or group support in a community setting for 3-6 months. The patient's progress is reported back to the referring health professional. Further scripts can be issued by the health professional if the patient feels they would benefit from ongoing support. The programme has been evaluated at two levels: provider (e.g. utilisation, barriers, attitudes) and patient (e.g. satisfaction, physical activity levels, weight loss).

Provider-level research

A recent nationwide survey of randomly-selected patients (n=2,858) given a GRx in 2013 found that the main reasons patients were issued a GRx were weight problems (54%), hypertension or risk of stroke (28%), arthritis (25%), back pain or problems (23%), high cholesterol (22%), and stress (20%) (Research New Zealand, 2014). Many respondents reported positive changes in their health (72%), spending more time being active (61%), and encouraging others to be more active (61%), since being prescribed a GRx.

GP experiences of administering the GRx have also been investigated in New Zealand. GPs prescribed the GRx for both primary preventive (e.g. weight control) and secondary management (e.g. type 2 diabetes management) purposes (Patel, Schofield, Kolt, & Keogh, 2011). GPs reported the benefits of the GRx were that it was a non-pharmaceutical approach to a healthier lifestyle as well as the additional benefits related to physical activity. The primary barrier to GRx use by GPs was perceived time constraints within the consultation. Time constraints were also identified as a barrier to use when the GRx was first introduced (Gribben, Goodyear-Smith, Grobbelaar, O'Neill, & Walker, 2000; Swinburn, Walter, Arroll, Tilyard, & Russell, 1997). GPs identified chronic health conditions, fear of injury, transportation constraints, set routines and lack of confidence as being barriers that some of their older patients have encountered when considering whether to become more physically active and, also, when engaging in actual physical activity (Patel, Kolt, Keogh, & Schofield, 2012).

Several New Zealand analyses have concluded that using the GRx in primary care settings is a cost-effective way to deliver counselling to increase physical activity levels (Dalziel, Segal, & Elley, 2006; Elley et al., 2011; Elley et al., 2004; Foley, Maddison, Jones, Brown, & Davys, 2011; Leung et al., 2012). These findings are further supported by a systematic review of international cost-effectiveness studies based on RCTs to increase adult physical activity that were based in primary healthcare or the community (Garrett et al., 2011).

Patient-level research

Several RCTs in New Zealand have assessed the effectiveness of the GRx among adults, and found that receiving a GRx was associated with increased physical activity and improvements on some quality of life measures compared to usual care after 1 year (Elley, Kerse, Arroll, & Robinson, 2003;

³¹ Support staff typically work within regional sports trusts.

Kerse, Elley, Robinson, & Arroll, 2005; Lawton et al., 2008) and 2 years (Lawton, et al., 2008), or verbal-only recommendations after 6 weeks (Swinburn, Walter, Arroll, Tilyard, & Russell, 1998). However, the difference in leisure physical activity levels between GRx and control groups after 1 year was small (34-40 minutes per week) (Elley, et al., 2003; Kerse, et al., 2005), and it was estimated that only (approximately) 10% of people who participated in the GRx achieved 150 minutes of at least moderate intensity physical activity a week³² after 1 year (Elley, et al., 2003). In the two RCTs where weight outcomes were assessed (Elley, et al., 2003; Lawton, et al., 2008), there was no statistically significant difference in BMI (mean difference -0.1kg/m², 95% CI -0.2 to 0.1kg/m², p=0.5), weight (p=0.6), or waist circumference (p=0.7) between those receiving the GRx or usual care. Another RCT found that providing participants with a pedometer in addition to a GRx was more effective at increasing physical activity levels than the GRx alone (the significant difference in leisure physical activity was 13 minutes per week, p<0.001), but showed no significant effect on BMI (difference between groups was 0.6kgm², p<0.06) (Kolt et al., 2012). Further, it has been shown that participants who chose to attend a 90-minute weekly community-based physical activity and education session for 10 weeks undertook more physical activity after 1 year compared to those who chose to have a 15-20-minute telephone consultation every 4-6 weeks for 4 months (Marshall et al., 2013).

Unfortunately, most interventions either did not report the ethnicity of participants (Kerse, et al., 2005; Marshall, et al., 2013; Swinburn, et al., 1998), only reported the percentage of participants of European ethnicity (Elley, et al., 2003; Kolt, et al., 2012), or recruited relatively few Māori participants (Lawton, et al., 2008). This makes it difficult to assess the effectiveness and acceptability of the GRx for Māori and to identify factors that may improve the effectiveness of the GRx for this population group. One study, however, recruited 24% Māori and 26% Pacific participants (Foley, et al., 2011). This study investigated the relative effectiveness of monthly phone calls versus weekly face-to-face community-based support group meetings over 3-4 months as part of the GRx. Participants could choose the mode of delivery depending on their personal preference, and most (92%) chose the community support option. Participants receiving community support reported significantly more days of physical activity per week compared to those receiving phone support (3.7 versus 2.7 days, 95% CI 0.3 to 1.7 days, p=0.0006), and a greater proportion of participants receiving community support (66%) were "very satisfied" overall with their mode of delivery compared to phone support (41%). A greater proportion of Māori and Pacific participants chose the community support option rather than telephone support. The authors suggest that this "may be due to the emphasis on face-to-face contact, social support, collective involvement, and participation, which is more culturally appropriate" (Foley et al., 2011, p. 52). The greater engagement of Māori and Pacific participants in the community support mode highlights one benefit of providing a choice of delivery options to patients so they can choose a programme based on their personal needs and preferences.

Some of the studies included follow-up telephone calls and face-to-face visits in addition to the monthly support for 3-4 months which is standard practice for the GRx in a primary care setting (Elley, et al., 2003; Foley, et al., 2011; Lawton, et al., 2008). Therefore, the outcomes may be greater

³² The New Zealand Ministry of Health recommends adults partake in at least 30 minutes of moderate-intensity physical activity at least five days a week Ministry of Health. (2014a). How much activity is recommended? Retrieved 13 February 2015, from http://www.health.govt.nz/your-health/healthy-living/food-and-physical-activity/physical-activity/how-much-activity-recommended.

than would be seen in the general population. In addition, in these interventions, a large proportion of participants were older adults (≥65 years), which makes the extrapolation to younger age groups less clear.

Some studies reported potential adverse outcomes of receiving a GRx. While two found no statistically significant difference in the percentage of participants experiencing falls or injuries between groups (Elley, et al., 2003; Kerse, et al., 2005), another found a higher prevalence of injuries and falls in the group receiving the GRx (Lawton, et al., 2008). While it is not clear why these studies showed differing results regarding adverse outcomes, the occurrence of activity-related injuries and falls highlights the need for thorough patient assessment prior to engaging in a new physical activity regime, support via instructor-led activities, and regular monitoring in the primary care setting.

Several studies indicated that there was significant drop-out between GRx referral and registration – for example, in one study only 32% of referrals registered with the GRx programme (Foley, et al., 2011). However, there was little discussion of the reasons for low uptake of the GRx. Therefore the factors that contribute to the low rate of uptake need to be explored, as well as how any barriers could be addressed.

A systematic review of primary care-initiated supervised exercise programmes found programme compliance was typically poor (Williams, Hendry, France, Lewis, & Wilkinson, 2007). Qualitative studies within the review identified personal barriers to participation (e.g. lack of self-efficacy, poor body image, poor time management, and lack of social support), as well as programme barriers (e.g. intimidating environments, inadequate supervision, and inconvenient exercise centre opening hours). The recent New Zealand survey (mentioned previously) of randomly selected patients given a GRx (n=2,858) found that 17% of respondents were temporarily not following their GRx, and a further 14% were no longer following their GRx (Research New Zealand, 2014). No longer following their GRx was significantly more common among young people (<25 years), students, and those who felt dissatisfied with the GRx service. The main reasons for not following their GRx (either temporarily or permanently) were injury or health problems (33%), lack of time due to family responsibilities (19%) or work (17%), lack of energy (17%), and it being too difficult to stick to a routine (11%). In a small qualitative study, interviews conducted with 15 sedentary adults who had been given a GRx found that a personalised approach was needed, as was continued structured external support (acknowledging the role of primary care practitioners, other health and exercise professionals, the role of significant others and social interaction), and the need to focus on barriers and enabling factors (Elley, Dean, & Kerse, 2007). Barriers included weather, physical environment, time, and health and psychological limitations, while internal motivators included immediate or long-term benefits, and guilt.

Patient attitudes to the GRx have been explored using qualitative and quantitative approaches. In the nationwide survey (mentioned previously), most patients were satisfied (or very satisfied) with the support service provided to them (Research New Zealand, 2014). The most common reasons for satisfaction were that the support provided was encouraging and helpful (33%), motivated the patient to be more active (17%), had noticed improved health (16%), thought the advice was useful (13%), and received follow-up contact (10%). In a qualitative study, Tava'e and Nosa (Tava'e & Nosa, 2012) conducted interviews with 20 Pacific women who had been part of a GRx programme in Auckland and Counties Manukau. The participants indicated they had positive experiences of the

GRx programme which could be attributable to the social and friendly atmosphere created by their peers and staff, the different exercise options, and the education workshop components. The main reason the women enjoyed and completed the programme was the social aspect.

Prescribed exercise training

There was no significant differences in weight, BMI, waist circumference or body fat between morbidly obese Māori and Pacific participants with type 2 diabetes who were randomised to either resistance training (n=13) or aerobic training (n=13) three times per week for 16 weeks (Sukala et al., 2011). There were also no differences in these measures between baseline and the end of the exercise programme. It has been stated that physical activity implementation strategies among Māori and Pacific participants should focus on cultural awareness and techniques to enhance participation and compliance (Sukala et al., 2012). One aspect is the use of a training venue that "preserves cultural and ethnic identities". While a community centre, marae or church may provide an appropriate venue for meetings or gatherings, they may not always be ideal for physical activity programmes. This trial demonstrated that a commercial venue was a feasible site for training, and the venue provided an environment where a significant proportion of the members and staff were of Māori and Pacific ethnicity, there was flexibility in class times, it was possible to bring support people, staff were culturally aware, and many participants were able to speak in their preferred language (Sukala, et al., 2012). Compliance was moderate (73% in the aerobic training and 67% in the resistance training). As family and work obligations were common reasons for non-attendance, it was suggested that future exercise programmes with Māori and Pacific participants could integrate exercise into work hours and involve other family members (Sukala, et al., 2011). In addition, the provision of incentives, the involvement of a behavioural psychologist, and using traditional forms of exercise may increase compliance (Sukala, et al., 2012).

General Practitioners' views of their role in weight management

In a recent qualitative study, GPs in the Wellington region felt that their role in weight management was to identify any weight issues, educate the patient, and use their position as a health professional to influence the patient (Claridge et al., 2014). However, they felt that the success rate of weight loss intervention was low and this was attributed to individual patient factors (e.g. motivation and stigma) and limited resources (e.g. within the practice, and external services). GPs mentioned the limited effectiveness of currently available interventions (e.g. calorie-restricted diets, physical activity, medications). Few discussed the role of commercial weight loss programmes, and those that did had mixed opinions on their effectiveness, and whether they would be willing to refer patients to them. There were mixed opinions on the benefits and risks of bariatric surgery (Claridge et al., 2014). From this study it appears that GPs in New Zealand might not be sufficiently resourced in the domain of obesity treatment and therefore may not be able to adhere to the clinical guidelines to their full extent.

Section summary

In this section, several studies of weight loss and weight maintenance interventions conducted in New Zealand have been presented that have been published since the release of the Clinical Guidelines for Weight Management in New Zealand (Ministry of Health Clinical Trials Research Unit, 2009). The findings generally concur with international evidence, in particular that tailoring and

regular continued contact appear to enhance adherence and effectiveness. However, there remains a paucity of evidence relating to the acceptability and effectiveness of different types of lifestyle weight loss interventions for Māori and Pacific groups, and appropriate ways to increase uptake and compliance. There is the potential that current inequities could increase further if interventions are more effective for non-Māori, non-Pacific participants. Some factors identified here (as in previous publications, including the 2009 Clinical Guidelines) highlight the need for programme content, setting and delivery that is individualised, relevant and appropriate, and the need to consider broader health and cultural beliefs, provide the opportunity for incorporating whānau support, and practices that are guided by Māori, Pacific, and other models of health. Most would consider cultural tailoring and culturally appropriate settings and delivery to be desirable and prudent, as the available research suggests that tailoring enhances intervention adherence and effectiveness. However, there does appear to be an implementation gap and published reports to date indicate that cultural tailoring has not yet been widely incorporated into successful, scalable programmes, despite some promising pilot-scale studies.

Characteristics associated with increased effectiveness among interventions for weight loss and weight loss maintenance

The previous sections have concluded that dietary and physical activity interventions can be effective in promoting modest weight loss among overweight and obese adults, at least in the short to medium term. However, the effective interventions included in the systematic reviews and meta-analyses were heterogeneous in terms of many characteristics such as content, duration, participant characteristics, and setting. These differences mean that it is likely that many types of interventions are effective and it is not possible to identify one intervention format alone that is the most effective.

It may be then that certain intervention characteristics are associated with increased effectiveness. Identifying these characteristics could aid the efficient development and selection of dietary and physical activity interventions that are likely to be more effective at promoting weight loss. There are several issues when trying to determine correlates of weight loss and/or maintenance (J. Stubbs et al., 2011), however robust findings from RCTs (i.e. causal evidence) suggest that the effectiveness of dietary and physical activity interventions was increased when the following characteristics were included:

- targeting both diet and physical activity behaviours
- engaging social support (such as from family members and friends), and
- using well-defined/established behaviour change techniques³³, in particular, motivational interviewing (Armstrong et al., 2011; Greaves et al., 2011; Johnston, et al., 2014; Ramage, Farmer, Eccles, & McCargar, 2014; Sweet & Fortier, 2010; Wadden, et al., 2014) (see also, Appendix E, Table 9).

Less robust evidence (including associative evidence from correlational and non-randomised studies) suggests that increased effectiveness was also associated with:

increased contact frequency

³³ See Appendix A, Table 4 for definitions of some behaviour change techniques

- person-to-person contact (as opposed to solely computer-based), and
- using a specific cluster of "self-regulatory" behaviour change techniques (e.g. goal-setting, self-monitoring, providing feedback on performance, and goal review) (Ali, Echouffo-Tcheugui, & Williamson, 2012; Burke, Wang, & Sevick, 2011; Greaves, et al., 2011; LeBlanc, et al., 2011; Wadden, et al., 2014; Wieland et al., 2012).

To maximise the effectiveness of weight loss interventions, the above characteristics could be incorporated in the intervention design. However, it is not possible to determine what combination or number of these characteristics would be the most effective. It is also important to note that the inclusion of any (or all) of the characteristics listed will not necessarily ensure the effectiveness of an intervention. Also, evidence on long-term effectiveness suggested the need for greater consideration of the use of techniques and strategies to support behaviour maintenance (Greaves, et al., 2011).

In addition, no clear relationships were found between increased effectiveness and the intervention:

- setting (e.g. workplace, healthcare venue, home, community)
- delivery mode (i.e. individual, group, or mixed)
- population (e.g. gender, age, ethnicity, health status)
- follow-up interval
- provider (e.g. GP, counsellor, nurse, dietitian, exercise specialist), or
- duration (Ali, et al., 2012; Greaves, et al., 2011; LeBlanc, et al., 2011).

This suggests that weight loss interventions can be delivered successfully by a wide range of providers in a variety of settings, using group or individual (or combined) formats, and can be effective for a wide range of people (Greaves, et al., 2011).

Some characteristics of the interventions included in the systematic reviews and meta-analyses were not well documented and therefore not able to be included in analyses to identify their impact of effectiveness. For example, the quality and fidelity of implementation of the intervention were not often reported (Greaves, et al., 2011), however it is logical to assume that these factors would impact greatly on the effectiveness of any intervention.

The above characteristics do not attempt to disentangle the specific diet and physical activity components of the interventions that are most effective (e.g. the duration, frequency and type of physical activity). While the in-depth investigation of the individual regimes is undoubtedly important, it is beyond the scope of this report, however a brief discussion of these components is summarised here.

In the main, the duration, frequency and type of physical activity specified were poorly described in the weight loss literature. Often, physical activity recommendations were made as part of weight loss counselling but the guidance was non-specific, thus requiring participants to guide their own progress. Some studies did report more detail and the more commonly described physical activity components included moderate intensity exercise such as brisk walking three to five days per week, structured group exercise classes (e.g. gym based), individual supervised exercise, and 'lifestyle' exercise. Some studies reported only the recommended frequency and duration of the sessions. A few studies employed *subsidised* supervised physical activity sessions as an intensive programme,

delivered by physical activity specialists. These studies were able to quantify and report detailed exercise prescription and outcome data (e.g. aerobic exercise days/week with duration; resistance training days/week with duration and/or specific sets of exercises), however this level of reported detail was rare. Generally, participants were 'left to their own devices' and it was therefore difficult to accurately determine the intensity, duration and frequency of physical activity undertaken. Studies that did include supervised exercise tended to report poor compliance with the high amounts of exercise needed for weight control (even when research studies dedicated time to ensuring protocol adherence and better follow-up rates). In addition, the exercise protocols specified in some trials may have been beyond what could be reasonably delivered in primary care settings³⁴.

Overall, a decrease in total dietary energy (calorie) intake is required for significant weight loss (Ramage, et al., 2014). Many different diet regimes which manipulate the macronutrient (carbohydrate, fat and protein) content of the diet have been assessed (e.g. low fat and high carbohydrate, or low carbohydrate and high protein), and although findings are variable, several different regimes have shown to promote weight loss, particularly those that are high in fibre (Carroll, Hall, Parry-Strong, Wilson, & Krebs, 2013; Johnston, et al., 2014; Ramage, et al., 2014). There is some evidence that a diet higher in protein and lower in carbohydrate may provide a small but significant weight loss benefit over and above other diet regimes, however findings are somewhat inconsistent (e.g., Clifton, Condo, & Keogh, 2014; Schwingshackl & Hoffmann, 2013). Therefore it appears that no one specific diet regime is overwhelmingly the most effective, and instead it is adherence to a reduced-energy diet that is associated with significant weight loss and long-term maintenance (Carroll, et al., 2013; Johnston, et al., 2014).

As adherence to long-term physical activity and diet behaviour change is possibly the most crucial and difficult factor in intervention effectiveness, a practical strategy may be for health professionals to work alongside their patients to choose an evidence-based intervention that aligns with their personal values and can be tailored to their lifestyle and abilities, to ensure long-term adherence and sustainability (Carroll, et al., 2013; Johnston, et al., 2014).

Even the most theoretically effective intervention cannot guarantee weight loss. There are many personal factors of intervention participants which will impact on success. Health professionals providing (and/or referring people to) weight loss interventions need to be aware of any barriers to participation that their patients may experience, in relation to factors such as health-related knowledge and/or skills, sociocultural and psychological factors, past experience, readiness and motivation to change behaviour, and environmental factors (Canadian Task Force on Preventive Health Care, 2015).

However, the inclusion of some or all of the above intervention components is no guarantee for programme effectiveness. It is true that the above components or so called *characteristics of effective interventions* have, in one study or another, been shown to be related to favourable weight loss outcomes, but this does not assume/ensure causation. Even in positive studies, the differences in the outcomes (the effect sizes) are typically small and it has not yet been possible to conclude that any one ingredient or particular combination of ingredients causes weight loss to occur in the

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 $^{^{34}}$ In community settings, extensive monitoring and support may not be available.

majority of participants. Therefore, applying a content analysis approach is a largely unproven method of evaluating the possible effectiveness of any one intervention, and caution should be adopted, despite the approach having intuitive appeal (also see Bogers et al. (2010) for an economics perspective on multi-component interventions). One perspective held by some researchers (e.g. the 2014 McKinsey Global Institute report) is that, in order to increase access to services, health systems and all sectors in society should deploy as many different interventions as possible and not focus unduly on prioritising interventions, because this can hamper constructive action. It can be argued that this approach does not reflect evidence-based medicine, whereby evaluation of effectiveness is a core activity. Bogers et al. (2010) observed considerable variation in weight loss between interventions with similar costs (a proxy for intervention intensity) and suggested that this variation may, among other factors, be caused by differences in the content of the interventions. Therefore, it would appear that the combination of included ingredients does matter.

Conclusions

Based on current evidence there is no single intervention for addressing overweight and obesity that is generally effective (Agha, Agha, & Sandell, 2014; Hafekost, et al., 2013; Kirk, et al., 2012; Swinburn, et al., 2011). Although popular in Western cultures, traditional behavioural approaches that attempt to restrict (net³⁵) energy to induce weight loss have achieved only moderate success to date. These programmes are typically characterised by high attrition rates and many participants fail to maintain the weight lost and sometimes gain back more weight after the end of the programme³⁶ (Schaefer & Magnuson, 2014).

The purpose of this report is to provide planners and decision makers with a synthesis of best evidence relating to individual-level behavioural (non-environmental, non-surgical, non-pharmacological) interventions for weight loss and weight loss management in overweight and obese adult populations, delivered (or at least suitable for delivery) in primary healthcare settings or commercial settings. The key findings are presented below.

Key findings

Effectiveness of inter-personal interventions

- Most structured weight loss programmes can reliably induce modest clinically significant³⁷ weight loss in overweight and obese participants, over short time periods, but interventions typically suffer from late-stage intervention failure³⁸.
- No one intervention approach is strikingly more effective than any other in achieving short- to medium-term weight loss.
- There is no universally agreed standard definition of 'success'. The basic parameters that might define 'clinically significant weight loss' (i.e. the proportion of total body weight lost and the time period over which this must be sustained and/or measured) have not been universally agreed or applied to the main body of literature in this field. Research findings are often framed with reference to an *arguably* optimistic definition of success, fashioned by short-term follow-up.

Translational research

 Few studies have been conducted in the real-world settings without the support of external expertise and research funding (translational trials typically induce only 30-50% of the weight loss found in clinical efficacy trials).

³⁵ In many high income countries, an energy balance flipping point seems to have occurred in the 1960s–70s.

³⁶ Some researchers are now raising ethical concerns with the current practice of recommending diets for weight loss, due to long-term ineffectiveness and potential adverse effects (Bacon & Aphramor, 2011; Hafekost, et al., 2013; Mann, et al., 2007).

³⁷ For this purpose, meaning a weight loss of ≥5% of baseline bodyweight.

³⁸ i.e. Characterised by high attrition rates and relapse.

Weight loss maintenance

- The majority of individuals appear unable to maintain weight loss over the long term and therefore do not achieve the assumed benefits of improved morbidity and mortality.
- Many programmes are characterised by high attrition rates but little is known about participants who drop-out (neither the predictive factors nor the outcomes).
- While long-term weight loss (years not months) is sparsely reported, the available evidence suggests that weight loss generally persists with continued treatment, and higher treatment intensity does tend to be associated with greater weight loss and weight loss maintenance.
- A small proportion of weight loss programme participants do achieve life-long weight loss maintenance (possibly less than 10% of enrolees). However the predictive factors of 'success' are poorly understood.

Harm

- Overall, little is known about the longer term (life course) effects of unsuccessful and repeated weight loss and subsequent weight regain.
- Reported harms include loss of fat-free mass, increased risk of developing metabolic syndrome, and psychological distress associated with failure.

Predictors of attrition

- Few reliable predictors have been identified in pre-treatment patient characteristics between completers and non-completers.
- However, financial difficulties or the need to pay for the treatment appear to be associated with attrition.
- Baseline BMI does not appear to be related to attendance and completion outcomes³⁹.

Economics⁴⁰

- Out-of-pocket expenses were not included as a variable in the statistical analysis of any identified effectiveness trial⁴¹. In practice, out-of-pocket expenses may lead to differential exposure to the intensity and duration of intervention on the basis of participants' ability to pay.
- The time, effort, and expense required for primary care practitioners to deliver intensive interventions would appear to be prohibitive for most practitioners, in the absence of adequate resources/reimbursement.
- Higher intervention costs (a proxy for intervention intensity) appear to be associated with more weight loss, however the association is non-linear. At higher costs, the additional weight loss associated with extra investments levels off dramatically⁴².

³⁹ At least within the range of overweight (BMI ≥25) through class-II obesity (BMI 35.0–39.9).

⁴⁰ Note that these findings are not based on a full economic evaluation of the evidence.

⁴¹ Apart from when out-of-pocket expenses were included in cost-effectiveness analyses, but then only as direct costs, not as moderators of treatment effect.

⁴² Findings limited to 12-month follow-up data only.

Settings

- Routine healthcare provided by GPs or primary care clinics does not yet seem sufficient in the treatment of overweight and obese patients, since many do not reach their treatment goals (however no other setting appears better)⁴³.
- It is not clear if the apparently high intensity of intervention required is feasible/sustainable in general practice⁴⁴. Other specialist settings may be feasible⁴⁵.
- Few studies/interventions have focused on healthcare professionals' knowledge, skills, behaviour and systems and substantial understanding is still required of features such as the patient journey and funding pathways.

Internet- and mobile technology-based interventions

- Although the weight loss reported in most internet and self-directed studies is small, an internet delivered programme has the potential to be successful and cost-effective when applied on a large scale. However, it is not possible to infer which techniques or delivery modes are most strongly associated with increased weight loss, for whom, and in what contexts.
- Research in this specific field lags behind that of the more conventional intervention modes (e.g. face-to-face individual and group), and no translational studies were identified.

Commercial weight loss programmes

- Modest weight loss can be achieved using commercial weight loss programmes in the short to medium term.
- Little published data exists regarding the effectiveness of specific weight loss programmes that are available in New Zealand.
- Evidence from the UK suggests that referral by primary care practitioners to commercial weight management programmes (at no additional cost to the patient) is a practical and modestly effective option, however programme attendance can be poor.
- The cost of commercial programmes is an important consideration, as those who need to use the services most may be the least likely to be able to afford them.

New Zealand context

- Findings from interventions conducted in New Zealand support international review literature, in particular that tailoring and regular continued contact enhance adherence and effectiveness.
- Findings highlight the need for programme content, setting and delivery that is individualised,
 relevant and appropriate, and the need to consider broader health and cultural beliefs, provide

⁴³ Most commonly, programmes have been trialled in formats and settings that approximate those found in typical primary care settings. If there is a better care setting than general practice (for example, disease management clinics, specialist clinics, commercial settings) then the evidence base does not make clear exactly which setting this might be.

⁴⁴ Primary care practitioners often face the need to deal with more acute issues and have less time to spend on delivery of lifestyle advice.

Long-term follow-up is extremely resource intensive and specialist settings (clinics), given the appropriate infrastructure, may represent an opportunity to address the setting-related issues necessary to ensure institutionalisation and sustainability of content delivery and follow-up.

the opportunity for incorporating whānau support, and practices that are guided by Māori, Pacific, and other models of health.

Characteristics of effective interventions

- The effectiveness of interventions may be enhanced when both diet and physical activity behaviours are targeted, social support is engaged, motivational interviewing is used, and well-defined/established behaviour change techniques are used.
- However, it is not possible to determine what combination or number of these characteristics would be the most effective. It is also important to note that the inclusion of any (or all) of the characteristics listed will not necessarily ensure the effectiveness of an intervention.
- As adherence to long-term physical activity and diet behaviour change is possibly the most crucial and difficult factor in intervention effectiveness, a practical strategy may be for health professionals to work alongside their patients to choose an evidence-based intervention that aligns with their personal values and can be tailored to their lifestyle and abilities.

Knowledge gaps

Further, review of the literature from a broader public health perspective highlights a number of significant gaps in knowledge and these gaps appear to be fundamental barriers or limiting factors to the development of more effective weight-loss and weight loss maintenance treatments. It is perhaps important to consider what can realistically be expected given current knowledge.

This literature review has highlighted an incomplete understanding of the:

- complexity of the energy balance model, including biological feedback mechanisms and other inputs
- role of specific nutrients and physical activity in weight loss and general health
- possible physical and psychological benefits and harms that might be associated with repeated weight-loss/weight-gain (relapse)
- optimal model of relapse prevention
- importance of population-level weight gain prevention and how this might be achieved
- influence that different funding models might have on weight loss outcomes
- real-world effectiveness of utilising commercial weight loss programmes in the context of the
 New Zealand primary care system
- acceptability and effectiveness of different types of interventions for Māori and Pacific groups,
 and appropriate ways to increase uptake and compliance.

Supplementary considerations

In recent years, at least in Western countries, the responsibility for addressing obesity has largely fallen on individuals, however many researchers attest that the likelihood of individual-level interventions achieving sustainable progress on the reduction of obesity is low, and *subconscious interventions* (e.g. environment, regulation, systems) offer more scope and potential impact (Acosta, et al., 2014; Bartsch, et al., 2015; Chan & Woo, 2010; Dobbs, et al., 2014; Hafekost, et al., 2013; Swinburn, et al., 2011). Increasingly, the dominant public health view is that the priority should be

for policy-led regulatory approaches that focus on influencing population-level energy balance. There also continues to be a popular view that obesity is the fault of the individual and that it lies firmly within the sphere of personal freedom and personal responsibility (Gendall, et al., 2015). Policy makers and healthcare practitioners should therefore consider the need for changes across a number of levels of influence.

To reiterate, individual-level interventions offer only a modest contribution to reducing the overall burden of overweight and obesity, nevertheless, people who are already overweight or obese do need additional individual-level support from healthcare providers. Weight loss interventions need to be pro-equity, cost-effective and be readily available for providers to refer patients to. Based on the literature reviewed, three broad considerations or determinants of future programme success appear prominent: equity, funding models, and models of extended care. Questions around determinants of programme success (and success itself) appear to be in part philosophical, ethical and applied. It appears that the acceptability (access), engagement with, and long-term effectiveness of weight-loss interventions may be shaped, perhaps dramatically, by applying different emphases on these important domains (for example fully-funding vs cost sharing, culturally-tailored vs generic, pro-active vs passive). With these ideas in mind, key supplementary considerations are outlined below, with respect to future intervention design, implementation, and ownership.

Based on the findings of this literature review, the following supplementary considerations are highlighted:

- Pro-equity practices need to be guided appropriately by Māori, Pacific, and other models of health.
- A greater understanding is needed of the effects of different funding models on weight loss outcomes. This might involve translational experimental research and/or modelling, by planners, funders, providers, researchers and economists.
- Different methods of providing extended-care need to be trialled in fully developed programmes within healthcare systems⁴⁶, and these need to be rigorously evaluated, by funders, providers, researchers and economists.
- Obesity should be seen to be and acted upon as a chronic and relapsing condition (but not disease), by planners, decision makers, funders, educators, providers, researchers and patients.
- Further studies/interventions should focus on healthcare professionals' knowledge, skills, behaviour and systems, to substantially improve aspects of care such as the patient journey and funding pathways.

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⁴⁶ For example, the development of and operationalisation of patient monitoring systems consistent with the "Algorithm" and key messages as outlined in Clinical Guidelines for Weight Management in New Zealand Adults (2009).

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Appendices

Appendix A: Behaviour change techniques used in interventions

Table 4: Definitions of 26 behaviour change techniques and illustrative theoretical frameworks used in interventions, from Abraham and colleagues' (2008) review and taxonomy of behaviour change techniques

| Definition |
|--|
| General information about behavioural risk, for example, susceptibility to poor |
| health outcomes or mortality risk in relation to the behaviour |
| Information about the benefits and costs of action or inaction, focusing on what |
| will happen if the person does or does not perform the behaviour |
| |
| Information about what others think about the person's behaviour and whether |
| others will approve or disapprove of any proposed behaviour change |
| Encouraging the person to decide to act or set a general goal, for example, to |
| make a behavioural resolution such as "I will take more exercise next week" |
| Identify barriers to performing the behaviour and plan ways of overcoming them |
| |
| Praising or rewarding the person for effort or performance without this being |
| contingent on specified behaviours or standards of performance |
| Set easy tasks, and increase difficulty until target behaviour is performed. |
| Telling the person how to perform a behaviour and/or preparatory behaviours |
| An expert shows the person how to correctly perform a behaviour, for example, in |
| class or on video |
| Involves detailed planning of what the person will do, including a definition of the |
| behaviour specifying frequency, intensity, or duration and specification of at least |
| one context, that is, where, when, how, or with whom |
| Review and/or reconsideration of previously set goals or intentions |
| |
| The person is asked to keep a record of specified behaviour(s) (e.g. in a diary) |
| |
| Providing data about recorded behaviour or evaluating performance in relation to |
| a set standard or others' performance, i.e. the person received feedback on their |
| behaviour. |
| Praise, encouragement, or material rewards that are explicitly linked to the |
| achievement of specified behaviours |
| Teach the person to identify environmental cues that can be used to remind them |
| to perform a behaviour, including times of day or elements of contexts |
| Agreement (e.g. signing) of a contract specifying behaviour to be performed so |
| that there is a written record of the person's resolution witnessed by another |
| Prompt the person to rehearse and repeat the behaviour or preparatory |
| behaviours |
| Contacting the person again after the main part of the intervention is complete |
| Facilitate observation of non-expert others' performance for example, in a group |
| class or using video or case study |
| |
| |
| Prompting consideration of how others could change their behaviour to offer the |
| Prompting consideration of how others could change their behaviour to offer the person help or (instrumental) social support, including "buddy" systems and/or |
| Prompting consideration of how others could change their behaviour to offer the |
| |

| Prompt self-talk | Encourage use of self-instruction and self-encouragement (aloud or silently) to support action |
|---|--|
| Relapse prevention (relapse prevention therapy) | Following initial change, help identify situations likely to result in readopting risk behaviours or failure to maintain new behaviours and help the person plan to avoid or manage these situations |
| Stress management (stress theories) | May involve a variety of specific techniques (e.g. progressive relaxation) that do not target the behaviour but seek to reduce anxiety and stress |
| Motivational interviewing | Prompting the person to provide self-motivating statements and evaluations of their own behaviour to minimise resistance to change |
| Time management | Helping the person make time for the behaviour (e.g. to fit it into a daily schedule) |

IMB, information-motivation-behavioural skills model; TRA, theory of reasoned action; TPB, theory of planned behaviour; SCogT, social-cognitive theory; CT, control theory; OC, operant conditioning.

Appendix B: Descriptive summary of systematic reviews and meta-analyses of interpersonal-based interventions for weight loss and weight loss maintenance included in this report

The following summaries are listed chronologically, in descending order (see **Table 5** for further details).

Effect of lifestyle intervention in patients with type 2 diabetes (Chen et al., 2015)

Chen et al. (2015) conducted a meta-analysis of 16 RCTs of comprehensive lifestyle interventions and the effects on clinical markers in patients with type 2 diabetes (BMI was a primary outcome in 11 of 16 studies). Comprehensive lifestyle change interventions included increased physical activity, reduced caloric intake, dietary education, and counselling and education regarding treatment adherence or disease monitoring. The duration of the studies ranged from 6 months to 8 years and the studies were conducted across a range of clinical settings. The interventions were delivered by trained healthcare professionals and/or researchers.

Most risk factors were improved at follow-up. Chen et al. (2015) (unconventionally) reported BMI as the sole weight outcome⁴⁷, and BMI improved statistically significantly, although the size of the effect was below the 5% threshold (for weight loss) commonly assumed to be clinically significant (BMI –0.29kg/m², 95% CI –0.52 to –0.06kg/m², p=0.014). This change in BMI equates to an approximately 1kg weight loss for a typical participant (for the purpose of comparison, assuming a mean weight of 100kg and a mean height of 1.7m, as no actual height/weight data were provided). In general, the meta-analysis found that lifestyle intervention showed significant benefit in risk factors that are known to be associated with development of CVD in patients with type 2 diabetes. However, the effects remain unclear as not all findings were consistent across studies. While meta-analysis found a statistically significant effect on BMI, favouring the intervention (–0.29kg/m²), the clinical significance of this modest change was not discussed.

Efficacy of interventions that include diet aerobic and resistance training components for type 2 diabetes prevention (Aguiar, Morgan, Collins, Plotnikoff, & Callister, 2014)

In the most recently published systematic review and meta-analysis of weight loss/type 2 diabetes prevention lifestyle interventions, Aguiar, Morgan, Collins, Plotnikoff and Callister (2014) evaluated eight studies including five RCTs, one quasi-experimental study, one two-group comparison, and one single-group pre-post study. Lifestyle interventions were described as multi-component diet + aerobic exercise + resistance training interventions that focused on weight loss as the primary outcome (note that studies that employed diet + aerobic exercise, but not resistance training were not eligible for this review). The median intervention duration was 12 months (range 4–48 months) with a follow-up of 18 months (range 6.5-48 months). The diet and exercise interventions varied slightly in terms of their specific prescriptions. Prescribed physical activity was aerobic activity averaging 5.0 ± 1.5 days/week, with a duration of 157.5 ± 44.4 minutes/week, and resistance training on 2.3 ± 0.7 days/week, with a duration of 90.0 ± 24.5 minutes/week. Five studies

⁴⁷ Most studies report mean weight lost in kilograms or the percentage of weight lost between baseline and follow-up (few studies report BMI as the only weight metric).

prescribed energy restriction for weight loss and seven studies prescribed a specific dietary macronutrient profile. The studies were conducted in clinical research settings and all but one included supervised exercise facilities. The interventionists were research staff and exercise and nutritional specialists. Weight loss was the primary outcome of interest with most studies also including measures of physical activity, nutritional changes and plasma glucose. Two studies only included type 2 diabetes incidence. The collective sample size of the studies at baseline was 1050 participants, with females comprising 62% of the sample. Mean $(\pm SD)$ age was 54.5 \pm 9.7 years. Meta-analysis favoured interventions over controls for weight loss, -3.79kg (95% CI -6.13 to -1.46kg). The time frame of assessments varied from four to 36 months.

The design characteristics of the interventions that achieved significant changes for weight loss and plasma glucose included: face-to-face intervention delivery mode (individual and/or group); an average of eight contacts per month (including face to face sessions, emails and phone calls); and a minimum of six (preferably 12) months of follow up. Lifestyle intervention characteristics included: 150–210 minutes (3–5 sessions) of aerobic exercise per week, 60–120 minutes (1–3 sessions) of resistance training per week, recommendations for a specified macronutrient diet profile, energy restriction for weight loss, and setting a weight loss goal of 5-10%.

The interventions were generally tightly structured, prescriptive, high-intensity supervised programmes conducted in clinical research settings by expert interventionists, and can best be described as efficacy trials (tests of the interventions conducted under ideal circumstances). The meta-analysis revealed that the interventions were modestly effective in inducing weight loss. While this review and meta-analysis provides an important source of information for clinical practice, the high-intensity supervised nature of the interventions has substantial implications for the feasibility and practicalities and costs of implementing these programmes into community and healthcare settings. Few healthcare systems can afford to provide ongoing supervision of exercise programmes (supervised, progressive, individually tailored aerobic exercise programmes and circuit-type resistance training sessions and/or close supervision of nutritional intake) by qualified personnel. Depending on the level of co-payments required, it is also questionable whether patients in primary care settings could afford such programmes for the length of time required to meet recommended weight loss goals.

Maintenance of weight loss after lifestyle interventions for overweight and obesity (Barte, et al., 2010), and differences in weight loss across different BMI classes (Barte, Veldwijk, Teixeira, Sacks, & Bemelmans, 2014)

Barte and colleagues (2010; 2014) conducted two separate systematic reviews to study the effects of weight loss interventions. Their first review (Barte, et al., 2010) focused on the effectiveness of multi-component interventions on weight loss and particularly maintenance of weight loss after an initial reduction phase. The second review (Barte, et al., 2014) investigated the effectiveness of weight loss interventions applied across BMI classes, with BMI stratified between 25 and 40.

Barte et al. (2010) reviewed 22 studies of multi-component interventions with a weight maintenance follow-up period of 1-year of unsupervised follow-up, in healthy mainly Caucasian populations of 18 years or older. Generally, most interventions contained behavioural group sessions led by a dietitian or another interventionist (psychologist, exercise physiologist, graduate student), carried out in a

healthcare setting. The primary outcomes were weight and the percentage weight loss maintenance at follow-up.

Intervention groups on average lost 9.5% of their baseline weight during the intervention and at 1-year follow-up the intervention groups on average maintained 54% of this weight with 44% maintenance at 2-year follow-up. There was no relationship between the percentage weight maintenance after 1-year of unsupervised follow-up and weight lost during the intervention period. The authors reasoned that 10% or more weight loss should be encouraged and favoured above a lower weight loss as this, on average, results in greater net weight loss after the unsupervised follow-up. However the authors cautioned that more research is needed to further clarify the association between weight loss and maintenance on an individual level, to determine optimal weight loss targets and to establish best practices for an optimal maintenance of weight loss. Further, participants who have a low percentage maintenance fluctuate in their body weight to a higher extent, compared with a high maintenance group, which may have detrimental consequences to health.

To extend these findings, Barte et al. (2014) updated their search and included a meta-analysis to investigate the differences in 1-year weight change and percentage weight change after lifestyle interventions for participants varying in initial BMI class. Barte et al. (2014) reviewed 22 interventions in mainly Caucasian populations, and analysed the weight change data of 2,431 participants. In general, interventions contained caloric restriction, a physical activity goal, and behavioural group sessions. The interventions were delivered across a range of settings including commercial providers, research settings and healthcare settings by professional healthcare providers such as dietitians, exercise specialists or behavioural interventionists. The primary outcome was differences in 1-year weight change and percentage weight change for participants varying in baseline BMI.

Overweight participants lost 1.1kg less (p <0.01) than participants with class-I obesity and 1.5kg less (p <0.01) than participants with class-II obesity (absolute differences). For percentage weight change, no significant differences were found between the BMI classes (0.6%; 0.1%, -0.3% respectively). Barte et al. (2014) found that average weight change during lifestyle interventions only differs to a small extent among people with BMI between 25 and 40. This implies that generally, multi-component interventions (lifestyle interventions) are equally appropriate for these BMI classes. Different intensities and components of an intervention may however give different results for different groups of people when tailoring is optimised at an individual or sub-group level but further research on this specific aspect is needed. As applied in representative settings, initial BMI appeared to make little difference to intervention effectiveness.

Effectiveness of behavioural weight loss interventions delivered in a primary care setting (Booth, et al., 2014)

In a recent systematic review and meta-analysis of 15 RCTs (4,539 participants) Booth et al. (2014) investigated the effectiveness of behavioural weight loss interventions conducted within the primary care setting. Obese or overweight adult participants (age ranged between 42 and 60 years) had to have been selected from their practice patient list and the intervention conducted within a primary care setting. Although expert input and guidance was typically provided by researchers, the interactions with participants were conducted by non-research staff (GPs, nurses and other health

professionals). These stipulations were intended to be reflective of the multidisciplinary teams that might now deliver primary care services. Weight loss was the primary outcome, and a minimum of 12 months of follow-up was required.

Pooled results from meta-analysis indicated a mean weight loss of −1.36kg (−2.10 to −0.63, p <0.0001) at 12 months, and -1.23kg (-2.28 to -0.18, p=0.002) at 24 months. Booth et al. (2014) concluded that behavioural interventions conducted in primary care settings appeared to have a negligible effect on participants' weight at 12 and 24 months. Weight loss interventions are generally considered to be clinically significant if participants lose ≥5% of their baseline total body weight and based on the range of mean baseline body weights observed in this review (82.9-107.7kg) the pooled estimates did not reach this threshold. Booth et al. (2014) acknowledged that previous systematic reviews on primary care management of obesity have indicated more favourable results. However, Booth et al. (2014) stressed that these previous reviews included studies conducted in specialist hospital or academic settings, with the researchers holding the view that they might be directly transferrable to the primary care setting. Booth et al. (2014) make the point that studies from specialist settings are likely to differ from those conducted within primary care in several important aspects: (1) the population is unlikely to be representative due to differences in motivation (2) the studies are typically conducted by research staff (3) interventions are likely to be more intensive than those in primary care and (4) more time is dedicated to ensuring protocol adherence and better follow-up rates. Booth et al. (2014) asserted that previous reviews may have overstated the potential effect of weight loss interventions in routine practice in primary care.

Long term maintenance of weight loss with non-surgical interventions in obese adults (Dombrowski, et al., 2014)

Dombrowski and colleagues (2014) sought to investigate *weight loss maintenance* after initial weight loss. A systematic review and meta-analysis was conducted of RCTs with participants randomised to a weight loss maintenance intervention following a structured weight loss programme of any type. Participants were adults (aged ≥18), with an average BMI of ≥30 at baseline, and had subsequently lost ≥5% of their body weight within 24 months, before being assigned to a weight loss maintenance treatment. Included studies reported weight outcomes after ≥12 months' follow-up of the inception of the maintenance intervention (45 studies). Any behavioural, lifestyle, pharmacological, food replacement/supplement, or alternative interventions were eligible for inclusion. Control conditions included no intervention, standard or minimal care, or placebo-controlled. In addition, the analysis examined different delivery modes, for example, intensive versus less intensive and in-person versus remote delivery.

The intervention settings were described as home, internet or phone, clinic, community, interactive television studio, or gym-based. Interventions were delivered by different types of therapists including dietitians, GPs, nurses, nutritionists, physiotherapists, exercise instructors, peer supporters, students, and were typically in group format or combined group with individual formats. Of the 42 studies that included a formal weight loss phase, the average weight loss across studies ranged from –4.0kg to –21.3kg, with a weighted average of averages of –10.8kg (the average starting point for the weight loss maintenance interventions).

At 12 months post-randomisation, 15 evaluable behavioural/lifestyle studies including 25 comparisons showed a mean difference in weight change of -1.56kg (95% CI -2.27 to -0.86kg)

compared to controls. At 24 and 30 months, only two studies reported outcomes. Overall mean differences in weight change remained significant at 24 months (–1.48kg, 95% CI –2.27 to –0.69kg) but not at 30 months (–0.85kg, 95% CI –1.81 to 0.11kg). Dombrowski et al. (2014) concluded that comprehensive behavioural interventions targeting dietary and physical activity behaviours are moderately effective in slowing regain of weight in obese adults after initial weight loss for follow-up periods of up to 24 months. Dombrowski et al. (2014) also noted that although energy prescriptions were poorly described in some studies, participants generally seemed to receive advice to follow a regimen that continued to create an energy deficit beyond the period of initial weight loss, which is perhaps an unrealistic expectation for the long term. Dombrowski et al. (2014) raised the concern that this obscures the important distinction between weight loss and weight loss maintenance, despite the exacting inclusion criteria employed in their review (also, none of the studies reported extended follow-up after a period of *unsupervised* maintenance). Compared with initiation of weight loss, the evidence base for maintenance of weight loss is in its infancy and further research is needed over periods of more than 24 months (Dombrowski, et al., 2014).

Effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes (Dunkley et al., 2014)

In a systematic review and meta-analysis of 25 pragmatic trials (including 11 RCTs and 11 before-&after studies), Dunkley et al. (2014) evaluated the effectiveness of lifestyle interventions (nutrition and physical activity) based on the recommendations of the type 2 diabetes prevention clinical trials (conducted between 1996 and 2001), NICE, and the European Guideline and Training Standards for type 2 diabetes prevention (IMAGE) recommendations. Although the review was oriented towards primary prevention (of type 2 diabetes, rather than overweight/obesity treatment per se), the primary outcome in all trials was weight change from baseline to 12 months and ≤10% of the population had established type 2 diabetes. Other outcomes included measures of plasma glucose and key dietary and physical activity targets (not reported here). The interventions were delivered across a range of settings including community settings, integrated healthcare organisations, outpatients, primary care, and one workplace. The pooled result of the meta-analysis shows that lifestyle interventions resulted in a mean weight loss of 2.32kg (95% CI -2.92 to -1.72kg). Adherence to guidelines was significantly associated with a greater weight loss (an increase of 0.4kg per point increase on a 12-point guideline-adherence scale).

Dunkley et al. (2014) found that the mean level of weight loss achieved was approximately one-half to one-third of the levels reported at the same time point within the intervention arms of clinical efficacy trials such as the U.S. Diabetes Prevention Programme (DPP). Dunkley et al. (2014) judged the level of weight loss reported as likely to have a clinically meaningful effect on type 2 diabetes incidence. However, the 5% threshold commonly cited as a minimum for clinical significance in weight loss trials was not achieved. This systematic review and meta-analysis of pragmatic trials demonstrated that most produce lower levels of weight loss than the more intensive interventions used in the clinical efficacy trials. Dunkley et al. (2014) highlight further difficulties in translating this evidence into practice, including a lack of resource for service provision, and a lack of engagement of politicians and healthcare organisations in funding national level programmes, including the substantial up-front investments necessary to accrue longer-term benefits. Dunkley et al. (2014) concluded that the findings may not translate into long-term therapeutic value due to uncertainty around sustaining outcomes, such as weight loss, in the longer term.

Effects of pharmaceutical weight loss agents, diet and exercise on weight loss maintenance after a VLCD or LCD (Johansson, et al., 2014)

The aim of the systematic review and meta-analysis conducted by Johansson, Neovius and Hemmingsson (2014) was to quantify the effects of pharmaceutical weight loss agents (out of scope for this report), diet, and exercise on weight loss maintenance after a VLCD or LCD period (<1000 kcal/day). The review included 27 RCTs with a total 3,017 participants. Interventions included pharmaceutical weight loss agents (not reported here), meal replacements (4 arms; n=322), high-protein diets (6 arms; n=865), dietary supplements (6 arms; n=261), other diets (3 arms; n=564), and exercise/exercise and diet (5 arms; n=347). The studies were conducted across a range of settings including research facilities, community settings, GP offices, and a university out-patient obesity clinic, by research staff and healthcare professionals. The primary outcome was the amount or percentage of weight regain at follow-up after the initial weight loss period (the run in period).

During the VLCD/LCD run-in period (median duration: 8 week; range 3-16 week), the pooled mean weight change was -12.3kg. Weight regain during the maintenance period differed between individual studies, ranging from a further mean weight change of -5kg to a regain of 14kg in the intervention groups and from -1kg to a gain of 13kg in the control groups (**Figure 6**). Compared with controls, meal replacements improved weight loss maintenance by 3.9kg (median duration 12 months), and high-protein diets by 1.5kg (median duration 5 months). Exercise, and dietary supplements did not significantly improve weight loss maintenance compared with control. In this meta-analysis of RCTs, the largest improvements in weight loss maintenance after a LCD were seen for meal replacements (and pharmaceutical weight loss agents). A high-protein diet also improved weight loss maintenance.

Unequivocally, all groups demonstrated a pronounced shift to weight regain, following the end of the weight loss period. Some of the maintenance-intervention groups demonstrating significantly reduced regain compared to controls, albeit over a relatively short follow-up period (mean follow-up of 5–22 months, depending on category).

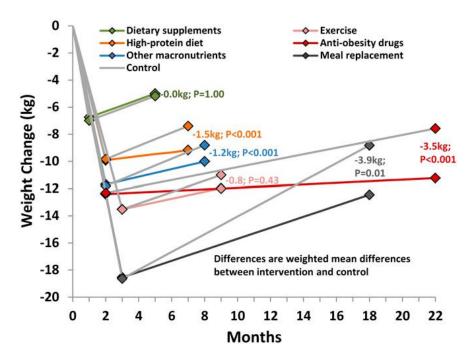


Figure 6: Changes in body weight during the rapid weight loss phase and the weight loss maintenance period in 20 RCTs (Johansson et al., 2014)

Overview of changes in body weight during the rapid weight loss phase and the weight loss maintenance period in 20 RCTs that evaluated different pharmaceutical weight loss agents, diet, and exercise weight loss maintenance strategies after an initial VLCD or LCD (,1000 kcal/d) as reported by Johansson et al. (2014). The grey lines represent the control subjects in each subcategory.

A limitation of the study was that the maintenance-phase duration of the included studies varied from 3 to 36 months and short- and long-term studies were assigned equal importance. In conclusion, Johansson et al. (2014) reported that weight regain was common during the maintenance phase, which highlights the need for an increased understanding of weight loss defences. Johansson et al. (2014) also confirmed previous findings that a VLCD induces a large short-term weight loss (compared to a standard 1500–1800-kcal/d diet for example) that is typically followed by a large regain. However, the clinical utility of this finding is not clear.

Effects of exercise and diet on weight loss maintenance in overweight and obese adults (Kouvelioti, et al., 2014)

Kouvelioti, Vagenas and Langley-Evans (2014) conducted a systematic review of 14 RCTs (efficacy trials) of interventions that recommended exercise and diet combined in overweight and obese adults (weight loss counselling). The trials were typically conducted in research facilities or community settings by research staff and were typically of short duration (an average of about 4-months from baseline) and with an average follow-up period of about 21-months. Overall estimations showed a weight loss of 11.1kg (13%) after the initial weight loss period with a weight loss maintenance of 5.8kg (about 52%) and a weight regain of 5.1kg after an average period of about 21 months. Kouvelioti et al. (2014) concluded that weight loss was successful but almost half of it (about 48%) was regained. Kouvelioti et al. (2014) rated the 14 studies very good to excellent in quality, however there was high average dropout (>20%) and this may have led to an overestimation of the treatment effect.

Physical activity and nutritional weight loss interventions in obese low-income women (Moredich & Kessler, 2014)

Moredich and Kessler (2014) used an integrative review process to allow for comparative analysis of diverse research methodologies. The focus of the review was to investigate the effectiveness of physical activity and nutrition interventions for weight loss in obese, low-income women. The interventions were delivered in community settings such as churches, community centres or health clinics. Of the seven included articles, five were RCTs and two employed quasi-experimental designs and three of the studies also included a focus group discussion/analysis. The intervention sessions ranged in duration from 90 minutes to 32 hours over a period of 4 to 12 months. All of the interventions included culturally and economically appropriate nutritional guidance. Reported weight loss across the interventions ranged from 0.36kg/week to 1.1kg/week for the duration of the intervention period. However, attrition rates were typically high, ranging from 17% to 43%.

The intention of this review was to include all evidence available and not reject studies based on their risk of bias alone. Findings from the studies reviewed indicated that the majority reported statistically significant weight loss from interventions designed to increase physical activity and change nutrition behaviour. Moredich et al. (2014) concluded that according to their synthesis of the best-available evidence, customised weight loss interventions appear to be effective in obese, low-income women. However, the findings must be considered in light of issues related to study quality (small sample sizes, some studies lacked a control group, and/or reported high attrition rates). According to this integrative review, effective interventions (1) are structured in a group, (2) can be led successfully by a peer educator, (3) should include pragmatic culturally and economically appropriate nutrition advice, and (4) must encourage increases in physical activity. Cultural congruency was integral to several of these successful interventions. No study included long-term follow-up therefore these results need to be interpreted with caution.

The effect of physical exercise strategies on weight loss in postpartum women (Nascimento, Pudwell, Surita, Adamo, & Smith, 2014)

Nascimento, Pudwell, Surita, Adamo and Smith (2014) conducted a systematic review and metaanalysis of RCTs and pilot RCTs of weight loss interventions specifically targeting postpartum women (at any point up to and including 18-months after delivery). The meta-analysis included 11 studies and a total of 769 participants. All of the interventions provided a structured programme that included supervised or unsupervised physical exercise or physical exercise guidance/counselling with a minimum follow-up of 10 weeks. No restrictions were placed on whether a complementary dietary intervention was utilised. The duration of interventions ranged from 10 weeks to 52 weeks and the interventions were conducted in research facilities or community settings by research staff.

The pooled effect of the exercise interventions, with or without dietary intervention, on weight loss during the postpartum period compared with usual care was significant, a mean difference of - 2.57kg (95% CI -3.66 to -1.47kg). After sub-group analysis, the effect observed among the eight studies that utilised short term interventions, ranging from 10 to 16 weeks in duration, was found to be significant, however the effect observed among the three studies that utilised long term interventions (24, 36 and 52 weeks duration) was not found to be significant.

Nascimento et al. (2014) stated that there appears to be benefit from lifestyle interventions in postpartum women: exercise programmes with objectively defined goals that are combined with intensive dietary intervention. Overall, there was a trend towards supervised exercise intervention strategies being more effective than unsupervised intervention strategies. However, the supervised programmes were intensive (4 to 5 days per week with staff being able to ensure that women achieved their intensity goals through heart rate monitors and/or pedometers) and these kind of strategies require significant financial and personal resources to attend classes. Studies that involved supervised exercise interventions also reported high refusal and attrition rates. Nascimento et al. (2014) concluded that further evaluation into the sustainability and long term effects of the interventions on the mother and child are needed.

Prevention of overweight and obesity in adult populations (Peirson, et al., 2014)

Peirson et al. (2014) conducted a comprehensive systematic review and meta-analysis of 68 studies of lifestyle interventions that they judged as generalisable to Canadian primary care or feasible for conducting in or referral from primary care (36 of these studies were brought forward from the 2011 USPTF review, LeBlance et al. (2011)). Only 41 of the 68 studies are relevant to this report as the remaining 27 studies used pharmaceutical components. The 41 intervention arms included eight diet, four exercise, 10 diet plus exercise and 19 lifestyle interventions. The review excluded studies of morbidly obese participants (BMI ≥40) and those treated in specialist clinics. The primary outcomes were change in body weight or BMI and/or change in waist circumference (and the incidence of type 2 diabetes in prediabetic populations).

Peirson et al. (2014) reported that the pooled effect of the behavioural interventions was a weight change of -3.13kg (-3.88 to -2.38kg) in 10,829 participants, across 33 moderate quality trials. The test for subgroup differences based on type of behavioural intervention in the behavioural trials (diet, exercise, diet + exercise and lifestyle) was significant: interventions using exercise alone did not lead to significantly greater reductions in weight, whereas diet alone showed the largest difference between groups. Peirson et al. (2014) summarised that modest weight reduction confers clinically important benefits and a substantial reduction in the incidence of type 2 diabetes in prediabetic populations, with the potential to improve population health. However, most studies were of relatively short duration (≤12 months), and there was a lack of evidence to address the question of whether (and for how long) weight loss is maintained after interventions are completed.

Behavioral treatment of obesity in patients encountered in primary care settings (Wadden, et al., 2014)

In 2011, the US Centers for Medicare & Medicaid Services (CMS) approved intensive behavioural weight loss counselling, recommending approximately 14 face-to-face, 10- to 15-minute sessions over 6 months for obese beneficiaries in primary care settings, when delivered by physicians and other trained primary care practitioners. The CMS recommend that such counselling sessions follow the U.S. Preventive Services Task Force (USPSTF) 5 A's approach to promote weight loss through high intensity interventions on diet and exercise, which includes clear, specific, and personalised behavioural change advice. Wadden, Butryn, Hong and Tsai (2014) conducted a systematic review and meta-analysis of trials purporting to implement the CMS recommends in primary care settings. Wadden et al. (2014) identified 12 trials, involving 3893 participants that were treated either in independent clinics, outpatient hospital clinics, physicians' offices, or in public health clinics, by

qualified primary care practitioners (i.e. GP, certified clinical nurse specialist, nurse practitioner, or physician assistant). Under CMS funding criteria, patients must have their weight assessed at the 6-month visit and to be eligible for continued visits in months 7 through 12, weight loss of 3kg or more must be achieved during the first 6 months of therapy.

Wadden et al. (2014) found that no studies delivered interventions at the recommended intensity (14 in-person sessions over 6 months) with the most intense interventions delivering counselling sessions approximately monthly. Across all 12 studies, the difference in weight loss between treatment and control groups (i.e. treatment–control) ranged from –1.5kg (i.e. 1.5kg greater weight loss in the control group) to 4.3kg. Three trials provided approximately monthly brief counselling visits, which were delivered by trained medical assistants in collaboration with primary care practitioners. Mean weight losses at 6 months ranged from 3.5kg to 4.4kg. Mean weight losses declined during the follow-up period. Smaller 12- to 24-month losses, from –0.6kg to –1.7kg, were observed when primary care practitioners, working alone, provided quarterly or less frequent weight loss counselling sessions. The provision of more counselling sessions appeared to be associated with greater weight loss, ranging from 3.5kg with 8 sessions to 6.6kg with 15 contacts (a notable doseresponse relationship). Wadden et al. (2014) concluded that a range of trained interventionists, who deliver counselling in person or by telephone, could be considered for treating overweight or obesity in patients encountered in primary care settings but that there is little research on primary care practitioners providing such care.

Multi-component weight-loss interventions for people with CVD and/or type 2 diabetes (Gallagher, et al., 2013)

Gallagher, Armari, White and Hollams (2013) conducted a systematic review of RCTs to determine whether weight loss interventions that combine dietary, exercise and behaviour change strategies, result in reduced weight and waist circumference at 12-months, in people with established coronary heart disease (CHD), hypertension and/or type 2 diabetes. The interventions were delivered in integrated healthcare or primary care or hospital clinics by trained healthcare professionals. Eight RCTs were included (total n=1428). Participants' mean age was 60.4 years and 61% were female. The included studies implemented interventions which combined dietary, exercise and behaviour change strategies. Interventions varied by contact time, content and delivery. The amount of contact time participants had with the intervention team members varied from a minimum of five two-hour sessions over 12 months to a maximum of a 2 ½-day workshop in a retreat format, followed by four hours of contact/week for six months. Weekly supervised exercise sessions also featured in six of the eight interventions. Mean weight loss ranged from -2kg to -4kg (SD 4kg) at 3-4 months, -1.3kg to -8.2kg (SD 4kg) at 5-6 months and -0.87 (SD 0.57kg) to -6.9kg (SD 4kg) at 12 months. Interventions that included weekly supervised exercise sessions achieved mean differences in weight loss that were ≥ 5% and thus clinically significant.

Gallagher et al. (2013) concluded that weight loss interventions that combine exercise, diet and behaviour change strategies result in minor weight loss at 3-12 months in people with CHD, type 2 diabetes or hypertension. However, many of the interventions were high intensity and included supervised exercise sessions and Gallagher et al. (2013) questioned whether or not this intensity would be sustainable in practice. Gallagher et al. (2013) reported that frequent contact appeared to support the cognitive behavioural strategies which were integral to the interventions, and that the

critical element is most likely the length of time over which contact occurs, rather than the total amount of contact alone. Gallagher et al. (2013) also noted that no study included in their review reported on how participants might achieve a level of independence (once support ends) or how a transition to community and group-based endeavours might be promoted.

Can type 2 diabetes prevention programmes be translated effectively into real-world settings and still deliver improved outcomes? (Johnson, et al., 2013)

Johnson et al. (2013) conducted a systematic review of 19 studies, including only those studies identified as applying a specified, known protocol that had previously been associated with a reduction in the incidence of type 2 diabetes as well as weight loss (as a primary outcome). Johnson et al. (2013) aimed to evaluate the *translation* of type 2 diabetes prevention protocols to real-world settings (adapted and modified for feasibility as necessary): including church settings, YMCAs, integrated healthcare settings, primary care and hospital clinics. The interventions were typically facilitated by trained educators with a variety of professional backgrounds. Generally, the programmes attracted predominantly women.

There was a strong trend toward weight loss following all but one of the interventions (in the range of 1.4 -7kg). Only one study provided results beyond 12 months follow-up (the DPP lifestyle group participants lost, then partly regained weight at 10-year follow-up) and the remaining studies fell between 4 and 12 months follow-up. Reduction in type 2 diabetes incidence was not measured in any controlled study. Most studies did not report on an intention-to-treat analysis and drop-out was high in some studies (range 2-33%). Johnson et al. (2013) concluded that group-based interventions can yield significant weight loss (with the expectation of reductions in the risk of type 2 diabetes), provided that changes are sustained over a number of years. Johnson et al. (2013) cited the main challenge as being how best to deliver and achieve engagement with interventions and how to sustain lifestyle change. Johnson et al. (2013) suggested that one potentially cost-effective mode of delivery might be that a highly qualified diet and physical activity professional is supported by a less-qualified individual in the delivery of community-based weight loss programmes.

Behavioural weight-loss interventions involving primary care practitioners in overweight and obese primary care patients (Yoong, et al., 2013)

Yoong, Carey, Sanson-Fisher and Grady (2013) conducted a systematic review of 16 studies (15 RCTs) of: lifestyle counselling delivered primarily by primary care practitioners (6 studies); lifestyle counselling delivered primarily by non-primary care practitioners including nurses or dietitians, but monitored by primary care practitioners (9 studies); and multi-component interventions (1 study). In all of the studies, weight change or BMI change was the primary outcome measure.

Six studies examined the effectiveness of lifestyle counselling and of these, three tested the use of brief, tailored lifestyle counselling targeting dietary and/or exercise behaviour in changing patients' weight compared with usual care, and one examined the effect of a physician-delivered group weight-management programme. Two studies targeted providers, with one assessing the effectiveness of providing an educational intervention and the other testing the use of a sticker in overweight/obese patients' charts representing diagnosis and treatment or referral for the condition. Of the six studies, three reported on low-intensity, one on moderate-intensity and two on high-intensity interventions. In the nine studies reporting on the effectiveness of lifestyle counselling

delivered by non-primary care practitioners, the personnel delivering the intervention were allied healthcare providers (including nurses or dietitians) or non-healthcare providers. The types of interventions included meal replacements, nurse- or dietitian-delivered counselling, weight-loss websites and counselling delivered by non-medical health coaches. Four of the studies were high intensity (more than monthly contact in the first 3 months), three were moderate intensity (monthly contact) and one was low intensity (less than monthly contact in the first 3 months).

None of the interventions targeting providers' behaviour resulted in statistically significant weight loss in their patients. Three studies targeting patients reported a statistically significant difference in amount of weight loss between the intervention and control group at end of intervention. Overall, eight studies reported non-clinically significant weight loss, four studies reported clinically significant weight loss and four studies did not report clinical significance. Yoong et al. (2013) tentatively suggested that high-intensity interventions delivered by non-healthcare providers in adjunct to primary care practitioner consult are effective in producing clinically significant weight loss. However, none of the physician-delivered interventions reported achieving clinically significant weight loss, making it questionable whether physician-delivered interventions alone are worth implementing in primary care. Further, most of the primary care practitioner-delivered interventions were of low to moderate intensity while the non-primary care practitioner-delivered interventions tended to be of moderate to high intensity. While the differences in intensity make direct comparisons difficult, these differences are likely to reflect clinical practice as primary care practitioners often face the need to deal with more acute issues and have less time to spend on delivery of lifestyle advice (Yoong, et al., 2013).

Effective weight management practice: a review of the lifestyle intervention evidence (Kirk, et al., 2012)

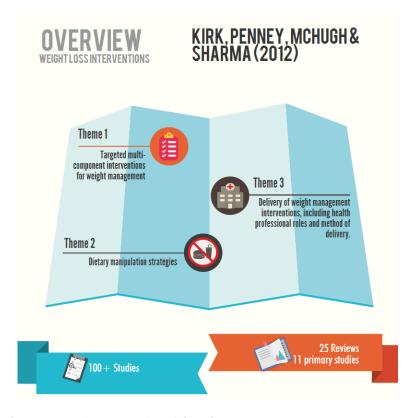


Figure 7: Summary of intervention themes in Kirk et al. (2012)

Kirk, Penney, McHugh and Sharma (2012) conducted an exhaustive search of meta-analytical reviews (n=6), systematic reviews (without meta-analysis) (n=10), non-systematic reviews (n=9) and primary papers (n=11), of lifestyle interventions for weight loss and weight loss maintenance. Kirk (2012) evaluated the evidence from systematic reviews and meta-analyses and classified the findings into three intervention themes or areas of context, in which more specific *most effective* and/or *promising* practice recommendations could be nested. The three themes were: (1) targeted multi-component interventions for weight management, (2) dietary manipulation strategies and (3) the delivery of weight management interventions, including health professional roles and method of delivery (**Figure 7**). The study settings covered workplace settings, community settings and all healthcare settings. Studies that had an exclusive focus on anti-obesity medications or surgery were not included and single component meal replacements or physical activity only interventions were also not included.

Kirk and colleagues' review blends information from a wider evidence base than might typically be utilised in traditional systematic reviews. Kirk et al. (2012) argue convincingly that their approach goes some way to addressing a common critique of recommendations based on other systematic reviews and meta-analyses that is being too broad to be clinically useful. Kirk et al. (2012) evaluated, categorised and discussed their findings in a matrix of three themes × two classes of recommendations, and these are summarised and reproduced in (Figure 8). Kirk et al. (2012) also provided some global summary statements including that (1) fundamentally, obesity should be viewed as a complex, chronic condition, requiring sustained contact with and support from trained health professionals; (2) interventions should be implemented over the long term and tailored toward individual characteristics; and (3) identified barriers to incorporating weight management into healthcare delivery, even when evidence is available, include provider uncertainty as to what to do, a lack of time, a lack of knowledge, and issues of reimbursement. Finally, Kirk et al. (2012) concluded that their review highlights the value of multi-component interventions that are delivered over the longer term, and reinforces the role of healthcare professionals. However, Kirk et al. (2012) cite the gap between evidence-based recommendations and current clinical practice as a serious impediment to better weight loss outcomes.

Practice Recommendations

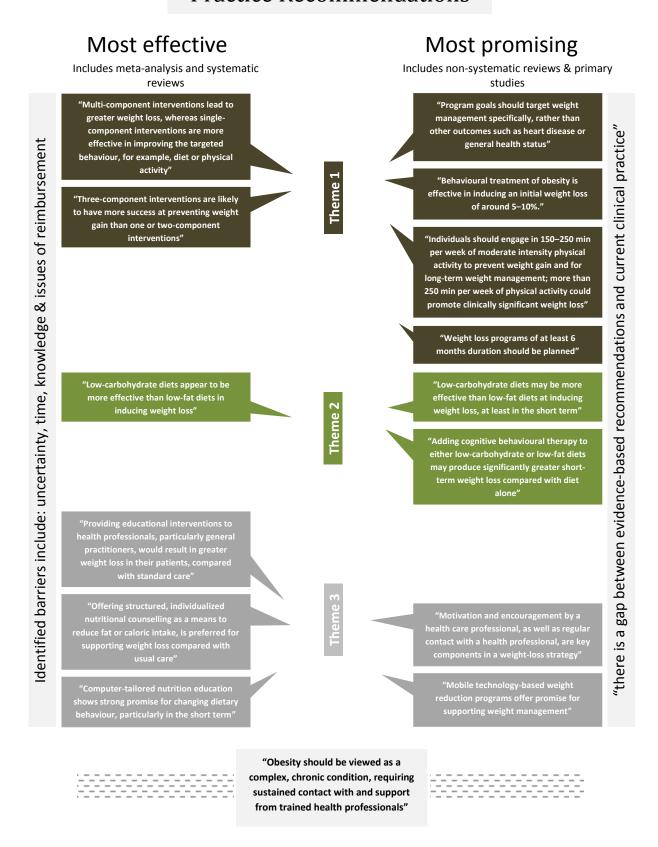


Figure 8: Summary of effectiveness and practice recommendations from Kirk et al. (2012)

The impact of extended care on the long-term maintenance of weight loss (Middleton, et al., 2012)

Middleton, Patidar and Perri (2012) conducted a systematic review and meta-analysis of 11 RCTs that assessed the impact of *extended care* on weight regain, after initial weight loss, in overweight and obese individuals. The extended care interventions were formulated within a *continual care* model, in which obesity is treated as a chronic disease and individuals are provided with continued therapist contact to prevent weight regain following initial loss. Interventions delivered via the internet were excluded. All studies used cognitive behavioural therapy (CBT). Specifically, extended care contact was based on reinforcing behavioural changes made during initial intervention, including meeting goals for reduced caloric intake and increased physical activity as well as a problem-solving component to help participants overcome barriers to maintaining behaviour change and/or relapse prevention training. Studies included in the meta-analysis had a mean follow-up period of 16.1 months (range 6-30 months) and during this time provided an average of 28.6 treatment contacts (either in-person or delivered via telephone; range 6-52 sessions). In-person contact was typically delivered in a group setting, with sessions lasting from 45-90 minutes. Follow-up contact via telephone was typically delivered in 5-20 minute individual telephone calls with the programme interventionists.

The effect of extended care on long-term weight loss maintenance varied by study. Using the pooled data, the effect would lead to maintenance of an additional 3.20kg of weight loss for participants provided extended care, over the mean duration of 17.6 months post-intervention. Middleton et al. (2011) concluded that their findings support the use of extended care for the long-term maintenance of weight loss, with a moderate effect found for impact of extended care on long-term weight loss maintenance. Attendance at extended care groups appeared to affect long-term outcome, such that individuals who regularly attended groups were more likely to be adherent to caloric intake and physical activity goals and thus regain less weight. Further, Middleton et al. (2011) observed that the trained interventionist contact appeared to be a critical component of successful maintenance programmes (i.e. non-interventionist [untrained] contact was not effective).

Middleton et al. (2011) recommended that further research be conducted to design and test interventions tailored to assist non-Caucasian participants. Most of the studies involved Caucasian participants and there was little evidence for other ethnic groups or on related factors (e.g. SEP, acculturation) that may interact with the effect of ethnicity and response to interventions. Middleton et al. (2011) caution that without this knowledge, the field risks creating programmes that are helpful to some with the exclusion of others.

Are nutrition and physical activity primary prevention interventions in the primary care setting effective at reducing biochemical and physical risk factors? (Quigley, et al., 2012)

In a systematic review and narrative synthesis of 28 studies Quigley, Brown and Schofield (2012) assessed the effectiveness of individual-level primary prevention interventions in the primary care sector for altering biochemical or physical endpoints via nutrition and physical activity. Quigley et al. (2012) defined *primary prevention* as the attempt to prevent people from developing diagnosed diseases and focused on individuals who did not yet have type 2 diabetes, CHD or another diagnosed disease, but had at least one risk factor such as hypertension, high lipids or elevated blood glucose (most had elevated BMIs, and were overweight/obese). The interventions were mainly education-

oriented/counselling and individually-focused multi-risk factor designs. Examples of intervention components included: multiple 15-minute physician visits including advice on incorporating lifestyle activity into daily routines, recommendations to begin an exercise programme to achieve 150 minutes per week of at least moderate intensity exercise; printed intervention materials that were individually prepared and tailored to each patient; intensive group education about the Mediterranean diet; counselling and supervised progressive, individually tailored aerobic exercise programmes; counselling for exercise; and health planning delivered predominantly by a health coach. The interventions were grouped as physical activity-only interventions, nutrition-only interventions, and joint nutrition and physical activity interventions. The reported outcomes were body weight (as a primary outcome) with cholesterol, lipids, HbA1c and blood pressure also being reported in a number of studies. Generally, the interventions were not delivered by the GP but instead by support staff. Nearly all of the studies reported positive behavioural outcomes (e.g. increased time spent being active, increased servings of fruit and vegetables consumed) but these did not translate into similar changes in biological endpoints at 6-36 months follow-up (most commonly studies were of 12-month duration). Quigley et al. (2012) concluded that the primary care sector is largely unsuccessful at individual-level primary prevention.

Many of the studies with no effect were impressive in their design, theoretical underpinning and multi-risk factor approach, however most did not induce meaningful changes in the measured endpoints. When viewed from a specifically *weight loss* intervention perspective, consideration should be given to the context: that the interventions were framed as down-stream education-oriented and individually-focused multi-risk factor interventions (primary prevention rather than obesity treatment interventions per se). Nevertheless, body weight (weight loss) was almost universally the primary outcome of interest (or at least included in the biochemical and physical endpoints in most studies) and the programmes can broadly be described as lifestyle interventions. Quigley et al. (2012) were clear in their description of primary care and stressed the primary prevention *framing* used in their review, therefore any wider application of the findings needs to make with caution. Further, while the research was conducted in New Zealand, no attempt was made to study the in-depth nature of success/lack of success within a New Zealand setting.

Quigley et al. (2012) recommend that any primary care practice wanting to develop and deliver an individual-level programme is strongly advised to include active research to assess whether the intervention is effective. If primary care becomes a focus for primary prevention policy in New Zealand (beyond population level health promotion) then substantial understanding would be required of features such as the patient journey and funding pathways (Quigley, et al., 2012).

Effectiveness of male-only weight loss and weight loss maintenance interventions (Young, Morgan, Plotnikoff, Callister, & Collins, 2012)

Young, Morgan, Plotnikoff, Callister and Collins (2012) conducted a systematic review and metaanalysis of 23 studies including 1,869 male participants. The included studies were male-only weight loss and weight loss maintenance interventions with clear intent to change behaviour or lifestyle. The settings included clinical settings, community settings, a workplace and one shipboard setting and the interventions were delivered by healthcare professionals or trained providers/commercial providers. Four studies included an additional weight loss maintenance intervention. Of interest, only five included studies tested 'gender-sensitive' weight loss interventions (i.e. tailored for men), whereas the majority trialled a standard, gender-neutral weight loss programme. Young et al. (2012) found a significant difference in weight change favouring the weight loss interventions over controls (weighted mean difference [WMD] -5.66kg [-6.35, -4.97]). Weight regain was significant but comparable across all groups, and this was evident at 6-23-month follow-up. Characteristics common to effectiveness were younger age (≤42.8 years), increased frequency of contact (>2.7 contacts/month), group face-to-face contact, and inclusion of a prescribed energy restriction.

Young et al. (2012) concluded that preliminary evidence suggests men-only weight loss programmes may effectively engage and assist men with weight loss but a common limitation is the absence of participant follow-up beyond immediate post-test assessment. Although the WMD of -5.66kg appears promising, these results are undermined by the generally low study methodological quality of studies, indicating an increased risk of bias, and should be interpreted with caution (70% of the studies did not use intention-to-treat analysis and 39% did not achieve adequate retention rates) (Young, et al., 2012). These factors are likely to bias the results by inflating both the success rate of participants and the magnitude of weight loss.

The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults (Loveman, et al., 2011)

Loveman et al. (2011) conducted a health technology assessment/systematic review of 12 RCTs to assess the long-term clinical effectiveness and cost-effectiveness of multicomponent weight management schemes for adults with at least 18 months' follow-up. Multicomponent weight management programmes combined diet, physical activity and behaviour change strategies. The interventions were delivered in research settings, leisure centres, primary care, pharmacies, and/or delivered in partnership with commercial weight loss organisations by researchers and appropriately trained professionals (e.g. registered dietitian, weight loss advisor, nutritionists, a health educator and psychologist, exercise physiologist, trained interventionists). The RCTs ranged in duration from 18 to 54 months.

Weight loss ranged from 0.21kg-6.6kg across the various studies with 3-4kg being typical. The longest follow-up study reported a 1.5kg weight loss at 54 months (not statistically significant). Attrition ranged from 7-46%. In general, weight changes across the included studies were small. Long-term multicomponent weight management interventions were generally shown to promote a small amount of weight loss in overweight or obese adults and weight regain was common. Loveman et al. (2011) concluded that, given the results, it was difficult to establish clinical significance. If the common assumption that a 5% weight loss is meaningful is applied, then participants in only 6 of 12 studies would be considered to have received clinical benefit from their weight loss. An alternative assumption could be that for participants to benefit meaningfully from an intervention any weight loss at the end of the intervention followed by longer-term weight stability would be acceptable. Based on this criterion none of the five studies that presented weight change results at more than one time point would be considered to have demonstrated acceptable weight loss. Loveman et al. (2011) concluded that any degree of weight loss or weight loss maintenance achieved may be meaningful depending on what threshold is considered a marker of success and from whose perspective it is taken (there does not appear to be a consensus as to what constitutes a clinically meaningful weight loss).

Relationship between costs of lifestyle interventions and weight loss in overweight adults (cost-effectiveness analysis) (Bogers, et al., 2010)

Bogers et al. (2010) carried out a cost-effectiveness analysis of 19 studies of lifestyle interventions carried out in a healthcare setting, for overweight adults. Generally, most of the interventions contained behavioural group sessions led by a dietitian or another interventionist (e.g. psychologist, exercise physiologist, graduate student). The mean drop-out percentage during one year was 23% (range 0 to 48%). The mean percentage of weight loss at one year was 4.9% (range 0 – 9.7%) and a clinically significant weight reduction of at least 5% was achieved in 15 of the 31 interventions. Bogers et al. (2010) found that higher intervention costs⁴⁸ of lifestyle interventions are associated with more weight loss by the participants after 1-year. This association was clearly non-linear (**Figure 9**). At higher costs the additional weight loss associated with extra investments levelled off dramatically⁴⁹. Bogers et al. (2010) also observed considerable variation in weight loss between interventions with similar costs and suggested that this variation may, among other factors, be caused by differences in the content of the interventions.

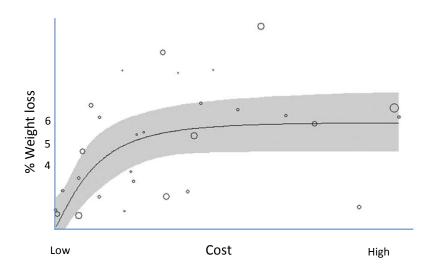


Figure 9: Scatter plot between costs of interventions per person and the percentage of weight loss at 1-year

The above figure shows the scatter plot between costs of interventions per person and the percentage of weight loss 1-year after the start of the intervention, for an intention-to-treat analysis of 31 intervention groups in which the regression line with 95% confidence intervals is drawn. The plot revealed that higher intervention costs were associated with more weight loss, but that with increasing costs the extra weight loss levelled off. A potential explanation for this finding may be that with an increasing intensity weight loss becomes more and more limited by physiological factors. **Note:** intervention costs are not shown as these are likely outdated, were calculated using Dutch reference prices expressed in 2007 Euros, and the estimated intervention costs may differ from the actual costs incurred in other countries. Adapted and simplified from Bogers et al. (2010).

While the shape of the curve is illuminating and relevant, Bogers et al. (2010) noted several limitations to their quantitative findings including: (1) the analysis was limited to a 1-year follow-up (and further research is needed to evaluate intervention programmes and the additional costs

48 Which can be regarded as a general measure of an intervention's intensity.
 49 A potential explanation for this finding may be that with an increasing intensity weight loss becomes more and more

limited by physiological factors.

needed for the long-term maintenance of weight loss) (2) the estimated intervention costs may differ from the actual costs (3) the estimated intervention costs were based on Dutch standard cost prices and in other countries the costs will probably be different and (4) all participants were volunteers in a scientific study and the results are generalisable to everyday practice probably only for patients motivated to lose weight and willing to change their behaviour. Notwithstanding these potential limitations, Bogers et al. (2010) concluded that lifestyle interventions in overweight adults in a healthcare setting are generally relatively cheap and that higher intervention costs are associated with more weight loss, although the effect of costs on weight loss levels off with growing costs. Bogers et al. (2010) suggest that this information should be considered by policy makers, clinicians and other health professionals in their choice to implement certain lifestyle interventions.

Reduction of type 2 diabetes risk in routine clinical practice: are physical activity and nutrition interventions feasible and are the outcomes from reference trials replicable? (Cardona-Morrell, et al., 2010)

Cardona-Morrell, Rychetnik, Morrell, Espinel and Bauman (2010) included only translational research in their systematic review of 12 RCTs of lifestyle interventions for people with impaired glucose tolerance, severe obesity, or metabolic syndrome. The trials were either single component programmes (either nutrition or physical activity) or combined nutrition and physical activity programmes of at least 3-months duration and followed up for at least another 3-months after the end of the active intervention period. All 12 studies were replications of the reference trial approaches from either the DPP or the DPS, however the inclusion criteria specified that the trials had to have been conducted in routine clinical practice settings, including primary health clinics, hospital outpatient clinics or specialist medical centres and be delivered by GPs, specialist physicians, practice nurses, dietitians, physiotherapists, or other allied health professionals or community health staff. Outcomes included weight or waist circumference, metabolic outcomes, behavioural outcomes and the incidence or delay in onset of type 2 diabetes. Cardona-Morrell (2010) calculated a pooled weight loss in the four RCTs with a 12-month follow-up assessment of 1.82kg (this is less than the 5.6kg loss observed in the lifestyle-only group of the reference DPP trial or the 4.2kg reported in the intervention group of the DPS). Loss-to-follow up rates in the 12 studies varied greatly, from 5% to 57% (median 14%).

Nine of the twelve studies explored in detail whether or not translation of the reference trials into clinical care was feasible. Eight concluded that modification of the original trial approaches for adaptation to real life practice made the lifestyle interventions feasible, affordable or replicable in clinical care settings despite some barriers to implementation. The remaining study reported that the transferability of the results from original trials to other settings remains questionable, and the positive effect on outcomes diminishes over time. Protocol adaptations included shorter duration; delivery of group sessions instead of individual face-to-face counselling; reduced number and frequency of counselling sessions and mixed group and individual programme approaches. Arguably, these adaptations collectively reduced the effectiveness of the programmes.

"out-of-pocket expenses lead to differential exposure to intensity and duration of intervention on the basis of participant's ability to pay" Cardona-Morrell (2010) concluded that despite convincing evidence from structured intensive trials, their systematic review showed that translation into routine practice has less effect on type 2 diabetes risk reduction (weight loss being the primary outcome). Further, in 10 of the

12 included studies the intervention incurred no charges or out-of-pocket expenses for each participant per session, and Cardona-Morrell (2010) cautioned that this may lead to differential exposure to intensity and duration of intervention on the basis of participant's ability to pay in real-world settings/health systems.

Treatment of obesity in primary care practice in the USA (Tsai & Wadden, 2009)

In a seminal review of obesity treatment in USA primary care settings, Tsai and Wadden (2009) examined the degree to which the 2003 USPSTF recommendations were being implemented in primary care settings and the effectiveness of such interventions on weight loss outcomes. The recommendations detailed that clinicians should screen all adult patients for obesity and offer intensive counselling and behavioural interventions to promote sustained weight loss for obese adults. A high-intensity intervention was defined as an intervention that delivered at least two visits per month for the first 3-months, a moderate intensity intervention monthly contact, and a low intensity intervention less than monthly contact for the first 3 months. Tsai and Wadden (2009) conducted an extensive search of the literature and included ten RCTs in their systematic review. The intervention approaches included primary care provider counselling alone, primary care provider counselling plus pharmacotherapy, and collaborative obesity care (treatment delivered by a non-physician provider). The settings were all explicitly intended to model a primary care and weight loss was the primary outcome in all studies.

Tsai and Wadden (2009) found that only two of the five studies met the USPSTF criteria for high-intensity intervention, most studies provided only low- or moderate-intensity counselling. High attrition rates were common with rates ≥35% being reported in several studies. Weight losses for primary care provider counselling interventions ranged from 0.1kg to 2.3kg; for primary care provider counselling plus pharmacotherapy, 1.7kg to 7.5kg; and for collaborative obesity care interventions ranged from 0.4kg to 7.7kg.

"available data do not indicate how best to incorporate primary care providers into more intensive approaches" Results of this review suggest that: (1) low-intensity primary care provider counselling alone is insufficient for achieving clinically meaningful weight loss in obese adults, and (2) available data do not indicate how best to incorporate primary care providers into more

intensive approaches (e.g. collaborative treatment) to achieve this goal. Tsai and Wadden (2009) provided detailed discussion of the critical issues relating to implementation in primary care settings and concluded that "without more effective therapies, greater resources in their practices, and more adequate reimbursement, primary care providers alone cannot be expected to provide effective weight management for all of their patients who require it" (Tsai & Wadden, 2009, p.1078).

Effectively, Tsai and Wadden (2009) judged that the time, effort, and expense required for primary care providers to provide such care would appear to be prohibitive (in the absence of adequate reimbursement). Tsai and Wadden (2009) asserted that the evidence reviewed did not support

"low-intensity primary care provider counselling alone is insufficient for achieving clinically meaningful weight loss in obese adults"

the use of low- to moderate-intensity physician counselling for obesity, by itself, to achieve clinically meaningful weight loss. Finally, Tsai and Wadden (2009) made clear the fact that their review intentionally excluded studies in which the primary care provider could elect to play a more supportive or consultative role, that is, to assess and then refer patients to more intensive weight loss interventions that are delivered outside of primary care settings. Tsai and Wadden (2009)

identified this as a distinctly different approach (and a different research question) and one that potentially has merit.

Table 5: Summary (alphabetical, by first author) of systematic reviews and meta-analyses of interpersonal-based interventions for weight loss and weight loss maintenance included in this report

| Reference | Design | Intervention | Results | Conclusions/clinical relevance |
|---------------|--|--|---|---|
| Aguiar (2014) | Systematic review and meta-analysis. Eight studies: including five RCTs, one quasi-experimental, one two-group comparison and one single-group pre-post study. Settings: Clinical research settings, special clinics and supervised exercise facilities. Providers: Research staff/exercise and nutritional specialists. | Multi-component (diet + aerobic exercise + resistance training) lifestyle interventions. Median intervention duration was 12 mo (range 4–48 mo) with a follow-up of 18 mo (range 6.5-48 mo). Physical activity: aerobic average 5.0 ± 1.5 days/wk (mean ± SD), duration of 157.5 ± 44.4 min/wk and resistance training 2.3 ± 0.7 days/wk duration of 90.0 ± 24.5 min/wk. Diet: Five studies prescribed energy restriction for weight loss and seven studies prescribed a specific dietary macronutrient profile. | Meta-analysis favoured interventions over controls for weight loss (–3.79kg, 95% CI –6.13 to -1.46kg), The time frame of assessments varied from 4-36 mo. Design characteristics of studies that achieved significant changes for weight loss and plasma glucose included: face-to-face intervention delivery mode (individual and/or group), an average of eight contacts per month (including face-to-face sessions, emails and phone calls), and a minimum of six (preferably 12) mo of follow up. Lifestyle intervention characteristics included: 150–210 min (3–5 sessions) of aerobic exercise per wk; 60–120 min (1–3 sessions) of resistance training per wk; recommendations for a specified macronutrient diet profile, energy restriction for weight loss and setting a weight loss goal of 5-10%. | Multi-component lifestyle type 2 diabetes prevention interventions that include diet and both aerobic and resistance exercise training are modestly effective in inducing weight loss and improving impaired fasting glucose, glucose tolerance, dietary and exercise outcomes in at-risk and prediabetic adult populations. Weight loss was the primary study outcome in all trials. However, all studies provided supervised individual or group exercise sessions for at least part of the intervention; only one study included a home-based exercise component. This has implications for feasibility. |
| Barte (2010) | Systematic review of 22 studies with a weight maintenance follow-up period of 1-yr of unsupervised follow-up. Settings: healthcare setting. Providers: Dietitian or another interventionist (e.g. psychologist, exercise physiologist, graduate student). | Twenty-two interventions (duration at least 1 mo) in healthy mainly Caucasian population of 18 yrs or older. Generally, most interventions contained behavioural group sessions led by a dietitian or another interventionist. | Intervention group on average lost 9.5% of their baseline weight during the intervention and 1 yr after the intervention on average 54% of this weight loss was maintained, 44% maintenance at 2-yr follow-up. | There was no relation between the percentage weight maintenance after 1 yr of unsupervised follow-up and weight lost during the intervention period. Therefore, 10% or more weight loss should be encouraged and favoured above a lower weight loss as this results in greater net weight loss after the unsupervised follow-up. Note: participants who have a low percentage maintenance fluctuate in their body weight to a higher extent, compared with a high maintenance group, which may have detrimental consequences to health. |

| Barte (2014) | Systematic review and meta-analysis of 22 interventions, mainly Caucasian population, and weight change data of 2,431 participants. Settings: Mixed: commercial providers, research settings, healthcare settings. Providers: A professional healthcare provider, such as dietitians, exercise specialists, or behavioural interventionists. | Dietary and physical activity components aiming at weight loss, and at least five contact sessions. In general, interventions contained caloric restriction, a physical activity goal, and (behavioural) group sessions. | Overweight participants lost 1.1kg less (p <0.01) than participants with class-I obesity and 1.5kg less (p <0.01) than participants with class-II obesity. However, for <i>percentage</i> weight change among the BMI classes, these differences were not statistically significant (0.6%; 0.1 %, -0.3% respectively). | Average weight change during lifestyle interventions only differs to a small extent among people with BMI between 25 and 40. This implies that these interventions are equally appropriate for these BMI classes. Different intensities and contents of an intervention may give different results for different groups of patients. It would be useful to show which intervention components work better for the different BMI classes. However, in general the content of the interventions was not described sufficiently and the number of included interventions was too low to compare intensity or components among the interventions. Further research on this specific topic is recommended. |
|---------------|--|--|---|---|
| Bogers (2010) | Cost-effectiveness analysis of 19 studies. Settings: a healthcare setting. Providers: Healthcare professionals, dietitian or another interventionist (e.g. psychologist, exercise physiologist, graduate student). | Generally, most interventions contained behavioural group sessions led by a dietitian or another interventionist. | The mean drop-out percentage during 1 yr was 23% (range 0 to 48%). The mean costs made during 1 yr were €236 and the mean percentage of weight loss at 1 yr was 4.9%. A clinically significant weight reduction of ≥5% was achieved in 15 of the 31 interventions. The costs on the regression line that corresponded with a weight loss of 5% were €110. | Higher intervention costs were associated with more weight loss, but with increasing costs the extra weight loss levelled off. A potential explanation for this finding may be that with an increasing intensity weight loss becomes more and more limited by physiological factors. Still, considerable variation in weight loss was observed between interventions with similar costs. This variation may, among other factors, be caused by differences in the content of the interventions. This analysis was limited to a 1-yr follow-up and further research is needed to evaluate intervention programmes and the additional costs needed for the long-term maintenance of weight loss. |

| Booth (2014) | Systematic review and | Behavioural interventions in obese or | Pooled results from meta-analysis indicated a | The results of this review suggest that behavioural |
|--------------|-----------------------------|---------------------------------------|--|---|
| , | meta-analysis of 15 RCTs, | overweight adult participants (age | mean weight loss of –1.36kg (95% CI –2.10 to | interventions conducted in primary care have a |
| | 4539 participants. | ranged from 41.8 to 60 yrs). | -0.63, <i>p</i> <0.0001) at 12 mo, and -1.23kg (95% CI | negligible effect on participants' weight at 12 and 24 |
| | Settings: Participants had | Tunged 11011 12.0 to 00 413/. | -2.28 to -0.18, p=0.002) at 24 mo. | mo. Based on the range of mean baseline body |
| | to be selected from their | | 2.20 το 0.10, β-0.002, ατ 24 πο. | weights observed in this review (82.9–107.7kg) the |
| | | | | |
| | practice patient list and | | | pooled estimates of weight loss did not reach clinical |
| | the intervention | | | significance. |
| | conducted within the | | | Previous systematic reviews on primary care |
| | primary care setting. | | | management of obesity have included studies |
| | Providers: Non-research | | | conducted in specialist hospital or academic settings, |
| | staff (GPs, nurses, other). | | | with a view that they are directly transferrable to the |
| | This is reflective of the | | | primary care setting. Studies from specialist settings |
| | multidisciplinary teams | | | are likely to differ from those conducted within |
| | that might now deliver | | | primary care in several important aspects: |
| | primary care services. | | | population is unlikely to be representative; |
| | | | | differences in motivation; conducted by research |
| | | | | staff; interventions are likely to be more intensive |
| | | | | than those in primary care, with more time |
| | | | | |
| | | | | dedicated to ensuring protocol adherence and |
| | | | | better follow-up rates. |
| | | | | Previous reviews may have overstated the potential |
| | | | | effect of weight loss interventions in routine practice |
| | | | | in primary care. |

| Cardona-Morrell | Systematic review of 12 | Lifestyle intervention ≥3 mo duration | Pooled weight loss in the four RCTs yielded a | Nine of 12 studies explored whether translation of |
|-----------------|---|--|--|--|
| (2010) | RCTs of translational | and followed up for ≥3 mo. Single | weight loss of 1.8kg at 1 yr (less than the 5.6kg | the reference trials into clinical care was feasible. |
| (2010) | RCTs of translational research. People at high risk: the presence of impaired glucose tolerance, severe obesity, or metabolic syndrome. Settings: Routine clinical practice (primary health clinics, hospital outpatient clinics or specialist medical centres). Providers: GPs, specialist physicians, practice nurses, dietitians, physiotherapists, allied health professionals, | and followed up for ≥3 mo. Single (either nutrition or physical activity) or combined nutrition and/or physical activity programmes. All studies were replicates of the reference trial approaches from either the DPP or the DPS. | weight loss of 1.8kg at 1 yr (less than the 5.6kg loss observed in the lifestyle-only group of the reference DPP trial or the 4.2kg reported in the intervention group of the DPS). Only four of the seven studies reported weight changes at 1 yr similar in magnitude to the DPP in the US (≈5kg). Loss-to-follow up rates in the 12 studies varied greatly, from 5% to 57% (median 14%). | the reference trials into clinical care was feasible. Eight concluded that modification of the original trial approaches for adaptation to real life practice made the lifestyle interventions feasible, affordable or replicable in clinical care settings despite barriers to implementation (adaptations included: shorter duration; delivery of group sessions instead of individual face-to-face counselling; reduced number and frequency of counselling sessions and mixed group and individual programme approaches). The remaining study reported that the transferability of the results from original trials to other settings remains questionable, and the positive effect on outcomes diminishes over time. Note: In 10/12 studies the intervention incurred no charges or out-of-pocket expenses for each session, which may lead to differential exposure to intensity and duration of intervention on the basis of |
| | community health staff, | | | participant's ability to pay. |
| | or research staff. | | | |
| Chen (2015) | Meta-analysis of 16 RCTs of comprehensive lifestyle interventions on clinical markers in patients with type 2 diabetes. Settings: Mixed clinical settings. Providers: Healthcare professionals. | Comprehensive lifestyle change interventions, such as diet, exercise, and education. Study duration ranged from 6 mo to 8 yr. | BMI (-0.29kg/m ² , 95% CI -0.52 to -0.06kg/m ² , p=0.014). | Of the 16 RCTs, 11 measured BMI as a primary outcome. While meta-analysis found a statistically significant effect favouring the intervention, the clinical significance of this modest change was not discussed. |

Dombrowski (2014)

Systematic review and meta-analysis of 45 RCTs with participants randomised to a weight maintenance intervention and ≥12 months followup from inception of the maintenance phase. Settings: Home, internet or phone, clinics, community, interactive television studio, or gym based settings. Providers: Mixed (e.g. therapists, dietitians, GPs, nurses, nutritionists, exercise instructors, students, peers) in group or combined group and individual format.

Any behavioural/lifestyle, pharmacological, food replacement/supplement, or alternative interventions.

Participants were adults (aged ≥18), an average BMI of ≥30, lost ≥5% of their body weight/mass within 24 mos before weight loss maintenance treatment.

Of the 42 studies that included a formal weight loss phase, the average weight loss across studies ranged from –4.0kg to –21.3kg, with a weighted average of averages of –10.8kg. At 12 mo, 15 behavioural/lifestyle studies including 25 comparisons showed a mean difference in weight change of –1.56kg (95% CI –2.27 to –0.86kg). At 24 and 30 mo, only two studies reported outcomes. Overall mean differences in weight change remained significant at 24 mo (–1.48kg, 95%CI –2.27 to –0.69kg) but not at 30 mo (–0.85kg, 95%CI –1.81 to 0.11kg).

Comprehensive behavioural interventions targeting dietary and physical activity behaviours are moderately effective in slowing regain of weight in obese adults after initial weight loss for follow-up periods of up to 2 yrs.

Further research is needed over periods of more than 2 yrs.

Dunkley (2014) Systematic review and meta-analysis, including 25 trials. 11 RCTs, 11 before-and-after studies, other. Settings: Mixed, community settings, integrated healthcare organisation, outpatients, primary care, and workplace. Participants ranged from 8 to >2,700, with 22

studies including at least

Providers: Mixed/not

50 participants.

clear.

Real-world/pragmatic
lifestyle interventions (nutrition and
physical activity) based on the
recommendations of the type 2
diabetes prevention clinical trials
(conducted between 1996 and 2001,
NICE, Development and
Implementation
of a European Guideline and Training
Standards for Diabetes prevention
(IMAGE) guideline
recommendations),

The pooled result of the meta-analysis shows that lifestyle interventions resulted in a mean weight loss of 2.32kg (95% CI -2.92 to -1.72kg). Adherence to guidelines was significantly associated with a greater weight loss (an increase of 0.4kg per point increase on a 12-point guideline-adherence scale). Although outside the scope of this report, the level of weight loss reported in this article is likely to have a clinically meaningful effect on type 2 diabetes incidence.

Real-world type 2 diabetes prevention programmes vary widely in their effectiveness, although most produce lower levels of weight loss than the more intensive interventions used in the clinical efficacy trials.

The mean level of weight loss achieved was approximately one-half to one-third of the levels reported at the same time point within the intervention arms of clinical efficacy trials such as the DPP.

The study is limited in that there were insufficient data to analyse outcomes beyond 12 mo; the findings may not translate into long-term therapeutic value due to uncertainty around sustaining outcomes, such as weight loss, in the longer term.

More research is needed to establish optimal strategies for maximising both cost-effectiveness and longer-term maintenance of weight loss and type 2 diabetes prevention effects.

Gallagher (2013)

Systematic review of eight RCTs (total n=1428). Settings: Integrated healthcare/primary care/hospital clinic. Individual sessions and group sessions and phone Providers: Healthcare professionals (dietitians, exercise physiologists, specifically trained registered nurses).

Interventions which combine dietary, exercise and behaviour change strategies. Interventions varied by contact time, content and delivery. Supervised structured exercise sessions. Dietary advice promoted caloric restriction. Behaviour change strategies involved the promotion of goal-setting and self-monitoring.

Participants' mean age was 60.4 years and 61% were female. Mean weight loss ranged from - 2kg to -4kg (SD 4kg) at 3-4 mo, -1.3kg to -8.2kg (SD 4kg) at 5-6 mo and -0.87 (SD 0.57kg) to -6.9kg (SD 4kg) at 12 mo.

The amount of contact time participants had with the intervention team members varied greatly: max = a 2.5 day workshop in a retreat format, followed by 4 hrs of contact/wk for 6 mo, & minimum five 2hr sessions over 12 mo. Inclusion of weekly supervised exercise sessions achieved mean differences in weight loss that were ≥5%. Weight loss interventions that combine exercise, diet and behaviour change strategies result in minor weight loss at 3-12 mo in people with CHD, type 2 diabetes or hypertension. Frequent contact appears to support the cognitive behavioural strategies which are integral to the interventions and the critical element is most likely the length of time over which contact occurs, rather than the total amount of contact alone. No study included in the review reported on how participants achieved this independence or how transition to community and group-based endeavours was promoted, and it would be an important consideration for future research.

| Johansson (2014) | Systematic review of 27 |
|------------------|----------------------------|
| | RCTs with a total of 27 |
| | intervention arms and |
| | 3017 participants. |
| | Settings: Mixed (research |
| | facilities or community |
| | settings e.g. GP's office, |
| | university out-patient |
| | obesity clinic). |
| | Providers: Mixed |
| | (research staff and |
| | healthcare professionals |
| | |
| | |
| | |

Interventions included pharmaceutical weight loss agents (3 arms; n=658), meal replacements (4 arms; n=322), high-protein diets (6 arms; n=865), dietary supplements (6 arms; n=261), other diets (3 arms; n=564), and exercise (5 arms; n=347).

During the LCD/VLCD run-in period, the pooled mean weight change was -12.3kg (median duration: 8 wk; range 3-16 wk).

Weight regain during the maintenance period differed between individual studies, ranging from a further mean weight change of -5kg to a regain of 14kg in the intervention groups and from -1kg to a gain of 13kg in the control groups.

Compared with controls, pharmaceutical weight loss agents improved weight loss maintenance by 3.5kg (95% CI 1.5 to 5.5kg; median duration 18 mo, range 12-36 mo), meal replacements by 3.9kg (95% CI 2.8 to 5.0kg; median duration 12 mo, range 10-26 mo), and high-protein diets by 1.5kg (95% CI 0.8 to 2.1kg; median duration 5 mo, range 3-12 mo). Exercise (0.8kg, 95% CI -1.2 to 2.8kg; median duration 10 mo, range 6-12 mo) and dietary supplements (0.0kg, 95% CI -1.4 to 1.4kg; median duration 3 mo, range 3-14 mo) did not significantly improve weight loss maintenance compared with control.

In this meta-analysis of RCTs, the largest improvements in weight loss maintenance after a LCD were seen for pharmaceutical weight loss agents and meal replacements. A high-protein diet also improved weight loss maintenance. However, the mean duration of follow-up in the studies in the meta-analysis was still relatively short (mean follow-up of 5–22 mo, depending on category).

Two of the three included RCTs on exercise indicated improved weight loss maintenance in the short term. The long-term follow-up data from the same trials were negative, however, probably because of reduced compliance with the high amounts of exercise needed for weight control (60–90 min/day).

| Johnson (2013) | Systematic review, of 19 | Type 2 diabetes prevention protocols | Most of the interventions attracted | The main challenge is how best to deliver and |
|----------------|---------------------------|---|--|---|
| | studies. | to real-world settings (translational | predominantly women. | achieve engagement with interventions and how to |
| | Settings: Community, | studies). | There was a strong trend toward weight loss | sustain lifestyle change. |
| | church, YMCA, integrated | Assessed only those studies that | following all but one of the interventions (in the | This review demonstrates that group-based |
| | healthcare, primary care, | applied a specified, known protocol | range of 2.5-7%). Reduction in type 2 diabetes | interventions can yield significant weight loss (with |
| | hospital clinic. | that has previously been associated | incidence was not measured in any controlled | the expectation of reductions in the risk of type 2 |
| | Providers: Trained | with a reduction in the incidence of | study. | diabetes), provided that changes are sustained over |
| | educators, with a variety | type 2 diabetes as well as weight loss. | Note: Only one study provided results beyond | a number of years. |
| | of professional | | 12 mo follow-up. Most studies did not report on | Further research is needed to identify the most cost- |
| | backgrounds. | | an intention-to-treat analysis and drop-out was | effective mode of delivery. From the findings of the |
| | | | high in some studies. | included papers, one option may be a highly |
| | | | | qualified diet and physical activity professional |
| | | | | supported by a less-qualified individual. |

Kirk (2012) A review of 6 metaanalytical reviews, 10 systematic reviews (no meta-analysis), 9 nonsystematic reviews, and 11 primary papers of relevance. Settings: Workplace, community and

healthcare.

Providers: All different

healthcare providers.

Lifestyle interventions for weight loss and weight loss maintenance including (1) targeted multicomponent interventions for weight management, (2) dietary manipulation strategies and (3) delivery of weight management interventions, including health professional roles and method of delivery.

Most effective practice recommendations

(includes meta-analysis and systematic reviews). **Overall:** Obesity should be viewed as a complex, chronic condition, requiring sustained contact with and support from trained health professionals.

Theme ONE Targeted multi-component interventions for weight management.

- (1) Multi-component interventions lead to greater weight loss, whereas single-component interventions are more effective in improving the targeted behaviour, for example, diet or physical activity.
- (2) Three-component interventions are likely to have more success at preventing weight gain than one or two-component interventions.

Theme TWO Dietary manipulation strategies.

(1) Low-carbohydrate diets appear to be more effective than low-fat diets in inducing weight loss.

Theme THREE Delivery of weight management interventions, including health professional roles and method of delivery.

- (1) Providing educational interventions to health professionals, particularly GPs, would result in greater weight loss in their patients, compared with standard care.
- (2) Offering structured, individualised nutritional counselling as a means to reduce fat or caloric intake, is preferred for supporting weight loss compared with usual care.
- (3) Computer-tailored nutrition education shows strong promise for changing dietary behaviour, particularly in the short term.

Most promising practice recommendations

(includes non-systematic reviews and primary studies)-

Theme ONE

- (1) Programme goals should target weight management specifically, rather than other outcomes such as CHD or general health status. Generally, interventions were found to have potential in changing energy balance-related behaviours and anthropometric outcomes.
- (2) Behavioural treatment of obesity is effective in inducing an initial weight loss of around 5–10%.
- (3) Individuals should engage in 150–250 min/wk of moderate intensity physical activity to prevent weight gain and for long-term weight management; more than 250 min/wk of physical activity could promote clinically significant weight loss.
- (4) Weight loss programmes of at least 6 mo duration should be planned.

Theme TWO

- (1) Low-carbohydrate diets may be more effective than low-fat diets at inducing weight loss, at least in the short term.
- (2) Adding CBT to either low-carbohydrate or low-fat diets may produce significantly greater short-term weight loss compared with diet alone.

Theme THREE

- (1) Motivation and encouragement by a healthcare professional, as well as regular contact with a health professional, are key components in a weight loss strategy.
- (2) Mobile technology-based weight reduction programmes offer promise for supporting weight management.

| Kouvelioti (2014) | Systematic review of 14 RCTs. Settings: Research facilities or community settings. Providers: Research staff | Interventions that recommended exercise and diet combined in overweight and obese adults. | Overall estimations showed a weight loss of 11.1kg (13%) after an average of about 4 mo from baseline, a weight loss maintenance of 5.8kg (about 52%) and a weight regain of 5.1kg after an average period of about 21 mo. | Weight loss was successful but almost half of it (about 48%) was regained, which agrees with previous findings. The 14 studies were rated very good to excellent quality however there was high average dropout (>20%). |
|-------------------|---|---|---|--|
| Loveman (2011) | Health technology assessment systematic review of 12 studies to assess the long-term clinical effectiveness and cost-effectiveness of multicomponent weight management schemes for adults. Settings: Research settings, leisure centres, primary care, pharmacies and schemes delivered in partnership with commercial weight loss organisations. Providers: Researchers and appropriately trained professionals e.g. registered dietitian, weight loss advisor, nutritionists, a health educator and psychologist, exercise physiologist, trained interventionists | Multicomponent weight management programmes (including diet, physical activity and behaviour change strategies), with at least 18 mo follow-up. | The RCTs ranged in duration from 18 to 54 mo. Weight loss ranged from 0.21kg to 6.6kg across the various studies with 3-4kg being typical. The longest follow-up study reported a 1.5kg weight loss at 54 mo (not statistically significant). Attrition ranged from 7-46%. In general, weight changes across the included studies were small. | Long-term multicomponent weight management interventions were generally shown to promote weight loss in overweight or obese adults. Weight changes were small however and weight regain was common. However, it is difficult to establish clinical significance. If an assumption that a 5kg weight loss is meaningful, then participants in only 6/12 studies would be considered to have received clinical benefit from their weight loss. Based on a criterion of weight maintenance, 0/5 studies that presented weight change results at more than one time point would be considered to have demonstrated acceptable weight loss. There is some evidence that weight management interventions are likely to be cost-effective, although caution is required as there were some limitations in the two cost-evaluation studies described. |

| Middleton (| 2012 |
|-------------|------|
|-------------|------|

Systematic review and meta-analysis of 11 RCTs that assessed the impact of extended care on weight regain, after initial weight loss, in overweight and obese individuals.

Settings: treatment contacts (either in-person or delivered via telephone), group setting.

Providers:
Interventionists

Extended care interventions for obesity within a 'continual care' model, in which obesity is treated as a chronic disease and individuals are provided with continued therapist contact to prevent weight regain following initial loss. Interventions delivered via the internet were excluded. All studies used CBT.

Maintenance of an additional 3.2kg of weight loss for participants provided extended care, over the mean duration of 17.6 mo post-intervention.

This review provided evidence for a moderate effect of extended care on long-term weight loss maintenance. Attendance at extended care groups appears to positively affect long-term outcome. It appears that interventionist contact (rather than peer led or untrained) is a critical component of successful maintenance programmes. The researchers recommended that further research be conducted to design and test interventions tailored to assist non-Caucasian participants. Also studies should focus on methods to improve cost-effectiveness and availability of these programmes, and investigation should be made into more cost-effective methods of delivery (e.g. via telephone or internet).

| Moredich (2014) | An integrative review | Physical activity and nutrition | Findings from the studies reviewed indicated | According to this synthesis of the best-available |
|-----------------|----------------------------|--------------------------------------|--|---|
| | (allows comparative | interventions used to combat obesity | that the majority reported statistically | evidence, customized weight loss interventions are |
| | analysis of diverse | in obese, low-income women. | significant weight loss from interventions | effective in obese, low-income women. However, |
| | research methodologies). | Intervention sessions ranged in | designed to increase physical activity and | the findings must be considered in light of issues |
| | Of the seven included | duration from 90 mins to 32 hrs over | change nutrition behaviour. | related to study quality. Several of the studies were |
| | articles, five were RCTs | a period of 4-12 mo. Included | | underpowered, lacked a control group, and/or |
| | and two employed quasi- | culturally and economically | | reported high attrition rates. Sample sizes ranged |
| | experimental designs; | appropriate nutritional guidance. | | from 19-144 women, and attrition rates varied |
| | three of the studies also | | | from17% to 43%. |
| | included a focus group | | | No study included long-term follow-up. Outcomes |
| | discussion. | | | were generally assessed at the end of the |
| | Settings: USA; occurred at | | | intervention period, i.e. 4-12 mo. |
| | community sites, such as | | | According to this integrative review, effective |
| | churches, community | | | interventions (1) are structured in a group, (2) can be |
| | centres, or health clinics | | | led successfully by a peer educator, (3) should |
| | Providers: Three studies | | | include pragmatic nutrition advice, and (4) must |
| | used peer leaders, three | | | encourage increases in physical activity. |
| | used healthcare providers | | | Cultural congruency was integral to several of these |
| | in the nurse-led | | | successful interventions. |
| | intervention, and one | | | |
| | researcher-led | | | |
| | intervention. | | | |

Nascimento (2014)

Systematic review of RCTs and pilot RCTs (excluded diet interventions without a physical activity component). Included 11 studies in the metanalysis, total of 769 participants.

Settings: Research facilities or community settings.

Providers: Research staff.

Interventions designed to promote weight loss in women postpartum and at any point up to and including 18 mo after delivery. Interventions provided a programme that included supervised physical exercise or physical exercise guidance/counselling with a minimum follow-up of 10 wks. No restrictions were placed on whether a complementary dietary intervention was utilised. The duration of intervention ranged from 10-52 wks.

The effect of exercise interventions, with or without dietary intervention, on weight loss during the postpartum period compared with usual standard of care was significant, a mean difference of -2.57kg (95% CI -3.66 to -1.47kg). Interventions that utilised heart rate or pedometer targets for goal setting and whose exercise regimen was coupled with intensive dietary interventions were found to be significantly more effective than those, which used other goal setting methods and dietary interventions. There was a trend towards supervised exercise interventions being more effective than unsupervised interventions, however, significance was not observed.

There appears to be benefit from lifestyle interventions; exercise programmes with objectively defined goals that are combined with intensive dietary intervention are effective in reducing weight in postpartum women.

Overall interventions that combined exercise with intensive dietary changes and monitoring resulted in greater postpartum weight loss than interventions that coupled exercise with dietary counselling or used exercise intervention only.

Overall, there was a trend towards supervised exercise intervention strategies being more effective than unsupervised intervention strategies.

These supervised programmes were intensive, 4-5 days/wk, and staff were able to ensure that women achieved their intensity goals through heart rate

achieved their intensity goals through heart rate monitors and/or pedometers. However, these kind of strategies require financial and personal resources to attend classes. Studies that involved supervised exercise interventions reported high refusal and attrition rates.

Further evaluation into the sustainability and long term effects of the interventions on the mother and child are needed.

| Peirson (2014) | Systematic review/meta- |
|----------------|-----------------------------|
| | analysis of 68 studies (of |
| | these 41 are relevant |
| | behavioural studies). |
| | Thirty-six of these studies |
| | were brought forward |
| | from the 2011 USPSTF |
| | review (LeBlanc 2011). |
| | Settings: Generalisable to |
| | Canadian primary care or |
| | feasible for conducting in |
| | or referral from primary |
| | care. |
| | Excluded morbidly obese |
| | participants (BMI ≥40) |
| | and those treated in |
| | specialist clinics. |
| | Providers: Research staff |
| | |
| | |
| | |

Of 68 studies, 41 were behavioural intervention arms (8 diet, 4 exercise, 10 diet plus exercise and 19 lifestyle). The remaining studies included pharmacological components and are not included in this report.

Behavioural: meta-analysis overall -3.13kg (95% CI -3.88 to -2.38), 10,829 participants across 33 moderate quality trials.

Modest weight reduction, corresponding to loss of ≥5% and ≥10% of baseline body weight (number needed to treat was 5 and 9, respectively) had clinically important effects, most notably a 38% reduction in the incidence of type 2 diabetes in prediabetic populations (number needed to treat was 17). The test for subgroup differences based on type

of behavioural intervention in the behavioural trials (diet, exercise, diet + exercise and lifestyle) was significant: interventions using exercise alone did not lead to significantly greater reductions in weight, whereas diet alone showed the largest difference between groups.

In summary, modest weight reduction confers clinically important benefits and a substantial reduction in the incidence of type 2 diabetes in prediabetic populations, with the potential to improve population health. Future research should include longer term follow-up to observe maintenance of weight loss, to study the effects of repeated weight loss and regain, and to determine if improvements in health outcomes are related to the intervention apart from weight loss. (Note: one of the most comprehensive studies published). Most studies were of relatively short duration (≤12 mo), and there was a lack of evidence to address the question of whether (and for how long) weight loss is maintained after interventions are completed. Future research should include longer term follow-up to observe maintenance of weight loss, to study the effects of repeated weight loss and regain, and to determine if improvements in health outcomes are related to the intervention apart from weight loss.

Quigley (2012)

Systematic review of 28 studies.

Settings: Primary care. Providers: Generally not delivered by the GP but instead by support staff. Individual-level primary prevention interventions in the primary care sector for altering biochemical or physical endpoints (e.g. weight) via nutrition and physical activity.

Nearly all of the studies reported positive behavioural outcomes (e.g. increased time spent being active, increased servings of fruit and vegetables consumed), but these did not translate into similar changes in biological endpoints. The primary care sector (from predominantly overseas studies) is largely unsuccessful at individual-level primary prevention.

Note: For the purposes of this review, the authors focused on individuals who did not yet have type 2 diabetes, CHD or another diagnosed disease, but had at least one risk factor such as hypertension, high lipids or elevated blood glucose (*primary prevention*). However, many of the included studies were of populations with elevated BMIs (overweight/obese) and included body weight as a/or the primary outcome, therefore could be classified as *treatment* interventions.

| Tsai (2009) | Systematic review of 10 | Primary care provider counselling | High attrition (≥35%) was observed in several | Current evidence does not support the use of low- to |
|-------------|-------------------------|------------------------------------|--|--|
| | trials. | alone, primary care provider | studies. Weight losses (1) primary care provider | moderate-intensity physician counselling for obesity, |
| | Settings: Primary care | counselling + pharmacotherapy, and | counselling alone: ranged from 0.1 to 2.3kg; | by itself, to achieve clinically meaningful weight loss. |
| | settings (or explicitly | "collaborative" obesity care | Primary care provider counselling + | Counselling plus pharmacotherapy, or intensive |
| | intended to model a | (treatment delivered by a non- | pharmacotherapy; ranged from 1.7 to 7.5kg; | counselling (from a dietitian or nurse) plus meal |
| | primary care setting). | physician provider). | "collaborative" obesity care; ranged from 0.4 to | replacements may help patients achieve this goal. Of |
| | Providers: Primary care | | 7.7kg and most studies provided low- or | the 10 studies, only two met the USPSTF's |
| | providers. | | moderate-intensity counselling. | recommendation of providing a high-intensity |
| | | | Results of this review suggest that: (1) low- | intervention (at least two visits per mo for the first 3 |
| | | | intensity primary care provider counselling | mo). |
| | | | alone is insufficient for achieving clinically | The time, effort, and expense required for primary |
| | | | meaningful weight loss in obese adults, and (2) | care providers to provide such care would appear to |
| | | | available data do not indicate how best to | be prohibitive for most practitioners in the absence |
| | | | incorporate primary care providers into more | of adequate reimbursement. |
| | | | intensive approaches (e.g. collaborative | |
| | | | treatment) to achieve this goal. More research | |
| | | | is needed on collaborative interventions that | |
| | | | involve other members of the clinical care team, | |
| | | | as well as call centres and other community | |
| | | | linkages. Without more effective therapies, | |
| | | | greater resources in their practices, and more | |
| | | | adequate reimbursement, PCPs alone cannot be | |
| | | | expected to provide effective weight | |
| | | | management for all of their patients who | |
| | | | require it. | |

Wadden, (2014)

Systematic review/metaanalysis of 12 trials, involving 3893 participants. Settings: Independent clinic, outpatient hospital, physician office, or public health clinic. Providers: Qualified PCP, i.e. GP, certified clinical nurse specialist, nurse practitioner, or physician

assistant.

Behavioural counselling to promote weight loss through high intensity interventions on diet and exercise, using the USPSTF 5 A's approach, which includes clear, specific, and personalised behavioural change advice.

This review found no studies that evaluated the efficacy of intensive behavioural weight loss counselling (14 in-person sessions over 6 mo) delivered by physicians and other eligible PCPs. No studies delivered interventions at the recommended intensity (i.e. as per the 2011 CMS recommendations) with the most intense interventions delivering counselling sessions approximately monthly.

Across all 12 studies, the difference in weight loss between treatment and control groups ranged from -1.5kg (i.e. 1.5kg greater weight loss in the control group) to 4.3kg.

Three trials provided approximately monthly

ranged from –1.5kg (i.e. 1.5kg greater weight loss in the control group) to 4.3kg.

Three trials provided approximately monthly brief counselling visits, which were delivered by trained medical assistants in collaboration with PCPs. Mean weight losses at 6 mo ranged from 3.5kg to 4.4kg. Mean weight losses declined during the follow-up period. Smaller 12- to 24-mo losses, from –0.6kg to –1.7kg, were observed when PCPs, working alone, provided quarterly or less frequent weight loss counselling sessions.

Intensive behavioural counselling can induce clinically meaningful weight loss, but there is little research on PCPs providing such care.

The present findings suggest that a range of trained interventionists, who deliver counselling in person or by telephone, could be considered for treating overweight or obesity in patients encountered in primary care settings.

The provision of more counselling sessions appeared to be associated with greater weight loss, ranging from 3.5kg with eight sessions to 6.6kg with 15 contacts (a notable dose-response relationship). Note that this review includes studies of various designs with only 8 of 20 being RCTs.

| Yoong (2013) | Systematic review of 16 studies (15 RCTs, 1 CBA). Settings: Primary care Providers: PCPs (6 studies), non-physician personnel with monitoring by PCPs (9 studies), multicomponent intervention (1 study). | (i) lifestyle counselling delivered primarily by PCPs; (ii) lifestyle counselling delivered primarily by non-PCPs; and (iii) multi-component intervention. | Eight studies reported non-clinically significant weight loss, four reported clinically significant weight loss and five studies did not report clinical significance. | These findings tentatively suggest that high-intensity interventions delivered by non-healthcare providers in adjunct to PCP consult are effective in producing clinically significant weight loss. None of the physician-delivered interventions reported achieving clinically significant weight loss, making it questionable whether physician-delivered interventions alone are worth implementing in primary care. Comparisons made here, however, are limited by differences in intensity of intervention, with most PCP-delivered interventions being of low to moderate intensity and non-PCP-delivered interventions being of moderate to high intensity. These differences are likely to reflect clinical practice as PCPs often face the need to deal with more acute issues and have less time to spend on delivery of lifestyle advice. |
|--------------|--|--|--|--|
| Young (2012) | Systematic review and meta-analysis of 23 studies including 1,869 participants. Settings: Clinical settings, community, workplace, shipboard (1 study). Providers: Healthcare professionals or trained providers/commercial providers. | Male-only weight loss and weight loss maintenance interventions (4 studies) with clear intent to change behaviour or lifestyle. | Significant difference in weight change favouring weight loss interventions over controls (WMD -5.66kg, 95% CI -6.35 to -4.97). Characteristics common to effectiveness were younger age (≤42.8 yrs), increased frequency of contact (>2.7 contacts/mo), group face-to-face contact and inclusion of a prescribed energy restriction. Weight loss maintenance: weight regain was significant but comparable across all groups, and this was also evident at 12/23-mo follow-up. | Preliminary evidence suggests men-only weight loss programmes may effectively engage and assist men with weight loss. Note: Treatments available to men are currently informed by weight management studies that have been largely conducted in females (typically approx. 75% of participants are female). Considering that men may be more likely to engage in male-only weight loss programmes it would be of interest to compare the recruitment and overall success of men in male-only programmes to men in mixed-sex programmes. |

BMI, body mass index; CBA, controlled before-and-after; GP, General Practitioner; IQR, inter-quartile range; NS, statistically non-significant; OR, odds ratio; PCP, primary care practitioner; QALY, Quality-adjusted life year; RCT, randomised controlled trial; SD; Standard deviation; UK, United Kingdom; USPSTF, United States Preventive Services Task Force; VLCD, very low-calorie diet / very low-energy diet.

Appendix C: Descriptive summary of systematic reviews and meta-analyses of internet-based, mobile phone, and self-directed interventions for weight loss and weight loss maintenance included in this report

The following summaries are listed chronologically (by included publication year range), in descending order (see **Table 6** for further details).

Effectiveness of mobile electronic devices in weight loss among overweight and obese populations (Khokhar et al., 2014)

In the most recently published systematic review and meta-analysis of mobile electronic devices in weight loss, Khokhar et al. (2014) evaluated six RCTs of interventions that used one or more mobile electronic device compared to usual care/not involving the use of a mobile device. The mobile electronic devices eligible for study included smartphones, PDAs, portable media players, hand-held video game consoles, and handheld computers but excluded notebooks/sub-notebooks/netbooks, pagers, pedometers, landline telephones and desktop personal computers. Three trials evaluated the effectiveness of text messaging versus printed material, two trials evaluated PDAs versus a paper diary and one trial evaluated the effectiveness of a smartphone application (app) versus a paper diary.

Using a random-effects model, the WMD for the effect of using mobile electronic devices on reduction in body weight was -1.09kg (95% CI -2.12 to -0.05kg). When stratified by the type of mobile electronic device used, this suggests that interventions using mobile phones (compared to other devices) were more effective at achieving weight loss; WMD = -1.78kg (95% CI -2.92 to -0.63kg) (note that the benefit associated with the single study using the mobile application strongly influenced the pooled effect size). The authors noted three important limitations to their research, firstly that the number of participants was typically small (ranging from 75 to 174), secondly that three of the studies reported loss-to-follow up exceeding 30% (overall range 9-34%) and finally, that the studies were typically of short duration. This systematic review and meta-analysis suggests that mobile phones (little evidence for PDAs) have the potential to facilitate weight loss in overweight and obese populations, but further work is needed to understand if these interventions have sustained benefit and how these interventions/tools can be implemented on a large scale.

Khokhar et al. (2014) broadened their discussion beyond simple effectiveness by suggesting that the use of mobile technology has the potential to reduce income-related disparities as the ownership and use of mobile phones has become just as prevalent among persons of low SEP as those from the general population (although no study in their review specifically tested the interventions in different SEP, ethnic, or otherwise culturally specific contexts). Khokhar et al. (2014) concluded that larger trials are needed to look at the cost-effectiveness, technical and financial feasibility of adapting such mobile phone interventions into real clinical settings.

Mobile devices and weight loss with an intervention content analysis (Lyzwinski, 2014)

Lyzwinski et al. (2014) conducted a systematic review and meta-analysis of 17 RCTs of mobile device weight loss trials. Eight out of the 12 interventions had a mobile phone as an intervention medium, two studies utilised a podcasting component employing an Mp3 player or an iPod and two studies used a PDA for weight loss. Nine studies targeted both diet and physical activity to induce weight

loss. The remaining three studies concentrated primarily on physical activity to induce weight loss. Seven out of the twelve mobile device trials had a text messaging component. A mobile app component was used in four studies. Most of the interventions had a health education component. Support from a health professional was utilised in three interventions (including, in person support, over the telephone, and via Twitter). The control interventions were either 'no intervention' or a similar intervention without the mobile device component (e.g. printed materials, diary without App and mobile components, book on calorie content of food items, goal setting). All studies reported weight as the primary outcome and other secondary outcomes included body fat, diet behaviours, physical activity behaviours and psychological measures. Most studies were of short duration (weeks or months) with small sample sizes (most <100).

A total of 11 out of the 12 interventions were included in the meta-analysis and the results of the meta-analysis indicate an overall medium effect size of 0.43 (95% CI 0.252 to 0.609), favouring the intervention (p-value <0.01). Six out of the eight (75%) mobile phone interventions favoured the mobile phone intervention groups over the controls. Three out of four of the interventions employing mobile devices other than mobile phones had significant findings, favouring the intervention. However, weight loss of 5% was not observed across all studies and most studies were of short duration. The authors concluded that mobile device weight loss interventions hold some potential as medium for behaviour change, in part due to their widespread population use and the complexity of features and behaviour change techniques that might be utilised (for example, self-monitoring with timely feedback). Lyzwinski et al. (2014) suggest that If improved interventions with longer duration and improved methodology demonstrate meaningful and sustained weight loss, then these interventions may be considered as part of the public health efforts in the health promotion sphere (either as stand-alone interventions or adjuncts to usual-care).

Use of mobile phones as a tool for weight loss (Aguilar-Martinez et al., 2014)

Aguilar-Martinez et al. (2014) conducted a systematic review of ten studies of information and communication technologies for weight loss. The included studies were specifically limited to the use of mobile devices (not desk-top computers) that could deliver interventions via phone or other mobile device applications (compared to usual care or similar interventions but without the mobile device component). Intervention content included a combination of nutritional information and general dietary recommendations. The intervention(s) component(s) identified included: selfrecording of weight; a phone-based diet game; a weight loss programme via mobile phone with feedback text messages; a weight-loss website; video calls, a mobile phone application; electronic step counter bracelet; podcasts; the use of 'web2.0 social tools' (e.g. Twitter); general motivational or participation reminder messages; and individualised responses to data entered by the participants. Participants were generally recruited via newspaper advertisements or other similar recruitment channels (not via referral from primary care settings). Of the ten studies reviewed, two studies found that the body weight values in the intervention groups decreased by 4.5kg and 1.6kg. Four studies found no differences between groups. In another study there was no significant difference in weight change between groups, although a within-group analysis revealed significant reductions of initial weight at 3 and 6 months, but not at 12 months. Three studies were pilot studies and not powered to detect between-group differences (most of the studies lasted 2-4 months, and the maximum duration was 1-year and all studies had small sample sizes).

Overall, absolute weight loss before and after the (typically) 2–4 months of intervention was less than 3kg in the intervention groups. The authors suggested that this level of weight loss is unlikely to be judged as clinically significant. Further, the success of an intervention might be a consequence of what could be called the novelty factor. None of the studies reported any post-intervention follow-up, so there was no evidence of the observed effect being sustained over time (in all studies, follow-up only lasted for the duration of the intervention). The authors concluded that further research is necessary, with larger samples in diverse populations and longer-term interventions in order to confirm the effectiveness of the use of mobile phones and apps as weight-loss tools.

Internet programmes targeting multiple lifestyle interventions in primary and secondary care (Vegting, et al., 2014)

Vegting et al. (2014) conducted a systematic review of nine studies of internet delivered care complementary to usual care. Internet programmes were designed for individual counselling with a personal login profile for each participant, allowing convenient and easy access. Most studies advised patients to regularly use the website (varying from once every two weeks to at least three times a week). The interventions (with or without the internet component) were delivered in primary or secondary healthcare setting by healthcare professionals including specialists in hospital outpatient departments or GPs. Vegting et al. (2014) reported that the mean weight differences between groups were small and only three studies reported statistically significant differences (Bennett et al., 2010; Park, Kim, & Kim, 2009; Southard, Southard, & Nuckolls, 2003) ranging from 1.6 – 2.5kg. The average intervention duration was 8.2 months (range 2 to 12). Most studies had small sample sizes, had a short follow-up duration and had high attrition rates. Mean loss to followup during the study period in the control groups was 14.6% (range 0-34.0%) and in the intervention groups 14.5% (range 0-29.3%). Two studies reported that respectively, 47% and 49% of patients never used the website. Vegting et al. (2014) concluded that the introduction of internet-based interventions in primary or secondary care does not seem superior over only face-to-face contact with healthcare physicians, and that no clinically relevant benefits in health outcomes were found. The authors suggest that the most challenging aspect is keeping patients motivated for an internetbased intervention. High attrition and low utilisation rates of websites are common in studies evaluating the effectiveness of internet healthcare interventions. No studies evaluating the efficacy of internet-based interventions over a longer period of time (i.e. years) have been performed. Further, Vegting et al. (2014) reasoned that an internet delivered programme has the potential to be successful in reducing the number of visits to the physician and may therefore be cost-effective when applied on a large scale, but only if patients could be motivated to engage with the programme.

Self-directed interventions to promote weight loss (Tang, et al., 2014)

In an effort to determine how effective self-directed interventions are and how they promote weight loss and weight maintenance, Tang et al. conducted a systematic review-of-reviews including an intervention content analysis. Included interventions were high-intensity, low-cost interventions where participants self-deliver intervention content using online programmes, mobile phone applications, text-messaging, email, electronic and print newsletters, telephone-based communication, print manuals, and booklets. The term self-directed intervention was used to describe interventions that require minimal professional contact. To explore findings, Tang et al.

grouped reviews according to the main delivery formats used by the interventions they considered: nine reviews focused on internet interventions; three reviews evaluated interventions based on electronic devices such as mobile phones (referred to as eHealth interventions); seven reviewed various multi-component interventions (some of which were described as home-based); and one reviewed text-messaging interventions (see **Figure 5** for an overview of the review structure and findings).

The authors highlighted the following results: (1) self-delivered interactive computer-based programmes were more effective than minimal interventions (e.g. printed newsletters) or no treatment, for short-term weight loss and weight maintenance. However, most trials included in these reviews did not examine weight outcomes beyond 1-year follow-up, so the impact of computer or internet-based interventions on long-term weight loss remains unclear, (2) computer or internet-based interventions are less effective than in-person treatment, (3) computer-based interventions delivered in conjunction with standard treatment enhance weight loss compared to standard treatment delivered alone (however the magnitude of weight lost advantage was small, <1.5kg) and (4) only a small number of studies reported achieving a percentage weight loss of 5% (0.8-7.8kg). Tang et al. concluded that although the weight loss reported in most internet and selfdirected studies is small, an internet-delivered programme has the potential to be successful and cost-effective when applied on a large scale. However, it was not possible to infer which techniques or delivery modes are most strongly associated with increased weight loss for whom and in what contexts. No translational studies were identified and most studies were pilot or efficacy trials and the evidence base therefore lacked the necessary studies using large samples with long-term weight loss follow-up. Recommendations for practice could not be made.

Summary of findings from reviews of technology-based interventions published 2010-2013.

Figure 10 (below) summarises the findings from 13 reviews of technology-based interventions published between 2010-2013 not otherwise reviewed in this report.



| Author (date) | Technology | Summary comments |
|----------------|---------------|---|
| Bacigalupo | Mobile | There is consistent strong evidence that weight loss occurs in the short-term because of mobile |
| (2013) | technology | technology interventions, with moderate evidence for the medium-term. |
| Donnelly | Phone | Phone delivery provided equivalent weight loss and maintenance to face-to-face delivery and |
| (2013) | | reduced programme cost. |
| Grunenberg | Web-based | Web-based psychological interventions are effective weight loss interventions. However, the |
| (2013) | psychological | effects are small and their clinical importance is limited. |
| Stephens | Mobile phone | All of the technology interventions that were supported by education or an additional |
| (2013) | | intervention demonstrated a beneficial impact of text messaging or smartphone application for |
| | | reduction of physical inactivity and/or overweight/obesity. There is no evidence to suggest that |
| | | text messages as a stand-alone intervention are effective. |
| Woo (2013) | Mobile phone | Due to the small number of high quality studies, modest evidence was found for the effectiveness |
| | | of mobile phones in the delivery of weight loss interventions. |
| Cavill (2012) | Web-based | Evidence to date suggests that the internet is no more effective than print materials, face-to-face |
| | | programmes and other health promotion methods. |
| Miners (2012) | e-learning | The current economic evidence base suggests that e-learning devices for managing the weight of |
| | devices | obese individuals are unlikely to be cost-effective unless their fixed costs are much lower than |
| | | estimated or future devices prove to be much more effective. |
| Reed (2012) | Computers | While the addition of computer-based technology to weight loss interventions led to statistically |
| | | greater weight loss, the magnitude (<1.5kg) was small and not sustained. |
| Shaw (2012) | SMS | SMS as an intervention tool for weight loss is still in its infancy. Initial results are promising. |
| Wieland | Interactive | Compared to in-person interventions, interactive computer-based interventions result in lower |
| (2012) | computer- | levels of weight loss and weight maintenance. The amount of additional weight loss, however, is |
| | based | relatively small and of brief duration (i.e. clinical significance is unclear). |
| Arem (2011) | Web-based | More rigorous, population-specific research is needed. |
| Khaylis (2010) | Technology- | The interface of technology and behaviour change is an effective foundation of a successful, short- |
| | based | term weight-loss programme and may provide the basis of long-term weight loss. |
| Neve (2010) | Web-based | It is not possible to determine the effectiveness of web-based interventions in achieving weight |
| | | loss or maintenance (more research is needed). |

Figure 10: Summary of findings from 13 reviews of technology-based interventions published 2010-2013 (not otherwise reviewed in this report).

Table 6: Summary (alphabetical, by first author) of systematic reviews and meta-analyses of internet-based, mobile device and self-directed behaviour change interventions for weight loss and weight loss maintenance

| Study | Design | Intervention | Results | Conclusions/clinical significance |
|----------|---------------------------|--|--|--|
| Aguilar- | Systematic review of 10 | Intervention components included: | Two studies found that the body weight in | Absolute weight loss before and after the 2–4 mo of |
| Martinez | studies of information | interventions based on a combination of | intervention groups decreased by 4.5kg to | intervention was <3kg in the intervention groups and this |
| (2014) | and communication | nutritional information and general | 1.6kg. Three studies found no differences | level of weight loss is unlikely to be judged as clinically |
| | technologies for weight | dietary recommendations; with self- | between groups. In another study there was | significant. Further, the success of an interventions might be |
| | loss. | recording of weight; a phone-based diet | no significant difference in weight change | a consequence of what could be called the novelty factor. |
| | Providers: Researchers, | game; a weight loss programme via | between groups, although a within-group | None of the studies reported any post-intervention follow- |
| | trained interventionists. | mobile phone with feedback text | analysis revealed significant reductions of | up, so there was no evidence of the observed effect being |
| | | messages; a weight-loss website; video | initial weight at 3 and 6 mo, but not at 12 | sustained over time. |
| | | calls; a mobile application; electronic step | mo. Three studies were pilot studies and not | The authors concluded that further research is necessary, |
| | | counter bracelet; podcasts; the use of 2.0 | powered to detect between-group | with larger samples in diverse populations and longer-term |
| | | social tools (Twitter); general motivational | differences (most of the studies lasted 2–4 | interventions. |
| | | or participation reminder messages; | mo, and the maximum duration was 1 yr | |
| | | individualised responses to data entered | and had small sample sizes). | |
| | | by the participants. | , , | |
| | | Settings: research settings & community | | |

Khokhar (2014)

Systematic review of six RCTs (2008 to 2013) of interventions that use one or more mobile electronic device versus usual care that does not involve use of a mobile device.

Providers: Researchers, trained interventionists.

Interventions using mobile electronic devices, such as smartphones, PDAs, portable media players, hand-held video game consoles and handheld computers (excludes desktop personal computers, notebooks/sub-notebooks/netbooks, pagers, pedometers and landline telephones).

Three trials text messaging (printed material), two trials PDAs (versus paper diary), one trial smartphone app (versus paper diary).

Settings: Research settings & community.

Using a random-effects model, the WMD for the effect of using mobile electronic devices on reduction in body weight was -1.09kg (95% CI -2.12 to -0.05kg). When stratified by the type of mobile electronic device used, it suggests that interventions using mobile phones were effective at achieving weight loss, WMD = -1.78kg (95% CI -2.92 to -0.63kg).

Note that the benefit associated with the single study using the mobile application strongly influenced the pooled effect size. The number of participants was small, ranging from 75 to 174 and three of the studies reported loss-to-follow up exceeding 30% (overall range 9-34%) However, all trials reported on intention-to-treat analysis. Three studies were <6 mo, two studies were 12 mo, and the remaining study 24 mo duration.

This systematic review and meta-analysis suggests that mobile electronic devices (mobile phones but little evidence for PDAs) have the potential to facilitate weight loss in overweight and obese populations, but further work is needed to understand if these interventions have sustained benefit and how these tools can be implemented on a large scale. However, whether mobile interventions result in sustained weight loss is not known.

The authors suggest that the use of mobile technology has the potential to reduce income-related disparities as the ownership and use of mobile phones has become just as prevalent among persons of low SEP as those from the general population (although no study in this review specifically tested the interventions in different SEP, ethnic, or otherwise culturally specific contexts).

Also, the use of text messaging to promote healthy

behaviour may be more or less effective depending on the target behaviour change. For example, text prompts and reminders may turn out to be more effective for simple behaviours such as preventive medication adherence compared to the complex behaviours associated with successful weight loss and more research is required. The population of interest may also belong to a certain literacy and SEP.

| Lyzwinski | Systematic review and |
|-----------|---------------------------|
| (2014) | meta-analysis of 17 |
| | RCTs of mobile device |
| | weight loss trials. |
| | Providers: Researchers, |
| | trained interventionists. |
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Eight out of the 12 interventions had a mobile phone as an intervention medium, two studies utilised a podcasting component employing an Mp3 player or an iPod and two studies used a PDA for weight loss. Nine studies targeted both diet and physical activity to induce weight loss. The remaining three studies concentrated primarily on physical activity to induce weight loss. Seven out of the twelve mobile device trials had a text messaging component. A mobile app component was used in four studies. Most of the interventions had a health education component. Support from a health professional was utilized in three interventions (including, in person support, over the telephone, and via Twitter). Research settings: community, hospital, university (mostly USA).

Most studies were of short duration (weeks or months) with small sample sizes (most <100). A total of 11 out of the 12 interventions were included in the meta-analysis and the results of the meta-analysis indicate an overall medium effect size of 0.43 (95% CI 0.252 to 0.609), favouring the intervention (p-value <0.01), 6 out of the 8 (75%) mobile phones interventions favoured the mobile phone intervention groups over the controls.

Although most studies found weight loss favouring the intervention groups, weight loss of 5% which is defined as the clinically significant weight loss threshold, was not observed across all studies and most studies were short in duration.

Note: The authors conclude that mobile device weight loss interventions hold some potential as mediums for behaviour change both through their widespread population use and complexity of features that allow for the integration of numerous theoretical constructs and behaviour change techniques, particularly self-monitoring with timely feedback. If improved interventions with longer duration and improved methodology demonstrate meaningful and sustained weight loss, then these interventions may be considered as part of the public health efforts in the health promotion sphere (either as stand-alone interventions or adjuncts).

Tang (2014)

Systematic review of 20 reviews to summarise efficacy evidence and design features of self-directed interventions designed to reduce weight and sustain weight maintenance (included 99 studies). Providers: Mixed (researchers).

High-intensity, low-cost interventions where participants self-deliver intervention content using online programmes, mobile phone applications, text messaging, email, electronic and print newsletters, telephone-based communication, print manuals, and booklets. The term self-directed intervention is used to describe interventions that require minimal professional contact.

Settings: Mixed research/community

settings

The authors summarised the findings and highlighted the following results: (1) selfdelivered interactive computer-based programmes were more effective than minimal interventions (e.g. printed newsletters) or no treatment, for short-term weight loss and weight maintenance. However, most trials included in these reviews did not examine weight outcomes beyond 1-year follow-up, so the impact of computer or internet-based interventions on long-term weight loss remains unclear, (2) computer or internet-based interventions are less effective than inperson treatment, (3) computer-based interventions delivered in conjunction with standard treatment enhance weight loss compared to standard treatment delivered alone (however the magnitude of weight lost advantage was small, <1.5kg) and (4) only a small number of studies reported achieving a percentage weight loss of 5% (0.8-7.8kg).

Authors concluded that although the weight loss reported in most internet and self-directed studies is small, an internet delivered programme has the potential to be successful and cost-effective when applied on a large scale. However, it was not possible to infer which techniques or delivery modes are most strongly associated with increased weight loss for whom and in what contexts. No translational studies were identified and most studies were short-term pilot or efficacy trials and the evidence base therefore lacked the necessary studies using large samples with long-term weight loss follow-up. Recommendations for practice could not be made.

| Vegting | Systematic review of | The use of internet and related | Mean weight difference between | Overall, no clinically relevant benefits in health outcomes |
|---------|--------------------------|--|--|---|
| (2014) | nine studies of internet | technologies to deliver health services at | groups: | were found with the introduction of an internet programme |
| | delivered care | distance in conjunction with usual care. | Bennett et al. 2.56kg (95% CI −3.60 to − | in a primary or secondary healthcare setting compared to |
| | complementary to usual | Included a 'usual care' control group. | 1.53kg). | usual care (face-to-face contact with healthcare physicians) |
| | care. | Internet programmes were designed for | Southard et al. 1.9kg (p=0.003) | alone. |
| | Providers: Healthcare | individual counselling with a personal | Park et al. 1.6kg (69.3 ± 10.3 to 67.7 ± 81kg) | It was difficult to compare internet studies with one another |
| | professionals including | login menu for each participant, allowing | compared to an increase of 1.0kg (68.3 ± | because of the diversity in intervention programme |
| | specialists in hospital | convenient and easy access. Most studies | 10.1 to 69.3 ± 8.1 kg) in the usual care group | (protocol intensity, level of self-management) and overall |
| | outpatient departments | advised patients to regularly use the | (p=0.034). | study design and quality. |
| | or GPs. | website, varying from once every two | All five other studies: NS between groups. | Most studies had small sample sizes, short follow-up |
| | | weeks to at least three times a week. | Average intervention duration was 8.2 | duration, low website utilisation, and high attrition rates. |
| | | Settings: primary or secondary healthcare | (range 2-12) mo. | The most challenging aspect is keeping patients motivated |
| | | setting. | Programme adherence varied among the | for an internet-based intervention. |
| | | | studies. Two studies reported that | An internet delivered programme has the potential to be |
| | | | respectively 47% and 49% of patients never | successful in reducing the number of visits to the physician |
| | | | used the website. | and may therefore be cost-effective when applied on a large |
| | | | Mean lost to follow-up during the study | scale, but it is challenging to keep patients motivated to |
| | | | period in the control groups was 14.6% | proceed with the programme. |
| | | | (range 0–34.0%) and in the intervention | No studies evaluating the efficacy of internet-based |
| | | | groups 14.5% (range 0–29.3%). | interventions over a longer period of time (patient follow-up |
| | | | | duration of years) have been performed. |

BMI, body mass index; GP, General Practitioner; IQR, inter-quartile range; NS, statistically non-significant; OR, odds ratio; PDA; Personal Digital Assistant; QALY, Quality-adjusted life year; RCT, randomised controlled trial; SD, Standard deviation; SEP, socioeconomic position; UK, United Kingdom; USA, United States of America; VLCD, very low-calorie diet / very low-energy diet.

Appendix D: Summary of studies of commercial weight management programmes for weight loss and weight loss maintenance included in this report

Table 7: Summary of systematic reviews and meta-analyses of commercial weight management programmes for weight loss and weight loss maintenance

| Reference | Review design | Programme description | Outcomes | Results | Conclusions/clinical significance |
|-----------------------|--|---|--|--|---|
| Asher (2013) | Systematic review of eight RCTs, two cohort and six prepost studies (n=6,579). | VLCDs for weight loss among obese adults in outpatient clinical settings. The majority of VLCDs were liquid meal replacements, and some interventions also included behavioural counselling and/or physical activity advice. Intervention duration range 4-14 wks. Follow-up range 4 wks-2 yrs. | Weight, BMI, percentage weight change, fat mass, FFM, percent body fat, waist circumference, adverse events. | All studies reported significant weight loss following VLCD use, and most reported some weight regain by first follow-up. Weight loss ranged from 5.5-13.1kg at 1 yr, and 3.3-9.1kg at 2 yrs. Five of 16 studies reported side effects, and <1% of participants experienced side effects. Few studies assessed compliance adequately. Half of studies had >80% retention rate at follow-up. | VLCDs were effective for short- term weight loss, however weight loss was not maintained in the long term. Studies were undertaken in controlled research settings, therefore VLCDs may not be as effective in community settings where extensive monitoring and support is not available. |
| Atallah (2014) | Systematic review of 26 RCTs, with either a usual care comparison group, or head-to-head comparisons between programmes (n=2,559). | WW, Atkins, South Beach, and Zone diets for weight loss among overweight or obese adults. Follow-up ≥12 mo. | Weight change, percentage weight change, BMI change, percentage BMI change, body fat, waist circumference, waist-to- hip ratio, adverse events. | At 1 yr only WW was consistently more efficacious at reducing weight compared to usual care (range of mean changes: -3.5 to -6.0kg versus -0.8 to -5.4kg; p<0.05). When comparing diets, Atkins (range -2.1 to -4.7kg), WW (-3.0kg), Zone (-1.6 to -3.2kg), and control (-2.2kg) diets all achieved modest weight loss at 1 yr. At 2 yrs, weight loss after Atkins or WW was partially regained over time. ≥20% dropout rate reported in 13 studies. | All diets modestly effective in the short term, but losses were not maintained at 2 yrs. |
| Finklestein (2014) | Cost-effectiveness and meta-analysis of 27 RCTs (total number of participants not stated). | Commercial weight loss programmes (i.e. WW, JC, Vtrim) and pharmaceutical agents for adults with BMI 25-40. Follow-up duration ≥1 yr. | Cost per kg of weight lost, cost per QALY. | Average cost per kg lost was \$USD155 (95% CI \$110 to 218) for WW and \$USD424 (95% CI \$302 to 594) for JC. Incremental cost per QALY was \$USD34,630 for WW and \$USD588,620 for JC. | WW was most cost-effective strategy. |

| Gudzune (2014) | Updated systematic review of 45 studies, including 39 RCTs (total number of participants not stated). | Commercial or proprietary weight loss programmes (e.g. WW, JC, VLCDs, Atkins) for overweight or obese adults compared with control, education, or behavioural counselling. Intervention duration ≥12 wk, and follow-up ≥12 mo. | Percentage weight change, adverse events. | At 1 yr, participants attending WW lost 2.6-3.2%, and those attending JC lost 4.9-8.3% more weight than control/education group or counselling groups. No serious adverse events were reported. Attrition and adherence were variable across studies. At 4-6 mo, participants receiving VLCD meal replacements lost 4.0-13.2% more weight than those receiving behavioural counselling. | Consistent evidence of efficacy of WW and JC over 1-2 yrs, with some weight regain. VLCDs results in significant short-term weight loss, however long-term maintenance is unclear. |
|--------------------|---|--|---|--|--|
| Johnston (2014) | Systematic review and meta-analysis of 48 RCTs (n=7,286). | Commercial weight loss programmes for overweight or obese adults. Programmes grouped by diet composition - low carbohydrate (e.g. Atkins, Zone), low fat (e.g. Ornish, RCDFC), or moderate macronutrient (e.g. WW, JC). Intervention duration ≥3 mo, and follow-up after 6 or 12 mo (±3 mo). | Weight, BMI, adverse events. | All diet groups had significantly greater weight loss than a control diet after 6 mo and 12 mo. Weight loss was less after 12 mo than 6 mo. At 12 mo, difference in mean weight between control and moderate macronutrient diet was 5.7kg (95% CI 4.1 to 7.4kg), low carbohydrate was 7.3kg (95% CI 5.3 to 9.3kg) and low fat was 7.3kg (95% CI 5.3 to 9.3kg). There was no significant difference in mean weight loss between the low fat diet and moderate macronutrient (1.6kg, 95% CI -0.2 to 3.3kg) or low carbohydrate groups (0.0kg, 95% CI -1.8 to 1.8kg). Weight loss in the low carbohydrate group was significantly greater than the moderate macronutrient group (1.6kg, 95% CI 0.1 to 3.0kg). | Differences in weight loss between individual diets were minimal. Therefore, patients can be referred to any energy-restricted diet that they can adhere to for weight loss. |

BMI, body mass index; JC, Jenny Craig; QALY, Quality-adjusted life year; RCDFC, Rosemary Conley Diet and Fitness Clubs; RCT, randomised controlled trial; VLCD, very low-calorie diet / very low-energy diet; WW, Weight Watchers.

Table 8: Summary of RCTs and observational studies of primary care referral to commercial weight management programmes for weight loss and weight loss maintenance

| Reference | Study design, programme description [†] , and inclusion criteria | Results (for those who attended at least one session) |
|------------------|---|--|
| Ahern | Retrospective observational study of 29,560 UK NHS patients | At baseline, median BMI 35.1; median age 49.0 yrs; 90% of participants were female. |
| (2011) | referred by their primary care provider to 12 funded sessions of WW ^b . Some patients completed multiple referrals. Inclusion criteria: No inclusion criteria described. | 54% of participants attended all 12 sessions. Median weight change was -2.8kg (IQR -5.9 to -0.7kg), or -3.1% of baseline weight. 33% of referrals resulted in ≥5% weight loss. Median weight loss significantly increased as number of sessions attended increased (p<0.0001). In participants completing a first referral course, median percent weight loss was significantly greater in males than females; in participants >40 years than in younger participants; in those with a BMI between 30 and 40, relative to BMI <30; and in those with a BMI <30 relative to BMI >40 (though the differences between groups were small). |
| Dixon (2012) | Prospective observational study of 880 patients from 12 UK GP surgeries referred to 12 funded sessions at either WW, SW, or RCDFC (according to patient choice). Inclusion criteria: Obese patients with either a raised waist measurement, or ≥1 co-morbidities; Age >16; Ready to lose weight; Must not have attended a similar programme in the previous 6 mo. (Some overweight patients were also referred.) | At baseline, mean BMI 37.8; Mean age 47.2 yrs; 86% of participants were female. 54% of participants attended at least 80% of sessions. Mean weight change was -4.8kg (95% CI -5.1 to -4.5kg), and percentage baseline weight loss was -4.6% (SD 3.7kg). Weight loss was significantly greater in those attending ≥80% of sessions. Significantly greater weight loss, BMI change and weight change was observed among those attending WW and RCDFC than SW. WW provided greater value for money than the other programmes. Participants with a higher baseline BMI experienced greater weight loss. |
| Fuller (2013) | Cost-effectiveness of RCT published by Jebb (2011), see below for details. | The cost per kg of weight lost tended to be lower in the WW group compared to the standard care (control) group in Australia and the UK (but not Germany), though data were not compared statistically. The cost per QALY year gained indicated cost-effectiveness of WW compared to standard care (i.e. <\$USD50,000, which is a commonly-used threshold). |
| Jebb (2011) | RCT of patients from 70 primary care practices in Australia, 39 in Germany and six in the UK randomly assigned to either a control (standard care - weight loss advice from a PCP using national clinical guidelines, n=395) or free membership to WW (n=377), for 1 yr. Inclusion criteria: Age ≥18; BMI 27-35; At least one other risk factor for obesity-related disease; No weight loss of >5kg in the previous 3 mo; No medical contraindication for a weight loss programme; Not pregnant or lactating. | At baseline, standard care group: Mean BMI 31.3; Mean age 48.2 yrs; 86% of participants were female, and WW group: Mean BMI 31.5; Mean age 46.5 yrs; 88% of participants were female. At 1 year, 61% of participants in the WW group and 54% in the standard care group completed the study. At 1 yr, mean weight change was -5.1kg in the WW group, and -2.3kg in the standard care group (adjusted difference -2.8kg, 95% CI -3.5 to -2.1kg). Decreases in weight, waist circumference and fat mass were significantly greater in the WW group than the standard care group (all p<0.0001), as were the odds of losing ≥5% (OR 2.9, 2.1-3.9), or ≥10% (OR 3.5, 2.3-5.4) of their baseline weight. Participants reported no adverse effects. |

| Jolly (2011) | RCT of 740 patients from 17 UK general practices randomly assigned to a funded 12 wk intervention at one of: WW, SW, RCDFC, group-based dietitian-led programme, general practice one-to-one counselling; pharmacy-led one-to-one counselling, a choice of any of the six programmes, or a control group (12 vouchers for free entrance to a local fitness centre). Inclusion criteria: Age ≥18; Not pregnant; For South Asians, BMI ≥25 with no comorbidities or ≥23 with comorbidities; For non-South Asians, BMI ≥30 with no comorbidities or ≥28 with comorbidities. | At baseline, mean BMI ≈33-34; Mean age ≈47-51 yrs; ≈64-75% of participants were female. Attendance was greatest for WW and RCDFC (70% and 74%, respectively, attended ≥50% of sessions), and lowest for pharmacy and GP groups (54% and 44%, respectively, attended <25% of sessions). After 1 year, mean weight change for all groups except pharmacy and GP groups was significantly lower than baseline (range -1.1kg for exercise to -3.5kg for WW). Only WW had a statistically significantly greater weight loss (-2.5kg, 95%CI -4.2 to -0.8, p=0.024) and percentage weight loss (-3.0%, 95% CI -4.5 to -0.9, p=0.022) than the control group. After 1 year, mean change in BMI for all groups except pharmacy and GP groups was significantly lower than baseline (range -0.54 for exercise to -1.2 for WW). There was no significant difference in weight loss between males and females, or between those who chose their programme compared to those who were randomised to the same programme. |
|-------------------|--|--|
| Madigan (2014) | Prospective cohort study of 3,290 adults referred through primary care to their choice of WW, RCDFC, SW or a NHS group programme for 12 wks. Inclusion criteria: Age ≥18; No medical contraindication for a weight loss programme; Not pregnant; For South Asians, BMI ≥25 with no comorbidities or ≥23 with comorbidities; For non-South Asians, BMI ≥30 with no comorbidities or ≥28 with comorbidities. | At baseline, mean BMI 35.1; Mean age 49.9 yrs; 87% of participants were female. Follow-up at 12 wks was 78% for WW, 75% for NHS, 70% for RCDFC and 81 for SW. At 12 wks, mean weight change for all participants was -4.2kg (SD 4.1kg) for WW, -1.6kg (SD 2.2kg) for NHS, -3.3kg (SD 3.7kg) for RCDFC and -4.0kg (SD 3.9kg) for SW. Weight loss of those attending SW and RCDFC was similar to WW, and weight loss of those attending NHS was significantly lower than WW. At 1 yr, mean weight change was -3.7kg (SD 6.4kg) for WW, -2.5kg (SD 4.2kg) for NHS, -3.1kg (SD 5.6kg) for RCDFC and -4.5kg (SD 7.0kg) for SW. Weight loss of those attending SW was significantly greater than WW, RCDFC was similar to WW, and comparison of NHS and WW was inconclusive. |
| Stubbs (2011) | Observational study of 34,271 UK NHS patients referred to 12 weekly funded SW sessions by a healthcare professional in primary or secondary care. Inclusion criteria: Age >16; Not pregnant. | At baseline, mean BMI 36.8; Mean age 47.3 yrs; 89% of participants were female. 58% of participants attended at least 10 of the 12 sessions. Mean weight change was -4.0kg (SD 3.7kg), percentage weight change was -4.0% (SD 3.6kg), and mean BMI change was -1.5kg/m² (SD 1.3). 35.8% of participants lost ≥5% of their baseline body weight, and 5.8% lost ≥10%. Those who attended ≥10 sessions experienced significantly greater weight loss, percentage weight loss, and change in BMI than those who attended <10 sessions. Males experienced significantly greater weight loss, percentage weight loss, and change in BMI, than females. |
| Stubbs (2012) | Observational study of 4,754 UK NHS patients referred to 24 weekly funded SW sessions (i.e. two consecutive 12-wk referrals) by a healthcare professional in primary or secondary care. Inclusion criteria: Age >16; Not pregnant. | At baseline, mean BMI 37.9; Mean age 49.8 yrs; 88% of participants were female. 76% of participants attended at ≥20 of the 24 sessions. Mean weight change was -8.9kg (SD 6.0kg), percent weight change was -8.6% (SD 5.3%), and mean BMI change was -3.3kg/m² (SD 2.2). 74.5% of participants lost ≥5% of their body weight, and 43.1% lost ≥10%. Those who attended ≥20 sessions experienced significantly greater weight loss, percent weight loss and change in BMI than those who attended <20 sessions. Males experienced significantly greater weight loss, percentage weight loss and change in BMI than females. BMI category at baseline was not significantly associated with percentage weight loss. |

[†] Weight Watchers (WW), Slimming World (SW) and Rosemary Conley Diet and Fitness Clubs (RCDFC) are group weight loss programmes that offer weekly meetings (≈60-90 minutes) at community venues, one-to-one telephone and/or email support, dietary advice and goal-setting, physical activity advice, and RCDFC also offers an optional 45-minute exercise class.

BMI, body mass index; CI, confidence interval; IQR, inter-quartile range; NHS, National Health Service; NS, statistically non-significant; OR, odds ratio; QALY, Quality-adjusted life year; RCDFC; Rosemary Conley Diet and Fitness Club; SD; Standard deviation; SW, Slimming World; UK, United Kingdom; WW, Weight Watchers.

Appendix E: Intervention components associated with increased effectiveness in dietary and physical activity interventions

Table 9: Recommendations for practice from Greaves and colleagues' (2011) systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions

| Grade ¹ | Recommendation |
|--------------------|---|
| А | Interventions should aim to promote changes in both diet and physical activity |
| А | Interventions should use established, well defined behaviour change techniques (e.g. Specific goal-setting, relapse prevention, self-monitoring) |
| Α | Interventions should encourage participants to engage social support in planned behaviour change (i.e. engage others who are important such as family, friends, and colleagues) |
| A | Interventions may be delivered by a wide range of people/professions, subject to appropriate training. There are examples of successful physical activity and/or dietary interventions delivered by doctors, nurses, dieticians/nutritionists, exercise specialists and lay people, often working within a multi-disciplinary team |
| Α | Interventions may be delivered in a wide range of settings. There are examples of successful physical activity and/or dietary interventions delivered in healthcare settings, the workplace, the home, and in the community |
| Α | Interventions may be delivered using group, individual or mixed modes (individual and group). There are examples of successful physical activity and/or dietary interventions using each of these delivery modes |
| A | Interventions should include a strong focus on maintenance. It is not clear how best to achieve behaviour maintenance but behaviour change techniques designed to address maintenance include: self-monitoring of progress, providing feedback, reviewing of goals, engaging social support, use of relapse management techniques and providing follow-up prompts |
| В | Interventions should maximize the frequency or number of contacts with participants |
| С | Interventions may consider building on a coherent set of "self-regulation" techniques, which have been associated with increased effectiveness (Specific goal setting; Prompting self-monitoring; Providing feedback on performance; Review of behavioural goals) as a starting point for intervention design. However, this is not the only approach available |
| С | No specific intervention adaptations are recommended for men or women, although it may be important to take steps to increase engagement and recruitment of men |
| D | If using established behaviour change techniques, a clear plan of intervention should be developed, based on a systematic analysis of factors preceding, enabling and supporting behaviour change in the social/organisational context in which the intervention is to be delivered. The plan should identify the processes of change and the specific techniques and method of delivery designed to achieve these processes. Such planning should ensure that the behaviour change techniques and strategies used are mutually compatible and well adapted to the local delivery context. Following the procedures of the PRECEDE-PROCEED model, Intervention Mapping, or a similar intervention-design procedure is recommended |
| D | People planning and delivering interventions should consider whether adaptations are needed for different ethnic groups (particularly with regard to culturally-specific dietary advice), people with physical limitations and people with mental health problems |

¹ Key to grades of recommendations:

A: At least one meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+.

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++.

D: Evidence level 3 or 4 (non-analytic studies or expert opinion); or Extrapolated evidence from studies rated as 2+.

Appendix F: Acronyms and abbreviations

Table 10: Acronyms and abbreviations used in this report

| Acronym / abbreviation | Definition |
|------------------------|--|
| ВМІ | Body mass index (kg/m²) |
| СВТ | Cognitive Behavioural Therapy |
| CHD | Coronary heart disease |
| CVD | Cardiovascular disease |
| CI | Confidence Interval (95%, unless otherwise stated) |
| CMS | Centers for Medicare & Medicaid Services (USA) |
| DPP | Diabetes Prevention Programme (USA) |
| DPS | Diabetes Prevention Study (Finland) |
| FFM | Fat-free mass |
| GP | General Practitioner |
| GRx | Green Prescription |
| LCD | Low-calorie diet / Low-energy diet |
| min | Minute |
| mo | Month |
| n | Number of people |
| NHS | National Health Service (UK) |
| NS | Not statistically significant (at the 0.05 level, unless otherwise stated) |
| OR | Odds ratio |
| PCP | Primary Care Physician/Practitioner |
| PDA | Personal Digital Assistant |
| QALY | Quality-adjusted life year |
| RCT | Randomised controlled trial |
| SD | Standard deviation |
| SEP | Socioeconomic position |
| SMS | Short Message Service |
| UK | United Kingdom |
| USA | United States of America |
| USPSTF | United States Preventive Services Task Force |
| VLCD | Very low-calorie diet / Very low-energy diet |
| wk | Week |
| WMD | Weighted mean difference |