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DOCTORAL THESIS

Maintaining Weight Loss: A Look at Habits

Cleo, Gina

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Maintaining Weight Loss: A Look at Habits

Gina Cleo

MNutr&Diet (Hons Class 1), Accredited Practicing Dietitian

Centre for Research in Evidence Based Practice
Faculty of Health Sciences and Medicine

Thesis submitted in total fulfilment of the requirements of the degree of

Doctor of Philosophy (PhD)

Dr Rae Thomas, Professor Paul Glasziou & Professor Liz Isenring

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Thesis summary

Background: The prevalence of overweight and obesity continues to gradually increase each year with worldwide obesity recorded to be more than double since 1980. Despite the significance placed on lifestyle interventions for obesity management, most weight loss is followed by weight regain. In fact, people who have lost weight on lifestyle programmes, regain approximately 40% of the weight they lose in the first year after losing it and much of the rest in the following three years. Recently, psychological concepts of habitual behaviour and automaticity have been suggested as plausible explanations for this overwhelming lack of long-term weight loss success. Consequently, habit-based interventions are becoming a novel and emerging strategy to help reduce excess weight in individuals with overweight or obesity

Aims: This thesis aimed to determine the efficacy of habit-based interventions for weight loss and weight loss maintenance in adults with overweight or obesity.

Methods: Four interrelated studies were conducted using a variety of research methods. Firstly, a formative literature review collated and describe the current evidence on weight management interventions including the role of habits in weight loss maintenance. Secondly, a randomised controlled trial assessed the efficacy of two habit-based interventions on weight loss and weight loss maintenance. This was followed by a qualitative study using semi-structured interviews to explore the general experience of a sub-sample of participants from the two-habit-based interventions implemented in the RCT. Lastly, we conducted a systematic review and meta-analysis to determine the weight loss and weight loss maintenance outcomes of habit-based interventions compared with active and non-active control groups.

Results: The initial study found that habit-based interventions show promising results in sustaining behaviour change. Weight loss maintenance may benefit from incorporating habit-focused strategies and should be investigated further. The RCT included 75 adults with a mean BMI of 34.5kg/m² (SD 6.2). After a 12-week intervention period, participants in the habit-based programs lost significantly more weight (combined mean -3.1kg) than those in the waitlist control group (-0.4kg) ($P < 0.001$). At 12-months post-intervention, participants in the habit-based interventions maintained their weight loss and achieved further weight loss (combined mean from baseline -5.1kg), with 65% (28/43) of participants reducing their total body weight by $\geq 5\%$; a clinically important change. The third study revealed five key themes relating the participants' general experience on the habit-based weight loss programs: (i) novelty of interventions and outcomes, (ii) convenience and practicality, (iii) indirect health benefits and wellness, (iv) accountability and (v) sustained behaviour change. Participants reported a positive experience whilst on the habit-based programs, highlighting it was refreshing to not

focus on diet and exercise. Participants also reported that the benefits continued long after the interventions had concluded; these included weight loss maintenance, general wellbeing, self-efficacy and sustained behaviour change, among others. Finally, the systematic review included five trials (630 participants) and showed a statistically significant difference in weight loss outcomes between habit-based interventions (range 8-14 weeks duration) and control groups (-1.4kg [95% CI -2.3, -0.5; $P= 0.004$]). Participants in the intervention groups were 2.4 times more likely to achieve clinically beneficial weight loss post-intervention than control participants. There was no statistically significant difference however at follow-up (range 6-24 months post-intervention), when we compared habit-based interventions with active control groups (-0.1kg [95% CI -2.5, 2.4; $P= 0.96$]). When observing single-armed results, four of the five included studies showed that habit-based interventions were successful at achieving weight loss maintenance.

Conclusions and Implications: The results of these studies highlight that habit-based weight loss programs are more effective at achieving clinically beneficial weight loss than lifestyle advice, non-habit based programs and waitlist groups in the short-term but these effects are not sustained when active weight loss programs are compared with habit-based programs over the long-term. Longer studies that are powered to examine at least a 12-month follow-up are required to evaluate weight loss maintenance. Habit-based programs are however practical and convenient for individuals to implement and offer a refreshing alternative to diet and exercise advice. Therefore, habit-based weight loss interventions offer health professionals and clinicians a useful tool for incorporating evidence-based health promotion with individuals desiring sustained benefits.

Keywords

Habit change, habit-based interventions, obesity, overweight, weight loss maintenance, weight management, automaticity, behavioural flexibility, habits

Statement of Authorship

This thesis is submitted to Bond University in fulfilment of the requirements of the degree of Doctor of Philosophy by Research (PhD).

I declare that the research presented within this thesis is a product of my own original ideas and work, and contains no material which has previously been submitted for a degree at this university or any other institution, except where due acknowledgement has been made.

Gina Cleo

12th October 2017

Research outputs arising from this thesis

Peer-reviewed publications

Cleo G, Isenring E, Thomas R, Glasziou P. Could habits hold the key to weight loss maintenance? A narrative review. *Journal of Human Nutrition and Dietetics*. 2017;30(5):655-664.

Cleo G, Isenring L, Glasziou P, Beller E, Thomas R. Habit-based interventions for weight loss maintenance in adults with overweight and obesity: a randomized clinical trial. *International Journal of Obesity*. 2018.

Cleo G, Hersch J, Thomas R. Participant experiences of two successful habit-based weight loss interventions in Australia: a qualitative study. *British Medical Journal Open (BMJ Open)*. 2018.

Cleo G, Beller E, Glasziou P, Thomas R. Efficacy of habit-based weight loss interventions: a systematic review and meta-analysis. *Obesity Reviews*. 2018 (Forthcoming)

Peer-reviewed conference abstracts: oral presentations

Cleo G, Isenring E, Thomas R, Glasziou P. Maintaining weight loss: a look at habits. *HDR Nutrition Summit*. 2015. Brisbane, Australia.

Cleo G, Isenring E, Thomas R, Glasziou P. Do making habits or breaking habits influence weight loss and weight loss maintenance? A randomised controlled trial. *Gold Coast Health and Medical Research Council (GCHMRC)*. 2015. Gold Coast, Australia.

Cleo G, Isenring E, Thomas R, Glasziou P. Do making habits or breaking habits influence weight loss and weight loss maintenance? A randomised controlled trial. *Australian and New Zealand Eating Disorders and Obesity Conference*. 2016. Gold Coast, Australia.

Cleo G. Maintaining weight loss: a look at habits. *Three Minute Thesis Competition*-awarded runner up. 2016. Gold Coast, Australia.

Cleo G, Isenring E, Thomas R, Glasziou P. Maintaining weight loss: a look at habits. *Psychology of Eating, Weight and Body Image*. *Australian Psychology Society*. 2016. Brisbane, Australia.

Cleo G, Isenring E, Thomas R, Glasziou P. Do making habits or breaking habits influence weight loss and weight loss maintenance? A randomised controlled trial. *Australian and New Zealand Obesity Society*. 2016. Brisbane, Australia.

Cleo G, Isenring E, Thomas R, Glasziou P. Could habits hold the key to weight loss maintenance? A randomised controlled trial. *Australian Society for Medical Research; Annual Scientific Meeting*. 2016. Gold Coast, Australia.

Cleo G, Isenring E, Thomas R, Glasziou P. Could habits hold the key to weight loss maintenance? A randomised controlled trial. *Gold Coast Health and Medical Research Council (GCHMRC)*. 2016. Gold Coast, Australia.

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International peer-reviewed conference abstracts: poster presentations

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Cleo G, Isenring E, Thomas R, Glasziou P. Maintaining weight loss: a look at habits. *United Kingdom Congress on Obesity*. 2016. Nottingham, United Kingdom

Cleo G, Isenring E, Thomas R, Glasziou P. Could habits hold the key to weight loss maintenance? A randomised controlled trial. *International Conference on Obesity and Chronic Disease (ICOCD)*. 2017. San Francisco, CA, USA.

Cleo G, Isenring E, Thomas R, Glasziou P. Could habits hold the key to weight loss maintenance? A randomised controlled trial. *24th European Congress on Obesity*. 2017. Porto, Portugal.

Ethics declaration

The research associated with this thesis received ethics approval from the Bond University Human Research Ethics Committee. Approval numbers RO1888 and RO1888b.

Financial declaration

This research was supported by an Australian Government Research Training Program Scholarship.

Copyright declaration

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Methodology and aims of studies

The core objective of this PhD is to determine whether habit-based interventions are effective at helping participants lose weight and maintain that weight loss for at least 12 months. In order to fulfil this main objective, four important investigations need to be explored: (a) what does the current literature report on the current state of overweight and obesity and what strategies are currently available; (b) what are the weight loss and weight loss maintenance outcomes from implementing a habit-based intervention; (c) what is the general experience of the individuals participating in the habit-based interventions- are habit-based interventions preferred over other conventional programs; and (d) how do habit-based programs compare with control groups when assessing weight loss and weight loss maintenance outcomes.

This PhD has four studies:

Study 1- Formative literature review

Study 2- Randomised controlled trial (pilot study and main study)

Study 3- Qualitative interviews with study participants

Study 4- Systematic review and meta-analysis of habit-based weight loss interventions

Chapter outline

- **Chapter 1** introduces the aetiology of overweight and obesity and collates, reviews and interprets how habitual behaviour plays a role in the lack of weight loss maintenance.

Aim: the formative literature review aims to inform the direction of this PhD research.

- **Chapter 2** provides a detailed description of the two programs used in the subsequent randomised controlled trial. This chapter draws information from published trials that have used the interventions relevant to this PhD.

Aim: to outline the conceptual theories and methodological procedures of the interventions used in study 2 (RCT).

- **Chapter 3** describes a 4-week pilot study, conducted to assess the feasibility and acceptability of the 2 interventions used in the subsequent randomised controlled trial.

Aim: to determine if the two interventions used in this PhD are feasible to implement and do participants find them acceptable?

- **Chapter 4** presents the main 3-arm randomised controlled trial. This study included 75 participants with overweight or obesity. Participants were randomised to one of 2 habit-based interventions or a wait list control group. Active intervention participants were followed up 6 and 12-months post-intervention.

Aims: (1) determine whether habit-based weight loss interventions are clinically beneficial in achieving and maintaining at least 5% body weight loss over 12-months; (2) assess whether making new habits, or breaking old habits is more effective at weight loss maintenance 12-months post-intervention.

- **Chapter 5** comprises a qualitative analysis which was conducted with a subsample of participants from the main RCT.

Aims: (1) explore the general experience of participants in the TTT and DSD interventions; (2) discover whether the different interventions affected the participants' behaviours and weight loss results (3) consider the acceptability and practical application of the two interventions as a method of process evaluation.

- **Chapter 6** presents a systematic review and meta-analysis examining the efficacy of habit-based interventions on weight loss and weight loss maintenance.

Aims: (1) assess the efficacy of habit-based interventions on weight loss and weight loss maintenance (2) determine if forming new habits or the combination of forming and breaking habits is more effective for weight loss and weight loss maintenance.

- **Chapter 7** synthesises these findings to form conclusions about the implementation of habit-based interventions as a strategy for weight loss and weight loss maintenance.

Aims: This chapter addresses the original research questions and discusses the results of the studies in a broader context. Recommendations for future research directions are also provided.

Chapter 1

Study 1: Literature review

*"Most of the time what we do is what we do most of the time,
sometimes we do something new."*

- David Townsend

This chapter is based on the article entitled *“Could habits hold the key to weight loss maintenance? A narrative review”*, published in the Journal of Human Nutrition and Dietetics in February 2017 (doi: 10.1111/jhn.12456). (Appendix A; page 205).

First, an introduction to the prevalence and determinants of overweight and obesity is presented, followed by the current weight-management interventions and their outcomes, and finally the theories and outcomes of using habit-based interventions for weight loss and weight loss maintenance.

Prevalence of overweight and obesity

National surveys show that overweight and obesity have become a major public health concern both in developing and developed countries, as evidenced by a rise in BMI across all ages and genders¹⁻³. Worldwide obesity has more than doubled since 1980, with 39% of adults classified as overweight in 2014, and 13% as obese internationally³. The prevalence of overweight and obesity has been progressively increasing at an average rate of 0.3%-0.8% per year, according to the National Institutes of Health and World Health Organization (WHO)^{3,4}.

In Australia, there has been a 7.5% increase in the prevalence of overweight or obesity over the past 20 years; with 63.4% of adults classified as overweight or obese in 2014-2015 (comprised of 35.5% overweight and 27.9% obese), compared with 56.3% in 1995⁵.

The burden of overweight and obesity

Comorbidities

Overweight and obesity are associated with a high prevalence of comorbidities, including cardiovascular disease, type II diabetes mellitus, certain cancers (liver, kidney, breast, endometrial, prostate, and colon)⁴, osteo-arthritis, kidney and gall bladder disease and respiratory and musculo-skeletal problems⁶. Furthermore, depending on age and race, obesity has revealed an associated 6-20 year decrease in life expectancy compared with people within a healthy BMI range⁷.

Mental health concerns

Obesity is often associated with major psychological burdens including depression and anxiety⁸. Depression is a significant condition that is commonly found in individuals with obesity, especially those with severe obesity and comorbidities such as diabetes and sleep disturbance^{9,10}. The combination of obesity and depression is often compounded by low income, poor employment opportunity, and very low self-esteem associated with guilt and a perceived lack of willpower¹⁰. The depression, stress and psychological disturbance experienced by many individuals with obesity are generated not only by being overweight or obese, but also by society's broad pejorative perceptions about the condition^{9,10}. Therefore, obesity has also been associated with social discrimination⁶ and similarly has adverse implications on individual self-image, and health-related quality of life¹¹.

Paradoxically, treating depression as a consequence of overweight and obesity with antidepressants can lead to increased hunger, weight gain and increased risk of developing type II diabetes and heart disease ^{9,10,12}. A systematic review and meta-analysis on antidepressants and body weight reviewed 116 studies and revealed, common antidepressants such as amitriptyline, mirtazapine, and paroxetine were associated with a greater risk of weight gain when compared to placebo control ¹². This appears to be a common and significant problem during both acute and long-term treatment with antidepressants ¹³. Psychological approaches to the treatment of obesity that might also impact depression such as behaviour conditioning therapy, cognitive behavioural therapy and hypnosis have shown good short-term weight loss success, however poor-long term weight loss maintenance ¹⁴. Therefore, effective obesity treatment is essential for improving quality of life, psychological wellbeing and adequately treating obesity-related complications including depression.

Economic burden

Morbidities and health complications related to excess weight impose substantial economic burdens on individuals, families and communities. The total direct cost of overweight and obesity in 2005 as estimated by the Australian Diabetes, Obesity and Lifestyle study totalled \$21 billion (\$6.5 billion for overweight and \$14.5 billion for obesity) ¹⁵. Direct financial costs include the cost of running hospitals and nursing homes, general practitioners and specialist services, the cost of pharmaceuticals, allied health services and research. The same study estimated additional indirect costs of \$35.6 billion per annum, which included loss of productivity, carer cost, burden loss from welfare and other government payments, as well as other costs including equipment, transport and respite. This resulted in an overall total yearly financial burden of \$56.6 billion ^{15,16}. Of these financial costs, 37% was borne by Federal Government, 29% by individuals, 16% by family and friends, 5% by State Governments, 0.1% by employers and 12% by the rest of society. In 2001, obesity was associated with over four million days lost from Australian workplaces ¹⁷.

Decreased rates of obesity would ameliorate this immense cost and benefit both individuals and governments by allowing those costs to be spent on other issues.

Aetiology

The actual causes of obesity are complex and multifactorial, including genetic, psychological, biochemical, environmental, social and economic influences ^{11,18}. Despite these complexities, the cause of obesity can be simplistically described as the imbalance between excessive caloric

intake in relation to an individual's daily energy requirements ¹¹. At a more practical level, it is compliance with dietary requirements and regular physical activity that ensures energy and nutrient balance.

Regular physical activity is recommended for general health and wellbeing as well as reducing and/or preventing obesity. The Australian Government's Department of Health recommends adults perform at least 30 minutes of moderate-intensity physical activity on most, preferably all days of the week ¹⁹. Moderate-intensity activity includes: brisk walking, swimming, tennis and medium-paced cycling as examples. The Australian Health Survey in 2014-2015 however revealed that of those adults surveyed, most did not meet these guidelines with 42% of men and 47% of women exercising less than 30 minutes a day ²⁰.

The National Health and Medical Research Council (NHMRC) recommends that adults eat a minimum of 2 serves of fruit and 5 serves of vegetables a day to ensure good nutrition and health. The latest Australian National Health Survey revealed only 5% of adults are meeting the Dietary Guidelines for minimum number of serves of fruit and vegetables per day ²⁰.

Additionally, the National Health and Nutrition Examination Surveys (NHANES) in the US revealed that between the 1970's (1971-1976) and 2000's (1999-2002) there was an increase in daily energy intake amongst children and adults which might contribute to the mean weight increase of 4kg and 8.6kg respectively over the 30 years ²¹. The estimated food energy intake for children was 1690 kcal/d (7.10 MJ/d) in the 1970's and 2043kcal/day (8.58 MJ/d) in the 2000's and for adults was 2398kcal/d (10.07 MJ/d) in the 1970's and 2895 kcal/d (12.16 MJ/d) in the 2000's (Figure 1.1) ²¹. These estimates were calculated using increased food energy supply and adjusted for wastage and assumed to be proportional to previous energy intake data ²¹.

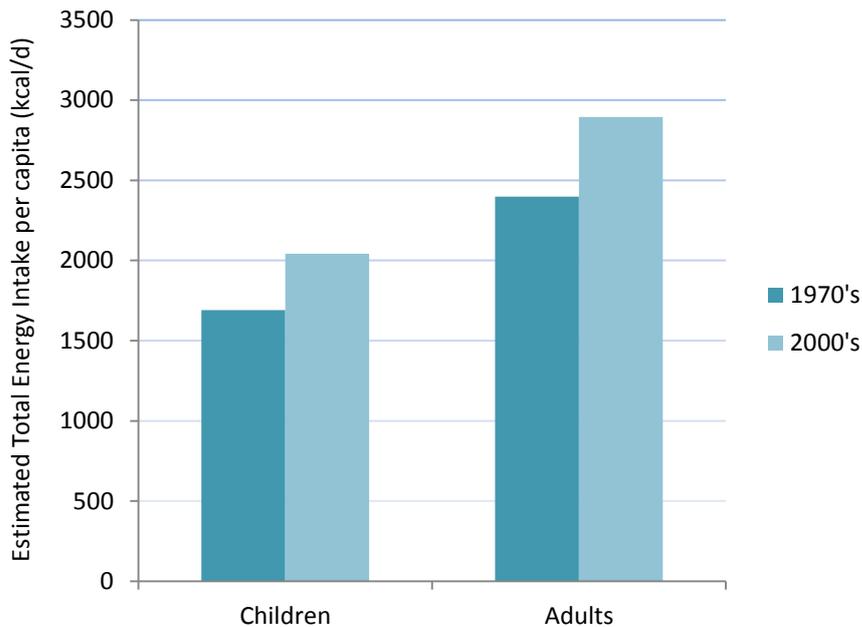


Figure 1.1 Changes in estimated daily energy intake per capita for US children and adults during the 1900's and 2000's ²¹.

This increased energy intake of 350 kcal/d (1500 kJ/d) in children is equivocal to 1 serving of hot chips; and 500 kcal/d (~2000 kJ/d) in adults is equivocal to 2 Mars bars; alternatively, an extra 85-110min of extra walking per day.

Amongst individuals in developed countries, food choice decisions are frequent, multifaceted, situational, dynamic, and complex ²². Individuals often have difficulty identifying true hunger and satiety cues ⁴. It appears that hunger can be stimulated by the presence of favourite foods, specific meal times, and social cues to eat ²³. Individuals also tend to eat more when a greater quantity of food is available as well as when there are a large variety of food options ²⁴. This demonstrates that hunger and satiety are at least partly determined by external cues and subconsciousness ⁴.

Therefore, in developing interventions which aim to regulate energy balance and reduce the prevalence of obesity and obesity-related comorbidities, both reflective, deliberate thinking processes and automatic and habitual behavioural processes should be considered ²⁵.

What has been done? Interventions and outcomes

Experimental studies show that simply knowing what one should eat, or how much to eat or exercise, does not ensure a healthy, balanced diet or body weight ²⁶. We do not eat simply when we feel hunger or our bodies require energy from calories. In an observational study of 331 adults which assessed the awareness of food-related decisions, it was demonstrated that individuals are aware of only a fraction of food decisions and how the environment influences those decisions ²⁷.

There are a wide range of interventions available for treating overweight and obesity ¹¹. These can be classified into three general categories: lifestyle, pharmacological and surgical ¹¹ (Figure 1.2).

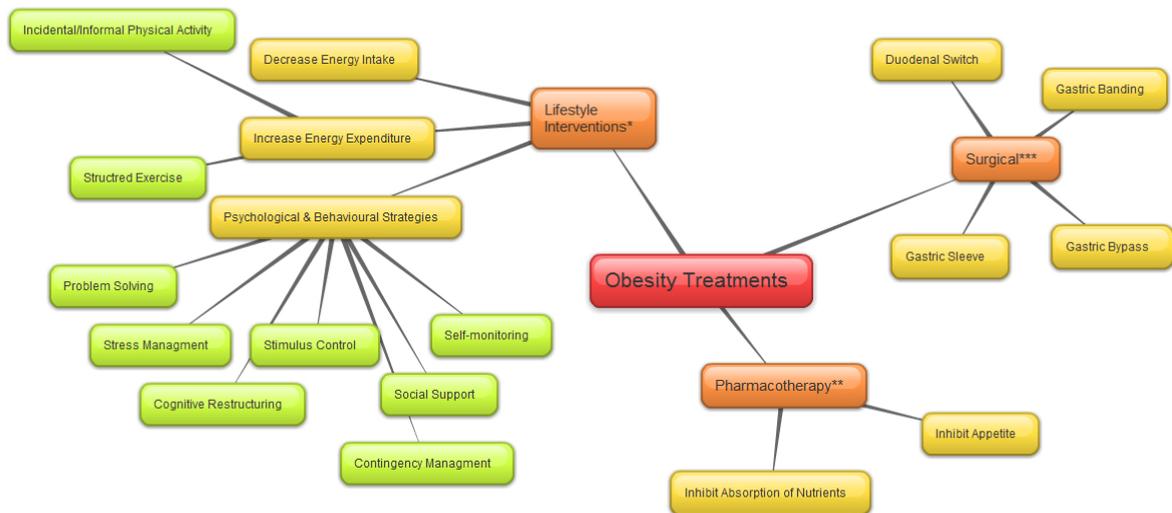


Figure 1.2 Weight management intervention categories

Adapted from: *Lifestyle Interventions 28; **Pharmacotherapy 11; ***Surgical 29

Lifestyle interventions

Lifestyle interventions constitute the foundation of any weight-management program ¹¹. They aim to decrease nutrient intake by decreasing calorie intake or modifying energy density of foods consumed as well as increase energy expenditure through structured exercise and incidental/informal physical activity. Lifestyle interventions can also be combined with psychological and behavioural strategies to improve adherence to treatment and encourage long-term change. Specific strategies may include stress management, problem solving, self-monitoring of eating habits and physical activity, social support, stimulus control, contingency management and cognitive restructuring.

A recent meta-analysis of 48 unique randomised controlled trials (including 7286 participants) compared weight loss from named diet programs compared with no diet in adults with overweight and obesity. The greatest weight loss was associated with low-carbohydrate diets with a mean weight loss of 8.7kg [95% CI, 7.3 to 10.2) at 6-month follow-up and 7.3kg (95% CI, 5.3 to 9.3) at 12-month follow-up, as well as low fat diets with a loss of 8.0kg (95% CI, 6.0 to 9.9) at 6-month follow-up and 7.3kg (95% CI, 5.26 to 9.34) at 12-month follow-up. Weight loss differences between individual diets were minimal ²⁸. This observation supports the practice of recommending any diet an individual will adhere to in order to lose weight. Still, adherence is the challenge ²⁸.

Despite the significance placed on lifestyle interventions, regaining the weight lost seems to be almost inevitable with about 40% of weight being regained over the first year following treatment and much of the rest over the following 3 years ²⁹.

Pharmacotherapy

Pharmacotherapy includes medications which inhibit appetite or inhibit absorption of nutrients ^{11,30}. When drug treatment is adhered to, a 5-10% weight loss is expected ³¹. A Cochrane review of approved anti-obesity medications in clinical trials of at least one-year duration assessed the long-term effects in double-blind, randomised placebo-controlled trials. Results were compared from 30 trials (19,888 participants) which used the popular anti-obesity drugs Orlistat, Sibutramine and Rimonabant. Compared to placebo, Orlistat reduced weight by 2.9 kg (95% CI 2.5 to 3.2), Sibutramine by 4.2 kg (95% CI 3.6 to 4.7 kg), and Rimonabant by 4.7 kg (95% CI 4.1 to 5.3 kg) based on a one year follow-up ³². This treatment however, is generally short-term (12 weeks) because adverse side-effects (e.g., elevated blood pressure and pulse rate, mood disorders, sleep disturbances, dizziness, headache,

nervousness, restlessness, gastrointestinal side effects, shortness of breath, chest pain and lowered HDL levels)^{32,33} Therefore with the ceasing of drug treatment, weight regain is invariable^{29,31,32}. Furthermore, cost-effectiveness data of pharmacotherapy to reduce obesity concludes that treatment with common anti-obesity drugs is not cost-effective and has a negligible impact on the total body weight-related disease burden³⁴.

Bariatric surgery

Finally, bariatric surgery interventions include restrictive surgery that limits dietary intake (e.g. gastric banding, gastric sleeve), malabsorptive surgery (e.g. intestinal bypass) and mixed interventions (e.g. gastric bypass, duodenal switch). Surgical treatments to manage obesity are increasing each year³⁵ and usually result in substantial weight loss over the first 6-12 months (20-45% of preoperative weight) and is generally well maintained²⁹. However due to the obesity classification required (BMI of $\geq 40\text{kg/m}^2$, or $\geq 35\text{kg/m}^2$ with a significant coexisting medical condition such as diabetes or high blood pressure) and the huge financial investment required (~AUD \$21,800 to \$33,300³⁶), only a small number of individuals qualify. Moreover, bariatric surgery has a significant risk of short and long-term post-operative complications and a considerable rate of perioperative mortality¹¹. The cost of bariatric surgery is also a huge burden on individuals with an investment range of approximately AUD\$21,800 to \$33,300. This often makes the procedure impossible even to those who are eligible.

Behavioural changes are an essential element and constitute the foundation of each intervention including lifestyle, pharmacotherapy and surgical treatments. An individual's behaviour is therefore a critical focus point in order to understand the changes required to achieve successful weight loss and weight loss maintenance.

Who succeeds at weight loss? What works?

The National Weight Control Registry (NWCR) was established in 1994 to study weight loss and weight maintenance strategies of successful weight loss maintainers. Now tracking over 10,000 individuals who have lost significant amounts of weight and kept it off for long periods of time, the NWCR is an important data source when evaluating successful long-term weight loss. Results from the NWCR demonstrate that individuals who are most successful at weight loss maintenance report: (a) frequent self-monitoring, (b) regular physical activity, (c) eating breakfast, (d) lower caloric intake, (e) reduced portion sizes, (f) reduced frequency of snacks and, (g) reduction in the percentage of calories from fat^{37,38}.

Results from the registry also demonstrate that the first 2-5 years after weight loss is the most vulnerable time for weight regain^{37,39}. Moreover, maintaining weight loss during those first few years decreases the risk of successive regain by 50%. Consequently, individuals who manage to maintain their weight loss for more than 2 years have a significantly greater chance of keeping the weight off long-term³⁷. Automaticity, behavioural flexibility and habit formation have not been measured by the NWCR, suggesting the need to investigate these factors further.

Benefits of weight loss maintenance

In recent years, it has become increasingly evident that even modest weight loss is associated with significant health benefits, especially when maintained over time. In individuals with overweight or obesity, a 5-10% reduction in body weight is associated with significant improvements in LDL cholesterol, total cholesterol, blood pressure, blood glucose and other health indices as evidenced by a systematic review of 26 randomised controlled trials⁴⁰. This therefore suggests that 5-10% weight reduction is a benchmark for weight loss aims. There is also evidence to suggest that if the lost weight is not regained, these health benefits are sustained¹. Weight losses of 10-15% body weight have even greater benefits⁴¹. Ideal weight is not essential in order for an individual to attain these health benefits⁴².

Over 90% of the NWCR participants who have maintained their weight loss for a number of years reported improvement in their overall quality of life, mobility, level of energy, general mood and self-confidence³⁷. Furthermore, a study of 588 individuals with overweight or obesity reported reductions in weight at 12 months to be associated with improvements in overall well-being, depression, anxiety, and ratings of self-control and vitality⁹. These findings are consistent with previous studies, which investigated the impact of weight change on various factors relating to quality of life. A cross-sectional study of 4601 individuals showed a significant association between excess weight and lower quality of life scores⁴³. Furthermore, a two-year randomised clinical trial of 423 participants showed a correlation between lower weight and better quality of life regardless of the method of treatment used⁴⁴.

Defining weight loss success

Weight loss maintenance implies keeping a weight loss result that has been accomplished by treatment interventions or by one's own efforts⁴⁵. There is currently no general consensus for what classifies successful weight loss maintenance in terms of amount of weight lost or duration of maintenance. Examples of definitions include 'achieving an intentional weight loss

of at least 10% of initial body weight and maintaining this body weight for at least one year'³⁷, or 'losing at least 5% of baseline body weight between baseline and follow-up, and maintaining that weight or less for a further two years'⁴⁶. Other definitions focus on the loss or gain of BMI points after initial weight loss⁴⁷.

In a systematic review of 29 trials looking at the maintenance of behaviour change following physical activity and dietary interventions, less than one third of trials included a follow-up assessment of 12-months post-intervention or longer⁴⁸. The issue of behaviour change maintenance following interventions is not receiving the required focus in the context of rigorous experimental designs. The authors of the review recommend intervention trials include a 12-month follow-up evaluation as a positive progression to improve our conceptual understanding of maintenance of behaviour change and how it can be achieved in the context of interventions⁴⁸.

Behavioural determinants of weight regain

Considering the majority of individuals with overweight or obesity will regain most of the weight they lose, understanding and addressing the determinants for weight regain is essential for successful weight loss maintenance interventions.

No single theory can fully explain decision making in health behaviour, therefore considering multiple analytical perspectives is essential²². Simply knowing what diet and exercise behaviours are necessary for long-term weight loss, does not equate to a healthy behaviour or predict health outcomes⁴⁹. In recent years, studies in psychology have shown robust evidence to suggest that unconscious, automatic processes strongly influence behaviour⁵⁰⁻⁵². This evidence of unconscious behaviour and automaticity has led to extensive research in the area of habits, self-control and the intention-behaviour gap.

Habits

Defining and explaining habits

Habits are generally formed by repeating a behaviour until it has become more or less automatic⁵³. By repeating behaviour in a consistent context, we forge a direct link in memory between the context and response⁵⁴. Therefore, we learn to associate the behaviour to that setting; this process is termed 'context-dependent repetition'. This reinforces a mental context-behaviour association, such that alternative options become less accessible in memory⁵⁵; eventually, the mere perception of the context automatically triggers the responding

behaviour^{49,56}. Habit formation involves a gradual shift in cognitive control from intentional to automatic processes⁵³. This is why a habit is defined as an action which has been triggered automatically in response to a contextual cue associated with its performance⁵⁷. Approximately 45% of everyday behaviours are repeated in the same location^{51,58}. Therefore, daily life consistently exposes people to numerous cues triggering wanted and unwanted habits⁵³.

Habit formation model

According to behavioural psychology research, the habit formation model follows a three-step pattern: 1) cue, 2) routine, 3) reward⁵⁹ (Figure 1.3)

Cues trigger the brain to perform pre-learned habitual behaviours. Routine is the automatic and repetitive nature of the act performed, which can be physical, mental or emotional. And finally, rewards help the brain to determine if the habit loop of that particular behaviour is worth remembering for the future⁵⁹. If the reward is positive, a desire to repeat the routine the next time the same cue is perceived occurs⁵⁹. Eventually, this forms a new habit.

To illustrate habit formation and how it relates to dietary intake, imagine that each time a person goes home in the evening, they eat a snack. When they first eat the snack upon getting home, a mental link is formed between the context (getting home) and their response to that context (eating a snack). Each time they subsequently snack in response to getting home, this link strengthens, to the point that getting home prompts them to eat a snack automatically, without giving it much prior thought; a habit has been formed⁵⁷ (Figure 1.3)

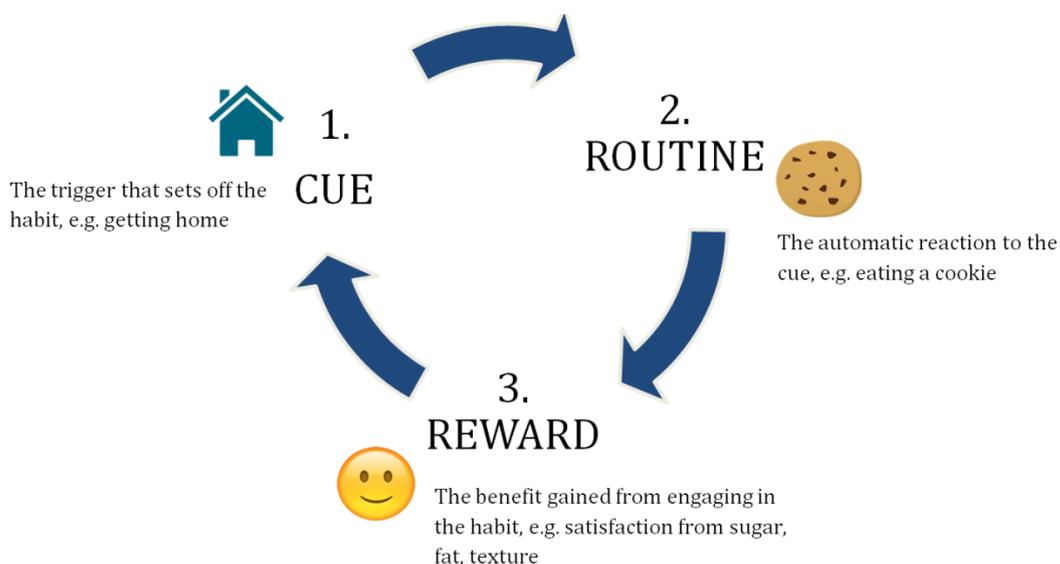


Figure 1.3 The Habit Loop⁵⁹

We make over 200 food decisions per day^{24,27}. Most of these decisions appear to be ‘automatic’ or habitual, which means that we unconsciously eat without reflection, deliberation or any sense of awareness of what or how much food we select and consume^{27,60,61}. Therefore, as a result of the lack of thought required to perform a habit, habitual behaviours over-ride intention⁶¹. The sight of the television remote control can derail a plan to exercise; the notification of a new email can trigger the common habit of procrastinating on the Internet⁴⁹. The ubiquitous effect of habits in everyday behaviour may be a key to understanding the struggle people recurrently experience in changing their lifestyles. Failed attempts at changing diet and exercise behaviour are typical⁶². Such failures are common considering that cues such as location and time of day, both trigger repetition of usual responses⁴⁹. Lack of will power or poor knowledge of health is not necessarily an indicator for failures to change, but instead the power of situations to trigger past responses. Although people are free to act in non-habitual ways, everyday demands such as time pressures and distractions reduce the capacity to engage in reflective thought: therefore, people tend to rely on eating habits⁶³. In a qualitative investigation of 11 adults, automatic behaviour patterns were identified as a perceived cause of weight gain⁶⁴. Habits keep us operating in the way we have always done, despite our best intentions to act otherwise⁵⁴.

Intention-behaviour gap

Social psychology theories suggest that forming a goal (e.g. ‘I intend to eat healthy’) is imperative in promoting behaviour change and goal attainment⁶⁵. However, a recent systematic review and meta-analysis of healthy eating and physical activity habits compared 22 studies ($n= 294$ participants) which showed that the stronger an individuals’ habit strength, the less impact their intentions had on their actions^{66,67}. Although individuals develop an intention to change their behaviour, they might not take any action; this discrepancy is called the ‘Intention-behaviour gap’⁶⁸. A cross-sectional study ($n= 538$) integrated habit strength in the theory of planned behaviour aiming to understand participants’ fruit consumption. The findings showed that stronger fruit consumption habits made fruit consumption less intentional⁶⁹. Therefore, participants with strong habits of fruit consumption ate fruit as a result of their habit to do so, and not their intention⁷⁰. The same participants were assessed for exercise behaviour, intention and habit strength. The findings indicated that exercise has both a cognitive and an automatic component and that stronger exercise habits make exercise less intentional, with the intention–exercise relationship being almost three times stronger at lower levels of exercise habit strength than at higher levels⁷⁰.

Habits are strengthened as behaviour is repeatedly performed in a consistent context⁶⁶ and when behaviour is reinforced by a pleasant experience or reward (i.e. the sweet satisfaction of a chocolate cookie or the comfort of a hearty, warm pudding)⁷¹. In a three-wave observational study of fruit and vegetable (FV) intake in adults ($n= 127$), it was hypothesised that the intrinsic reward value of FV consumption (e.g. feeling good about eating healthy) would strengthen FV consumption habits. Habit strength was assessed with an automaticity-specific abbreviation of the Self-Report Habit Index⁷². Questionnaires measured participants' intrinsic reward, intention and self-efficacy at baseline and after 2 and 4 weeks. The results indicated that intrinsic reward had a positive indirect effect on habit strength through its influence on the frequency of FV consumption. Furthermore, the relationship between FV consumption and habit was stronger where consumption was considered more intrinsically rewarding. These findings highlight the potential relevance of intrinsic reward to habit and should be considered as a tool in habit-based interventions⁷³. People with strong habits are generally not observant to information about the adverse effects of their behaviour⁷¹.

To illustrate, Ji and Wood⁷⁴ studied college students ($n= 219$) over a 1-week period and predicted how often they watched television or purchased fast food from their behavioural intentions and their habits. The findings showed that students acted on their intentions only when their habit strength was weak or moderate. Students with strong habits continued their typical behaviour in purchasing fast food, despite their intentions. Therefore, as the habit strength increased, intentional behaviour decreased. Indeed, intentions guided actions largely when habits had not been formed. These findings support the theory that habitual behaviour can be triggered independent of an individual's intentions⁵⁴. Consequently, this automatic eating behaviour has been described as the most plausible factor explaining the lack of weight loss maintenance success^{26,63}.

Automaticity

Once a habit has formed, automaticity is considered to be an important determinant of that habit⁵³. Automaticity can be described as a behaviour which features efficiency, lack of awareness, unintentionality and uncontrollability⁷⁵. Automatic behaviours occur without reflective decision-making processes⁶⁰ and increase with continuous repetition of the behaviour⁷⁵.

The complexity of a particular behaviour impacts the development and strength of automaticity^{57,75}. In a recent study of 96 participants who chose an eating, drinking or exercise

behaviour to carry out daily in the same context for 12 weeks, the average time participants took to reach automaticity of their chosen behaviour was 66 days, (range of 18-254 days) ⁶⁶. Exercise behaviours (considered more complex than eating or drinking) took one and a half times longer to reach a level of automaticity than eating and drinking habits ⁷⁵. In another study, automaticity strength peaked more rapidly for simple actions (e.g. drinking water) than for more elaborate procedures (e.g. doing 50 sit-ups) ⁵⁷. Other studies report consistent findings, with participants automatically performing lifestyle behaviours after around 10 weeks ^{75,76}; moreover, participants maintained their new habitual behaviours over 32 weeks and the behaviours increased in automaticity ⁷⁶.

Automaticity is suggested to be a powerful tool in positive habit formation as there is a reassurance that doing a new and healthy behaviour will get progressively easier ⁷⁵. Therefore, maintaining motivation and consistently working on the new behaviour is only necessary until the habit forms and the new behaviour becomes 'second nature' ⁵⁷. Lifestyle changes commonly last only a short period of time as individuals generally return to their previous patterns ⁷⁷. Once a behaviour becomes automatic however, it is more resilient to change than purposeful or intentional behaviours ^{75,78} and therefore lasts longer and achieves continued or maintained results ⁷⁹.

Habit advice, should therefore include behaviour changes which are simple for individuals to implement as this provides realistic long-term effects. Gardener et al. ⁵⁷ developed a sample tool for health professionals to use with patients in order to encourage habit formation (Figure 1.4).

Make a new healthy habit

1. Decide on a goal that you would like to achieve for your health.
2. Choose a simple action that will get you towards your goal which you can do on a daily basis.
3. Plan when and where you will do your chosen action. Be consistent: choose a time and place that you encounter every day of the week.
4. Every time you encounter that time and place, do the action.
5. It will get easier with time, and within 10 weeks you should find you are doing it automatically without even having to think about it.
6. Congratulations, you've made a healthy habit!

My goal (e.g. 'to eat more fruit and vegetables') _____

My plan (e.g. 'after I have lunch at home I will have a piece of fruit')
(When and where) _____ I will _____

Some people find it helpful to keep a record while they are forming a new habit. This daily tick-sheet can be used until your new habit becomes automatic. You can rate how automatic it feels at the end of each week, to watch it getting easier.

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
Monday										
Tuesday										
Wednesday										
Thursday										
Friday										
Saturday										
Sunday										
Done on >5 days, yes or no										
How automatic does it feel? Rate from 1 (not at all) to 10 (completely)										

Figure 1.4 Habit formation checklist ⁵⁷

Habit formation begins with an 'initiation phase', during which the new chosen behaviour and the context in which that behaviour will be performed are selected; for example, 'eating a piece of fruit at breakfast'. Automaticity develops in the subsequent 'learning phase', during which the behaviour is repeated in the chosen context to strengthen the context-behaviour association (self-monitoring through a tick sheet may help ⁸⁰[Box 1]). Finally, habit formation is accomplished in the 'stability phase', at which the behaviour persists over time with minimal conscious thought or effort ⁵⁷. This tool has not been formally tested, although it synthesises evidence based on the current literature of habit theory ⁵⁷.

Behavioural flexibility

Behavioural flexibility has an inverse relationship to automaticity and is a measure of a person's range of behaviours across different situations ⁸¹. An individual with more behavioural flexibility has a greater behavioural reservoir and behaves in less habitual ways than a person with less behavioural flexibility ⁸².

In a study sampling over 1,000 people, behavioural flexibility was found to correlate negatively and significantly with BMI⁸³. This finding led to the novel hypothesis proposing that, if behavioural flexibility is negatively correlated with BMI, then increasing behavioural flexibility would lead to weight reduction⁸⁴. By introducing different daily activities, individuals are challenged to break existing habits and increase their behavioural flexibility. This approach avoids the need for sustained willpower and may provide the impetus for positive change by altering the daily habits that trigger overeating and the broader changes needed for positive health behaviour generally⁸¹.

Self-control and the strength model

Self-control is defined as ‘*the capacity of the individual to alter, modify, change, or override his or her impulses, desires, and habitual responses*’⁸⁵. Plainly speaking, it is the ability to exert control over one’s self. When done successfully, an individual is able to overcome urges, impulses and well-conditioned or habitual responses⁸⁶. Alternative terms for self-control include willpower, self-discipline, and self-regulation⁸⁷⁻⁸⁹.

Self-control is essential in health-related behaviour and has been shown to have a positive effect on healthy eating and successful weight management⁹⁰. Conversely, low levels of self-control have been associated with a reduced level of compliance to healthy behaviours such as physical activity, alcohol and smoking cessation, as well as following a healthy diet regimen⁹⁰. Baumeister et al. developed the *Strength Model of Self-Control* to provide a universal explanation for self-discipline failure⁹¹. According to the strength model, self-control is comparable to a muscle. Just as a muscle requires energy to apply force, acts which demand high levels of self-control also require energy to be performed. Moreover, as muscles become fatigued with sustained exertion resulting in reduced ability to exert further force, self-control also draws from a limited ‘reservoir’ which depletes with demand resulting in a reduced capacity for further self-regulation⁸⁶. This state of diminished self-control is termed ‘ego-depletion’.

Long-term demands on self-control have also been hypothesized to cause ego-depletion. Dieters are a prime example of this theory as they are frequently faced with tempting situations where self-control is necessary to restrain and control their eating behaviour (i.e. resisting tempting foods)⁹². Not only does this eating restraint cause a reduced capacity to regulate eating when self-control resources are depleted, it may also result in a reduced self-

control capacity and vulnerability to ego-depletion, especially if faced with a subsequent task or activity which requires further self-control resources⁹⁰.

Fatigue has also been conceptualised as a potential explanation for ego-depletion. Evidence from mental fatigue literature suggests performing difficult or challenging tasks causes impaired performance on succeeding tasks⁹². An experiment which demonstrated this theory included 57 students' physical activity levels during periods of exam stress. The mental fatigue caused by exam stress had a significant negative impact on students' health-related behaviours which required self-control, including physical activity⁹³. The students opted for a sedentary option which does not require self-control, instead of exercising which necessitates focused planning as well as preparation for the expected physical effort and discomfort physical activity produces⁹⁴. A review study similarly described that an individual with depleted resources of self-control is also less likely to consume less appetising food, even if those foods promote good health. A stressful day in the office can therefore be a potential trigger for an unhealthy take-away meal on the way home, or an extra serve of dessert⁹².

Regenerating self-control

Research suggests the depletion of self-control is only temporary and can be replenished with rest and recuperation, just as a muscle's strength is restored after a period of relaxation⁸⁶. The restoration of self-control follows a 'dose effect', such that it is proportional to the duration of the recovery period; longer periods of rest result in greater restoration of self-control and counteract the impact of resource depletion⁹⁵. Regenerating self-control through rest could include: sleep; eliciting positive emotions such as those from watching a comedy video clip or other positive mood enhancing activities; meditation; and introducing periodic breaks during a continual task.

To explore the role of recovery in self-control, one study⁹⁸ randomly assigned 40 participants to a relaxation interval condition or control group and asked them to perform a series of tasks requiring self-control. The results indicated the ego-depleted participants who were allowed to relax, performed significantly better on their subsequent regulatory task, than the less-relaxed control group⁹⁵. The improvement of participants allowed to recover through relaxation, equalled the self-control of participants who experienced no initial regulatory depletion. Therefore, the researchers conclude that taking relaxing breaks between effortful tasks, may serve to effectively, yet temporarily, replenish one's depleted self-control resources. This finding supports earlier research which found 10-minute breaks during ongoing tasks produced significant improvement in participants' subsequent performance⁹⁶.

Once a habit is formed, self-control is no longer required as the behaviours are performed automatically and without deliberation. This means self-control reserves can be utilised in other areas of one's life, for example work and self-development, and not exhausted on daily lifestyle behaviours such as eating well and exercising.

Habit change interventions for weight loss

Breaking unwanted habits can be achieved by restructuring an individual's environment, or programming new responses to their existing environment ⁶⁶. Interventions, that focus on changing an individual's behaviour, are not usually successful at changing an individual's habits because they do not incorporate the strategies required to break unwanted habits and form new healthful habits ^{30,76}. General health advice is usually based on advising individuals on what to change and why (e.g. reduce daily calorie intake to achieve weight loss). Such advice requires conscious, deliberative thoughts ⁹⁷. However, motivation and attention to change behaviours wane over time; therefore, the effects of behaviour change are typically short-lived ⁹⁷. Advice on how to change at the same time as engaging automatic behaviours (including efficiency, lack of awareness, unintentionality and uncontrollability ⁷⁵) may offer a valuable alternative with potential for long-term impact.

To explore the potential role of habits in weight loss and weight loss maintenance, a focused search was conducted in July 2016, for weight loss interventions specifically based on habit-theory. Electronic databases included PubMed for its generality and PsychInfo for its focus on psychological interventions. Figure 1.5 outlines PRIMSA flow diagram of the process for identification of studies. Inclusion criteria were studies reported to use habit-based methods to reduce weight and excluded were review papers, studies that included participants with pre-existing psychological disorders or interventions without a specific weight loss focus (i.e., drugs and alcohol intervention studies). Extracted data included study design, intervention method and delivery, control group treatment and total weight change (Table 1.1). Three interventions were identified: 'Ten Top Tips' ^{76,79}, 'Do Something Different' ^{81,84} and 'Transforming Your Life' ^{98,99}. Table 1.1 displays key details on the three interventions as per previous trials.

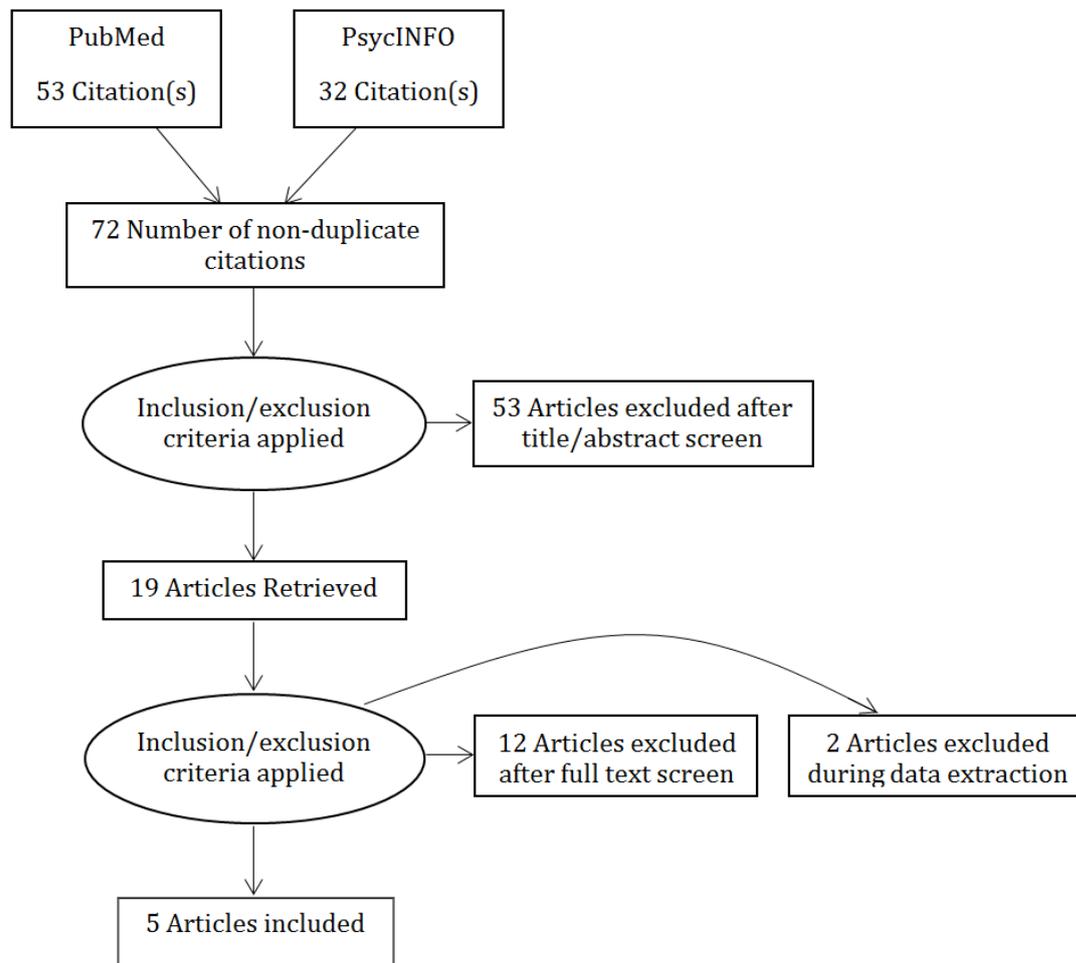


Figure 1.5 PRISMA flow diagram of processes for identification of studies

The Ten Top Tips (TTT)

Ten Top Tips is a weight loss intervention based on habit formation theory, using written materials to guide participants through a set of simple weight management behaviours with the intention of making those behaviours habitual. For example, participants are required to keep to a meal routine, eat off a smaller plate, eat mindfully and pack a healthy snack. There are 2 published studies on TTT (Table 1.1).

Results from a randomised controlled trial with 104 participants with overweight or obesity, showed the TTT intervention achieved a statistically significant mean weight loss of 2.0kg at 8 weeks compared to a mean weight loss of 0.4kg in the control group. Moreover, participants in TTT continued to lose weight with an average of weight loss of 3.8kg at 32 weeks. In another study of 389 participants, those receiving TTT lost significant more weight over 3-months than those receiving usual care (mean difference -0.87kg; 95% CI -1.47, -0.27; $P= 0.004$)¹⁰². At 24-month follow-up ($n= 312$) the TTT group had maintained their weight loss, but as did the usual

care group. TTT participants reported an automaticity of some of the healthy habits prescribed in the intervention, therefore sustainability of their weight loss was predicted ⁷⁶.

Semi-structured interviews were conducted at the completion of the intervention with pilot study participants ($n= 10$), in order to gather feedback and explore general experiences. Results showed that behaviour change was initially experienced as cognitively effortful but as automaticity increased, enactment became easier. Most participants reported characteristics of habit: Automaticity, the importance of repetition and “feeling strange” when not doing the behaviour ¹⁰⁰.

The greatest challenge for weight loss interventions is maintenance ³⁷. Encouragingly, the results of these studies indicate that participants were not only able to maintain the weight they lost on the TTT intervention, but continued to lose further weight up to 24 months post-intervention. The theory of habit formation is that repeated behaviours become automatically cued by the environment and therefore become easier to perform over time. Overall, the TTT program can be disseminated on a large scale at low cost and has the potential to result in significant weight loss and weight loss maintenance. Further replication of the TTT, would support the work further and help determine the role of potential confounders.

Do Something Different (DSD)

Do Something Different is a behavioural intervention, which focuses on increasing participants' behavioural flexibility by breaking daily habits. The authors describe the aim of DSD is to break the distal habits proposed to play a role in unhealthy dietary and exercise behaviours. DSD requires participants to do something different each day and to engage in novel, weekly activities to expand their behavioural repertoire. What makes this intervention particularly novel is that these activities are not food or exercise related. In a longitudinal, two-armed controlled trial of 31 participants, the DSD intervention achieved a gradual and continuous weight loss with a statistically significant mean average of 2.6kg loss over a 4-week period, compared with 0.88kg loss in the control group. Two months post-intervention, DSD participants had continued to lose weight with a total mean weight loss of 5.18kg ($SD = 3.85$), compared with 0.43kg ($SD = 1.94$) loss in the control group ⁸¹; suggesting the changes effected in the DSD intervention were maintained.

A key finding in the study was a dose-response relationship between changes in behavioural flexibility that occurred as a result of the 4 week DSD program and the amount of weight loss

observed. This supports the hypothesis that behavioural flexibility may facilitate in weakening poor lifestyle habits and therefore contribute to weight loss⁸⁴.

Transforming Your Life (TYL)

Transforming Your Life is an environmental modification approach to weight loss, which combines promoting healthy habits as well as disrupting unhealthy habits. Individuals were taught to create their personal food and exercise environment in a manner that minimises unhealthy eating and sedentary behaviour cues/choices, maximises healthy eating and exercise-related cues/choices, and encourages automatic responding to goal-related cues⁹⁹. In a 12-week randomised controlled trial, 59 participants with overweight or obesity were randomised to either TYL ($n= 29$), or a weight loss program which emphasized reducing unhealthy relationship with food (New Perspectives [NP]) ($n= 30$). Despite equivalent mean weight loss at the end of treatment (-6.6kg, SD 5.3), after 6 months of no intervention, the TYL participants were significantly more effective at maintaining their weight loss with a further average weight loss of -2.2kg (SD 4.4) while NP participants regained an average of +2.1kg (SD 7.3)⁹⁹.

In another study of 54 participants, the TYL and active control groups lost equivalent amounts of weight after a 14-week intervention, but both had a slight regain (+1.5kg) at 6-months post-intervention⁹⁸. However, TYL appeared to represent an attractive option for individuals seeking an alternative to traditional behavioural approaches to weight loss.

A comparison of the TYL intervention with a non-active control group, would be a valuable addition to the current body of literature.

Table 1.1 Comparison of intervention methods and weight loss results of the Ten Top Tips, Do Something Different and Transforming Your Life interventions.

	<i>Ten Top Tips</i> (Habit formation)		<i>Do Something Different</i> (Habit disruption)	<i>Transforming Your Life</i> (Habit formation & habit disruption)	
	TTT – Study 1 ¹⁰¹	TTT – Study 2 ¹⁰²	DSD ⁸⁴	TYL – Study 1 ⁹⁸	TYL – Study 2 ⁹⁹
Intervention method and delivery	Study 1: Based on habit formation theory to promote automaticity . Participants attended an information meeting where they were provided with a leaflet, which outlined the 10 tips as well as a daily self-monitoring form . The program was self-guided at home and no therapeutic contact was provided during the intervention period	Study 2: Based on habit formation theory to promote automaticity . Participants attended an information meeting where they were provided with a leaflet, which outlined the 10 tips as well as a daily self-monitoring form . The program was self-guided at home and no therapeutic contact was provided during the intervention period	Aimed to break distal habits proposed to play a role in unhealthy dietary and exercise behaviours . Participants attended a 2-hour group induction session where they were provided with a task booklet, which guided them to do something different every day . The tasks were not diet and exercise related. The intervention was self-guided at home	An environmental modification approach, which combined promoting healthy, habits as well as breaking unhealthy habits . Participants attended weekly, group, 90 minute, face-to-face sessions conducted by a licensed clinical health psychologist or psychology doctoral student. Sessions included weight assessment and provided a combination of didactic instruction, individual activities and out-of-class assignments	An environmental modification approach, which combined promoting healthy, habits as well as breaking unhealthy habits . Groups of 12-16 individuals met weekly for a 90-minute, face-to-face session conducted by a licensed clinical health psychologist and/or graduate students in psychology. Sessions included weight assessment and provided a combination of didactic instruction, group and individual in-class activities, and take-home assignments
Control group treatment	Wait list group were offered the intervention after 8 weeks	Referred to their general practitioner’s usual care treatment	Participants engaged in daily tasks not expected to influence behavioural flexibility	LEARN weight loss program, which encourages increasing physical activity and decreasing energy and fat intake	New Perspectives weight loss program, which emphasises reducing unhealthy relationships with food, body image dissatisfaction and internalised weight bias
Outcomes measured	Weight, BMI, satisfaction with life, development of habits using Self-Reported Habit Index (SRHI)	Weight, BMI, waist circumference, proportion achieving 5% weight reduction, blood pressure, cholesterol/LDL, blood glucose, automaticity change (SRHI), cost analysis.	Weight	Average daily energy intake (kcal), average daily energy expenditure (kcal), average energy expenditure from physical activity, exercise duration, and weight	Weight, BMI, average daily energy intake (kcal), average daily energy expenditure (kcal), Binge Eating Scale, Emotional Eating Scale, several other scales

Trial duration	8-week intervention; 8-month follow up	3-month intervention; 24-month follow-up	4-week intervention; 2-month follow up	14-week intervention; 6-month follow up	12-week intervention; 6-month follow up
Inclusion criteria	BMI ≥ 25 kg/m ² , age ≥ 18	BMI ≥ 30 kg/m ² , age ≥ 18	BMI ≥ 25 kg/m ² , no medical contraindications	BMI ≥ 27 kg/m ² , non-smokers, free from cardiovascular disease and insulin dependent diabetes	BMI ≥ 27 kg/m ² , free from major medical conditions
Mean baseline weight	89.8kg (<i>SD</i> = 15.0)	100.8kg (<i>SD</i> = 17.2)	N/A	N/A	109.8kg (<i>SD</i> = 32.2)
Mean baseline BMI	30.9 kg/m ² (<i>SD</i> = 4.5)	Median (IQR) 35 kg/m ² (32.6-39.2)	29.6 kg/m ² (<i>SD</i> = 4.8)	37.2 kg/m ² (<i>SD</i> = 6.7)	39.7kg/m ² (<i>SD</i> = 10.3)
Mean age	40.5 years (<i>SD</i> = 10.4)	Median (IQR) 59.4 (48.7-66.8)	44.2 years (<i>SD</i> = 7.3)	47.3 years (<i>SD</i> = 11.2)	44.3 years (<i>SD</i> = 13.2)
N	104	537	31	54	59
Study design	Quasi randomised controlled trial	Two-armed randomised controlled trial	1-month longitudinal prospective cohort study	Two-armed randomised controlled trial	Two-armed randomised controlled trial
NHMRC level of evidence ³⁹	III-1 Exploratory trial	II Intervention	III-2 Intervention	II Intervention	II Intervention
AND quality criteria ¹⁰³	Positive	Positive	Positive	Positive	Positive
Mean weight loss post-intervention	8 weeks: -2.0kg (<i>SD</i> = 1.9)	3 months: -1.7kg (<i>SD</i> = 3.2)	4 weeks: -2.6kg	14 weeks: -5.4kg (<i>SD</i> = 4.8)	12 weeks: -6.6kg (<i>SD</i> = 5.3)
Mean weight loss at final follow-up from baseline	8 months: -3.6kg	24 months: -2.2kg (<i>SD</i> = 5.8)	2 months: -4.5kg	6 months: -3.9kg (<i>SD</i> = 4.9)	6 months: -8.8kg (<i>SD</i> = 9.7)

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; TYL = Transforming Your Life; BMI = Body Mass Index; kg = kilogram; kcal = kilocalorie; SRHI = Self-Reported Habit Index; NHMRC = National Health and Medical Research Council; QOL = Quality of Life; LDL = Low-density lipoprotein; AND = Academy of Nutrition and Dietetics.

Making or breaking habits

Given the global problem of overweight and obesity and the lack of effective weight loss maintenance, the phenomenon of forming new habits or breaking old habits for successful weight loss maintenance is novel and important to explore. Which is more effective forming or breaking habit? TTT and DSD function in opposing ways. TTT works to promote habits and establish automaticity in healthy lifestyle behaviours. DSD conversely, promotes behavioural flexibility by disrupting daily routines and therefore, breaking habits. In contrast, TYL does not disentangle breaking or making habits.

Conclusion

Ample evidence suggests that a significant part of daily eating behaviours consists of habits. In line with this, the concept of habit is increasingly incorporated into studies investigating the behavioural and psychosocial determinants of food choice, yielding evidence that habit is one of the most powerful predictors of eating behaviour and therefore weight loss success ⁷¹.

Best intentions are not sufficient to elicit behaviour change. People with strong habits tend to continue their typical behaviour despite their well-meaning and often well-informed intentions ⁶¹. Indeed, theory and empirical research suggests that intentions guide actions largely when habits have not yet been formed ⁵⁶. This phenomenon supports the theory that habitual behaviour can be triggered independent of an individual's intentions ⁵⁸. Therefore, a deeper focus on habit-change interventions would be beneficial to better inform weight management interventions.

Despite using different methods, the habit-based interventions highlighted in this review (i.e. TTT, DSD and TYL) all show significant weight loss results with promising long-term weight loss maintenance. Only one of the studies however, published results regarding maintenance of the participants' weight loss longer than 12-months ¹⁰². For those who adhere to weight loss lifestyle programs, weight loss is often the outcome but typically loss is regained. Research in weight loss programs would benefit from long-term follow-up periods beyond the immediate and short-term. Additionally, there is currently a dearth of studies focused primarily on habit-change theories for the treatment of obesity. Perhaps a fresh look at habits and the intention behaviour gap will shed some light on this significant problem.

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Chapter 2

Program descriptions

“Motivation is what gets you started. Habit is what keeps you going.”

- Jim Rohn

This chapter describes the two programs which are used as the active interventions in this PhD study: Ten Top Tips (TTT) and Do Something Different (DSD). The conceptual theory is first presented, followed by the background of the programs and finally the aims.

Introduction

Public health attempts to change health behaviours are often centred around an information deficit model ¹. This model assumes people lack knowledge about how to live a healthy lifestyle. Therefore, people lack education and when they receive it they will make the necessary changes to improve their own wellbeing ¹. Despite public health attempts however, and the multitude of health information, obesity rates continue to rise ². This demonstrates a disconnect between knowledge and behaviour, (e.g. intention-behaviour gap) ^{3,4} and supports the theory that behaviour is often elicited habitually rather than mindfully ^{5,6}.

Ten Top Tips

Conceptual theory of the Ten Top Tips

The goal of most lifestyle-based weight loss programmes is to create healthy habits, specifically in regards to healthy eating and exercise behaviours ⁷. Few however, focus explicitly on the theory of habit formation to create healthy habits.

Researchers at the University College London (UCL), UK, hypothesized that a habit-formation model could provide the basis for a simple weight control intervention. In the first therapeutic application of habit theory to address weight concerns, the researchers developed an intervention promoting a set of negative energy balance behaviours. They created a leaflet listing the target behaviours alongside advice on repetition and context-stability; called 'Ten Top Tips' (TTT) (www.weightconcern.org.uk/tentoptips). The ten tips were selected by researchers, clinicians and policy makers based on a set of everyday eating and activity behaviours demonstrated to be associated with weight loss (Table 2.1). To promote habit formation, advice also suggested repeating the tips in consistent contexts and self-monitoring the tips daily. After receiving the TTT leaflet, participants do not engage in any further clinical contact.

Habits and TTT

Since habits are developed through the incremental strengthening of the association between the cue and action ^{8,9}, the TTT are recommended to be performed in a consistent context such as the same time or location, every day. The TTT intervention period is 3 months because this was defined as the duration of time required for a habit to form and the period over which participants are recommended to keep self-monitoring records (logbooks) to aid habit acquisition ^{7,10}.

Background and aims of TTT

Nutrition advice from general practitioners (GPs) is held in high regard and considered by the general public as one of the most trustworthy sources of diet information ¹¹. Primarily for this reason, GPs were identified by the TTT researchers as the ‘first port of call’ for advice on weight control ¹². This created a need for simple, effective intervention that can be delivered by a GP without specialist weight management skills.

The Tips

Seven of the 10 tips are associated with negative energy balance (choose low-fat options, low calorie snacks, low-calorie drinks, eat five servings of fruit and vegetables a day, have small portions and no second helpings, walk 10,000 steps a day, sit for no more than 50 minutes in each hour), two tips help improve nutrition awareness (do not perform other activities while eating, read food labels), and one tip promotes meal routine (eat at the same time each day) (Table 2.1). If all tips were adhered to daily, as opposed to doing none, the negative energy balance behaviours were estimated to create a daily deficit of up to 800-900 kcal (3350-3770 kJ).

Table 2.1 Scientific Justification for the 'Ten Top Tips'

Tip	Scientific Justification	Estimated daily calorie deficit
1. Keep to your meal routine		
Try to eat at roughly the same times each day, whether this is two or five times a day.	People who succeed at long term weight loss tend to have a regular meal rhythm (avoidance of snacking and nibbling) and show ‘flexible’ rather than ‘rigid’ control’ of eating. A consistent diet regimen across the week and year also predicts subsequent long-term weight loss maintenance.	This tip helps encourage habit development.
2. Go reduced fat		
Choose reduced fat foods (e.g. dairy foods, spreads, salad dressings) where you can. Use high fat foods (e.g. butter and oils) sparingly, if at all.	There is a great deal of evidence to support the effectiveness of low-fat diets (where 30 % or less of total daily energy is from fat), which produce weight loss by decreasing calorie intake. Following a low-fat diet is also associated with better weight maintenance.	- 200 Kcal (-840 kJ)
3. Walk off the weight		
Walk 10,000 steps (equivalent to 60–90min moderate activity) daily. You can use a pedometer to	Achieving the UK government recommendation of at least 30 minutes of at least moderate intensity physical activity on 5	-100 to 200 Kcal (-420 to 840 kJ)

help count the **steps**.

or more days a week would increase most people's energy expenditure and contribute to weight management. More activity (45–60 mins) may be required to prevent the transition to overweight and obesity and maximize weight loss. People who have lost weight may need to do 60–90 minutes of activity a day to maintain their weight loss. Doing 10,000 steps/day is approximately the equivalent to at least 60 minutes of walking at a brisk pace (4.5 mph/7.2 km/h).

4. Pack a healthy snack

If you snack, choose a healthy option such as fresh fruit or low-calorie yogurts instead of chocolate or crisps.

Readily-available snack foods and drinks are often high in energy and tend to be used to supplement rather than replace meals. Between 1993 and 1998 sales of snacks more than tripled in the UK from £173 million to £541 million (Approximately AUD \$327 million to AUD \$1023 million). Snack consumption is related to a higher daily energy intake.

-150 Kcal (-630 kJ)

5. Learn the labels

If you snack, choose a healthy option such as fresh fruit or low-calorie yogurts instead of chocolate or crisps.

Food labels detailing the caloric and nutritional content of foods provide a basis for making healthy food choices. Inadequate labelling can have a negative impact on nutrition. Providing individuals with simple methods to understand labels will facilitate informed choices.

This tip helps people to make informed choices

6. Caution with your portions

Do not heap food on your plate (except vegetables). Think twice before having second helpings.

Portion sizes have increased in the past 30 years. Larger portions contain more calories and can contribute to excess energy intake and weight gain. Eating satisfying portions of low-energy-dense foods can help enhance satiety and control hunger while restricting energy intake for weight management.

-100 Kcal (-420 kJ)

7. Up on your feet

Break up your sitting time. Stand up for ten minutes out of every hour.

Inactive people are more likely to be obese than active people. Time spent in sedentary behaviours is related to overweight and obesity, independent of physical activity level. Decreasing sedentary time and increasing light-to-moderate activity may bring substantial health benefit.

-100 Kcal (-420 kJ)

8. Think about your drinks

Choose water or sugar-free squashes. Unsweetened fruit juice contains natural sugar so limit to one glass a day (200 ml/one-third pint). Alcohol is high in calories; limit to one unit a day for women and two for men.	Intake of sugar-sweetened soft drinks has increased over the last 30 years; up by 135% (278 kcal) in 5 years. Higher consumption of sugar-sweetened beverages is associated with greater weight gain. Intake of calorific drinks may lead to excess energy intake that is not compensated for elsewhere in the daily diet.	-150 Kcal (-630 kJ)
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9. Focus on your food

Slow down. Do not eat on the go or while watching TV. Eat at a table if possible.	More TV viewing tends to be associated with a higher calorie intake. Internal cues regulating food intake may not be as effective while distracted by the TV.	This tip helps place the focus on current habits and to avoid unconscious slips in behaviour.
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10. Don't forget your 5 a day

Eat at least 5 portions of fruit and vegetables a day (400g in total).	The UK Department of Health recommends 400g of fruit and vegetables a day. Fruits and vegetables have high nutritional quality and low energy density. Eating the recommended amount produces health benefits including reduction in the risk of cancer and coronary heart disease.	This tip is important for health.
--	---	-----------------------------------

Total Calorie Deficit	-800 to -900 Kcal (3350-3770 kJ)
-----------------------	----------------------------------

Abbreviations: Kcal = Kilocalorie; kJ = kilojoule; AUD = Australian Dollars; TV = Television; min = minimum
 Note: This table was re-printed with permission from the TTT researchers. References deleted from table and are available in original publication ¹³.

Implementing TTT

Participants are provided with the leaflet outlining the 10 tips, and a logbook for self-monitoring during the habit acquisition phase (Appendix C; page 222). Each tip is outlined in the leaflet and includes an explanation of why it supports weight control and suggestions on incorporating it into one's lifestyle.

Participants of TTT are encouraged to self-monitor using a logbook. Monitoring of behaviours should encourage the performance of those behaviours and therefore increase the chance of habit formation. Systematic reviews, analysing the relationship between self-monitoring and weight loss have shown a significant association, with self-monitoring being a significant predictor of decreased body weight ^{14,15}. Evidence shows there is a strong linear relationship between self-monitor and weight loss ¹⁶ with more self-monitoring predicting greater weight

loss^{17,18}. The theoretical foundation of self-monitoring is self-awareness, self-evaluation and self-reinforcement of progress made towards one's goal¹⁵.

Do Something Different

Conceptual theory of Do Something Different

When usual contexts that trigger habits are changed, habits are not cued and therefore their performance is disrupted¹⁹. For example, a person who's cued to drink coffee as soon as they arrive to work, will not have the same trigger on holiday; drinking coffee on holiday becomes an intentional decision rather than an automatic habit.

Do Something Different (DSD) is a behaviour change intervention which aims to disrupt small lifestyle routines that exist in daily life and thereby break existing habits. This method stimulates the 'doing' channels in the brain as opposed to the 'knowing' channels²⁰; therefore, bypasses the intention-behaviour gap. To disrupt habits, participants of DSD are required to perform unstructured tasks, which are non-diet or exercise related, three to four days a week¹. By doing this, participants are engaging in conscious decisions rather than automatic decisions and therefore act out of intention rather than habit.

Background and aims of DSD

Do Something Different (DSD) was developed by health psychology researchers at the University of Hertfordshire, UK. DSD is an online behaviour change program currently available in over 60 countries and has a community clinic in East Sussex, UK. There are numerous DSD programs including: 'Happiness', 'Not smoking', 'Stress less', 'Money' and others (www.dsd.me/programme).

Behavioural flexibility is a measure of a person's range of behaviours across different situations²¹. An individual with more behavioural flexibility has a greater behavioural reservoir and behaves in less habitual ways than a person with less behavioural flexibility. Behavioural flexibility is negatively correlated to BMI²². The DSD weight loss programme was developed to explore the hypothesis that by increasing behavioural flexibility you could reduce weight²².

Do Zone

The program is implemented and managed via an online software designed by the developers, named the 'Do Zone'. When logged into the Do Zone, participants can see the tasks they are required to perform, mark off their compliance and make comments.

Prior to commencement, participants are asked to complete a self-classification questionnaire which personalises the habit breaking tasks they receive on the program. The self-classification tool is presented to the participant in a 6x5 grid; each cell contains a description of a behaviour. The participant is instructed to, "*Click on the behaviours below that best describe you. Select as many or as few as you like, so long as they describe how you generally are. There are no right or wrong answers*". There are 30 behaviours consisting of 15 pairs of opposites (positioned far apart in the grid), as shown in Figure 2.1. Participants can choose as many behaviours as they wish, including both behaviours from a pair of opposites, such as both "predictable" and "unpredictable". Similarly, participants are free to select neither behaviour from a pair.

When hovering over a cell, an 'expander' or explanation appears. This gives a description of the behaviour in that particular cell; e.g., '*Conventional*' is defined as '*Traditional, formal, according to normal custom*', or '*Predictable*' is defined as "*Habitual, people know what you will do next*". See Appendix D (page 227) for full list of expanders. This allows all participants to have a similar understanding of the meaning of each behaviour and therefore, select their self-classification more accurately.

Which of the following describes you best?

Click on the behaviours below that best describe you. Select as many or as few as you like, so long as they describe how you generally are. There are no right or wrong answers. Click on the Next button at the bottom when you have finished.

Not sure which behaviours to click on?

Firm	Unpredictable	Individually-centred	Behave as others want you to	Behave as you wish
Reactive	Lively	Definite	Calm/Relaxed	Gentle
Play it safe	Proactive	Not lively/Laid back	Open-minded	Traditional, formal, according to normal custom.
Introverted	Systematic	Extroverted	Predictable	Conventional
Flexible	Trusting	Group-centred	Spontaneous	Risk-taker
Wary of others	Unconventional	Single-minded	Unassertive	Energetic/Driven

Figure 2.1 Self-classification questionnaire 6x5 grid ²⁰

Results from the self-classification questionnaire are used to personalise the DSD program for each individual by assigning them with an inversely related task, termed a ‘Do’; e.g., if a participant selects they are ‘Introverted’, a ‘Do’ may be “Be more outgoing today, initiate a conversation with someone you don’t usually speak to”. This also works if a participant doesn’t select a box which indicates that characteristic doesn’t describe them; e.g., if a participant doesn’t select that they are ‘Trusting’, a ‘Do’ may be, “Be more trusting of others today; reveal something personal, let them do it their way or give with no expectation of return”. In this way, the self-classification questionnaire serves to inform the Do’s each participant receives during the DSD program ²³.

Implementing DSD

After completing the questionnaires in the Do Zone, the participants receive tailored “dos” 3 to 4 days a week. Table 2.2 displays examples of daily and weekly Do’s. Do’s are designed to bring about actual behaviour change through small, fun, motivating actions, rather than simply offer information ²³. They are sent to the participant via text message and/or email.

Table 2.2 Example Do’s

-
- Do not watch television all day. If you normally don’t watch television, cut out the radio
 - Write something for 15 minutes
 - Don’t have your favourite drink
 - Go for a 15-minute walk and think about your life and what you want from it
 - Get up an hour earlier
 - Make a list of what you want to achieve by this time next year
 - Do a good-natured deed for someone else
 - Listen to a new genre of music
 - Drive a different route to work
 - Contact a long-lost friend or relative
 - Try a new food you’ve never eaten before
 - Paint or draw
 - Go to the cinema by yourself to watch a film
 - Visit a museum or exhibition
 - Use a dictionary to learn ten new words
-

Self-monitoring of Do’s

Engagement in the Do Zone is optional; however, it is a valuable tool for participants to self-monitor their progress. On each day a task is assigned, participants can log into the Do Zone using a personal email address and self-assigned password and select whether they completed the Do. Participants are also able to rate how difficult the task was and rate how much they enjoyed performing it on a scale from 1 to 5. A feedback box is provided if they wish to make a comment or upload a picture. Personal comments are not analysed and do not affect outcome results.

Once the first Do has been recorded in the Do Zone, a progress calendar becomes available for participants to self-monitor. Each day is highlighted with a different colour to indicate a specific action. A green box indicates a recorded completed Do for the day, an orange box indicates the participant has not completed the self-monitoring tool yet; a red box indicates

the participant failed to complete the Do for that day and a grey box indicates a day which is yet to occur (Figure 2.2).



Figure 2.2 Example Do Zone progress calendar ²⁰

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Chapter 3

Study 2a: Pilot study

"I have no special talent. I am only passionately curious."

- Albert Einstein

This chapter outlines the details of the pilot study which followed the literature review in Chapter 1. Additional methodology is displayed in the Supplementary file on page 60.

Abstract

Objective: The objectives of this pilot study were to determine if the Ten Top Tips (TTT) and Do Something Different (DSD) interventions are feasible to implement and whether participants find them acceptable? The results were to inform the main randomised controlled trial to follow.

Methods: We implemented a 4 week, 2-armed randomised trial with overweight adults, using TTT and DSD interventions. We collected data on the acceptability of the interventions through one-on-one qualitative interviews with each participant after intervention completion. Secondary outcomes including changes to weight, BMI and waist circumference were also collected pre- and post-intervention.

Results: Six overweight adults participated in the pilot study and reported the TTT and DSD interventions were enjoyable and acceptable. Some changes to be made in the main RCT that resulted directly from participant qualitative interviews and study methods include: removing food diaries due to high participant burden, incorporating weekly contact with participants to provide accountability and including a wait list control group as a third study arm.

Conclusion: Both TTT and DSD interventions were feasible to implement with no expressed barriers or challenges and have the potential to be applied to a larger number of participants.

Introduction

It is essential to determine the feasibility and acceptability of interventions prior to large scale trials. Pilot studies can help address challenges to feasibility and highlight possible practical difficulties associated with implementing a larger study ^{1,2}. The objectives of this pilot study were to assess the feasibility and acceptability of the Do Something Different (DSD) and Ten Top Tips (TTT) weight loss interventions prior to implementing them on a larger scale (Figure 3.1). This was a 4-week, two-arm, randomised trial.

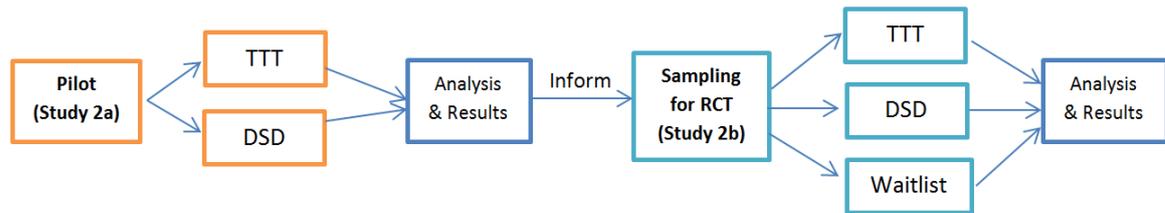


Figure 3.1 Study sequence; Pilot (Study 2a) to inform main RCT (Study 2b)

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different.

Methods

Sample size

There are no specific recommendations for the number of participants required for a pilot study ³. To investigate feasibility and acceptability, we aimed to recruit approximately 10% of the sample required for the full study which was calculated to require a total of 75 participants. Due to time constraints, this was a guide and not a requirement.

Recruitment

We identified potential participants via a flyer emailed to Bond University student and staff members and a printed poster displayed in two local medical centres (Appendix E; page 229). Potential participants were initially screened on the phone for eligibility by GC. Eligible participants were aged 18-75 years, able to consent, had an overweight or obese BMI classification ($\geq 25.0\text{kg/m}^2$), able to speak English, live locally or could attend all required appointments, had daily access to email and/or phone and were free from exercise limiting comorbidities. To ensure a broad sample, participants were included regardless of obesity-related comorbidities. Exclusion criteria included: pregnancy or potential pregnancy, significant illness, participating in other weight management programs, or taking any medications

affecting appetite, metabolism or weight. Participants were recruited between January and February 2015 and provided informed consent prior to entry to the study.

Participants were randomly allocated to receive either TTT or DSD by the principal investigator (GC) (Figure 3.2). GC selected a piece of folded paper from a box containing 6 pieces of paper with identical size and shape. The paper squares were either labelled “1” (TTT) or “2” (DSD). Participants were allocated to the group nominated on the paper.

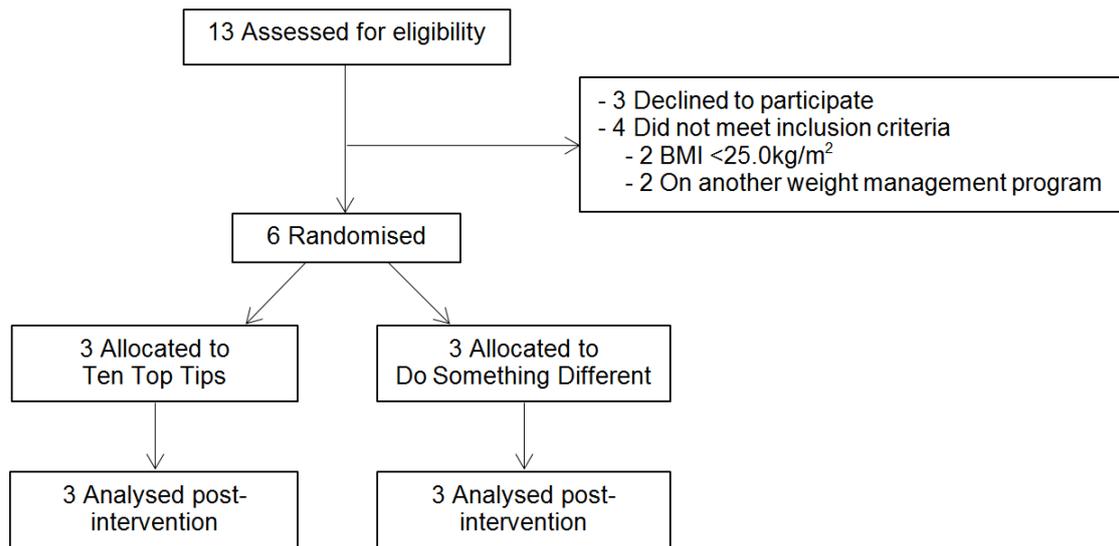


Figure 3.2 Participant flow diagram

This study was conducted at Bond University, Institute of Health and Sport, Gold Coast, Australia. Ethics approval was granted by Bond University’s Research Ethics committee (BUHREC) under reference number RO1888 on the 4th of November 2014 (Appendix F; page 231).

Interventions

The interventions investigated in the pilot study were TTT and DSD. See Chapter 2 for detailed descriptions of the interventions.

Participants in each group attended a 1-hour group induction seminar facilitated by GC which explained the intervention to which they were allocated. Participants received written information on the intervention and completed baseline assessment. All participants also received a daily food and exercise diary to complete for the 4-week intervention duration and

self-monitoring diaries to record intervention-compliance. The interventions commenced on the Monday following the initial meeting.

No further contact was made with the participants during the 4-week intervention period (February to March 2015). Participants were able to make contact with GC if there were any concerns; however, this was not required.

Outcome measures

Primary outcomes for the study were the participants' acceptability of the interventions as well as the feasibility of implementing them. Secondary outcomes included post-intervention changes in participant's weight, BMI, waist circumference, hours of exercise per week, dietary intake and psychometric data.

Acceptability

We conducted one-on-one, face-to-face, semi-structured interviews post-intervention with each participant to gather qualitative data on their experience on the intervention, intervention compliance, self-monitoring, understanding instructions and acceptability of the intervention (Table 3.1). The participants were also given an opportunity to provide any further feedback or comments regarding the intervention process. Prior to commencing the interview, each participant was made aware of the objectives of the interview as well as the nature of the questions. The participant was then given the opportunity to ask questions before proceeding. GC conducted all interviews which lasted between 15 and 25 minutes.

Table 3.1 Post-intervention interview schedule

Interview question	Study objective
How would you describe your general experience on the program?	Experience
How did you manage with completing the tasks prescribed?	Compliance*
How did you record your progress? What was that like for you?	Self-monitoring
How easy was it to follow and comprehend the instructions?	Understanding
Did you find the intervention more or less enjoyable compared to other weight loss methods you've used before? Why? How likely are you to take part in a program like this again or recommend it to friends and family? Why/why not?	Acceptability
Do you have any further feedback or comments about this program or have suggestions for improvement?	General feedback

*Compliance was also measured using the self-monitoring diaries participants received at their baseline meeting.

Feasibility

Feasibility was determined by reflecting on the practical implementation of the TTT and DSD interventions. The researchers considered the practical resources available in order to adapt the study protocol to make it more feasible for future studies. This included the feasibility of working with intervention developers, research investigators expertise and experience, clinic space, patient accessibility, time investment and collection of outcome measures. These considerations were arbitrated subjectively.

Secondary outcomes

Anthropometric measures were body weight (measured to the nearest 0.1 kg using Seca 700 medical scales), BMI (weight [kg] ÷ height [m²]), and waist circumference (soft tape over light clothing)⁴. These data were collected by GC at pre- and post-intervention. Self-reported data were collected for diet, exercise, and psychometric measures. Dietary intake was measured using an estimated food record (EFR), a validated tool for dietary intake measures⁵ and exercise was recorded as hours of exercise performed per week. Although psychometric data (including: wellbeing, depression, anxiety, habits and openness to change) were collected, they were not analysed due to insufficient trial length for any habit change to be meaningful (average time required for habit acquisition is 66 days)⁶.

Statistical analysis

Interviews were audio-recorded, transcribed, checked, and corrected against the audio file by GC. Content analysis was used to analyse interview data. Content analysis was selected as it is most appropriate when existing theory or research literature on a phenomenon is limited⁷. Preconceived categories were avoided, instead allowing the categories to flow from the data. As this was a pilot study only, GC analysed the qualitative data herself without a second data analyst. Due to the small sample size, changes to weight, BMI, waist circumference and exercise from baseline to post-intervention were not statistically analysed.

Results

A total of 13 participants responded to the invitation to participate in the study. Of these, 3 declined to participate and 4 did not meet inclusion criteria (Figure 3.2). We included 6 participants with a mean BMI of 31.1kg/m² and mean age of 51.3 years. Only one participant was male and participants in TTT reported more exercise per week than those allocated to

DSD. Baseline characteristics of participants by intervention group are displayed in Table 3.2. All participants receiving an intervention, completed post-intervention analysis.

Table 3.2 Mean baseline characteristics of participants by intervention group

	TTT (n = 3) (SD)	DSD (n = 3) (SD)	Total (n = 6) (SD)
Age, years	49.7 (11.7)	53.0 (1.7)	51.3 (7.7)
Gender F/M	2/1	3/0	5/1
Weight, kg	80.7 (14.1)	85.5 (16.0)	83.1 (13.7)
BMI, kg/m ²	29.2 (0.9)	32.9 (8.7)	31.1 (5.9)
Waist circumference, cm	92.5 (10.6)	98.0 (18.2)	95.3 (13.7)
Exercise, hr/week	4.0 (4.0)	1.3 (2.3)	2.7 (3.3)

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; SD = Standard Deviation; F= female; M= Male; kg = kilogram; cm = centimetre; hr = hours.

Primary outcomes

Qualitative Post-Intervention Interviews

General experience

Overall, DSD participants enjoyed the program. Unique to DSD, the participants specifically enjoyed performing different tasks to their usual routines.

“It was very enjoyable and not pushy or invasive to my life. I thought it had some great ideas”.

“It was really good, very enjoyable”.

Participants in TTT reported their experience on the program was positive overall, however, stated they needed more accountability through weekly contact from the researcher.

“I forgot I was on a program half way through because there was no contact at all during the past month, but the tips are good and I can see that I’d definitely lose weight if I stuck to them all”.

“I was really into it at first for a few days but I felt like I needed more accountability”.

“I’d like if there was some kind of weekly contact”.

Compliance and Self-Monitoring

During the interviews, participants were asked: *“Did you manage to perform all the tasks prescribed?”* Compliance was assessed at the qualitative interview and through the use of self-monitoring diaries.

Participants in the DSD group completed most of the Do’s during the 4-week intervention.

“Yes, mostly. If I ever missed a day, I would do the Do on a different day”.

“I missed only a couple of Do’s during the past month”.

“I completed most of them. Some of the Do’s I felt I already did in my day”.

All three participants in DSD self-monitored their intervention compliance but only two kept a food and exercise diary. The participant who did not complete the food and exercise diary reported it was too labour intensive.

“I didn’t keep a food diary or track my exercise; it just seemed like too much work”.

None of the participants in the TTT group managed to complete the 10 required tasks, every day during the intervention.

“I did 4-5 tips per day. It’s hard to focus on 10 tasks.”

“No I didn’t. Walking 10,000 steps was difficult. I ate off a small plate mostly. Some of the tips I found I already did- like keeping to a meal routine and eating low fat, but I didn’t do all of the tips every day.”

“I didn’t participate in the program as I got a new job where I had to commute long distances and I was out of routine”.

One TTT participant completed a food and exercise diary for the duration of the intervention with the two others starting a food diary, however discontinuing after the first few days due to high burden.

In analysing the TTT logbooks which were completed by 2 of the 3 participants, it appeared that all the tips had been attempted during the course of a week, however not all the 10 tips were completed every day during the course of the trial. The minimum number of tips performed per day was 3 and the maximum 10. Careful analysis of the individual tasks

revealed no particular pattern of preferred or disregarded tasks, with all the tips appearing to be performed at random. Interestingly, logbooks indicated that as the intervention continued, daily completion of tips increased. During the first two weeks, participants completed 53-56% of the tips, compared with 91% of tips completed in the fourth week.

Acceptability

Despite the short intervention period, participants in DSD reported the intervention had a positive impact on their life and would recommend the program to friends and family.

“Even though I didn't lose weight I would definitely recommend it to my family and friends because it's changed some things in my life for the better. For example, I now don't watch TV on two nights of the week and I eat off a smaller plate, so it's all positive”.

“It was like a nudge or a reminder, not intimidating like going to a doctor or dietitian. I found it to be a successful, yet gentle approach”.

The TTT participants also reported good acceptability of the intervention as it's not a fad diet or strict eating plan. The tips were described as good lifestyle behaviour-changes which would benefit anyone.

“I felt in control of my life, it's very thorough”.

“I would definitely recommend this to people I know. Definitely a good basic way to live”

“It's good in that it's not a prescribed diet. I like that I can still pick what foods I want to eat. It's definitely better than being on a strict diet where you can't enjoy yourself or go out for a nice dinner. I would recommend it to friends and family yes- especially ones who just want to live a healthier lifestyle”.

Encouragingly, the participants in both TTT and DSD wanted to continue implementing the interventions in their daily lives.

“I'm going to keep going and monitor myself with the logbook. I think in time I'll be able to do all ten or at least most of the tips every day”.

“I hope to keep going with the Do's”.

Feasibility

The interventions were easy to disseminate and implement to members of the community with no observed barriers to practically implement the interventions on a larger scale. The interventions were low cost and all the required resources were available at Bond University, including: sufficient clinic rooms, tools for outcome measures (scales, tape measures and computers) and easy patient accessibility (parking spaces, reception support and elevator lifts). The developers of both TTT and DSD made available timely information and resources. For example, they provided detailed intervention information, self-monitoring diaries and the introduction power-point presentations used to introduce the programs to participants. This ensured the interventions were presented and implemented as per the original TTT and DSD studies. Overall, GC found the trial to be manageable especially as the interventions required minimal contact with participants, therefore making a short or long intervention period realistic to implement.

Secondary outcomes

Although the primary purpose of the study was to consider the feasibility of implementation and the acceptability of the interventions, changes in weight, body mass index, waist circumference and hours of exercise per week were collected from baseline to post-intervention and are displayed in Table 3.3.

Table 3.3 Change in weight, BMI, waist circumference and exercise hours in TTT and DSD at post-intervention

	Baseline Mean (SD)	Post-Intervention Mean change (SD)	95% CI
<i>Weight, kg</i>			
TTT	80.7 (14.1)	+0.8 (2.1)	-4.4, 6.0
DSD	85.5 (16.0)	-1.2 (0.7)	-2.9, 0.4
<i>BMI, kg/m²</i>			
TTT	29.2 (0.9)	+0.3 (0.8)	-1.6, 2.2
DSD	32.9 (8.7)	-0.5 (0.2)	-1.0, 0.1
<i>Waist circumference, cm</i>			
TTT	92.5 (10.6)	+0.7 (1.6)	-3.3, 4.7
DSD	98.0 (18.2)	-0.3 (0.6)	-1.8, 1.1
<i>Exercise, hr/week</i>			
TTT	4.0 (4.0)	+0.3 (0.6)	-1.1, 1.8
DSD	1.3 (2.3)	+1.0 (1.7)	-3.3, 5.3

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; CI = Confidence Interval; kg = kilogram; cm = centimetre; hr = hours.

Weight, BMI and waist circumference

At post-intervention, on average, participants in DSD had small reductions in weight (-1.2kg; 95% CI -2.9, 0.4), BMI and waist circumference whereas, on average, participants in TTT had a small increase in weight (+0.8kg; 95% CI -4.4, 6.0), BMI and waist circumference (Table 3.3). This appears to be attributed to one participant who did not comply with the program due to an unforeseen increase in work commitments. Table 3.4 displays individual participant changes in anthropometry from pre- to post-intervention.

Table 3.4 Weight, BMI, waist circumference and exercise hours at baseline and post-intervention per participant for TTT and DSD intervention groups

Participant	Baseline weight, kg	Post-Intervention weight, kg	Baseline BMI, kg/m ²	Post-Intervention BMI, kg/m ²	Baseline waist, cm	Post-Intervention waist, cm	Baseline exercise hr/week	Post-Intervention exercise hr/week
<i>TTT</i>								
1	71.5	71.3	30.1	30.0	88.5	88.5	8	8
2	73.7	76.9	28.3	29.5	84.5	87.0	0	0
3	97.0	96.4	29.3	29.1	104.5	104.0	4	5
<i>DSD</i>								
1	83.5	83.0	31.6	31.4	89.0	89.0	4	4
2	102.4	101.0	42.2	41.6	119.0	119.0	0	0
3	70.6	68.8	25.0	24.4	86.0	85.0	0	3

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; kg = kilogram; BMI = Body Mass Index; cm = centimetres; hr = hours.

Physical activity levels

Overall, participants in both groups increased the amount of exercise they performed each week. Per week, participants in DSD increased their exercise by 1 hour (95% CI -3.3, 5.3), and TTT participants increased an average of 20 minutes (95% CI -1.1, 1.8) after the 4-week intervention (Table 3.3).

Dietary intake

An analysis of participant food diaries was expected, however only half the sample (2 DSD, 1 TTT) completed these, making analysis impractical.

Discussion

Assessing the feasibility and acceptability of two novel weight loss interventions, TTT and DSD was conducted to inform a larger randomised controlled trial. Data from this trial suggests both TTT and DSD interventions were feasible to implement and could be applied on a larger scale. However, as a dietitian, GC found it challenging not providing dietary advice to participants. The conceptual theory of these interventions is habit-change and not conventional diet and exercise modification therefore despite it being a challenge, no dietary advice was provided. Overall, there were no barriers or challenges to implement the interventions with the available space, resources and investment of time required by the researchers.

Interestingly, despite the short intervention period and lack of significant amounts of weight lost, participants enjoyed being part of both interventions and wanted to continue the interventions even once the study had concluded. Participants especially valued the programs not being a 'prescribed diet' and were not restrictive to their desired foods. Participants also reported the interventions were easy and promoted a healthy lifestyle rather than a strict, short-term regimen.

Participants suggested the addition of weekly contact with the researcher to establish accountability and increase program engagement. The presence of a perceived support person has been described as a key component to weight loss interventions as it motivates participants to achieve weight loss⁸. As per participant feedback, contact would preferably be made through a phone call or personal email. This method is both convenient and efficient to both the researchers and participants and although adds to the researcher tasks, is feasible and is expected to enhance participant acceptance and accountability and study retention.

Results from the TTT logbooks demonstrated that the longer the intervention duration, the more tips the participants completed per week. This is likely due to familiarisation and automaticity of the tips which is expected with repetition. Therefore, when implementing this intervention over 12-weeks, it is expected that there will be a higher level of compliance with the tips as well as possible automaticity towards the end of the intervention period when compared with the first few weeks. Expectations regarding the length of time required for habit formation may aid TTT participants should they fail to complete all tasks in the first few weeks. This in turn may prevent intervention attrition.

Estimated food records were of low acceptability and high burden for the participants to

complete and only 3 out of the 6 participants had completed food diaries at post-intervention. During the analysis process, the researchers agreed that food diary data analysis was of little value to the research question and discontinued the assessment. Two major factors contributed to this decision, the first being limited data received from participants; the second is the interventions are based on habit-change and not dietary change. Although dietary changes may occur indirectly as a result of the interventions, this was not the empirical data we aimed to explore.

Strengths and limitations

Despite the small sample size, participants were randomised to TTT or DSD and there was no attrition although one person did discontinue the intervention due to work commitments. With the exception of program length, the programs were delivered as in previous trials, included the same introductory presentation and written materials, and were delivered as intended.

However, the 4-week intervention duration is shorter than the recommended 12-weeks and appeared insufficient time to achieve meaningful weight loss. However, this study was designed as a pilot to assess feasibility and acceptability and we believe the primary outcomes may not have changed significantly had the trial been 12-weeks. Unfortunately, due to the trial nature of the project, the primary investigator conducted both the interventions and the post-intervention qualitative interviews and analyses. This poses a risk for biases, however, in the interviews, participants were happy to share critiquing opinions and offer suggestions to better improve the interventions.

Conclusion and future directions

This pilot trial demonstrated that the two interventions, TTT and DSD are feasible to implement as well as acceptable by the participants. Some changes to be made in the main RCT as informed by this pilot study include:

1. Remove the estimated food record diaries- the data collected from the diaries did not add value to the results of the study. The diaries were also high burden on participants as evidenced by both low levels of compliance and verbal feedback.
2. Incorporate weekly contact with the participants to provide accountability and increase compliance.
3. Include a wait list group to compare TTT and DSD with a control.

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Supplementary material for Chapter 3

Table S3.1 Baseline characteristics per participant for TTT and DSD intervention groups

Table S3.2 Exercise hours performed per week at baseline and post-intervention per participant for TTT and DSD intervention groups

File S3.1 Pilot study additional methodology

Supplementary Table 3.1 Baseline characteristics per participant for TTT and DSD intervention groups

Participant	Age, years	Gender	Weight, kg	BMI, kg/m ²	Waist circumference, cm	Exercise hr/week
<i>TTT</i>						
1	63	F	71.5	30.1	88.5	8
2	41	F	73.7	28.3	84.5	0
3	45	M	97.0	29.3	104.5	4
<i>DSD</i>						
1	52	F	83.5	31.6	89.0	4
2	55	F	102.4	42.2	119.0	0
3	52	F	70.6	25.0	86.0	0

Abbreviations: TTT= Ten Top Tips; DSD= Do Something Different; kg = kilogram; BMI = Body Mass Index; cm = centimetres; hr = hour; F = Female; M = Male.

Supplementary Table 3.2 Exercise hours performed per week at baseline and post-intervention per participant for TTT and DSD intervention groups

Participant	Baseline hours of exercise per week	Post-Intervention hours of exercise per week	Total change
<i>TTT</i>			
1	8	8	0
2	0	0	0
3	4	5	+1
<i>DSD</i>			
1	4	4	0
2	0	0	0
3	0	3	+3

Abbreviations: TTT= Ten Top Tips; DSD= Do Something Different

Supplementary File 3.1 Pilot study additional methodology

Research design

This was a 4-week randomised trial. The research design was selected for the pilot study as this was the chosen methodology for the main study to follow. The rationale for conducting a randomised controlled trial (RCT) research design in this study is to rigorously evaluate whether a cause-effect relation exists between treatment and outcome⁹, more specifically the interventions used in this study and 12-month weight loss maintenance. A RCT is also considered NHMRC level II evidence¹⁰.

Ethical considerations

Eligible participants were provided with an information package; see Appendix G (participant information form; page 247). The information package included contact details of the principal investigator and the ethics committee in case the participant had any queries. Participants willing to take part in the study were asked to complete a consent form. Potential participants were informed of: voluntary participation into the study; the purpose and any possible disadvantage of taking part in the study; liberty to withdraw from the study at any time without any consequence.

Recruitment and procedures

Participants were recruited through a flyer sent out via internal email at Bond University, Gold Coast, Australia as well as flyers displayed in two local medical centres. Staff members from all faculties were included in the email invitation except for the faculty of Health Science and Medicine as per ethical regulations in order to reduce the likelihood that power relations could interfere with participant's freedom to decline in taking part, or to withdraw should they wish.

The flyer briefly explained the pilot study and recruitment criteria. Potential participants replied via email to the principal investigator with their expression of interest. The principal investigator then contacted potential participants via phone in order to screen for eligibility. Phone screening was performed as the first step and prior to arranging the initial baseline meeting.

Introducing the interventions

Once recruited, the participants in each group attended a 1-hour induction seminar which explained the intervention they were allocated to. This was a group meeting and all participants attended their allocated intervention's seminar. The principal investigator conducted both seminars in a conference room at Bond University.

During the induction meetings, participants individually completed the baseline psychometric measures. Participants were also taken one by one into a private adjoining room where baseline measures were taken and the post-intervention appointment was arranged.

Ten Top Tips (TTT)

During the meeting, TTT participants received an information package including the TTT leaflet, supporting material, logbook (Appendix C; page 222) and daily food and exercise diary.

Do Something Different (DSD)

DSD participants received a daily food and exercise diary to complete for the 4-week intervention duration.

Data collection and measures

Baseline data on demographics were collected including: gender, education level, date of birth, health concerns, current medications and/or supplements and current exercise levels; see Appendix G (page 247) for the participant registration form and S3.1 Table 1 for measures taken at baseline and post-intervention. All measurements were collected by the principal investigator.

Anthropometric measures were body weight (measured to the nearest 0.1 kg using Seca 700 medical scales), BMI (weight [kg] ÷ height [m²]), and waist circumference (soft tape over light clothing)⁴. These data were collected by GC at pre- and post-intervention. Self-reported data were collected for diet, exercise, and psychometric measures. Dietary intake was measured using an estimated food record (EFR), a validated tool for dietary intake measures⁵ and exercise was recorded as hours of exercise performed per week. Although psychometric data (including: wellbeing, depression, anxiety, habits and openness to change) were collected, they were not analysed.

File S3.1 Table 1 Measures collected at baseline and post 4-week intervention.

Measure	Tool	Evidence/ Reference
Weight	Seca 700 medical scale	4
Height (baseline only)	Stadiometer	4
Waist circumference	Soft tape measure	4
Number of fruit and vegetables consumed per day	Self-reported	11
Hours and type of exercise engaged in each week	Self-reported	11
Wellbeing	Wellbeing psychometric questionnaire	12-14
Depression and free-floating anxiety	Thoughts and Feelings scale	12-14
Habit strength	Habit rater and Self-Reported Habit Index (SRHI)	12-14
Openness to change	Behaviour rater	12-14
4-week food and exercise diary (post-intervention only)	Self-reported diary	11

Measurement of anthropometry

Body weight was measured to the nearest 0.1 kg using Seca 700 medical scales. The Seca 700 is a non-automatic mechanical column scale. As per the NHMRC clinical practice guidelines for the management of overweight and obesity ⁴, participants were asked to remove any outer garments, take off their shoes and empty pockets. Participants were also asked to stand centred on the scale with weight evenly on both feet.

Height was measured in centimetres using a stadiometer with integrated level. As per NHMRC standard protocol for measuring height; participants were instructed to stand with feet together and flat on the ground (no footwear), with heels, shoulder blades and buttocks touching the wall ⁴. Participants were also asked to look straight ahead and measurement was taken as the participant took a deep breath in and stretch to their fullest height.

Body Mass Index was calculated using body weight in kilograms (kg), divided by height in metres squared (m)².

Waist circumference was measured using a soft tape measure over light clothing. As per NHMRC standard protocol, participants were asked to remove heavy outer garments, loosen any belts and empty pockets. Participants were asked to stand with their feet close together (about 12-15cm) with their weight equally distributed and to breathe normally ⁴. Waist was defined as the point midway between the iliac crest and lower rib (approximately in line with the umbilicus). Measurement was taken in centimetres at the end of normal expiration ⁴.

Measurement of dietary intake and physical activity

Dietary intake and physical activity behaviours were collected using self-reported measures. Participants in both interventions were asked to complete a food and exercise diary for the duration of the intervention; this diary served as an estimated food record (EFR), a validated tool in dietary intake measures⁵ and was provided to each participant in a printed A5 booklet.

The food diary included time of day, the type of food consumed and the quantity of food that was consumed. Participants were educated on how to complete an estimated food record in the initial group meeting. They were encouraged to write down as much detail as they can, including all food and beverages consumed. Participants were also made aware that studies reveal significant associations between self-monitoring and weight loss; this evidence is based on a systematic review and meta-analysis of 22 studies¹¹.

The exercise diary included the type of exercise and duration of exercise performed. As with the food diary, participants were educated on how to complete the exercise diary at the initial group meeting. Exercise was measured as hours of formal physical activity performed per week.

Measurement of psychometrics

Psychometric measurements including wellbeing, depression, anxiety, habits and openness to change were collected from all participants pre and post-intervention. The psychometric questionnaires can be found in Supplementary File 4.1 (page 95).

Management of psychometric data

The information entered into the online psychometric questionnaire was exported as a complete data file to a password protected Microsoft Excel document. These data were accessible to only the research team working on this project.

File S3.1 References

1. Gul RB, Ali PA. Clinical trials: the challenge of recruitment and retention of participants. *Journal of Clinical Nursing*. 2009;19(1-2):227-233.
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Chapter 4

Study 2b: Main randomised controlled trial

*“The difference between who you are and
what you want to be is what you do.”*

- Bill Phillips

This chapter consist of the paper entitled "*Habit-based interventions for weight loss maintenance in adults with overweight and obesity: A randomised controlled trial*". This manuscript is currently under review by the International Journal of Obesity.

Authors: Gina Cleo, Paul Glasziou, Elaine Beller, Elisabeth Isenring, Rae Thomas.

Additional methodology and 6-month follow-up results are presented in the Supplementary material.

Key Points

Question: Can habit-based weight-loss interventions achieve and maintain clinically important weight loss?

Findings: In this randomised clinical trial of 75 adults with overweight or obesity, those receiving the two active interventions (Ten Top Tips and Do Something Different) lost significantly more weight than those in the waitlist control. At 12-months post-intervention, 28/43 (65%) of participants receiving the intervention reduced their total body weight by $\geq 5\%$, a clinically important change.

Meaning: Habit-based weight-loss interventions are effective for long-term (12 months) weight-loss maintenance.

Abstract

Objectives: The objective of this study was to determine whether habit-based interventions are clinically beneficial in achieving and maintaining long-term (12-month) weight loss maintenance and assess whether making new habits, or breaking old habits is more effective.

Methods: Volunteer community members aged 18-75 years who had overweight or obesity ($\text{BMI} \geq 25 \text{ kg/m}^2$) were randomized in a single-blind, 3-arm, randomized controlled trial. Ten Top Tips (TTT), Do Something Different (DSD) and the attention-only waitlist (WL) control groups were conducted for 12 weeks from July to October 2015. Participants were followed up post-intervention (all groups), and at 6 and 12-months post-intervention (Ten Top Tips and Do Something Different only). The primary outcome was weight-loss maintenance at 12-month follow-up. Secondary outcomes included weight loss at all time points, fruit and vegetable consumption, exercise, wellbeing, depression, anxiety, habit strength and openness to change.

Results: Of 130 participants assessed for eligibility, 75 adults (mean BMI 34.5 kg/m^2 [SD 6.2]), with a mean age of 51 years were recruited. Assessments were completed post-intervention by 66/75 (88%) of participants and by 43/50 (86%) at 12-months. At post-intervention, participants in the Ten Top Tips (-3.3kg; 95% CI -5.2, -1.4) and Do Something Different (-2.9kg; 95% CI -4.3, -1.4) interventions lost significantly more weight ($P = <.001$) than those on the waitlist control (-0.4kg; 95% CI -1.2, 0.3). Both intervention groups continued to lose further weight to the 12-month follow-up; TTT lost an additional -2.4kg (95% CI -5.1, 0.4) and DSD lost -1.7kg (95% CI -3.4, -0.1). At 12-months post-intervention, 28/43 (65%) of participants in both intervention groups had reduced their total body weight by $\geq 5\%$, a clinically important change.

Conclusions: Habit-based weight-loss interventions - forming new habits (TTT) and breaking old habits (DSD), resulted in clinically important weight-loss maintenance at 12-month follow-up.

Trial Registration: anzctr.org.au Identifier: ACTRN12615000114549

Introduction

The weight loss – weight regain cycle can defeat many. The majority of individuals with overweight or obesity, who lose weight, regain 40% of the loss in the first year after treatment and most of the rest in the following three years ^{1,2}. Hence addressing the determinants for weight-loss maintenance is essential. Knowing what diet and exercise behaviors are necessary for long-term weight loss, does not seem to equate to healthy behavior or predict health outcomes ³. Weight management recommendations are usually based on advising individuals on what to change and why (e.g. reduce daily calorie intake to achieve weight loss). Acting on this advice requires conscious, deliberative thoughts ⁴. However, motivation and attention to change behaviors wane, so the behavior changes are typically short-lived and weight is regained ⁴. The loss of all ‘excess weight’ is not essential to achieve health benefits: a 5% reduction in body weight in individuals with overweight or obesity is associated with significant improvements in LDL and total cholesterol, blood pressure, blood glucose and other health indices ^{5,6}.

Psychological studies show that habitual behaviors strongly influence health outcomes ⁷⁻⁹. Habit-based interventions may therefore be effective – focused either on forming new healthy habits, breaking unhealthy habits, or a combination of both¹⁰. Interventions which offer advice on lifestyle change whilst engaging automatic behaviors (including efficiency, lack of awareness, unintentionality and uncontrollability ¹¹) may offer more benefit ⁴ because automatic behaviors do not require self-control or willpower, and strengthen with repetition ¹⁰. Furthermore, breaking old habits by re-structuring daily routines and engaging in novel behaviors, increases an individual’s mindful behaviour through conscious, deliberative thought ¹⁷. This increase in conscious thought is proposed to draw attention to the behaviour, making it easier to recognize compliance with behavioural goals ¹⁹. However, habit-based weight-loss studies with data beyond 6-months post-intervention are scarce; only two studies to date provide weight loss outcomes for 8 months ¹³ and 24 months post-intervention ³³, of which both are the same intervention focusing solely on habit formation.

We conducted a three-arm, randomised clinical trial to evaluate the effectiveness of two habit-based weight-loss interventions, Ten Top Tips (TTT) (forming new habits) and Do Something Different (DSD) (breaking old habits) with a waitlist control group (WL). We compared weight-loss of the three groups at post-treatment and then followed-up the active treatments for 12 months to assess weight-loss maintenance. Secondly, we compared the two active interventions to assess if forming new habits, or breaking old habits is more effective.

Methods

Recruitment

We identified potential participants via local televised news and radio interviews. Participants were initially screened on the telephone for eligibility. Eligible participants were between 18 and 75 years of age, able to consent, had a BMI ≥ 25.0 kg/m², lived locally or could attend all required appointments, had daily access to email and/or phone and free from exercise limiting comorbidities. Participants were recruited regardless of obesity-related comorbidities (e.g., cardiovascular disease and diabetes). Exclusion criteria included participants who were or could be pregnant, significantly ill, participating in other weight management programs, or taking any medications affecting appetite, metabolism or weight. Participants were recruited between July and October 2015 and attended an initial interview to provide informed consent prior to randomization. Computer generated randomization occurred after baseline assessment to allocate participants to either: TTT, DSD or WL control (allocation ratio 1:1:1). We used minimization stratified on BMI categories (overweight, obese class I, II, III), age (18-32, 33-47, 48-62, 63-75 years); and gender.

The trial was conducted at Bond University, Institute of Health and Sport in Gold Coast, Australia. There were no changes to methodology after trial commencement.

Sample Size

Sample size calculations were based on the mean weight lost from previous DSD and TTT studies at the last available follow-up^{12,13}. We expected any weight loss during the intervention to be maintained at the 12-month post-intervention time-point; therefore. We calculated the sample size based on data from the last available time-point (8 weeks for TTT and 4 weeks for DSD). Our power calculation suggested 19 participants were required in each of the 3 arms to achieve a 90% power and 5% significance criterion to detect a 2.4kg (SD 2.2) weight change post-intervention. To account for 30% attrition,¹⁴ we recruited 75 participants.

Interventions

The Ten Top Tips (TTT)

The Ten Top Tips is a 12-week, self-guided, leaflet-based intervention focusing on the recommendations of habit-formation theory. Founded on eating and activity behaviors associated with weight loss, the tips are a list of seven behaviors associated with negative energy balance, two behaviors designed to improve awareness of food intake and one

behavior to promote routines¹³ (Appendix C; page 222) (www.weightconcern.org.uk/tentoptips). To encourage habit development, participants were advised to plan ahead to effectively incorporate the tips into their daily routines and repeat the behaviors in a consistent context. Self-monitoring is a valuable component of behavior change programs^{15,16}. A logbook was provided to participants for recording tips adherence. If participants were consistently failing to achieve a tip they had space to make notes and plan how to achieve it the following week. Space was also provided to record weight weekly. TTT was originally a single-session intervention with no further contact. However, to control for intervention length and to aid in habit formation, we implemented TTT for 12 weeks. Participants attended a 2-hour group induction meeting in groups of 5, facilitated by GC to receive information, booklets and to complete baseline assessments.

Do Something Different (DSD)

DSD, focuses on increasing participants' behavioral flexibility by breaking daily habits¹² purported to play a role in unhealthy dietary and exercise behaviors¹⁷. DSD requires participants to do something different each day and to engage in novel, weekly activities to expand their behavioral repertoire¹⁸. What makes this intervention particularly novel is that these activities are not diet or exercise related and can include '*drive a different way to work today*', '*choose a charity or local group to help*' or '*write a short story on any subject*'.

DSD is implemented and managed via online software where participants complete pre and post intervention measures which records personal behaviors and habits and tailors the program to each individual. For example, a participant might report they are '*extroverted*', and may receive the task '*be more introverted today*'. When logged into the software (<https://dsd.me/>), participants are able to see the tasks they are required to perform, mark off their compliance and make comments each day. Originally DSD was conducted for 4 weeks; however, the average length of time to alter habits is reported as 66 days¹⁹. Therefore, we requested to conduct an extended 9-week program. As participants were recruited, they attended a 2-hour group induction meeting in groups of 5 facilitated by GC where they individually completed the baseline assessments. Three to four tasks per week were automatically sent out to each participant via text message and/or email.

During the intervention period, participants in all three arms received a weekly phone call from GC to promote accountability and help preclude attrition. In the active interventions, phone calls commenced with "How have you managed on the program this week?" opening

discussion regarding the barriers and facilitators of program adherence. Problem solving strategies were discussed as necessary; although GC is a dietitian, no specific diets or exercise regimens were offered. For self-monitoring purposes, participants were encouraged to record a food diary¹⁵; which were not analysed. Intervention adherence was monitored by the weekly phone calls, the logbook (TTT) and DSD online software. GC checked log book completions fortnightly and monitored DSD compliance with the online software. Intervention fidelity was not formally measured; however, GC followed procedure manuals provided by the original developers and used standardized introductory presentations and resources for each intervention. No training was provided in implementing the interventions and all were delivered as intended.

Interventions commenced July to October 2015 and concluded September to December 2015; 12-month follow-up was conducted from September to December 2016.

Attention-only waitlist (WL)

The WL group was instructed to continue as usual during the 12-week intervention period. They were contacted weekly via telephone for 12 weeks (by GC) and at their discretion offered either the DSD or TTT intervention after this time. They received no weight-loss advice.

Outcome measures

The primary outcome was weight-loss maintenance from post-intervention (12-weeks) to 12-month follow-up in the two active intervention groups. Secondary outcomes included changes in weight, BMI, waist circumference, daily fruit and vegetables consumption, weekly exercise, and psychological data (wellbeing, depression, anxiety, habits and openness to change) from baseline to post-intervention, baseline to 12-month follow-up and post intervention to 12-month follow-up, and proportion of participants achieving $\geq 5\%$ total body weight loss. See Figure 4.1 for data collection timeline.

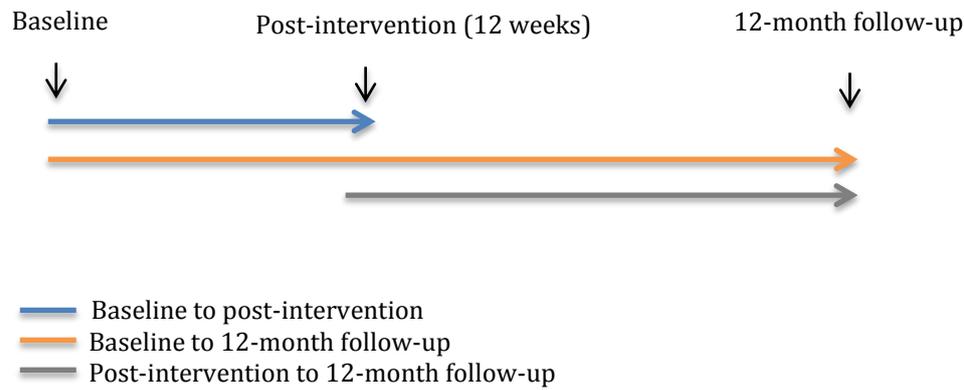


Figure 4.1 Data collection timeline

Anthropometric measures were body weight (measured to the nearest 0.1 kg using Seca 700 medical scales), BMI (weight [kg] ÷ height [m²]), and waist circumference (soft tape over light clothing)²⁰. These data were collected by a research assistant blind to group allocation.

Self-reported data were collected for diet, exercise, and psychometric measures. Following Australian dietary guidelines, fruit and vegetable intakes were measured as a count of serves, from 0 to 3+ for fruit and 0 to 5+ for vegetables²¹. Exercise was recorded as hours of exercise performed per week. Psychometrics were used to collect data for participant wellbeing, depression, anxiety, habit strength and openness to change²².

The 8-item wellbeing questionnaire assesses an individual's perceived level of quality of life, including ability to cope with problems/issues, ease in making decisions, personal value and happiness²². Each item is scored on a 0-100 scale where the larger number suggests better wellbeing (max score 800). Depression and anxiety are measured using a four-point ordinal scale ranging from 'Very frequently/often' to 'Never', the lower score representing less depression and anxiety (max score 16). There are 4 items for each²². The 12-item habit rater questionnaire measures daily healthy habits and frequency of behaviors ranging from "a little" (0) to "a lot" (100). Values are totaled and range from 0 to 1200 where the greater value represents more healthy habits²². The openness to change scale is an 8-item questionnaire assessing an individual's behaviors and attitudes to change. Scores range from 'a little' (0), to 'a lot' (100) with a maximum score of 800, where larger scores represent more healthy behaviors and attitudes to change²². See supplementary material for all questionnaires.

Statistical analysis

The pre-planned statistical analysis aimed to compare treatment outcomes between the three groups, we used two strategies. First, we conducted 2-way mixed factorial analyses of covariance (ANCOVAs); three groups (TTT vs DSD vs WL) by two time points (e.g., baseline vs post-intervention) with baseline data as the covariate. If statistically significant results were observed, we then conducted a two group (e.g., WL vs TTT) by two time point (e.g., baseline vs post-intervention) direct group comparison for each group and time point. To determine any baseline differences between intervention completers and non-completers, we conducted independent t-tests and chi-squared tests. As intervention dropouts occurred prior to intervention commencement and because there were only a small number of missing data, we conducted available case analyses. Post-hoc analyses were conducted using 2 (Group) x2 (time) ANCOVAs with baseline data as the covariate, to assess differences on measures from baseline to 12-month follow-up. Statistical software used to perform analysis was, IBM SPSS Statistics v23.

Patient involvement

The acceptability of the TTT and DSD interventions were assessed by participants in a preceding pilot study. Qualitative data were collected from semi-structured interviews conducted with the pilot study participants and helped inform the present study. Specifically, the addition of weekly phone calls (which was not part of the original study designs of TTT or DSD) to increase accountability and support, and the removal of daily food and exercise diaries to lower participant burden.

Results

We assessed 130 community members for eligibility between June and October 2015. Of these, 18 did not meet inclusion criteria and 37 declined to participate. We included 75 eligible participants with a mean BMI 34.5 kg/m² (SD 6.2) and mean age of 51 years (SD 11) who were randomized to one of three groups (Figure 4.2).

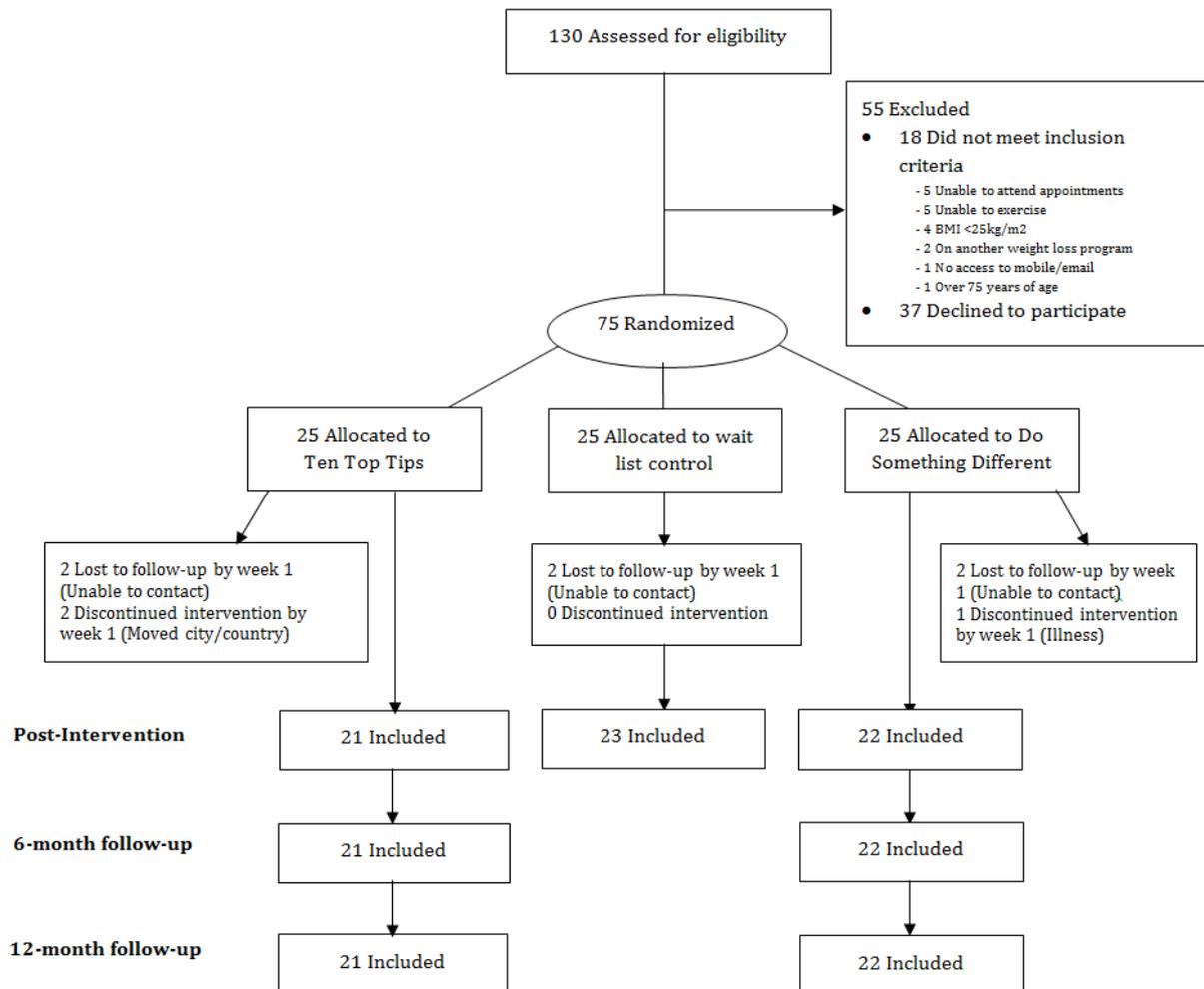


Figure 4.2 Participant Flow Diagram

Baseline characteristics were similar in the 3 groups (Table 4.1). All participants received intervention information; however after initial interview nine participants failed to commence the intervention (4 TTT, 3 DSD, 2 WL). There were no significant differences in baseline characteristics between non-completers and completers (Supplementary Table 4.1).

Table 4.1 Baseline characteristics of participants by intervention group

	TTT <i>n=25</i>	DSD <i>n=25</i>	WL <i>n=25</i>
Age, years (<i>SD</i>)	48.2 (11.3)	51.3 (10.0)	52.0 (12.3)
Gender			
Male	5 (20%)	6 (24%)	5 (20%)
Female	20 (80%)	19 (76%)	20 (80%)
Weight, kg (<i>SD</i>)	95.8 (18.5)	97.9 (22.4)	94.7 (20.4)
BMI, kg/m ² (<i>SD</i>)	34.6 (5.2)	35.2 (7.4)	33.6 (6.1)
Waist circumference, cm (<i>SD</i>)	111.8 (13.4)	117.5 (14.1)	114.8 (16.1)
Exercise performed/week, hours (<i>SD</i>)	2.7 (2.9)	2.5 (2.5)	3.9 (4.4)
Fruit consumed/day, serves (<i>SD</i>)	1.4 (1.1)	1.3 (0.8)	1.5 (0.8)
Vegetables consumed/day, serves (<i>SD</i>)	2.7 (1.5)	2.6 (1.3)	2.6 (1.3)
Education Level			
Did not complete school	2 (8%)	2 (8%)	4 (16%)
High school	12 (48%)	15 (60%)	16 (64%)
University degree	11 (44%)	8 (32%)	5 (20%)

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; WL = Waitlist; SD = Standard Deviation; kg = kilogram; BMI = Body Mass Index; cm = centimetre.

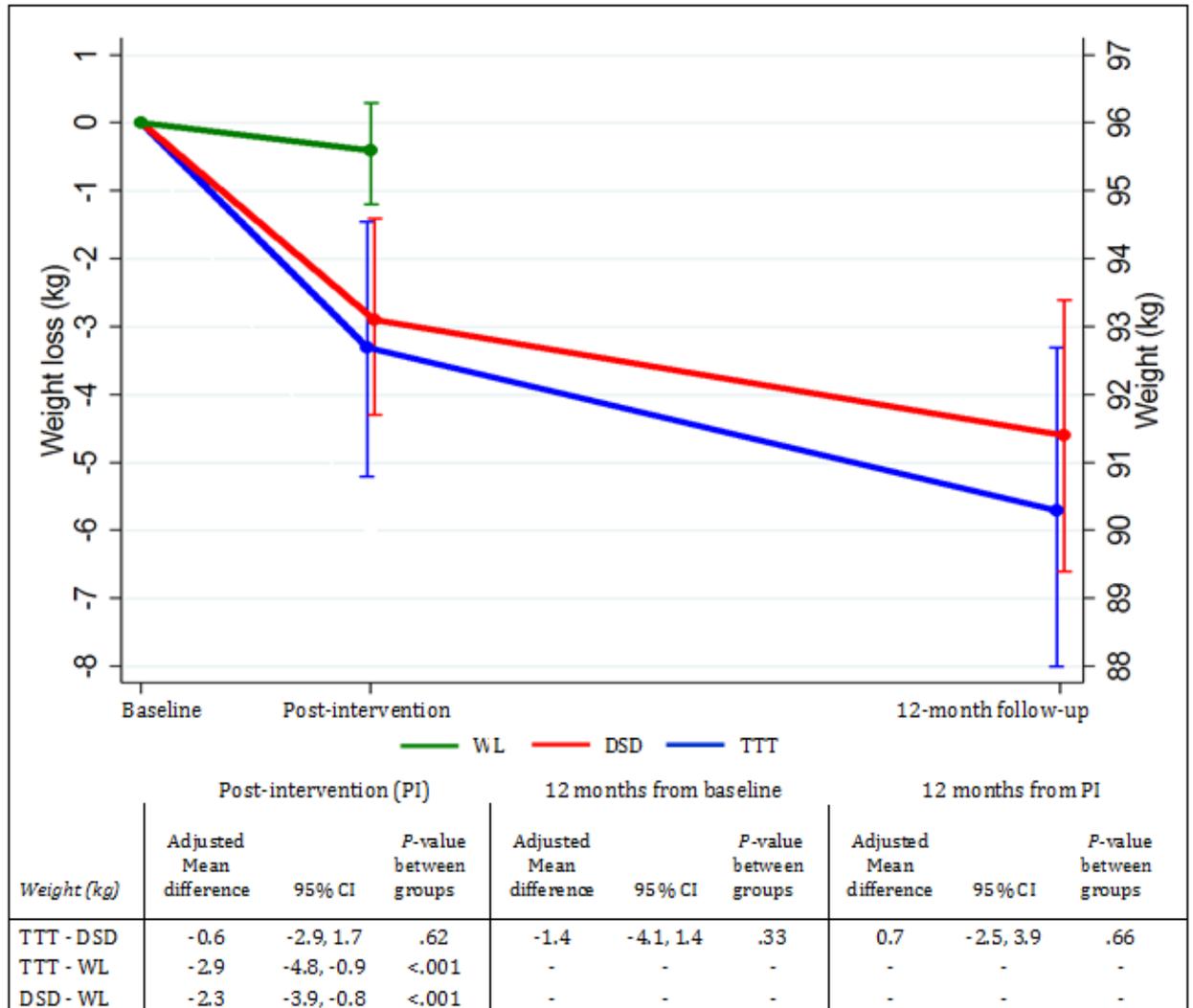
Values are mean

Primary outcome

Post-intervention to 12-month follow-up weight loss and waist circumference

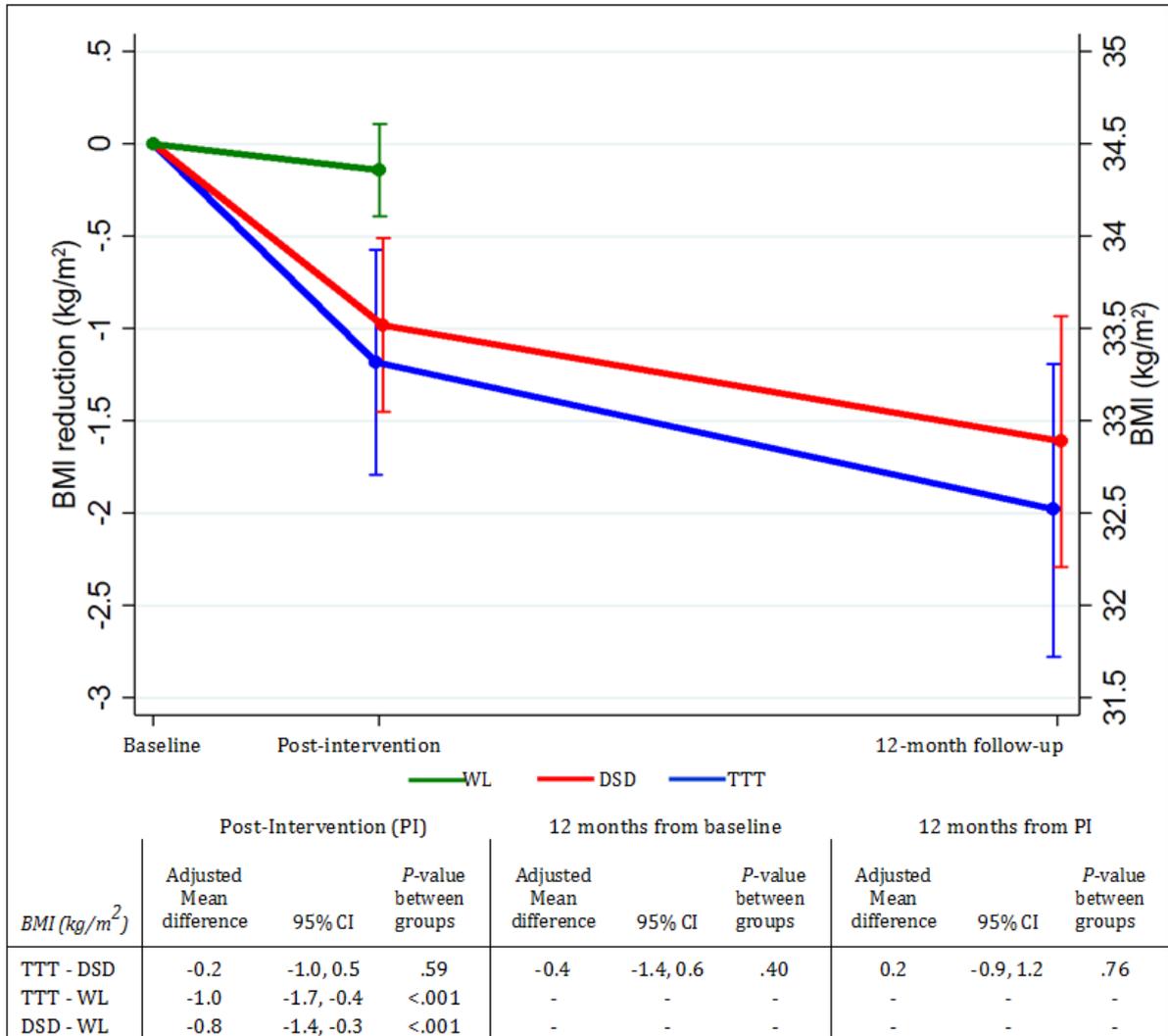
After the interventions concluded, participants continued to lose weight up to 12-month follow-up. TTT participants lost a further -2.4kg (95% CI 0.4 to 5.1) and DSD participants lost -1.7kg (95% CI -3.4 to -0.1). BMI and waist circumference also continued to decrease at 12-month follow-up (BMI: TTT -0.8kg/m² [95% CI -1.8 to 0.1], DSD -0.6kg/m² [95% CI -1.2 to -0.04]; waist circumference: TTT -3.1cm [95% CI -5.6 to -0.6], DSD -2.0cm [95% CI -4.7 to 0.7]) (Figures 4.3a, 4.3b, 4.3c).

Figure 4.3a Mean weight and adjusted mean differences between TTT, DSD and WL at baseline and 12-month follow-up



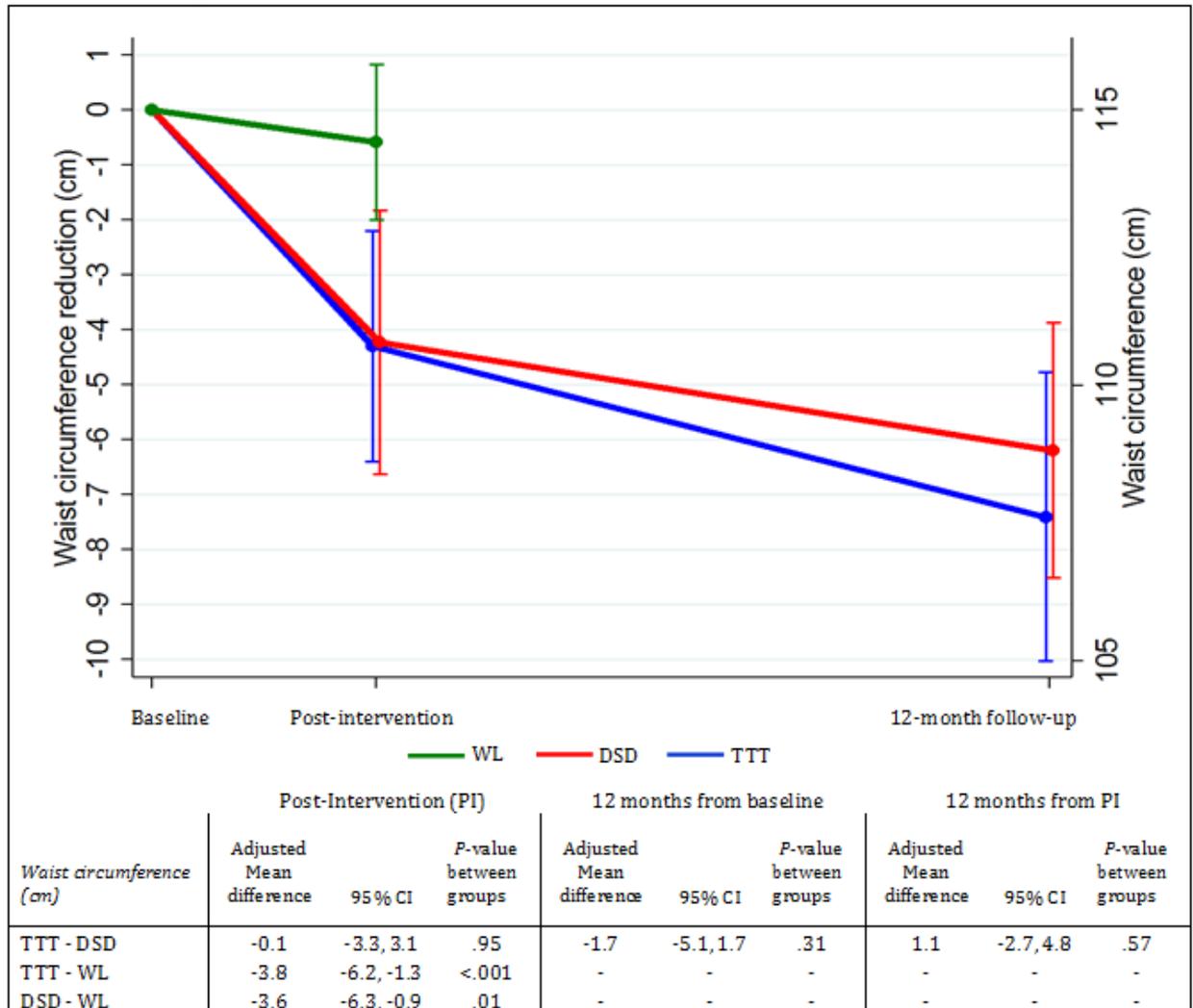
Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; WL = Waitlist; kg = kilogram; PI = Post-intervention; CI = Confidence Interval.

Figure 4.3b Mean Body Mass Index (BMI) and adjusted mean differences between TTT, DSD and WL at baseline and 12-month follow-up



Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; WL = Waitlist; BMI = Body Mass Index; PI = Post-intervention; CI = Confidence Interval.

Figure 4.3c Mean waist circumference and adjusted mean differences between TTT, DSD and WL at baseline and 12-month follow-up



Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; WL = Waitlist; cm = centimeter; PI = Post-intervention; CI = Confidence Interval.

Secondary outcomes

Baseline to post-intervention

Weight and waist circumference

At post-intervention, participants in the TTT (-3.3kg) and DSD (-2.9kg) interventions lost significantly more weight ($P < .001$) than those on the WL control (-0.4kg). BMI (TTT $-1.2\text{kg}/\text{m}^2$; DSD $-1.0\text{kg}/\text{m}^2$) and waist circumference were also reduced significantly in the active interventions compared with the WL group (BMI $-0.1\text{kg}/\text{m}^2$, waist circumference -0.6cm) (Figure 4.3).

Psychometric measures

Average WL participant wellbeing and openness to change decreased between baseline and post-intervention, but improved in the TTT and DSD groups. Active interventions did not differ significantly from each other but both showed statistically significant increases compared with control (Supplementary Table 4.3).

Compared with DSD, TTT participants improved significantly more in healthy habits, depression and anxiety and in habits and depression only when compared with WL participants. There were no statistically significant differences between DSD and WL groups for habits, depression or anxiety.

Post-intervention to 12-month follow-up*Weight and waist circumference differences between groups*

Adjusted mean differences between TTT and DSD from post-intervention to 12-month follow-up were: weight, 0.7kg (95% CI -2.5 to 3.9, $P= .66$), BMI, 0.2kg/m² (95% CI -0.9 to 1.2, $P= .76$) and waist circumference, 1.1cm (95% CI -2.7 to 4.8, $P= .66$) (Figure 4.3).

Psychometric measures

There were slight improvements in wellbeing and depression in both groups between post-intervention and 12-month follow-up, with mixed results for anxiety. Although there were positive changes in healthy habits post intervention, there was a decrease in the engagement of healthy habits in the TTT group from post-intervention to 12-month follow-up (-81.9 points [95% CI -172 to 8.3]) (Table 4.2). However, there were no statistically significant differences between groups for any of the psychometric measures (Supplementary Table 4.3).

Baseline to 12-month follow-up*Weight and waist circumference*

A large proportion of participants in both intervention groups had clinically important weight loss from baseline to 12-month follow-up. Total body weight loss of $\geq 5\%$ was achieved by 14/21 (67%) participants in the TTT group and 14/22 (64%) in DSD, with the majority of participants (24/43, 65%) losing between 5.0-9.9% body weight in both interventions (Supplementary Table 4.4).

Psychometric measures

All psychometric measures (wellbeing, depression, anxiety, habits and openness to change) improved from baseline to 12-month follow-up in both TTT and DSD (Table 4.2), with no significant differences between groups (Supplementary Table 4.3).

Table 4.2 Comparison of changes in outcomes measured between TTT, DSD and WL at post-intervention and 12 month follow-up.

Variable	Baseline	Post-Intervention (PI)			12 months from baseline			12 months from PI	
	Mean (SD)	n*	Mean change	95% CI	n*	Mean change	95% CI	Mean change	95% CI
Secondary analysis of primary outcome									
<i>Weight (kg)</i>									
TTT	95.8 (18.5)	21	-3.3	-5.2, -1.4	22	-5.7	-8.0, -3.3	-2.4	-5.1, 0.4
DSD	97.9 (22.4)	22	-2.9	-4.3, -1.4	22	-4.6	-6.6, -2.6	-1.7	-3.4, -0.1
WL	94.7 (20.4)	23	-0.4	-1.2, 0.3	-	-	-	-	-
<i>BMI (kg/m²)</i>									
TTT	34.6 (5.2)	21	-1.2	-1.8, -0.6	22	-2.0	-2.8, -1.2	-0.8	-1.8, 0.1
DSD	35.2 (7.4)	22	-1.0	-1.5, -0.5	22	-1.6	-2.3, -0.9	-0.6	-1.2, -0.04
WL	33.6 (6.1)	23	-0.1	-0.4, 0.1	-	-	-	-	-
<i>Waist (cm)</i>									
TTT	111.8 (13.4)	21	-4.3	-6.4, -2.2	22	-7.4	-10.0, -4.8	-3.1	-5.6, -0.6
DSD	117.5 (14.1)	22	-4.2	-6.6, -1.8	22	-6.2	-8.5, -3.9	-2.0	-4.7, 0.7
WL	114.8 (16.1)	23	-0.6	-2.0, 0.8	-	-	-	-	-
Secondary outcomes									
<i>Fruit serves/day</i>									
TTT	1.4 (1.1)	21	0.5	0.1, 0.9	22	0.1	-0.5, 0.6	-0.4	-0.8, -0.006
DSD	1.3 (0.8)	22	0.2	-0.1, 0.6	22	0.3	-0.03, 0.7	0.1	-0.2, 0.4
WL	1.5 (0.8)	23	-0.2	-0.5, 0.2	-	-	-	-	-
<i>Vege serves/day</i>									
TTT	2.7 (1.5)	21	0.9	0.4, 1.4	22	0.7	0.1, 1.4	-0.1	-0.7, 0.4
DSD	2.6 (1.3)	22	0.1	0.3, 0.6	22	0.4	-0.1, 0.8	0.2	0.4, 0.8
WL	2.6 (1.3)	23	0.0	-0.5, 0.5	-	-	-	-	-
<i>Exercise hr/week</i>									
TTT	2.7 (2.9)	21	2.6	1.6, 3.7	22	2.5	1.4, 3.6	-0.1	-1.1, 0.9
DSD	2.5 (2.5)	22	2.4	-0.02, 4.7	22	2.8	1.5, 4.1	0.5	-1.3, 2.2
WL	3.9 (3.4)	23	-0.8	-1.7, 0.1	-	-	-	-	-
<i>Wellbeing/800</i>									
TTT	525.1 (150.0)	17	93.0	38.2, 147.8	17	112.2	28.2, 196.1	24.6	-41.0, 90.1
DSD	486.0 (137.8)	22	66.8	30.1, 103.6	22	65.6	153.0	-1.2	-72.9, 70.6
WL	535.9 (183.4)	18	-38.7	-114.3, 37.0	-	-	-	-	-
<i>Depression/16</i>									
TTT	10.3 (2.7)	20	-1.9	-3.0, -0.7	22	-2.6	-4.0, -1.1	-0.9	-2.1, 0.3
DSD	10.4 (2.6)	22	0.4	-0.7, 1.5	22	-1.7	3.9, 0.4	-2.1	4.2, 0.1
WL	10.5 (3.0)	22	0.5	-0.9, 1.8	-	-	-	-	-
<i>Anxiety/16</i>									
TTT	9.0 (2.3)	20	-1.0	-2.1, 0.1	22	-0.1	-1.4, 1.2	0.7	-0.5, 1.8
DSD	10.7 (2.2)	22	0.1	1.1, 1.4	22	-0.7	2.3, 1.0	-0.8	2.6, 1.0
WL	9.7 (2.6)	22	0.2	-1.3, 1.8	-	-	-	-	-
<i>Habits/1200</i>									
TTT	694.0 (150.6)	20	208.3	142.9, 273.7	21	111.5	0.3, 223.4	-81.9	-172.0, 8.3
DSD	656.9 (140.3)	22	65.5	-1.7, 132.7	22	88.5	-1.2, 150.4	4.4	-50.7, 68.9
WL	714.5 (171.3)	22	10.9	-48.7, 70.5	-	-	-	-	-
<i>Openness to change/800</i>									
TTT	550.0 (114.2)	21	52.4	7.2, 97.5	22	41.9	-24.7, 108.4	-0.8	-47.9, 46.3
DSD	484.5 (123.6)	25	66.5	19.3, 113.7	22	79.9	15.5, 124.9	-6.3	-51.2, 58.5
WL	542.8 (125.9)	22	-14.4	-55.5, 26.8	-	-	-	-	-

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; WL = Waitlist; PI = Post-Intervention; SD= Standard Deviation; CI = Confidence Interval; kg = kilogram; cm = centimetre; hr = hours; Vege = vegetables.

Note: PI data is change from baseline. 12-month data are change from baseline and change from PI

*Number reflects number of participants who completed assessment or questionnaire and not reflective of number of participants in the study.

Discussion

Our primary outcome was weight loss maintenance at 12-months post-intervention and we found, participants in both habit-based interventions – forming new habits (TTT) and breaking old habits (DSD) – achieved weight-loss maintenance and lost further weight. Corresponding with the changes in weight, participants on the TTT and DSD programs had reductions in BMI and waist circumference. These results are promising against the background of most weight-loss programs reporting weight regain post-intervention and failing to keep the weight off long-term^{1,6,23,24}.

The active interventions in this study were not directly compared to a non-habit-based weight-loss intervention at the final time-point; however, we can compare the results with systematic reviews which evaluated long-term weight-loss maintenance after lifestyle interventions. Previous results show that 12-months post-treatment, an average of 46-50% of weight loss is regained^{6,23,24}. In contrast, participants in our study continued to lose weight at 12-months post-intervention, suggesting habit-based interventions are promising interventions to combat the weight loss – weight regain cycle over more conventional weight-loss programs. Although interest is growing in habit-change strategies, and habits consistently correlate with behaviour²⁵, weight loss interventions applying this approach are still scarce and their mechanisms of action are not completely understood; therefore, what mechanisms are influencing the relationship between habit change and weight loss are still not known. There has been one study to date, which explicitly assessed the potential mechanisms of a habit-based intervention for weight loss²⁶; the study focused on TTT. Overall the results showed, TTT promoted changes in self-regulatory skills and these changes, alongside changes in automaticity, mediated the effect of TTT on weight loss. These findings support the theoretical basis of the intervention and are in line with the suggestion that interventions which require the development of goals, planning and monitoring of behaviour, improve self-regulatory capacity^{15,19,27}. No mediator analyses for DSD or other habit-based weight loss interventions have been published. We hypothesize that although the aim of DSD is to promote behavioural flexibility and increase behavioural repertoire, it does not aim to break previously established healthy habits, such as eating breakfast, or engaging in physical activity. In fact, as an individual behaves from a heightened state of awareness, as opposed to mindlessly (habit), they are more likely to perform the behaviors which align with their health and weight goals¹². Therefore, the observation of participants in DSD increasing their healthy habits according to the habit rater, was to be expected.

This study was not powered for secondary outcomes; therefore, these analyses should be regarded as exploratory. We observed an increase in engagement in healthy habits and openness to change in both active interventions, even at 12-month follow-up. A qualitative analysis in a previous TTT study showed the participants reported the target behaviours became more habitual gradually and acquired characteristics of habits including automaticity, repetition and 'feeling strange' for not doing the behaviour³¹. The increase in openness to change and sustained change in habits could correspond to the long-term weight-loss maintenance observed in our study. Of note, TTT participants received direct recommendations to improve their healthy habits (e.g., 'walk 10,000 steps per day' and 'eat 2 fruit and 5 vegetables a day'); while DSD participants did not receive targeted recommendations instead receiving daily individualized text messages to disrupt daily routines. Despite not receiving habit-forming recommendations, DSD still improved their overall engagement in healthy habits. For example, both interventions doubled the hours of exercise performed per week from baseline to follow-up and doubled the global recommendations on physical activity for health³². This suggests that explicit advice on how to form new healthy habits may not be necessary to improve an individual's healthy habits. By simply altering an individual's current habits, new habits can be substituted and ultimately disrupt unhealthy habits.

There are several strengths to our study. First, we included an adequate sample size to detect important changes in dependent variables; second, we conducted a rigorous 3-armed randomised controlled trial design with good retention and accountability; and finally, we endeavoured to replicate previous research.

However, there were limitations. We did not collect data for body composition or cardiometabolic risk factors. Although this limits the scientific scope of the study, the correlation between weight and waist reduction and cardiometabolic risk factors is well documented²⁸⁻³⁰. There is currently no clear definition for 'successful long-term weight loss'³³. For the purpose of this study, we defined 'long-term weight loss' as 12-months post-intervention as proposed by Wing RR, 2005. We acknowledge however, that 12-months may not represent 'long-term'. DSD and TTT differ in length. We acknowledge that differences between the two interventions could have been different had they both been the same duration. But there were no significant differences between groups in weight loss and weight-loss maintenance. Groups were equivalent and intervention duration was still around 66 days, which is the average time it takes to change a habit¹⁹, so it is possible that habit change

occurred. It is also plausible that a dietitian/facilitator may have contributed to the weight loss and maintenance success of participants. However, we did not offer specific dietary advice and believe health practitioners following the prescribed manuals would achieve similar outcomes. This will need to be explored in future research. Finally, we do not know the mechanisms that influenced the weight loss outcomes in our study. Building on the work of Kliemann and colleagues²⁶, to improve the theoretical understanding of how habit-based interventions might bring about weight loss, is essential to provide guidance on the development of effective weight-management interventions.

To aid in study retention and to increase accountability, we included weekly check-in phone calls for the 12-week intervention to all three groups. These phone calls are not in the original study designs of either TTT or DSD^{12,34}. We hypothesized this difference would achieve greater weight loss than previous TTT and DSD trials as accountability has consistently demonstrated to be a key facilitator for weight loss³⁵. This appeared to be the case for TTT, but did not apply for DSD. Previous studies show, TTT participants³⁴ ($n= 153$) lost, $2.4\text{kg} \pm 5.5$ and DSD participants¹² ($n= 31$) lost, $5.2\text{kg} \pm 2.7$ from baseline to 12-month follow-up. We conclude that weekly monitoring did not achieve greater weight-loss results however could have improved retention. Whether weekly monitoring influenced retention requires further research.

Conclusion

Despite the different underlying mechanisms of these two interventions, TTT and DSD achieved significant weight-loss maintenance for 12-months post-intervention and improved diet and exercise habits. Approximately 65% of participants in the active intervention groups lost over 5% of their total body weight which is the benchmark of successful and healthful weight loss and kept it off 12-months after the intervention completed. Habit-based interventions have the potential to change how we think about weight management and importantly, how we behave.

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Registered clinical trial: This study was registered on the 10th of February 2015 through the Australian New Zealand Clinical Trials Registry (ANZCTR). The allocated Australian Clinical Trial Registry Number (ACTRN) is: ACTRN12615000114549.

Ethics: This study complied with the ethics guidelines recommended by the National Health and Medical Research Council (NHMRC) and Bond University Research Ethics Committee (BUHREC). This study was granted ethical approval by BUHREC (No. RO1888B) on 17 February, 2015.

Authors' contribution: Gina Cleo had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Cleo, Glasziou

Acquisition of data: Cleo

Analysis and interpretation of data: Cleo, Thomas, Beller

Drafting of the manuscript: Cleo, Thomas, Isenring

Critical revision of the manuscript for important intellectual content: Cleo, Thomas, Beller, Isenring, Glasziou

Statistical analysis: Cleo, Thomas, Beller

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Supplementary material for Chapter 4

Table S4.1a Comparison of study variables between participants with complete and incomplete data at baseline

Table S4.1b Chi-Squared analysis comparing education level between participants with complete and incomplete data at baseline

Table S4.2 Ten Top Tips

Table S4.3 Differences between TTT, DDD and WL for secondary outcomes at post-intervention and 12-month follow-up

Table S4.4 Proportion of weight lost on TTT and DSD at 12-month follow-up

Table S4.5 CONSORT checklist

File S4.1 Psychometric questionnaires

File S4.2 Randomised controlled trial additional methodology

File S4.3 6-month results

Supplementary Table 4.1a Comparison of study variables between participants with complete and incomplete data at baseline

Variables	Completers vs non-completers	N	Mean	SD	95% CI of the Difference		F	P-value
					Lower	Upper		
Age, years	Completers	66	51.5	10.7	.8	16.3	.96	.33
	Non-completers	9	43.0	12.7	-1.4	18.5		
Exercise hours/week	Completers	66	3.0	3.5	-2.2	2.6	2.90	.09
	Non-completers	9	2.9	1.8	-1.4	1.7		
Fruit serves/day	Completers	66	1.5	.9	-.3	1.0	1.33	.25
	Non-completers	9	1.1	.8	-.3	1.0		
Vegetable serves/day	Completers	66	2.7	1.3	-.6	1.3	.40	.53
	Non-completers	9	2.3	1.6	-.9	1.6		
Weight, (kg)	Completers	66	95.5	20.2	-19.3	9.5	.25	.62
	Non-completers	9	100.4	21.0	-21.4	11.6		
BMI, (kg/m ²)	Completers	66	34.3	6.4	-5.8	3.1	.54	.46
	Non-completers	9	35.6	5.1	-5.4	2.8		
Waist circumference (cm)	Completers	66	114.4	15.1	-12.8	8.0	.62	.43
	Non-completers	9	116.8	10.5	-11.0	6.1		
Depression/16	Completers	64	10.4	2.8	-1.6	2.7	1.0	.32
	Non-completers	7	9.9	2.1	-1.4	2.6		
Anxiety/16	Completers	64	9.9	2.5	-1.0	2.9	3.0	.09
	Non-completers	7	9.0	1.9	-.9	2.7		
Wellbeing/800	Completers	57	506.9	157.8	-193.3	73.2	.36	.55
	Non-completers	6	567.0	124.5	-190.7	70.6		
Habits/1200	Completers	63	691.7	154.2	-77.4	167.7	.02	.88
	Non-completers	7	646.6	153.4	-97.8	188.1		
Openness to change/800	Completers	64	523.2	125.7	-112.7	84.5	1.4	.24
	Non-completers	7	537.3	106.4	-113.8	85.6		

Abbreviations: SD = Standard Deviation; CI = Confidence Interval; kg = kilogram; BMI = Body Mass Index; cm = centimeter.

Note: Data calculated using T-test and Independent Samples test: t-test for Equality of Means and Levene's Test for Equality of variances.

Supplementary Table 4.1b Chi-Square analysis comparing education level between participants with complete and incomplete data at baseline

	N	Education Level			P-value (2-sided)
		Did not complete School	Completed School	University Degree	
Completers	9	0	6	3	.54
Non-completers	66	8	37	21	

Supplementary Table 4.2 Ten Top Tips¹⁹

Ten Top Tips for Weight Loss
1. Keep to your meal routine

Try to eat at roughly the same times each day, whether this is two or five times a day.

2. Go reduced fat

Choose reduced fat foods (e.g. dairy foods, spreads, salad dressings) where you can. Use high fat foods (e.g. butter and oils) sparingly, if at all.

3. Walk off the weight

Walk 10 000 steps (equivalent to 60–90min moderate activity) each day. You can use a pedometer to help count the steps.

4. Pack a healthy snack

If you snack, choose a healthy option such as fresh fruit or yogurts instead of chocolate or crisps.

5. Learn the labels

Be careful about food claims. Check the fat and sugar content on food labels when shopping and preparing food.

6. Caution with your portions

Do not heap food on your plate (except vegetables). Think twice before having second helpings.

7. Up on your feet

Break up your sitting time. Stand up for ten minutes out of every hour.

8. Think about your drinks

Choose water. Unsweetened fruit juice contains natural sugar so limit to one glass a day (200 ml/one-third pint). Alcohol is high in calories; limit to one unit a day for women and two for men.

9. Focus on your food

Slow down. Do not eat on the go or while watching TV. Eat at a table if possible.

10. Do not forget your 5 a day

Eat at least 5 portions of fruit and vegetables a day (400g in total).

Supplementary Table 4.3 Differences between TTT, DSD and WL for secondary outcomes at post-intervention and 12-month follow-up

	Post-Intervention (PI)			12 months from baseline			12 months from PI		
	Adjusted Mean difference	95% CI	P-value between groups	Adjusted Mean difference	95% CI	P-value between groups	Adjusted Mean difference	95% CI	P-value between groups
<i>Fruit serves/day</i>									
TTT - DSD	0.3	-0.7, 0.8	.10	-0.1	-0.5, 0.3	.57	-0.2	-0.6, 0.2	.25
TTT - WL	0.6	0.2, 1.1	.01	-	-	-	-	-	-
DSD - WL	0.3	-0.1, 0.7	.16	-	-	-	-	-	-
<i>Vegetable serves/day</i>									
TTT - DSD	0.7	0.1, 1.3	.03	0.3	-0.4, 1.0	.32	-0.1	-0.8, 0.7	.86
TTT - WL	0.8	0.2, 1.5	.01	-	-	-	-	-	-
DSD - WL	0.1	-0.5, 0.7	.67	-	-	-	-	-	-
<i>Exercise hr/week</i>									
TTT - DSD	0.4	-2.1, 2.9	.77	-0.3	-2.0, 1.3	.70	-0.4	-2.0, 1.3	.64
TTT - WL	3.2	1.9, 4.5	<.001	-	-	-	-	-	-
DSD - WL	2.9	0.5, 5.4	.02	-	-	-	-	-	-
<i>Wellbeing/800</i>									
TTT - DSD	0.6	0.5, 0.8	<.001	73.8	-11.7, 159.3	.09	61.8	-19.5, 143.2	.13
TTT - WL	122.5	40.6, 204.4	.01	-	-	-	-	-	-
DSD - WL	87.5	16.7, 158.3	.02	-	-	-	-	-	-
<i>Depression/16</i>									
TTT - DSD	-2.3	-3.7, -1.0	<.001	-1.0	-2.8, 0.7	.23	0.8	-2.6, 1.0	.39
TTT - WL	-2.3	-4.0, -0.6	.01	-	-	-	-	-	-
DSD - WL	0.0	-1.6, 1.7	.96	-	-	-	-	-	-
<i>Anxiety/16</i>									
TTT - DSD	-2.0	-3.5, -0.4	.02	-1.1	-2.6, 0.4	.14	-0.6	-2.1, 0.9	.41
TTT - WL	-1.5	-3.2, 0.3	.09	-	-	-	-	-	-
DSD - WL	0.6	-1.1, 2.4	.47	-	-	-	-	-	-
<i>Habits/1200</i>									
TTT - DSD	149.1	88.1, 210.1	<.001	55.6	-51.9, 163.1	.30	-48.7	-168.9, 71.4	.42
TTT - WL	0.5	0.3, 0.7	<.001	-	-	-	-	-	-
DSD - WL	32.6	-40.3, 105.4	.37	-	-	-	-	-	-
<i>Openness to change/800</i>									
TTT - DSD	19.6	-31.4, 70.7	.44	9.0	-62.4, 80.4	.80	10.1	-55.9, 76.1	.76
TTT - WL	69.1	15.0, 123.3	.01	-	-	-	-	-	-
DSD - WL	60.5	4.0, 117.1	.04	-	-	-	-	-	-

Abbreviations: PI = Post-Intervention; CI = Confidence Interval; TTT = Ten Top Tips; DSD = Do Something Different; WL = Waitlist; hr = hour.

Note: PI data is change from baseline. 12-month data are change from baseline and change from PI

Supplementary Table 4.4 Proportion of weight lost on TTT and DSD at 12-month follow-up

	TTT (n = 21)	DSD (n = 22)
0.0-4.9%	33.3% (7/21)	36.4% (8/22)
5.0-9.9%	52.4% (11/21)	59.1% (13/22)
10.0-14.9%	9.5% (2/21)	4.5% (1/22)
15.0-19.9%	4.8% (1/21)	0% (0/22)
Total ≥5%	67% (14/21)	64% (14/22)
Mean % weight loss	-6.2%	-4.8%

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different.

Supplementary Table 4.5 CONSORT checklist

 CONSORT CHECKLIST
Table. CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial^a

Section and Topic	Item No.	Checklist Item	Reported on Page No.
Title and abstract	1a	Identification as a randomized trial in the title	67
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	70
Introduction Background and objectives	2a	Scientific background and explanation of rationale	72
	2b	Specific objectives or hypotheses	72
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	73
	3b	Important changes to methods after trial commencement (such as eligibility criteria),	73
with reasons Participants	4a	Eligibility criteria for participants	72-73
	4b	Settings and locations where the data were collected	73
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	73-74
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	75
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	73
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomization Sequence generation	8a	Method used to generate the random allocation sequence	73
	8b	Type of randomization; details of any restriction (such as blocking and block size)	73
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	73
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	73
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	75-76
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	76
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	76
Results Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	77
	13b	For each group, losses and exclusions after randomization, together with reasons	77
Recruitment	14a	Dates defining the periods of recruitment and follow-up	77
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	78
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	84
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	84
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Comment Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	86
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	86
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	86-87
Other information Registration	23	Registration number and name of trial registry	88
Protocol	24	Where the full trial protocol can be accessed, if available	88
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	In paper

^aWe strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, nonpharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming; for those and for up-to-date references relevant to this checklist, see <http://www.consort-statement.org>.

Supplementary File 4.1 Psychometric questionnaires

Your Wellbeing

Thinking about how your life has been in the last month, indicate how much you agree with the wellbeing statements.

	A LITTLE	A LOT
I have coped well with problems / issues		
I have found it easy to talk to others		
I have found it easy to make decisions		
I have felt valued / appreciated		
I have felt happy		
I have felt like life has meaning		
I have good physical health		
I have had a good relationship with the person closest to me e.g spouse / partner/ significant other.		

Thoughts & Feelings

	Very frequently / often	Now & again	Very rarely	Never
Feeling of sadness first thing in the morning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Finding it difficult to "think on the spot" and concentrate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling low and wanting to give up trying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling as though you are "falling apart at the seams" but unsure why	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of interest and enjoyment in food	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling uneasy and wanting to "escape"	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling life is difficult to cope with	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Worrying about things that cause feelings of tension and strain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Note: Questions 1,3,5,7 measure depression. Questions 2,4,6,8 measure anxiety.

Habit Rater. How often do you...

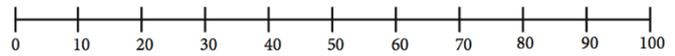
	A LITTLE	A LOT
Put effort into the relationships that matter most to you?		
Skip breakfast? (Reverse score)		
Eat meals at the table without the TV or electronic distractions?		
Spend at least half an hour a day being active e.g. playing sport or walking?		
Take time out just to relax?		
Smoke cigarettes? (Reverse score)		
Drink alcohol? (Reverse score)		
Eat at least 5 portions of veg and fruit a day?		
Try new things?		
Put your health needs at the top of your to-do list?		
Stick to healthy eating habits?		
Feel stressed? (Reverse score)		

Tell us a bit more

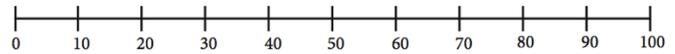
In general, how would you rate your satisfaction with your life?



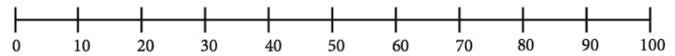
How highly would you rate your level of confidence?



How well have you been sleeping?



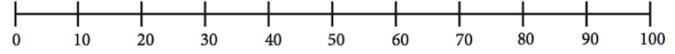
How optimistic do you feel about the future?



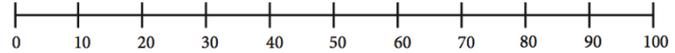
To what extent do you feel in control of your life?



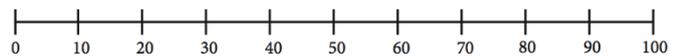
To what extent do you consider yourself to be open-minded?



How much do you enjoy change?



How frequently do you look for new ways of doing things?

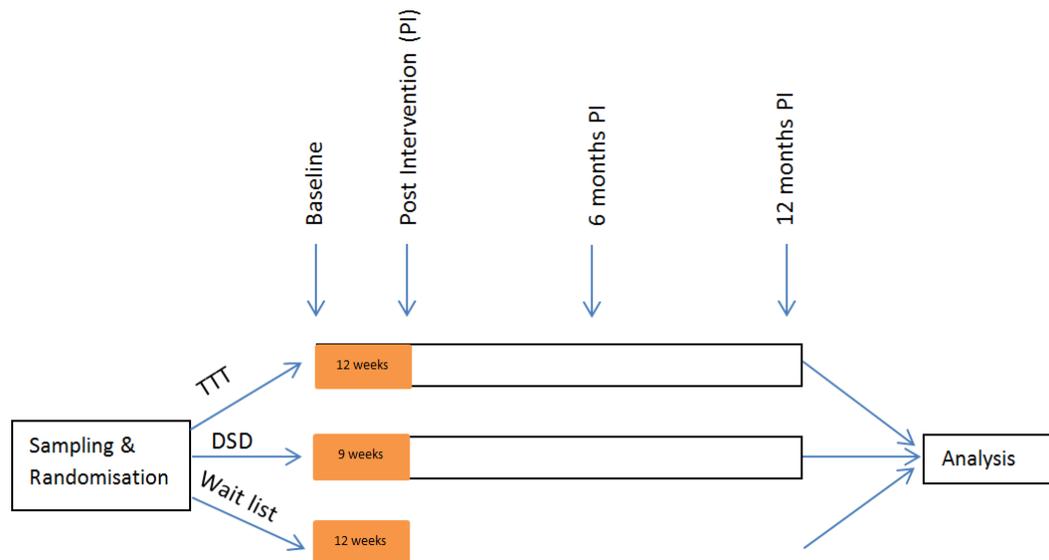


Note: This scale measure 'Openness to change'

Supplementary File 4.2 Randomised controlled trial additional methodology

Research design

This was a 15-month, three arm, randomised controlled trial, which included a 9-12-week active intervention phase, followed by a 12-month tracking/monitoring phase (File S4.2 Figure 1). The rationale for conducting a randomised controlled trial research design in this study was to quantitatively evaluate weight loss outcomes of each intervention ¹.



File S4.2 Figure 1 Measurement points of randomised controlled trial

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; PI = Post Intervention

Sample

Based on the average weight lost in previous DSD and TTT trials, a 2.4kg weight loss and standard deviation of 2.19kg was required from participants in the two treatment interventions (TTT and DSD) compared with participants in the waitlist (WL) (standard deviation was calculated based on the weight loss results from the two interventions from previous published trials ^{2,3}). The sample size calculation was performed using PS software (Power and Sample Size Calculation) and confirmed by the faculty statistician and suggested 19 participants were required in each of the 3 arms to achieve a 90% power and 5% significance criterion to detect clinically important weight change post-intervention. To account for 30% expected attrition ⁴, we recruited 75 participants.

$$19 \times 3 = \frac{57}{0.7} = 75$$

Ethical Considerations

Informed consent was obtained from eligible subjects prior to entry to the study. Eligible participants were provided with an information package (Appendix G; page 247) which included contact details of the principal investigator and the ethics committee in case there were any queries. Potential participants were informed of: voluntary participation into the study; the purpose and any possible disadvantage of taking part in the study; and that they were free to withdraw from the study at any time without any consequence.

Registered Clinical Trial

This study was successfully registered on the 10th of February 2015 through the Australian New Zealand Clinical Trials Registry (ANZCTR) in accordance with the National Health and Medical Research Council (NHMRC) and the National Research Infrastructure for Australia (NCRIS). The allocated Australian Clinical Trial Registry Number (ACTRN) is: ACTRN12615000114549.

A Universal Trial Number (UTN) was also obtained on the 20th of January 2015 through the World Health Organization for this study with registration number: U1111-1166-3131.

Recruitment and Procedure

Radio

A radio segment was broadcasted on local ABC radio to explain the nature of the study. The station contact number was provided during the broadcast for interested participants to call in with their contact details, which were then passed on to the primary researcher via the station. Interested participants were called back and surveyed through the eligibility questionnaire.

Eligible participants were enrolled into the study. Non-eligible participants were advised to speak with their medical practitioner for weight management assistance and/or further referral to a dietitian or appropriate weight loss program.

Television Broadcast

A local news reporter was made aware of this study through the public relations team at Bond University. The reporter made contact with the principle investigator to arrange a television

broadcasting segment for the local news. This segment was broadcasted in order to make the local community aware of this novel study in weight management, as well as aid in recruiting eligible participants to the study. The lead researcher's contact details were made available on the broadcast.

Enrolment and randomisation

Eligible participants were invited to attend an initial baseline appointment to gather anthropometric and psychometric data and sign informed consent. Randomisation through minimisation occurred once eligible participants had attended the initial baseline appointment. Once allocated to their intervention, participants were given a phone call approximately one week after the baseline appointment to inform them of which intervention they had been randomised to. The investigator then arranged a second meeting with the participant to explain the intervention and get them started on the program. The reason participants were given a week between the initial meeting and the follow-up phone call was to help filter the uncommitted participants who were not willing to wait a week to commence the trial; a delay in commencing a study has been shown to increase retention⁵.

Minimisation

A stratification process is beneficial when randomising the participants in order to divide participants into homogenous subgroups before sampling. Due to the small sample size of this study ($n=75$), randomising the participants equally into the 3 intervention groups with each of the strata's mentioned above would mean very small numbers in each stratum and a high risk of imbalances overall. In order to overcome this, the stratification method used in this study was minimisation⁶. Minimisation is a method of adaptive stratified sampling which aims to minimise the imbalance between the number of patients in each treatment group over a number of factors⁷. In use, minimisation often maintains a better balance than traditional blocked randomisation, and its advantage rapidly increases with the number of stratification factors⁸. The MINIM program was used to perform the minimisation method.

The stratification groups included BMI categories (File S4.2 Table 1); age categories (18-32, 33-47, 48-62, 63-75 years); and gender (male/female). This method improves the representativeness of the sample by reducing sampling error as well as produces a weighted mean that has less variability than the arithmetic mean of a simple random sample of the population⁹.

File S4.2 Table 2 BMI Classifications for the purpose of sample stratification

Category	BMI kg/m ²
Overweight	25.0-29.9 kg/m ²
Obese class I	30.0-34.9 kg/m ²
Obese class II	35.0-39.9 kg/m ²
Obese class III	≥40.0 kg/m ²

Abbreviation: BMI = Body Mass Index; kg = kilogram.

Allocation concealment

Although participants could not be blinded to their treatment, both programs were presented as active treatments. The lead researcher recruited the participants and randomly allocated the intervention groups (TTT, DSD or WL). The lead researcher also administered the interventions and therefore was not blinded to allocation.

Waitlist group

Participants randomised to the waitlist were treated as an intention to treat group (ITT). They were then given the choice to commence either the DSD or TTT intervention after waiting 12 weeks (intervention period). A 15-month wait (3-month intervention + 12-month follow-up period) would have been more ideal for the purpose of this study in order to compare 12-month post-intervention data and compare the 2 active interventions with usual care, however due to increased attrition rates with longer waiting periods⁴, the wait was capped at only 3 months. The waitlist group were instructed to continue behaving as per usual during the 12-week intervention period. Participants in the control group were advised that they were on a waitlist and would receive an intervention after 12 weeks from recruitment. During the wait period, wait-list participants received no weight loss advice or support until after the intervention period concluded and they were able to commence either the TTT or DSD programs. They were also asked not to participate in any other weight management programs during the intervention period to ensure a comparison of the two active interventions with what individuals would normally do when not assigned to any weight loss interventions. Anthropometric and psychometric data were measured at baseline and post-intervention.

Data Collection and Measures

A summary of the measures collected for all three arms of the study (TTT, DSD and waitlist) are presented in File S4.2 Table 2. Post-intervention measurements and 6 and 12 month post-intervention measurements were collected by a blinded research assistant independent of the study in order to avoid detection bias.

File S4.2 Table 2 Summary of baseline and follow-up assessments

Measure	Baseline	9-12 weeks	6-months	12-months
		Post-intervention	Follow-up	
Weight	x	x	x	x
Waist circumference	x	x	x	x
Number of fruit and vegetable serves consumed per day	x	x	x	x
Hours of exercise performed per week	x	x	x	x
Wellbeing	x	x	x	x
Depression	x	x	x	x
Anxiety	x	x	x	x
Habits	x	x	x	x
Openness to change	x	x	x	x
Qualitative Interview			x	

Measurement of Anthropometry

Body weight was measured to the nearest 0.1 kg using Seca 700 medical scales. The Seca 700 is a non-automatic mechanical column scale. As per the NHMRC clinical practice guidelines for the management of overweight and obesity¹⁰, participants were asked to remove any outer garments, take off their shoes and empty pockets. Participants were also asked to stand centred on the scale with weight evenly on both feet.

Height was measured in centimetres using a stadiometer with integrated level. As per NHMRC standard protocol for measuring height; participants were instructed to stand with feet together and flat on the ground (no footwear), with heels, shoulder blades and buttocks touching the wall¹⁰. Participants were also asked to look straight ahead and measurement was taken as the participant took a deep breath in and stretch to their fullest height.

Body Mass Index was calculated using body weight in kilograms (kg), divided by height in meters squared (m)².

Waist circumference was measured using a soft tape measure over light clothing. As per NHMRC standard protocol, participants were asked to remove heavy outer garments, loosen any belts and empty pockets, stand with their feet close together (about 12-15cm) with their weight equally distributed and to breathe normally¹⁰. The waist was defined as the point midway between the iliac crest and lower rib (approximately in line with the umbilicus). Measurement was taken in centimetres at the end of normal expiration¹⁰.

Dietary Intake and Physical Activity Measures

A consideration was made to measure dietary intake and physical activity behaviours through food and exercise diaries and using a food group tally method to assess the number of food groups participants consumed compared to the Australian dietary guidelines and number of hours of exercise performed each week compared to the Australian physical activity guidelines. Due to high participant burden, however (as identified in the pilot study), and factors including compliance and accuracy of self-reported data, dietary and physical activity behaviours were not formally measured in this study. The main study outcome was weight loss maintenance in relation to behavioural and habitual modifications; therefore, this was the primary focus. Furthermore, the Habit included diet and exercise related questions such as: 'How often do you...': 'skip breakfast'; 'spend at least half an hour a day being active'; 'drink alcohol' and; 'eat at least 5 portions of veg and fruit a day?' This data was analysed and assessed for changes pre and post-intervention as well as at 6 and 12 months post-intervention.

A simple question, "*How many serves of fruit do you consume each day?*" was asked at all measurement time points. Similarly, with "*How many serves of vegetables do you consume each day?*" and "*How many hours of exercise do you perform each week?*" Serves of fruit consumed per day were capped at a range of 0-3, as this is the recommended intake of fruit serves per day as per the Australian Dietary Guidelines¹¹. Similarly, vegetable serves were capped at a range of 0-5 serves per day as 5 is the recommended daily intake for adults¹¹. Participants were guided in quantifying a fruit and vegetable serve as per the Australian dietary guidelines¹¹ where 1 fruit serve is considered to be 1 medium piece of fruit or 2 small pieces of fruit or 1 cup of canned fruit (File S4.2 Figure 2)

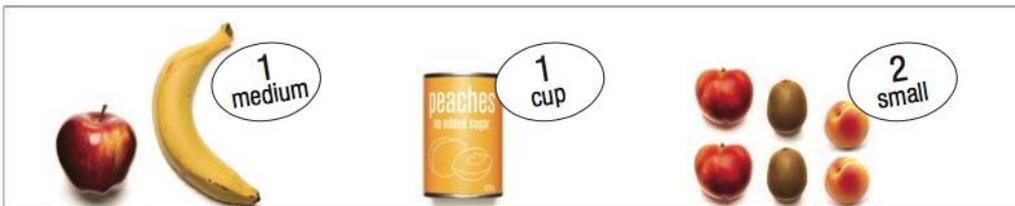
What is a serve of fruit?

A standard serve is about 150g (350kJ) or:

- 1 medium apple, banana, orange or pear
- 2 small apricots, kiwi fruits or plums
- 1 cup diced or canned fruit (no added sugar)

Or only occasionally:

- 125ml (½ cup) fruit juice (no added sugar)
- 30g dried fruit (for example, 4 dried apricot halves, 1½ tablespoons of sultanas)



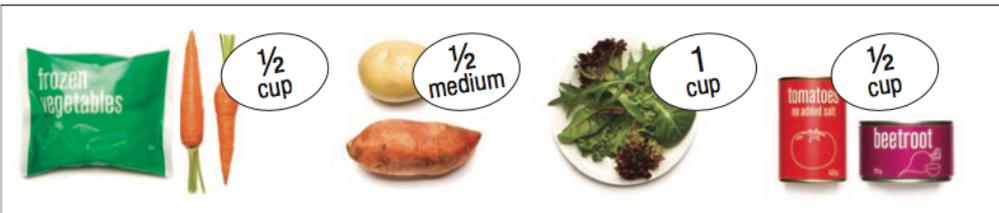
File S4.2 Figure 2 A serve of fruit as per the Australian Dietary Guidelines

A standard serve of vegetables is considered to be ½ a cup of cooked vegetables or 1 cup of salad (File S4.2 Figure 3).

What is a serve of vegetables?

A standard serve is about 75g (100–350kJ) or:

- ½ cup cooked green or orange vegetables (for example, broccoli, spinach, carrots or pumpkin)
- ½ cup cooked dried or canned beans, peas or lentils (preferably with no added salt)
- 1 cup green leafy or raw salad vegetables
- ½ cup sweet corn
- ½ medium potato or other starchy vegetables (sweet potato, taro or cassava)
- 1 medium tomato



File S4.2 Figure 3 A serve of vegetables as per the Australian Dietary Guidelines

Exercise was measured by the number of hours engaging in intentional physical activity and included all and any form of exercise. The National Health and Medical Research Council (NHMRC) recommends in the Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia to follow a consistent exercise routine and limit sedentary activities such as television viewing¹⁰.

Intervention Process Evaluation

Throughout the study, participants in both interventions self-monitored their progress. The DSD participants self-monitored through the DoZone and TTT participants through the logbook.

The principal researcher performed ongoing process evaluation and monitored participants' compliance on a fortnightly basis through the DoZone and TTT logbooks. The DoZone is a live forum and the researchers have access to the participants' compliance, comments and feedback. The TTT logbook was printed in one-week blocks and the participant sent the logbook back to the researcher at the end of each fortnight for the duration of the 12-week intervention period (they were provided with 6 stamped envelopes). During the weekly phone calls (described in the section below), TTT participants were reminded to post back the logbooks.

Weekly Phone Calls

The principal researcher made weekly phone calls to all participants in the TTT and DSD interventions. Participants in the pilot study identified this as a preference. These phone calls were semi-structured and aimed to remind the participants to continue self-monitoring their progress, as well as help motivate them to remain active in the program and offer support as required. This process evaluation strategy also assisted in monitoring the participants' compliance and active participation in the program. Participants that were no longer active in the intervention were identified through these weekly phone calls; any issues that were able to be worked through were discussed.

File S4.2 References

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Supplementary File 4.3 Six-month results

Six-month results

Baseline to 6-month follow-up

Weight and waist circumference

Weight, BMI and waist circumference decreased in both TTT and DSD groups from baseline to 6-month follow-up with no significant differences between groups. TTT participants lost an average of -4.2kg (95% CI -6.0, -2.3), and DSD lost -3.4kg (95% CI -5.2, -1.6) (File S4.3 Table 1).

Adjusted mean differences between TTT and DSD from baseline to 6-month follow-up were: weight, -1.0kg (95% CI -3.4, 1.4; $P = .42$), BMI, $-0.3\text{kg}/\text{m}^2$ (95% CI -1.1, 0.5; $P = .49$) and waist circumference, -1.2cm (95% CI -3.8, 1.5; $P = .38$).

Psychometric measures

All psychometric measures (wellbeing, depression, anxiety, habits and openness to change) improved from baseline to 6-month follow-up in TTT and DSD participants, with no significant differences between groups (File S4.3 Table 1).

Post-intervention to 6-month follow-up

Weight loss and waist circumference

After the interventions concluded, participants continued to lose weight at 6-month follow-up. TTT participants lost a further -0.9kg (95% CI -3.5, 1.8) and DSD participants lost -0.5kg (95% CI -2.0, 1.0). BMI and waist circumference also continued to decrease at 6-month follow-up (BMI: TTT $-0.3\text{kg}/\text{m}^2$ [95% CI -1.1, 0.6], DSD $-0.2\text{kg}/\text{m}^2$ [95% CI -0.7, 0.3]; waist circumference: TTT -1.7cm [95% CI -3.5, 1.4], DSD -0.2cm [95% CI -2.4, 2.0]) (File S4.3 Table 1).

Adjusted mean differences between TTT and DSD from post-intervention to 6-month follow-up were: weight, -0.5kg (95% CI -3.4, 2.4; $P = .73$), BMI, $-0.1\text{kg}/\text{m}^2$ (95% CI -1.1, 0.8; $P = .81$) and waist circumference, -1.47cm (95% CI -4.6, 1.6; $P = .34$).

Psychometric measures

There were slight improvements in wellbeing, anxiety and openness to change in the TTT group and Depression, anxiety and habits in the DSD group. Interestingly, DSD had a small

decrease in openness to change and wellbeing. There were no statistically significant differences between groups for any of the psychometric measures (File S4.3 Table 1).

Discussion¹

Six months after intervention completion, both habit-based interventions- forming new habits (TTT) and breaking old habits (DSD) achieved weight-loss maintenance and lost further weight. Moreover, participants on both programs had reductions in BMI and waist circumference.

There were no statistically significant differences between TTT and DSD in any of the variables measured at 6-month follow-up.

¹ Full discussion for this randomised controlled trial is found in the main chapter document on page 81

File S4.3 Table 1 Comparison of changes in outcomes measured between TTT, DSD and WL at post-intervention and 6 month follow-up.

Variable	Baseline	Post-Intervention (PI)			6 months from baseline			P-value between groups	6 months from PI		P-value between groups
	Mean (SD)	n*	Mean change	95% CI	n*	Mean change	95% CI		Mean change	95% CI	
<i>Weight (kg)</i>								.416			.726
TTT	95.8 (18.5)	21	-3.3	-5.2, -1.4	21	-4.2	-6.0, -2.3		-0.9	-3.5, 1.8	
DSD	97.9 (22.4)	22	-2.9	-4.3, -1.4	22	-3.4	-5.2, -1.6		-0.5	-2.0, 1.0	
WL	94.7 (20.4)	23	-0.4	-1.2, 0.3	-	-	-		-	-	
<i>BMI (kg/m²)</i>								.488			.811
TTT	34.6 (5.2)	21	-1.2	-1.8, -0.6	21	-1.4	-2.0, -0.8		-0.3	-1.1, 0.6	
DSD	35.2 (7.4)	22	-1.0	-1.5, -0.5	22	-1.1	-1.8, -0.5		-0.2	0.7, 0.3	
WL	33.6 (6.1)	23	-0.1	-0.4, 0.1	-	-	-		-	-	
<i>Waist (cm)</i>								.380			.342
TTT	111.8 (13.4)	21	-4.3	-6.4, -2.2	21	-5.5	-7.4, -3.6		-1.1	-3.5, 1.4	
DSD	117.5 (14.1)	22	-4.2	-6.6, -1.8	22	-4.4	-6.3, -2.5		-0.2	-2.4, 2.0	
WL	114.8 (16.1)	23	-0.6	-2.0, 0.8	-	-	-		-	-	
<i>Fruit serves/day</i>								.882			.314
TTT	1.4 (1.1)	21	0.5	0.1, 0.9	21	0.0	-0.5, 0.5		-0.5	-0.9, -0.1	
DSD	1.3 (0.8)	22	0.2	-0.1, 0.6	22	0.1	-0.2, 0.5		0.1	-0.4, 0.2	
WL	1.5 (0.8)	23	-0.2	-0.5, 0.2	-	-	-		-	-	
<i>Vege serves/day</i>								.080			.771
TTT	2.7 (1.5)	21	0.9	0.4, 1.4	21	0.7	0.1, 1.3		-0.1	-0.6, 0.4	
DSD	2.6 (1.3)	22	0.1	0.3, 0.6	22	0.1	-0.3, 0.6		0.0	-0.5, 0.5	
WL	2.6 (1.3)	23	0.0	-0.5, 0.5	-	-	-		-	-	
<i>Exercise hr/week</i>								.849			.798
TTT	2.7 (2.9)	21	2.6	1.6, 3.7	21	2.1	1.0, 3.3		-0.5	-1.5, 0.6	
DSD	2.5 (2.5)	22	2.4	-0.02, 4.7	22	2.3	0.8, 3.8		-0.0	-1.8, 1.8	
WL	3.9 (3.4)	23	-0.8	-1.7, 0.1	-	-	-		-	-	
<i>Wellbeing/800</i>								.130			.319
TTT	525.1 (150.0)	17	93.0	38.2, 147.8	17	95.9	19.1, 172.8		5.0	-62.3, 72.3	
DSD	486.0 (137.8)	22	66.8	30.1, 103.6	22	62.2	17.0, 107.4		-4.6	-40.7, 31.5	

WL	535.9 (183.4)	18	-38.7	-114.3, 37.0	-	-	-		-	-	
<i>Depression/16</i>								.285			.486
TTT	10.3 (2.7)	20	-1.9	-3.0, -0.7	22	-1.6	-2.8, -0.3		0.1	-1.0, 1.3	
DSD	10.4 (2.6)	22	0.4	-0.7, 1.5	22	-1.0	-3.3, 1.4		-1.4	-3.4, 0.7	
WL	10.5 (3.0)	22	0.5	-0.9, 1.8	-	-	-		-	-	
<i>Anxiety/16</i>								.132			.857
TTT	9.0 (2.3)	20	-1.0	-2.1, 0.1	22	-0.9	-2.2, 0.5		-0.1	-1.0, 0.8	
DSD	10.7 (2.2)	22	0.1	1.1, 1.4	22	-1.2	-2.9, 0.5		-1.4	-2.9, 0.1	
WL	9.7 (2.6)	22	0.2	-1.3, 1.8	-	-	-		-	-	
<i>Habits/1200</i>								.055			.597
TTT	694.0 (150.6)	20	208.3	142.9, 273.7	21	141.1	54.4, 227.7		-33.1	-106.2, 40.0	
DSD	656.9 (140.3)	22	65.5	-1.7, 132.7	22	72.3	15.7, 128.9		6.8	-51.9, 65.5	
WL	714.5 (171.3)	22	10.9	-48.7, 70.5	-	-	-		-	-	
<i>Openness to change/800</i>								.159			.455
TTT	550.0 (114.2)	21	52.4	7.2, 97.5	21	66.6	10.5, 122.6		16.7	-12.9, 46.4	
DSD	484.5 (123.6)	25	66.5	19.3, 113.7	22	58.8	16.6, 100.9		-7.8	-42.4, 26.8	
WL	542.8 (125.9)	22	-14.4	-55.5, 26.8	-	-	-		-	-	

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; WL = Waitlist; PI = Post-Intervention; SD= Standard Deviation; CI = Confidence Interval; kg = kilogram; cm = centimeter; hr = hours; Vege = vegetables.

*Number reflects number of participants who completed assessment or questionnaire and not reflective of number of participants in the study.

Chapter 5

Study 3: Qualitative interviews

“Courage is to tell the story of who you are with your whole heart.”

- Berne Brown

This chapter consist of the paper entitled *“Participant experiences of two successful habit-based weight loss interventions in Australia: a qualitative study”*. This manuscript is currently under review by the British Medical Journal Open (BMJ Open).

Authors: Gina Cleo, Jolyn Hersch, Rae Thomas.

Additional methodology is presented in the Supplementary material

Abstract

Objectives: Habit-based weight loss interventions have shown significant weight loss results and superior long-term weight loss maintenance compared with most diet and exercise interventions. Understanding why habit-based interventions work is therefore of great value, but there is little qualitative evidence about the experiences of participants in such programs. We explored the perspectives of individuals who completed two habit-based weight-management programs, Ten Top Tips and Do Something Different.

Design: One-on-one, face-to-face, semi-structured interviews were conducted and analysed thematically.

Setting: Participants from the community were interviewed at Bond University, Australia.

Participants: Using a maximum variation design we recruited 15 participants (8 men, 7 women) aged 39-69 years (Mean 53.3 years, SD 10.3) with a range of education levels (no high school to university degree) and percentage weight change on the programs (+4.0% to -10.4%).

Main outcome measures: 1) The general experience of participants who completed the Ten Top Tips or Do Something Different intervention, b) whether and how the interventions affected the participants' lifestyle post-intervention, and c) participants' views regarding the acceptability and practical application of Ten Top Tips and Do Something Different.

Results: Participants reported positive experiences of the two programs, both during and after the interventions. Participants particularly enjoyed the novelty of the interventions as they shifted focus from diet and exercise, to practical everyday habit changes. They also reported indirect health benefits such as increased energy levels, increased confidence and improved self-awareness. Accountability throughout the program and convenience of the interventions were identified as key themes and facilitators for weight loss success.

Conclusions: This study offers insight into how and why habit-based interventions might work. Overall, Ten Top Tips and Do Something Different are practical and convenient to implement, and are viewed favourably by participants when compared with conventional lifestyle programs for weight control.

Introduction

The global prevalence of obesity has risen dramatically over the past three decades with more than a third of adults currently classified as overweight or obese ¹. Many weight-management interventions are successful in helping individuals lose weight, however maintaining weight loss is rare ². As time passes after weight loss, individuals start disengaging from weight-management programs, reengaging old habits and impairing any progress they had made whilst following the recommendations ³.

Habits are automatic behavioural responses to environmental cues. When a new behaviour is performed, a mental association between context and behaviour is created ⁴. As behaviour is repeated in the same context, regulation of the behaviour gradually shifts from being internally guided (e.g., beliefs, attitudes, intentions) to being triggered by situational or contextual cues, making alternative behaviours less accessible ⁵. Habits, therefore, almost always override intention ^{6, 7}. Habit-change is an important goal for behaviour change interventions as habitual behaviours are elicited automatically, with minimal prior deliberation and are therefore likely to be maintained ⁸. Furthermore, breaking habits, increases an individual's mindful actions as they engage in conscious and purposeful thought ⁹. Mindfulness is suggested to draw attention to the behaviour, making it easier to recognise compliance with health-related goals and disengage in inimical habits ⁴.

Despite the promising outcomes of habit-based weight loss interventions, it is a new and evolving area of investigation and therefore little research is currently available, especially qualitative work. Understanding and evaluating the influences of change and the general experiences of participants on habit-based weight loss interventions is important to help inform future interventions in this novel and emerging field.

Recently, we conducted a randomised controlled trial of two habit-based weight loss interventions which focus on forming new healthy habits and/or breaking old unhealthy habits ¹⁰. Our trial explored the quantitative effects of two habit-based weight loss interventions: Ten Top Tips (TTT) ¹¹ and Do Something Different (DSD) ¹², compared against a waitlist control. These data show significant weight loss results (Adjusted mean difference post-intervention: TTT – WL -2.9kg, $P = <0.001$; DSD – WL -2.3kg, $P = <0.001$) with promising long-term (12-months) weight loss maintenance for both interventions (Total mean change: TTT -5.7kg [95% CI -0.8, -3.3]; DSD -4.6kg [95% CI -6.6, -2.6]) ^{10, 13}. The objectives of the present qualitative study were to a) explore the general experience of participants who had completed the TTT or DSD intervention, b) discover whether and how the interventions affected the participants'

lifestyle post-intervention, and c) consider the participants' views regarding the acceptability and practical application of TTT and DSD.

Methods

The research team

Using the COREQ checklist (COnsolidated criteria for REporting Qualitative research) for reporting qualitative research¹⁴ we report the research team has expertise across: dietetics (GC), psychology (RT, JH) and qualitative research (JH, RT) and (GC, RT) have previously published on habit-change interventions¹³. The primary researcher (GC) is an accredited practicing dietitian and engaged in full time research in the area of habit-change for weight loss maintenance (S1 Table).

Participants

Participants for this qualitative study were recruited via invitation from a randomised controlled trial of habit-based weight-management interventions¹⁰ (Trial registry details: www.anzctr.org.au Identifier: ACTRN12615000114549). Participants were eligible for the trial if they had overweight or obesity as per BMI classification $\geq 25\text{kg/m}^2$, were aged 18-75 years and had no clinical contraindications to participate in the study. They were randomly assigned to either TTT ($n= 25$) or DSD ($n= 25$) interventions, or to a waitlist control ($n= 25$); control group participants were not recruited for this qualitative study). Interventions were conducted for 12 weeks, after which post-assessment measures were undertaken. Participants were followed-up 6 and 12 months post-intervention to collect anthropometric and psychometric outcome data.

Interventions

Detailed descriptions of TTT and DSD are reported elsewhere¹⁰. In brief, TTT is based on habit formation theory. Written materials guided participants through a set of weight-management behaviours to be performed routinely with intent to make those behaviours habitual. For example, participants were recommended to keep to a meal routine, eat from a smaller plate, eat mindfully and pack a healthy snack¹¹ (www.weightconcern.org.uk/tentoptips). A key component of TTT is repeating the behaviour in a consistent context (e.g. time or place). A logbook ('tick-sheet') was provided to participants for daily self-monitoring¹⁵.

In contrast, DSD focuses on increasing the participants' behavioural flexibility by breaking daily habits. The aim of DSD is to break the distal habits proposed to play a role in unhealthy dietary and exercise behaviours^{16, 17}. DSD required participants to engage in novel activities to expand their behavioural repertoire. Interestingly, these activities often did not relate to food or exercise. For example, tasks included 'listen to a different genre of music today', 'call a long-lost friend or relative' and 'spend 15 minutes writing a short story' (www.dsd.me)⁹. The tasks were sent via text message and/or email 3-4 days per week and a program-specific online platform was used for self-monitoring adherence.

To promote accountability and help reduce attrition, participants in both TTT and DSD interventions received a weekly phone call from GC. Phone calls commenced with an open-ended question, "How have you managed on the program this week?" which was designed to open up discussion regarding the barriers and facilitators of program adherence. Problem solving strategies were discussed as necessary. Participants were encouraged to record a food diary for self-monitoring purposes.

Qualitative interview study

We conducted purposeful maximum variation sampling¹⁸ to recruit participants from both active intervention groups, multiple age groups, education levels, a variety of percentage weight change (loss and gain), and different genders. These variations were selected based on recent research showing age, education level and weight loss success affects perceived barriers to weight loss programs¹⁹. An invitation was sent via email to potential participants based on their demographic and 12-week post-intervention weight change data. The email included the aim of the interview and the nature of the questions to be asked. Participants then replied with an acceptance or decline to participate in the qualitative study. The interviews were conducted 6 months after the interventions concluded, during the participant's scheduled follow-up appointment with GC. There had been no contact between participants and researchers during this time.

Interview schedule and procedure

The interview schedule was iteratively developed, using the study objectives, by GC, RT and an independent external qualitative methodologist with expertise in weight-management research (DR). The interview questions were piloted within the team, and refined accordingly,

prior to participant recruitment. The full interview schedule is included in the Supplementary material (S2 Table).

Participation in the interviews was entirely voluntary and written informed consent was obtained prior to the interviews. Additionally, participants provided verbal consent prior to the commencement of the interviews. Semi-structured, one-on-one, face-to-face interviews were conducted with each participant by the principal researcher (GC) and lasted 35-60 minutes. Interviews were audio-recorded, transcribed verbatim, checked, anonymised and corrected against the audio file by GC. The participants were encouraged to engage in in-depth discussions during the interview. No field notes were taken during the interview as to not distract the interviewee as well as to maintain an easy flow of conversation and casual atmosphere to the session. A \$20 gift card was given to participants as an honorarium for their participation in the interview.

Data capture, coding and analysis

This study examined the experiential knowledge of participants. Drawing from the theoretical framework, we used a phenomenology approach to understand the “constructs, concepts or ideas people use in everyday life to make sense of their world”²⁰. The method of thematic analysis was based on an inductive approach which directly draws codes, categories or themes from the data²¹.

Interview audio recordings were transcribed in encrypted Microsoft Word documents and qualitative data were extracted to Microsoft Excel. First, GC read the data carefully to identify meaningful units of text relevant to the study objectives. Second, units of text dealing with the same content were grouped together in analytic categories and given provisional definitions. The same content of text could be included in more than one category. Third, the data were systematically reviewed to ensure that a name, definition, and exhaustive set of data to support each category were identified. The coherence and replicability of the themes were verified by an independent researcher (RS), who recoded the entire set of transcripts. Indexing and coding of themes were discussed with an external qualitative researcher (SS) and reviewed by JH.

The primary researcher (GC) was closely engaged with the research process and the participants and conducted the original RCT study. Potential personal and analytical biases were acknowledged and addressed by reflexive commentary and a reflexive diary maintained

during the analytical stages, as a measure of quality assurance ^{14, 22}. The participant quotes presented in the results section exemplify the themes described.

Results

Participant characteristics

Of the 16 potential participants invited to join the qualitative study, one was unable to participate due to unrelated ill health and hospitalisation (TTT group). Fifteen participants (8 men, 7 women), aged 39-69 years (Mean 53.3 years, SD 10.3) were recruited and interviewed. Education level ranged from incomplete high school to university degree, and percentage weight change on the programs ranged from +4.0% to -10.4% which represented the full spectrum of weight change observed in the trial (Table 5.1). Mean values of participant characteristics per intervention are displayed in S3 Table.

Table 5.1 Participant characteristics

Code	Gender	Age, years	Education level	Weight change during program, %
TTT				
T1	Male	55	High school	+4.0
T2	Female	69	High school	-3.7
T3	Female	42	University	-4.2
T4	Male	62	Did not complete school	-6.2
T5	Male	39	University	-7.0
T6	Male	54	University	-9.8
T7	Female	50	University	-10.4
DSD				
D1	Male	39	University	-0.9
D2	Male	41	High school	-1.2
D3	Female	49	University	-2.3
D4	Female	56	University	-3.7
D5	Female	64	High school	-4.3
D6	Female	60	High school	-5.0
D7	Male	55	High school	-5.0
D8	Male	65	High school	-10.4

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different

Theme identification and common themes

Our inductive thematic analysis resulted in 84 categories, which were grouped into five key themes relating to the participants' experience of either DSD or TTT interventions (S5 Table). Themes we can construe which have the potential to inform future iterations of these

interventions include: (i) novelty of interventions and outcomes; (ii) convenience and practicality; (iii) indirect health benefits and wellness; (iv) accountability; and (v) sustainable behavior change.

Novelty of interventions and outcomes

Lifestyle weight loss interventions typically include some form of dietary restriction and/or a structured exercise regimen. Participants in both TTT and DSD interventions typically had previous experience with ‘diets’ and expressed dislike of these due to their restrictive nature and short-term weight loss. Participants reported that, in contrast, continuing with the TTT and DSD interventions was manageable long-term as it was a lifestyle change rather than just a quick-fix diet regimen.

“I’ve really tried everything that’s been going... Ten Top Tips is more how to fit in a normal lifestyle where you can still live and eat and go out and live what I think is a relatively normal life, you can fit those into your lifestyle and even still have a social life...with the other diets you are much more restricted.” [T7]

“The point of difference with this program compared to others it’s really changing your life and not putting an end-date on it. It’s really more than a weight loss program; it’s almost like a lifestyle program.” [T5]

DSD participants particularly valued the novelty this program offered, especially the lack of dietary restriction and sustained weight loss.

“It is so different! It’s not your usual diet and exercise program it’s something that moves you to thinking differently, not even just consciously but unconsciously.” [D7]

“All the other diets I’ve done drove me crazy, I was hungry and I always put the weight back on. I haven’t put any weight back on with Do Something Different, I was also never hungry.” [D5]

Convenience and practicality

Weight loss programs produce better results when they are convenient and practical to implement in daily life ²³. The convenience and practicality of both DSD and TTT were a frequent theme in participants’ reflections on the interventions.

“The intervention fits in to my lifestyle and daily habits and routines as it’s similar to my lifestyle.” [T6]

“I hardly felt it [the intervention] to be honest, it was just so practical.” [D3]

These were intentional features of both interventions^{11, 12}. Behaviour change research shows that small and simple tasks can lead to quicker and more successful behaviour changes than more complex tasks⁴. Therefore, an intervention which fits into an individual’s lifestyle, such as TTT and DSD, demands only small changes and consequently is easier to both implement and sustain.

“It’s not like this whole big weight loss program it’s just really good habits to get into that you can incorporate into your life without making huge changes. I think the tips fit in really well with a normal lifestyle so it doesn’t take a lot to be able to put them into practice.” [T7]

Participants in DSD particularly reported on the method of delivery, stating the text message they received (which enclosed a task for them to complete) was non-obtrusive and convenient. We speculate that the practicality of the intervention also enabled long-term behaviour change.

“I still try to do things differently, I’m still more aware of my eating and my exercise, I’ve changed the way I see things.” [D4]

Behaviour change achievements, however small, can increase self-efficacy, which can in turn stimulate the pursuit of further positive changes²⁴.

Indirect health benefits and wellness

Rothman et al. (2009) argued that people with high optimism may be able to switch their focus and priorities on the improvements they experience in different domains to their original outcome goal²⁵. For example, if a healthy change in diet and exercise does not produce the desired weight loss, an individual may focus on their improved wellbeing or increased energy levels. Participants in the present study were impressed by the indirect ‘ripple effect’ of health benefits they experienced beyond just weight loss.

“If you take the weight loss side out of it for me, you feel better, sleep better, feel alert, feeling fitter and being about to do more, those benefits are great too even if you don’t

lose as much weight, I mean I didn't lose as much as I would have liked, but the benefits of this program have been excellent in other areas as well.” [T5]

“I find I'm walking and socialising a bit more. I prioritise things differently now [healthy eating and exercising]. I feel clearer in the head and I have more energy”. [D2]

Studies show that the greater an individual's repertoire of behaviour, the happier they feel ¹⁶, ¹⁷. This was especially evident amongst DSD participants who reported the program improved creativity, triggered imagination and was beneficial to mental health.

“The program made me think more and made me more aware of all the things that you do have to do to make a lifestyle change. I actually started looking for more things to do other than what you were texting. I would create little games that would get me out of my routine.” [D7]

In addition to this main theme, a sub-theme identified was 'self-belief'. Participants repeatedly reported the interventions were enjoyable, supportive and promoted empowerment, self-awareness, self-confidence and self-efficacy. DSD participants particularly reported the intervention increased confidence, especially when out of their comfort zone. The intervention's aim was to break habits by interfering with an individual's habitual behaviours and suggesting tasks often outside their normal routine. Interestingly the participants felt they gained a great deal of confidence by participating in these tasks.

“I'd think 'yeah I can be into that', 'I can do that' or 'I can try that', 'I can do a 10 kilometre walk'. Before the program I wouldn't even think about it, I'd think 'well this won't happen'.” [D8]

Accountability

A major theme that emerged was the participants' sense of accountability throughout the active intervention period; this included accountability to the researcher, the study, and in the TTT group, to the logbook.

A recent qualitative exploration into the facilitators and barriers of weight loss and weight loss maintenance revealed that accountability to others was a key factor of successful weight-management ²⁶. Lack of accountability to someone (including researchers) and an absence of

support from others were commonly reported as barriers to achieving weight loss and weight loss maintenance ²⁶.

“You took an interest; it was like someone participating with you rather than just yourself. You know, a phone call is pretty personal”. [D8]

“Having that someone to check in with you, you feel sort of responsible to them as well to do a good job.” [D1]

The presence of a perceived support person has been described as a key component to the weight loss interventions, motivating participants to achieve weight loss ²⁶. In the current study, participants did not describe self-accountability.

“I have no self-discipline. If I was left to my own devices and I hadn’t come here I know that I would not have lost weight.” [D5]

“When there’s someone there counting on you to do it, it gets you through whereas when no one’s interested you think well it doesn’t matter it’s just me.” [T3]

One participant felt a fear of judgment if they had not achieved any weight loss at the follow-up appointment.

“The fact that I have to face somebody, and when I face them while they may not be like ‘oh why have you put on [weight] this week or why have you not lost more than 0.2 kilo’s this week’ I feel like that’s what their opinion is going to be, so it makes it easier to try hard to do what I’m supposed to do or to do the right thing or to make the right choices because I know I’ve got to face them, and I don’t want to face them and the scale’s gone up.” [T2]

A sense of accountability to the programs and to the study was reported.

“Knowing that I had a number of tasks to do each week kept me focused.” [T4]

“Being on the program gave me a reason to focus on losing weight. I felt somewhat accountable to the results.” [T3]

Interestingly, health-promoting actions which are extrinsically motivated (i.e., satisfy external demands, comply with instructions or avoid punishments) are theoretically less likely to be sustained than actions pursued due to genuine personal interest (i.e., intrinsic motivation) ²⁷. Therefore, intervention developers are encouraged to promote behaviours in a way that

encourage people to internalise the need and desire for change, therefore prompting self-determined, rather than compliant behaviour change²⁸.

Participants in the TTT intervention also reported feeling a sense of responsibility and accountability to the logbook (where participants ticked-off when they had successfully completed a task). The logbook was a physical representation of the participants' compliance with the program. They were required to complete ten tasks each day and according to participant reports, the more ticks they marked in the logbook, the greater the sense of achievement they would feel.

"The logbook always reminds you all the time, like you have to be on track you can't just not worry about it." [T1]

"Eventually as the tips sunk in and it got better and then you started feeling much better when you could tick off all the boxes." [T2]

Feelings of satisfaction are important in maintaining new behaviours as they validate the initial decision to change behaviour²⁹. Once a novel behaviour has been initiated, self-monitoring draws attention to this behaviour making it easier to recognise compliance and achievement of behavioural goals^{4,30}.

Sustainable behaviour change

Habits are formed by repeating a behaviour until it becomes automatic⁵. Once a habit is established, the behaviour is performed unconsciously, without reflection, deliberation, or awareness¹³. When healthy diet and exercise habits are formed, a healthy weight and lifestyle are easier to maintain³¹. Participants emphasized the long-term nature of their sustained results in areas including behaviour change, weight loss and awareness.

A frequent report from TTT participants was that with time, the tasks became automatic and habitual. DSD participants reported since breaking old habits whilst on the program, weight loss maintenance has been achievable.

"I've really got in to those good habits now and I find it easy. It's automatic. The tips are just in my head." [T1]

"Everything about weight loss before has been strictly about food, nothing about changing habits. I'd just go off the program and just pile the weight back on because of old habits but I've maintained my weight loss since Do Something Different." [D6]

Habit change, however, can be challenging, especially in the initial stages before a person has reached automaticity. A persistent level of conscious thought is required to perform a new behaviour each day to establish a habit; this can be exhausting and discouraging. Participants reported that changing their habits was uncomfortable to start.

"At first some of the tips were really hard and I was like 'I can't do it, I can't do it', but some of the easy ones I focused on and I thought right I'll master the easy ones and try for the harder ones as often as I can and I guess most of those got easier as well over the twelve weeks." [T3]

Therefore, it's important to reassure weight-management clients that performing a new behaviour will progressively get easier as automaticity of that behaviour strengthens. Hence, maintaining motivation to consistently perform the new behaviour is only necessary until the habit forms and the new behaviour becomes 'second nature'³¹.

Discussion

We have previously shown in a randomised controlled trial that TTT and DSD interventions achieved significant weight reductions and importantly, weight loss maintenance from pre- to post-intervention and post-intervention to 12-month follow up¹⁰. In this qualitative study, we explored the participants' experiences of these two habit-based weight loss programs 6 months after intervention completion. Five key themes emerged, relevant to the implementation of the interventions, influencers of change and general experience of the participants. These were: (i) novelty of interventions and outcomes, (ii) convenience and practicality, (iii) indirect health benefits and wellness, (iv) accountability and (v) sustainable behavior change.

The major point of difference between conventional weight-management programs and TTT and DSD is that these programs do not focus solely on diet and exercise but follow a habit-based approach. This is novel and participants reported feeling less constrained than with other weight loss programs because they could continue most aspects of their current lifestyle and still enjoy a social life which they valued. This point was emphasised during the interviews

and contributed to participants continuing with the program recommendations even after the interventions had concluded. The novelty of these programs potentially contributed to maintaining new habits which consequently may have resulted in continued and sustained weight loss.

Changes that are small and easy to manage are easy to maintain, convenient and often practical. TTT and DSD participants valued the ease and enjoyed the small changes that were a feature of both programs. TTT participants valued creating new habits through repetition of ten tips and DSD participants valued the changes made to their routines by doing different tasks. They all reported the interventions fit easily into their normal lifestyle and daily routines. Current weight-management programs often require grand and ambitious changes (e.g., calorie counting, eliminating food groups, vigorous exercise regimens, etc.), but when developing future programs, consideration should be afforded to encouraging small and subtle changes as these have been shown to produce successful and sustainable change^{31,32}.

The indirect 'ripple effect' of health benefits that participants experienced on the programs was a key theme. Better sleep, increased energy and alertness, increased wellbeing, increased confidence and feeling encouraged to exercise were all benefits that participants reported having gained from the programs independent of how much weight they lost. These indirect benefits are valued by individuals but often over looked by clinicians when discussing weight loss programs with their clients. Given small weight losses correlate with reduced risk for cardiovascular disease, type II diabetes and certain cancers³³, it may be beneficial for clinicians to highlight the indirect benefits of participation in a program to encourage or help motivate individuals to participate. For example, drinking less alcohol improves sleep and general wellbeing³⁴, and limiting refined sugar helps balance blood sugar levels leading to increased energy levels and better concentration³⁵. A focus on tangible health benefits may be a strong motivator and a powerful strategy in behaviour change interventions.

Another motivator is accountability. Accountability is a strong facilitator to compliance to weight-management efforts and has been demonstrated extensively in previous research^{26,36,37}. In fact, just expecting to have to explain one's actions can stimulate conscious thought and alter behaviour³⁷. Our participants expressed accountability with reference to different aspects of the programs including the researcher personally, the overall study results and the TTT logbook. But they did not report self-accountability. This is curious given that all but one participant (who gained weight due to an emerging health problem) continued to lose weight after six months of no contact with the researchers or the programs.

Accountability to study investigators was perceived as a key component of the TTT and DSD interventions, motivating and supporting participants to achieve weight loss. Previous research has shown that without an individual (i.e. study investigator or clinician) monitoring their progress, participants perceived a drastic drop in motivation for weight loss maintenance²⁶. Because our participants continued to lose weight while not actively enrolled in the intervention, this seems not to be the case. Participants did know that the researchers would contact them in 6 and 12 months to assess progress, but due to the significant time delay between intervention completion and these time points, it is unlikely these drop-in sessions were enough accountability to motivate weight loss maintenance. Unlike other weight loss programs, TTT and DSD were founded on habit-based theory; participants engaged in behaviours designed to become 'second nature', which therefore are sustainable long-term. This may explain their continued weight loss without regular external monitoring or accountability. We hypothesize that weekly monitoring may have improved retention, however, further research is required to make such conclusions.

Intervention comparison

Despite participants in both interventions achieving similar quantitative outcomes at post-intervention and 12-month follow-up¹⁰, participants expressed some differences in their perceptions at the 6-month interview. TTT participants expressed a sense of accountability to the logbook whereas DSD participants did not report accountability to the online platform used to self-monitor their progress. TTT participants may have felt more engaged with the logbook because of the frequency of tasks and the physical representation of their compliance when the logbook was completed. TTT involved daily engagement of ten individual tasks with daily self-monitoring, whereas DSD involved only 3-4 tasks a week.

Another difference between the interventions was that DSD participants reported an increase in confidence post-intervention, especially when out of their comfort zone; TTT participants did not report a change in confidence. This could be due to the nature of tasks on the DSD program which explicitly encouraged participants to increase their behavioural repertoire and perform tasks out of their comfort zone. Therefore, feeling the discomfort of performing a novel task was well-practised amongst DSD participants; whereas TTT participants repeatedly performed the same tasks each day.

Lastly, participants in the two programs differed somewhat in the way they described automaticity. TTT participants experienced automaticity of some of their new behaviours. DSD

participants made the conscious decision to continue to do something different. This could be due to the repetitive nature of the TTT program; repetition creates automaticity of that behaviour.

Strengths and limitations

This study offers insight into how and why habit-based interventions might work and builds on previous research in the area⁸. The findings generated some practical recommendations for effective proportion of healthy habits and weight loss maintenance; for example:

recommending small changes, the importance of external accountability and the lack of need for restrictive diet regimens.

Qualitative methods can provide rich and diverse data that is not obtainable through quantitative means, and semi-structured interviews were ideal to explore participants' in-depth lived experiences of the interventions. Using purposeful maximum variation sampling to select the participants potentially allowed for heterogeneous responses across a diverse range of participants from varied ages, education levels, genders and extent of weight change on the programs. Two experienced researchers independently analysed the data and agreed on the themes and subthemes. This achieved data trustworthiness and ensured no common themes were missed. Importantly, our qualitative data supported the quantitative findings of our RCT¹⁰. For example, the participants' comments on sustained behaviour change aligns with their continued weight loss at follow-up.

As in all lifestyle intervention studies, participation in the RCT was voluntary and this may mean our participants were more motivated to lose weight than community members who chose not to participate. This would likely have resulted in improved outcomes for study participants in comparison to unmotivated individuals in the community. However, our purpose in this qualitative study was to understand the experiences of individuals who do take part in a structured weight management program, and we used a maximum variation method to select participants. Therefore, we have broad and varied experiences of individuals from the two programs from which to draw conclusions. It is possible participants felt grateful to GC for the weekly phone calls throughout the intervention and therefore may have wanted to say positive things about the program. The research team discussed this limitation prior to the study commencing and attempted to address it by explicitly asking for burdens of implementation, e.g., "*what was the lowlight of the program?*" and "*were there any tasks you found particularly difficult on the program?*". Participants were also given the opportunity to provide any feedback or comments on how they thought the programs could be improved.

Conclusions

The themes generated in this qualitative analysis show that participants in two different habit-based weight loss interventions had overall positive experiences whilst on the programs and continued to report self-perceived benefits long after the interventions had concluded. In our studies, most participants in TTT and DSD achieved clinically significant weight loss during the 12-week programs and weight loss maintenance over 6 to 12 months¹⁰. Participants in these qualitative interviews reported that the habit-based intervention strategies were simple and practical to implement and maintain in daily life and therefore compared favourably to typical lifestyle programs for weight control.

Considerations for future interventions:

- Include strategies for sustainable behaviour modifications which allow participants to live close to their current lifestyle by recommending small, manageable changes.
- Interventions should be convenient and practical to implement in daily life, taking into consideration a person's work, family and other commitments.
- Highlight indirect health benefits to the program such as better sleep, improved general wellbeing, increased confidence and increased energy levels.
- Incorporate external accountability strategies in the form of a support person and tangible self-monitoring tools.

Ethics: Ethics approval was obtained from the Bond University Human Research Ethics Committee (RO1888B).

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Author contributions: GC and RT conceived the trial. GC conducted and analysed the interviews. GC wrote the first draft of the manuscript and JH and RT provided extensive feedback and contributed to the final paper.

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Transparency declaration: The lead author, Gina Cleo, affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered, have been explained.

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Supplementary material for Chapter 5

Table S5.1 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Table S5.2 Interview schedule and inquiry logic for semi-structured interviews

Table S5.3 Mean value of participant characteristics per intervention

Table S5.4 Characteristics of participant sample

Table S5.5 Complete list of themes and codes developed from interview data

Table S5.6 Themes and additional examples of responses

Figure S5.1 Conceptual map of themes and codes developed from interview data

File S5.1 Qualitative interviews additional methodology

Supplementary Table 5.1 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Topic and Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Gina Cleo
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Gina Cleo, MNutrDiet (Hons), APD, PhD Scholar Jolyn Hersch, BLibStud (Hons), MAppSc (Hlth Psych), PhD Rae Thomas, Bed, Grad Dip Couns Psych, PhD
3. Occupation	What was their occupation at the time of the study?	Dietitian, PhD scholar, Teaching fellow
4. Gender	Was the researcher male or female?	Female
5. Experience and training	What experience or training did the researcher have?	The researcher gathered data in face-to-face interviews at Griffith University prior to this study in 2008. She has also worked in clinical practice where in-depth data collection is required
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	GC implemented the weight loss intervention with the participants prior to the qualitative interviews. The interventions ran for 9-12 weeks, 6 months prior to the interviews
7. Participant knowledge of the interviewer	What did the participants know about the researcher? <i>e.g. personal goals, reasons for doing the research</i>	Participants were provided with an information sheet and consent form which outlined the aim of the study
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? <i>e.g. Bias, assumptions, reasons and interests in the research topic</i>	Participants knew the researcher was a dietitian and PhD scholar with an interest in weight loss maintenance
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse analysis,</i>	Thematic analysis

ethnography, phenomenology, content analysis

Participant selection

10. Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	Purposive maximum variance
11. Method of approach	How were participants approached? <i>e.g. face-to-face, telephone, mail, email</i>	Face-to-face
12. Sample size	How many participants were in the study?	16
13. Non-participation	How many people refused to participate or dropped out? Reasons?	1, due to illness

Setting

14. Setting of data collection	Where was the data collected? <i>e.g. home, clinic, workplace</i>	Bond University clinic room
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? <i>e.g. demographic data, date</i>	Gender, age, education level and weight percentage change during the program

Data collection

17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes, participants were asked to reflect on their personal experience of the respective program. The questions were pilot tested amongst work colleagues
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Data were audio recorded using a digital recorder
20. Field notes	Were field notes made during and/or after the interview or focus group?	No
21. Duration	What was the duration of the interviews or focus group?	Ranged between 35-60 minutes
22. Data saturation	Was data saturation discussed?	Yes
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No

Domain 3: analysis and findings

Data analysis

24. Number of data coders	How many data coders coded the data?	2
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25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes (Supplementary Table 5.5 and Figure 5.1)
26. Derivation of themes	Were themes identified in advance or derived from the data?	Themes were derived from the data
27. Software	What software, if applicable, was used to manage the data?	Data were transcribed verbatim into Word documents by GC, and grouped by cutting and pasting between documents
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? <i>e.g. participant number</i>	Yes
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Supplementary Table 5.2 Interview schedule and inquiry logic for semi-structured interviews

Objective	Question	Example prompts
Explore the general experience of participants who had completed the TTT or DSD intervention	You were on the TTT/DSD program for 12 weeks, what was that experience like for you?	What was it about the program that gave you that experience? xxxx sounds like it was most useful to you, why do you think that was?
	How useful did you find the tick sheet/text messages/weekly phone calls?	
	Did you experience a highlight on the program?	What was it and why was it a highlight?
	Did you experience a lowlight on the program?	What was it and why was it a lowlight?
	Making lifestyle changes can be quite challenging. Was there anything you did (either from your own initiative or from the program) that helped you through some of those challenges?	How did that help you stay on track?
	Do you have any further feedback or comments on the program?	
Discover whether the interventions affected the participants lifestyle post-intervention	Since you completed the program is there anything that you have carried on doing?	Why do you think you have kept doing them? Why have you not carried on with some of the other recommendations?

Consider the acceptability and practical application of TTT and DSD

How easy or hard was it to follow and understand the instructions?

Is there anything you feel could have been done to make the instructions easier?

How practical was this program to implement in your daily life?

Why was it practical/impractical?

Were there any tips or tasks you found particularly easy on the program?

Why were they easy for you?

Were there any tips or tasks you found particular difficult on the program?

Why were they difficult for you? How could these have been made easier/more practical for you?

Often times life presents problems that make it hard to follow the program perfectly. Did you experience any of these?

What were they and how did you manage them

People who have been on weight loss programs have often tried several methods to lose weight. How did you find the program compared to other weight loss methods you've used before?

What were the similarities and differences?

Would you recommend a weight loss program like this to friends or family?

Why?/Why not?

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different

Supplementary Table 5.3 Mean value of participant characteristics per intervention

Program	Gender m/f	Age, years (SD)	Education level	% Weight change during program (SD)
TTT	4/3	53 (10.6)	1 Did not complete school	-5.3% (4.8%)
			2 Completed school	
			4 University degree	
DSD	4/4	53.5 (9.9)	0 Did not complete school	-4.1% (2.9%)
			5 Completed school	
			3 University degree	

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; m/f = male/female

Supplementary Table 5.4 Characteristics of participant sample

Attribute		<i>n</i> = 15
Gender	Male	8
	Female	7
Age	35-44 yrs	4
	45-54 yrs	3
	55-64 yrs	6
	65+ yrs	2
Education level	Did not complete school	1
	Completed school	7
	University degree	7
Weight lost on program	Gained weight	1
	0-3 kg	6
	4-7 kg	5
	8-11 kg	2
	12-15 kg	1

Abbreviations: yrs = years; kg = kilograms

Supplementary Table 5.5 Complete list of themes and codes developed from interview data

Theme	Codes
Novelty of interventions and outcomes	Novel No hunger No dietary restriction Other diets cause hunger Sense of achievement when tick sheet full Awareness to tick sheet Physically seeing is tangible accountability Dislike fad diets Not restrictive Refreshing Maintenance is point of difference from other programs Booklet is reference point Portion/scales/plates/booklet/tick sheet- physical to see Free will (not forced) Choice
Convenience and practicality	Phone call is convenient Practical to implement in daily life Text message is non-obtrusive Text message is convenient Intervention fits into lifestyle and daily habits/routines Practical to implement in daily life Easy tasks Easy change Enjoyable Easy to incorporate into lifestyle Similar to lifestyle Comfortable change Straight forward GC easy to talk to Easy to understand Simple instructions Instructional
Indirect health benefits and wellness	Indirect benefits Beneficial to mental health Personally beneficial Encouraged exercise General wellness Improved creativity Increased energy Increased wellbeing Weight loss success Triggered imagination Ripple effect Awareness Enjoyable Mindful Insightful Exciting Triggered imagination Motivated Self-confident Empowered Personal growth Personal

	Self-efficacy Supportive Increased confidence Confidence to be out of comfort zone Learning curve Anticipation
Accountability	Responsibility to GC Accountability to study Accountability to/through tick sheet Accountability to tips Meaningful accountability Enjoyed accountability Accountability to GC Fear of judgment (not losing weight)
Sustainable behaviour change	Change of habits Change of focus Lifestyle change Habits through repetition Lifestyle program Holistic approach Set focus Changed mindset Changed attitude Behavioural change Initial stages are challenging Uncomfortable to start Changing habits is challenging Manageable long term Progressively easier Long-term change Changing routines Sustained weight loss Sustained benefits Sustained awareness Sustained behaviour change

Supplementary Table 5.6 Themes and additional examples of responses

Novelty of interventions and outcomes

- I didn't see this as a diet I saw it as a way to change the way I ate and the way I behaved as far as food was concerned, it was really different but it was excellent (TTT).

- I've done so many diets. I would get bored out of my mind and the food I wanted to eat I couldn't eat. Everything is focused on what you put in your mouth whereas this was being focused on other things other than weight. On Do Something Different I wasn't forced into anything which was great (DSD).

- I've done all of it, I'm one of those yoyo dieters and I just wanted to put a stop to that. This is much more balanced than other diets I've been on (TTT).

Convenience and practicality

- Oh it was very easy to do because it wasn't a huge task (DSD).

- It was done in a really straightforward way that it didn't seem onerous (TTT).

- It doesn't impinge or interfere with your day, it's just there, you can pick it up when you want to (DSD).

- It was pretty easy to follow, it was pretty much common sense really (TTT)

Indirect health benefits and wellness

- On the program I was feeling really good. I was feeling strong and healthy (TTT).

- It has really changed the way I think, I feel more confident and started believing I can do things I didn't think I could before (DSD).

- I'm just so much more aware, I'm aware of how much beer I drink, I'm aware of what I'm eating, I'm mindful (TTT).

Accountability across contexts: personnel, program, materials

- Accountability just makes me make better decisions (TTT).

- When you've got to tell somebody what you've done it makes you think about what you're doing (DSD).

- If I had 2 days where there was no ticks it was like 'ok you're obviously forgetting about this one, you need to focus on it (TTT).

- Calling me every week was useful. I'm a person that has to be kept accountable, I can't do it myself (DSD).

Sustainable behaviour change

- I've found that doing something different helped me get back in to healthy eating rather than getting stuck in the rut of unhealthy eating and I've found it definitely easier to do that than I've found it in the past (DSD).

- I'm still doing things differently today because it's easy and enjoyable (DSD).

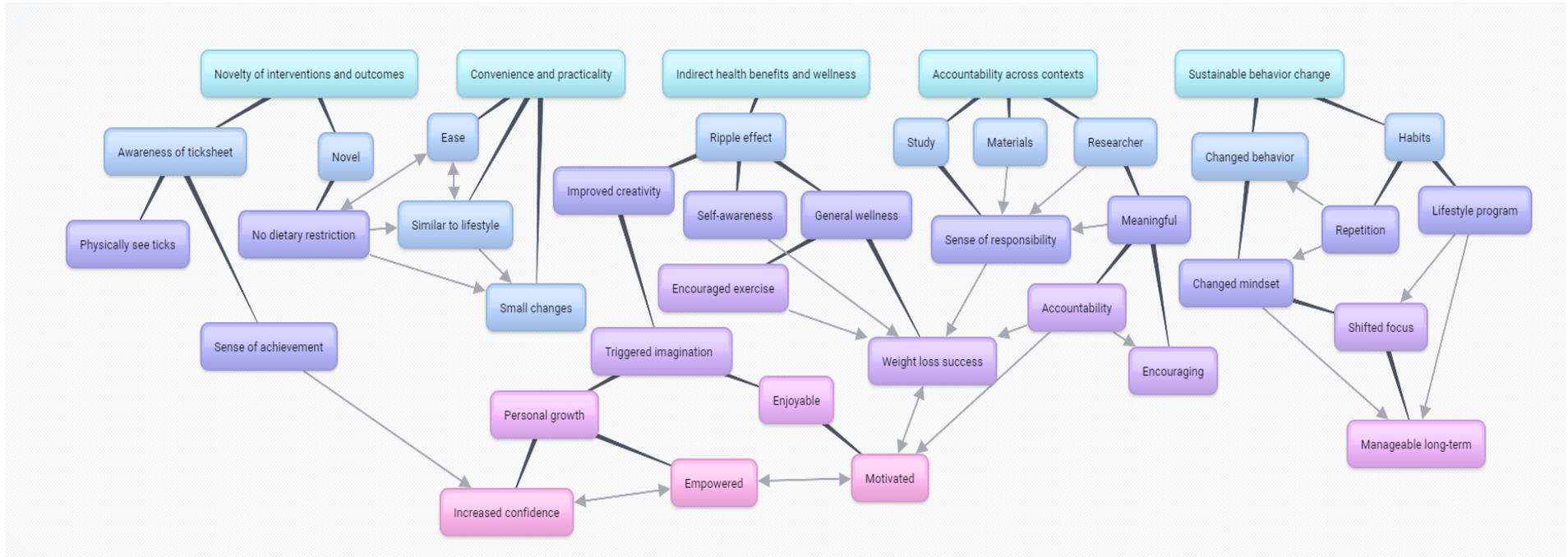
- Some of the tips are just ingrained in my mind now; I do them without even thinking about it (TTT).

- Some of the tips have just become habit now and others I do because I've realised the importance of them, they're not quite habit yet but I just know I've got to do them (TTT).

- There's no finite period, it's not just a 12 week period even though the study was over the course of 12 week it's about habit-forming for the rest of your life and that's really what weight loss is all about (TTT).

- Although targeting eating habits is a part of it, it's more so targeting your lifestyle changes which I think is what makes it more sustainable (DSD).

Supplementary Figure 5.1 Conceptual map of themes and codes developed from interview data



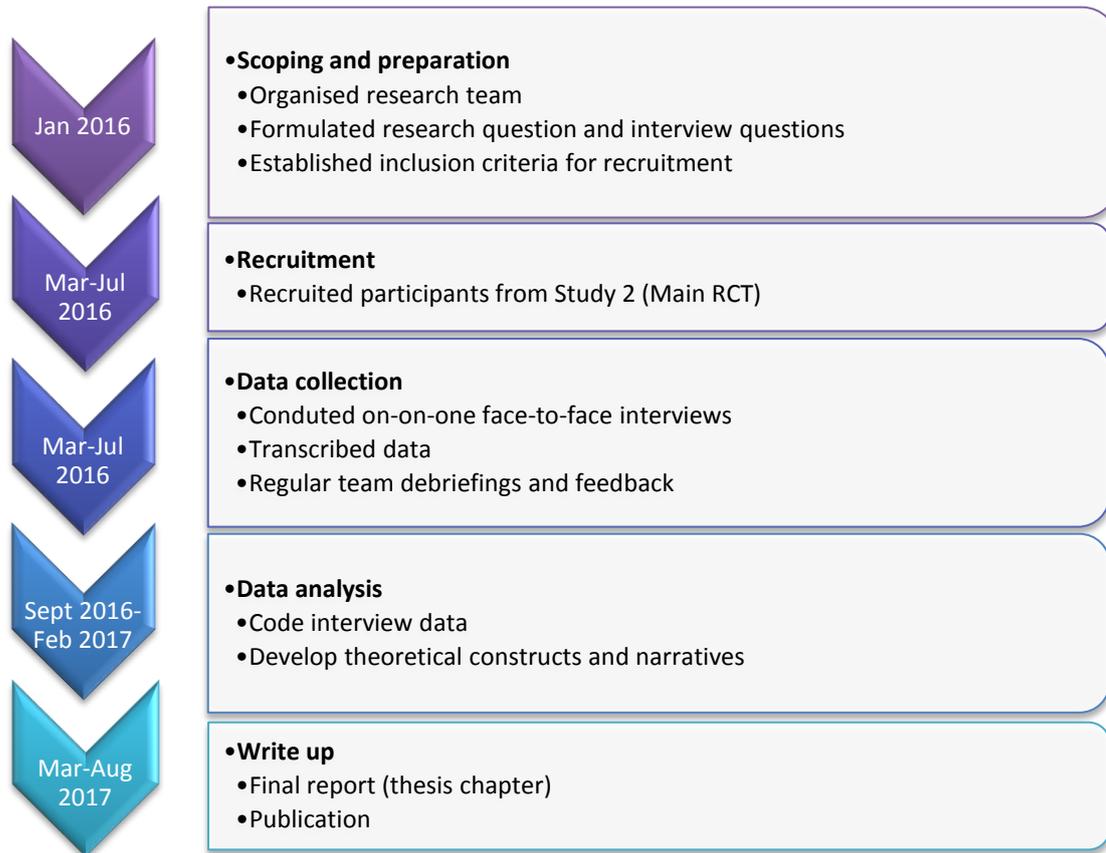
Supplementary File 5.1 Qualitative interviews additional methodology

Qualitative research explores complex phenomena by using non-quantitative methods to contribute new knowledge and to provide new perspectives in health care. The two most common methods of qualitative research for exploring patient experiences are, in-depth and semi-structured interview as well as focus group discussions¹.

For this study, qualitative interviews were selected as the preferred method of data collection as weight management is a personal experience and the researchers sought to explore the diversity of perspectives represented.

Timeline

File S1 Figure 1 displays the timeline for this study including scoping and preparation, recruitment, data collection, data analysis and finally write up. The scoping commenced in January 2016 where the lead researcher organised the research team to formulate the study aims and interview questions. Recruitment and data collection commenced in March and went through to July 2016; face-to-face interviews were also conducted and transcribed during that time. After all data were collected, analysis commenced in September 2016 and took 5 months between the two researchers (principal researcher [GC] and research assistant [RS]). Write up of the final report and publication followed straight after completion of analysis and went from March to August 2017.



File S5.1 Figure 2 Timeline of qualitative study process

The COREQ checklist

The reporting guideline this study used was the ‘Consolidated Criteria for Reporting Qualitative Studies’ (COREQ) 32-item checklist ¹. The COREQ checklist was developed to promote explicit and comprehensive reporting of qualitative studies and contains a comprehensive 32-item checklist that covers necessary components of study design, which should be reported to improve the quality of reporting. See Supplementary Table 5.1 (page 135) for the full COREQ checklist and description.

Team roles

The key research team for this study included:

Lead researcher (GC)- Dietitian, PhD scholar; identified and recruited participants, managed and conducted interviews, transcribed interviews, lead on data analysis and write-up.

Primary supervisor (RT)- Psychologist, Senior Research Fellow; assisted in formulating interview questions, overall supervision of study including regular research meetings and critically reviewed write-up.

Study advisor 1 (JH)- Psychologist, Research Fellow; advised on qualitative methodology and critically reviewed write-up.

Study advisor 2 (DR)- Dietitian, qualitative methodologist; advised on recruitment strategy, assisted in formulating interview questions and advised on data analysis methodology.

Study advisor 3 (SS)- Psychologist, qualitative methodologist; advised on data analysis methodology; assisted in searching for themes and defining and naming themes.

Research assistant (RS)- Provisional psychologist, research assistant; second data coder and data analysis.

Methods

Sample size

In qualitative research, the answer to ‘how many interviews is enough?’, is summarised by qualitative methodologists as ‘it depends’². The concept of saturation is argued to be one of the most important factors to consider when deciding on a sample size in qualitative research³. Saturation is defined as the point at which the data collection process no longer offers new or relevant data⁴. In the case of this study where the aim was to collect data from a wide range of participants and consider heterogeneous responses, the sample size was determined based on the number of participants that could be included following a maximum variation strategy; taking in to consideration, age, gender, education level and percentage weight lost on the TTT and DSD programs. This study focused on gathering an in-depth understanding of the participants’ general experience and acceptability of the programs.

Consent

Ethics approval was obtained from the Bond University Human Research Ethics Committee (Protocol Number RO1888B). Participation in the interviews was entirely voluntary and informed consent was obtained prior to the intervention. Additionally, participants provided verbal consent prior to the commencement of the interviews.

Confidentiality, anonymity and data management

The interviews conducted were audio recorded, transcribed by the principal researcher (GC) who was also the interviewer, and assigned an anonymised code to ensure the participants are not identifiable from the transcript. Names of the interviewees were not used at any stage of

the data collection process, each audio file and transcript was identified with a pre-determined interview number. Therefore the interview data were confidential and all information anonymised.

Transcripts were typed into and saved in an encrypted Word document where only the researchers involved in this study had the password to open it; the same password protected measures were put in place for participant contact details and audio files. All data collected were treated with complete confidentiality and not made accessible to any person outside of the researchers working on this project. Hard copy documents including contact forms, enrolment forms, consent forms and any other physical documentation were stored in a secured location at Bond University and will be for a period of five years in accordance with the guidelines set out by the Bond University Human Research Ethics Committee.

Bias and reflexivity

The primary researcher (GC) was closely engaged with the research process and the participants; therefore completely avoiding personal bias was not possible¹. Potential biases were acknowledged and address by epistemological and personal reflexivity.

Epistemological reflexivity: Multiple researchers were involved in the formation and refinement of the research questions and design in order to give rise to a number of different understandings of the phenomenon under investigation⁵.

Personal reflexivity: Reflexive commentary during the analytical stages was engaged by both the lead researcher and research assistant through the use of a reflexive diary, as a measure of quality assurance⁵.

Risks and benefits

The interview questions did not include sensitive information and not known to cause emotional or psychological discomfort; therefore there was minimal risk for participants.

The participants may have felt a sense of worth and pride in assisting the researchers in their evaluation of the weight loss interventions used in this study. Findings from the interviews have the potential to assist research aimed at developing successful weight loss interventions, which focuses on the maintenance of lost weight and in understanding the role of habits and eating behaviours.

The Interview process

Introduction to the interview

Information about the objective of the interview and overall study was provided to each participant verbally by the principal researcher at the commencement of the interview session. Confidentiality and anonymity was explained. The participants were then asked if he/she consented to the interview being audio recorded and transcribed for analysing purposes.

Carrying out the interview

Interviews were conducted in a private clinic room at Bond University, only the interviewer and interviewee were present during the session. Audio recording commenced as soon as the participant consented to this. The semi-structured interview schedule, (Supplementary Table 2) were available in hard copy and in easy view of the interviewer in order to guide the topics discussed during the interview. No notes were taken during the interview as to not distract the interviewee as well as to maintain an easy flow of conversation and casual atmosphere to the session.

Completion of interview and Honorarium

On completion of the interview, each participant was presented with a \$20 Coles-Myer voucher to thank them for their time and participation. Participants were aware of this honorarium as it was stated in the recruitment letter. Audio recording stopped once the participant left the interview room.

Transcription

Audio recordings were listened to carefully and transcribed into a Microsoft Word document by the principal researcher (GC) who was also the interviewer. This ensured an immersion in the data to the extent that the GC became familiar with the depth and breadth of the content.

The audio recordings were transcribed verbatim, including all hesitations, utterances, cross-talking and incomplete sentences. The transcriptions were proof-read against the audio file to check for accuracy and identify any missing or misheard words⁶. All queries and changes were made using Microsoft Word's track changes tool. A final cleaned version of the transcripts was then created for analysis.

Data analysis

We originally used a conventional content analysis approach to analyse the data as this type of analysis is most appropriate when existing theory or research literature on a phenomenon is limited ⁷. However once analysis was complete, the results seemed repetitive with little deviant themes emerging. Therefore, we conducted a thematic analysis with two individual coders (GC, RS).

We avoided using preconceived categories, instead allowing the codes and names for codes to flow from the data. The study aimed to create themes from the codes and then analyse relationships between codes ³. The primary researcher immersed themselves in the data to allow new insights to emerge ⁸, also described as inductive category development ⁷.

Data analysis occurred in 6 phases as according to Braun and Clarke ⁹:

1. Familiarising with the data
2. Generating initial codes
3. Searching for themes
4. Reviewing themes
5. Defining and naming themes
6. Producing the report

Each phase is described in more detail below.

Phase 1: Familiarising with the data

The primary researcher (GC) conducted the interviews and transcribed the data, reading and re-reading the transcripts and noting down initial ideas. Transcribing the data meant GC developed a thorough understanding and familiarisation of the data. Transcripts were also checked back against the original audio recordings for accuracy.

Phase 2: Generating initial codes

Data were read word by word by GC to derive codes by first highlighting the exact words from the text that appeared to capture first impressions, thoughts or concepts or refer to 'the most basic segment, or element, of the raw data or information that can be assessed in a meaningful way regarding the phenomenon' ¹⁰. An independent researcher (RS) repeated the coding process in order to achieve cross-checking of coding strategies. The researchers worked systematically through the entire data set, giving full and equal attention to each data item

and identified interesting aspect in the data items which had potential to form basis of repeated patterns (themes). Codes were data-driven and coded manually by writing notes on the texts being analysed and using different coloured highlighters to indicate potential patterns.

Codes were collated by each researcher to form a long list of the different codes that were identified across the data set (Supplementary Table 5). Multiple coding is considered the quantitative equivalent of “inter-rater reliability” and is a valuable strategy in creating a coding template and developing theoretical constructs and narratives¹¹.

Phase 3: Searching for themes

Provisional themes started to emerge as the researchers collated relevant codes based on how they were related and linked, into what appeared to form an overarching theme. These emergent themes were used to organise and group codes into meaningful clusters and create a coding template¹². A thematic mind-map was used as a visual representation of the themes. The researchers then began to gain a sense of the significance and the relationship between codes, themes and between different levels of themes (main overarching themes and sub-themes within them).

Phase 4: Reviewing themes

Once the researchers devised a set of preliminary themes, the themes were revised and refined with a co-investigator (SS). This process was conducted by eliminating themes that were not supported with enough data or the data were too diverse. This process ensured the data within themes cohered together meaningfully, while certifying clear and identifiable distinctions between themes.

The researchers considered the validity of the individual themes in relation to the data set, as well as whether the provisional thematic map accurately reflected the meanings evident in the data set as a whole. These themes were cross-checked with co-investigator (SS) for discussion and elaboration. No further re-coding was necessary at this stage as the themes fit together and the overall story they tell about the data become apparent.

Phase 5: Defining and naming themes

Once the researchers had a satisfactory thematic map of the data, the 'essence' of what each theme was representing was identified. A detailed analysis of each theme was conducted by two researchers (GC, RS) to identify the story that each tells and how that story fits in to the bigger message of the data in relation to the research questions.

Phase 6: Producing the report

The final phase of thematic analysis was to produce the report. This involved analytically narrating the data and making an argument in relation to the research question. The quotes presented in the results illustrate and exemplify the themes described.

File S5.1 References

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Chapter 6

Study 4: Systematic review and meta-analysis

"Science is the systematic classification of experience."

- George Henry Lewes

This chapter consists of the paper entitled "*Efficacy of habit-based weight loss interventions: a systematic review and meta-analysis*". Submission of this manuscript is pending the acceptance of the randomized controlled trial, presented in Chapter 4 of this thesis document. This manuscript will be submitted for publication to Obesity Reviews.

Authors: Gina Cleo, Elaine Beller, Paul Glasziou, Elisabeth Isenring, Rae Thomas

Abstract

Aim: Habit-based interventions are a novel and emerging strategy to help reduce excess weight in individuals with overweight or obesity. This systematic review and meta-analysis aims to determine the efficacy of habit-based interventions on weight loss and weight loss maintenance.

Methods: We identified potential studies through electronic searches in PubMed, Embase, CINAHL, Cochrane CENTRAL and Web of Science, in June 2017. Included studies were randomised /quasi randomised controlled trials comparing habit-based weight loss interventions with a control, enrolled adults with overweight or obesity ($\text{BMI} \geq 25\text{kg/m}^2$), and reported weight change. We used random effects meta-analysis using mean difference in weight loss between groups as the summary estimate. Risk of bias of included studies was assessed using the Cochrane Collaboration Risk of Bias tool.

Results: Five trials (630 participants) met our inclusion criteria. After the intervention (range 8-14 weeks) weight loss was modest but statistically different between groups (1.4kg [95% CI 0.5, 2.3; $P= 0.004$]) favouring habit-based interventions. Intervention groups averaged 2.5kg (range 1.7 to 6.7kg) weight loss compared with control 1.5kg (range 0.4 to 5.8kg) and were 2.4 times more likely to achieve clinically beneficial weight loss ($\geq 5\%$ total body weight reduction) than control participants. Meta-analysis for some outcomes had large statistical heterogeneity and all trials did not blind participants or personnel.

Conclusion: Average weight losses in adults with overweight and obesity using habit-based weight loss interventions appear to be of clinical benefit. There were statistically significant differences in weight loss between habit-based interventions and controls post-intervention. Longer studies powered to examine at least 12-months follow-up are required to accurately determine the role of habit-based interventions on long-term weight loss maintenance.

Trial registration: Prospero ID: CRD42017065589 Available from

https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017065589

Introduction

Given the increasing prevalence of overweight and obesity, and the lack of consistent long-term weight loss success^{1,2}, the scope of research to explore novel strategies for effective intervention has broadened. A synthesis and comparison of these emergent weight management strategies is essential.

There is overwhelming evidence that modest weight loss of $\geq 5\%$ reduction in body weight is associated with significant health benefits, especially when maintained over time^{3,4}. Recent studies have demonstrated the potential for habit-based interventions to positively influence health behaviours and reduce excess weight⁵⁻⁷. Habits can be impulsive reactions to a desirable stimulus (e.g., pop-corn at the cinema), or automatic reactions that were initially instigated with intention but now are performed mindlessly (e.g., eating lunch at 12:00pm)⁸. Daily eating behaviours largely consist of mindless, automatic habits⁹. Because of this, habits almost always override intention in predicting behaviour^{10,11}. Habit-change is an important goal for weight-management interventions as habitual behaviours are elicited automatically and are therefore likely to be maintained^{12,13}.

This systematic review and meta-analysis is the first to assess the efficacy of habit-based weight loss interventions on weight loss outcomes and includes all known randomised controlled trials and quasi-randomised controlled trials irrespective of publication date, study setting, or country of implementation.

Our primary objective is to determine the efficacy of habit-based interventions on weight reduction in adults with overweight and obesity. Secondary outcomes are to determine: 1) the efficacy of habit-based interventions on weight loss maintenance in adults with overweight and obesity compared with control; 2) the proportion of participants achieving clinically beneficial weight loss and weight loss maintenance ($\geq 5\%$ total body weight loss).

Method

Data sources and searches

To identify potentially eligible studies using habit-based interventions to reduce weight, an experienced medical librarian conducted electronic searches within five databases, PubMed, Embase, CINAHL, Cochrane CENTRAL and Web of Science, in June 2017. Key search terms used were: habit (formation or disruption or based or breaking or break) and weight loss (or weight control or weight reduction). The systematic review registration and search strategy are

provided in the supplementary file (File S6.1-S6.2). A manual search through reference lists of original studies and other relevant articles was also performed. No language restrictions or publication dates were applied.

Studies included in this review focused used habit-based weight-loss interventions that focused specifically on habit-change as the conceptual theory; therefore, habit-change was the primary strategy for behaviour change and subsequent weight loss. Randomised studies were eligible if they 1) enrolled participants with overweight or obesity defined as BMI $\geq 25.0 \text{ kg/m}^2$; 2) participants were over 18 years of age; 3) included a control group; and 4) reported quantified weight change outcomes at least at post-intervention.

Study selection and data extraction

All studies were screened independently against eligibility criteria by two reviewers. Screening of titles, abstracts and full-texts was conducted using EndNote X7.2.1. Articles that did not meet inclusion criteria were rejected on initial review. If uncertainty existed, the full text article was reviewed. The same two reviewers independently extracted and recorded data in pre-piloted data extraction forms. Disagreements were resolved by consensus and discussion. Extracted data included study design, setting, participant characteristics, intervention and comparator characteristics and weight change outcomes. If there were inadequate data for a given outcome, the corresponding author was contacted via e-mail at least twice and the data were requested.

Quality assessment

Risk of bias of included studies was independently assessed by two reviewers (GC, RS [acknowledged]) using the Cochrane Collaboration Risk of Bias tool ¹⁴. Additionally, we uploaded included studies to RobotReviewer (www.robotreviewer.net/) to confirm accuracy of manual risk of bias assessment. To enhance the usability of this review, we extracted and reported summaries of the main intervention components for each study. These were described using the items from the Template for Intervention Description and Replication (TIDieR) checklist ¹⁵.

Data analyses

Data were analysed using available cases in Review Manager 5.3 ¹⁶. For analyses of weight change, mean change was extracted or calculated per group, from baseline to post-intervention (primary outcome) and from baseline to last available follow-up (secondary

outcome). For analysis of statistically significant differences between groups, mean difference (MD) was calculated at post-intervention and at follow-up. Proportion of participants achieving $\geq 5\%$ total body weight reduction was extracted from reported data and compared in tabular form. The risk ratio (RR) for achieving clinically important weight loss in the intervention groups compared with control was calculated using Review Manager 5.3. We conducted subgroup analyses to examine MD between the intervention group and active compared with non-active controls. We also conducted subgroup analyses comparing MD in interventions which used forming habits as their theoretical basis compared with interventions that used forming habits in combination with breaking habits. If multiple follow-up assessments were reported, the last available follow-up (i.e., longest duration from baseline) was used.

Effect size heterogeneity

The I^2 statistic was used to assess variability in effect size among studies (heterogeneity). We expected statistically significant heterogeneity due to methodological differences in the studies, including variations in study duration and intervention characteristics. A random effects model was therefore used to synthesise the data. There were too few studies to perform a meta-regression analysis; therefore, we described the differences in methods, duration and intervention characteristics in narrative and tabular form.

Results

The systematic search identified 653 potentially relevant studies (Figure 6.1). Of these, 229 were duplicates. Therefore, 424 titles and abstracts were screened for eligibility; 412 did not meet inclusion criteria and were excluded. Of the 12 full text articles assessed, 7 were excluded as they were duplicates or preliminary findings of the included studies, 2 because the intervention used was not habit-based, and 3 because the study was non-randomised (study details provided in supplementary file [Table S6.1]). Five articles fulfilled our inclusion criteria and were included in the qualitative synthesis.

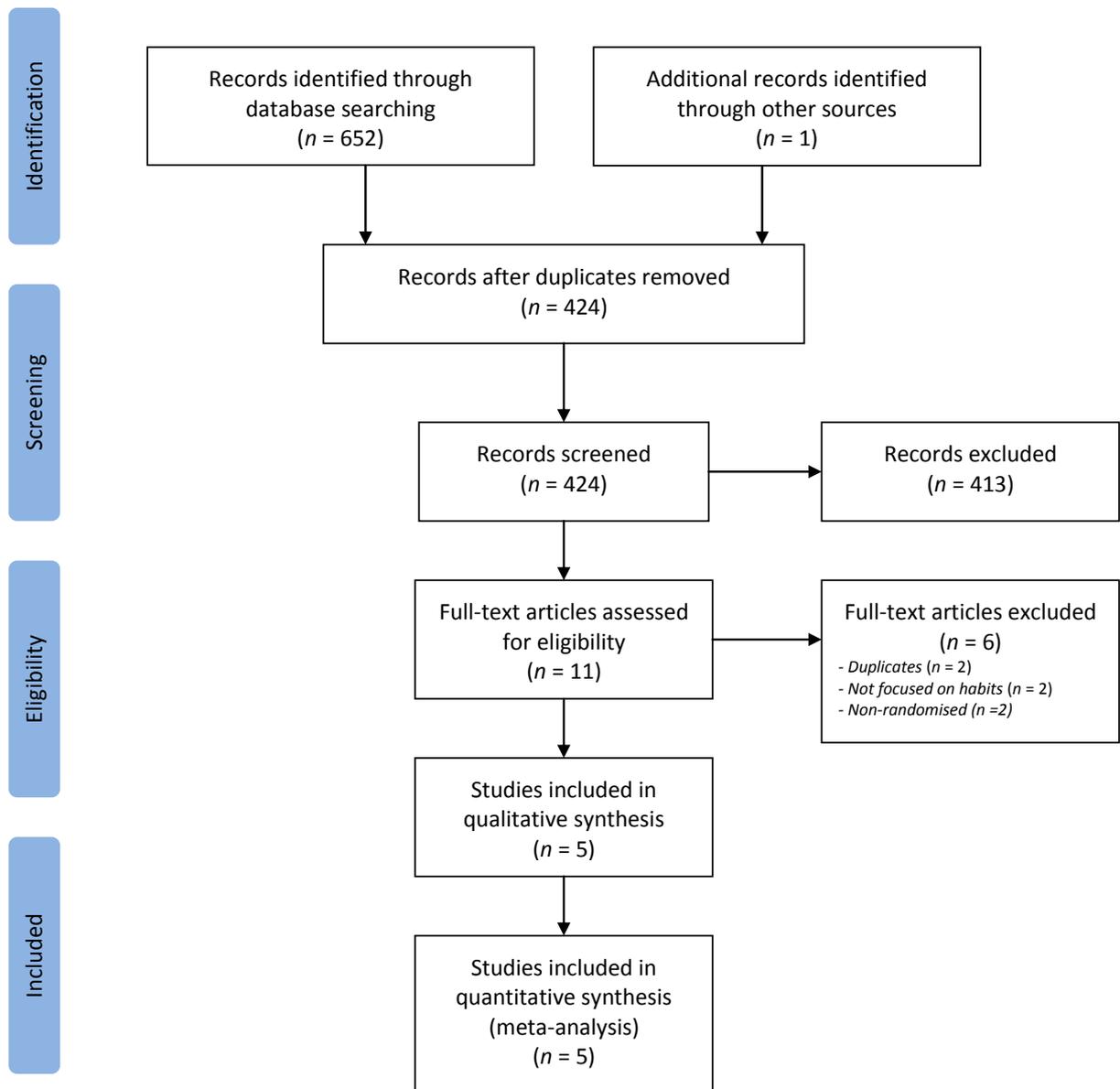


Figure 6.1 PRISMA flow diagram

Study characteristics

The studies reported results from Australia¹⁷, USA^{18,19} and UK^{20,21}. Most studies were conducted in university clinics^{17,19,21,22} and one study in a primary care setting (general practice clinics)²⁰. The five studies included 630 participants (study size ranged from 54 to 537), with a pre-intervention mean body weight of 90-109kg (BMI 31-38kg/m²), mean age from 44 to 66 years and all studies reported a majority of female participants, 66-80%. See Table 6.1 for a list of included studies and their characteristics.

Table 6.1 Characteristics of included studies

Reference	Beeken, 2017 ⁽²⁰⁾	Carels, 2011 ⁽¹⁹⁾	Carels, 2014 ⁽¹⁸⁾	Cleo, 2017 ⁽¹⁷⁾	Lally, 2008 ⁽²¹⁾
Study design	Two-armed randomised controlled trial	Two-armed randomised controlled trial		Three-armed randomised controlled trial	Quasi randomised controlled trial
Study setting	Medical clinic, UK	University clinic, USA		University clinic, Australia	University clinic, UK
Risk of Bias					
Inclusion criteria	BMI ≥30kg/m ² , age ≥ 18 years	BMI ≥27kg/m ² , non-smokers, free from cardiovascular disease and insulin dependent diabetes	BMI ≥27kg/m ² , free from major medical conditions	BMI ≥25kg/m ² , age 18-75 years, had daily access to email and/or phone, free from exercise limiting comorbidities	BMI ≥25kg/m ² , age ≥ 18 years
N	537	54	59	75	104
Intervention	Ten Top Tips (TTT) - habit formation	Transforming Your Life (TYL) - habit formation and habit disruption		Ten Top Tips (TTT) – habit formation and Do Something Different (DSD) - habit disruption	Ten Top Tips (TTT) - habit formation
Intervention method and delivery	Based on habit formation theory to promote automaticity. Participants attended an information meeting and provided with a leaflet which outlined the ten tips as well as a daily self-monitoring form. The program was self-guided at home	An environmental modification approach, which combined promoting healthy, habits as well as breaking unhealthy habits. Groups of 12-16 individuals met weekly for a 90-minute, face-to-face session conducted by a licensed clinical health psychologist and/or graduate students in psychology. Sessions included weight assessment and provided a combination of didactic instruction, group and individual in-class activities, and take home assignments		TTT was delivered as a 12-week self, guided intervention (as per the description of Beeken, in this table). DSD was a 9-week intervention aimed to break habits proposed to play a role in unhealthy dietary and exercise behaviours. Participants were sent text messages with random tasks to perform something different every day. The tasks were not diet and exercise related	Based on habit formation theory to promote automaticity. Participants attended an information meeting and provided with a leaflet which outlined the ten tips as well as a daily self-monitoring form. The program was self-guided at home
Control intervention	Active: Referred to their general practitioner’s usual care treatment	Active: LEARN weight loss program, encourages increasing physical activity and decreasing energy and fat intake	Active: New Perspectives weight loss program emphasises reducing unhealthy relationships with food, body image dissatisfaction and internal weight bias	Non-active: Waitlist control group were offered either intervention after 12 weeks	Non-active: Waitlist control group were offered the intervention after 8 weeks
Facilitator	Nurse or healthcare assistant	Psychologist or psychology doctoral students	Psychologist and/or graduate psychology students	Dietitian	Clinical psychologist and/or research team
Outcomes measured	Weight, BMI, waist circumference, blood pressure, cholesterol/LDL, blood glucose, Self-Reported Habit Index (SRHI), cost analysis	Weight; self-reported: daily energy intake (kcal), energy expenditure from physical activity, exercise duration; average daily energy expenditure (kcal) (Caltrac accelerometer)	Weight, BMI; self-reported daily energy intake (kcal), average daily energy expenditure (kcal) (Caltrac accelerometer), Binge Eating Scale, Emotional Eating Scale, several other scales	Weight, BMI, waist circumference, daily fruit and vegetables serves, weekly exercise hours, psychometric data (wellbeing, depression, anxiety, habits, and openness to change)	Weight, BMI, satisfaction with life, development of habits using Self-Reported Habit Index (SRHI)
Mean baseline weight	100.8kg (± 17.2)	Not reported	109.8kg (± 32.2)	96.1kg (± 20.4)	89.8kg (± 15.0)
Baseline BMI	Median (IQR) 35 kg/m ² (32.6-39.2)	Mean 37.2 kg/m ² (± 6.7)	Mean 39.7kg/m ² (± 10.3)	Mean 34.5kg/m ² (± 6.2)	Mean 30.9 kg/m ² (± 4.5)
Participant age	Median (IQR) 59.4 years (48.7-66.8)	Mean 47.3 years (± 11.2)	Mean 44.3 years (± 13.2)	Mean 50.5 years (± 11.2)	Mean 40.5 years (±10.4)
Female, %	66	80	78	79	66
Trial duration and mean weight loss post-intervention	12 weeks: Intervention : -1.7kg (± 3.2) Control: -0.8kg (± 2.8)	14 weeks: Intervention: -4.9kg (± 4.9) Control: -5.8 (± 4.7)	12 weeks: Intervention: -6.7kg (± 8.7) Control: -5.6kg (± 8.7)	12 weeks: TTT: -3.3kg (± 4.3); DSD -2.9kg (± 3.3) Combined intervention: -3.1kg (± 2.0) Control: -0.4kg (± 1.7)	8 weeks: Intervention: -2.0kg (± 1.9) Control: -0.4kg (± 1.6)
Mean weight loss at follow-up from baseline	24 months: Intervention : -2.2kg (± 5.8) Control: -3.0kg (± 7.2)	6 months: Intervention: -3.5kg (± 5.4) Control: -4.2 (± 4.4)	6 months: Intervention: -8.9kg (± 12.0) Control: -3.5 (± 5.4)	12 months: TTT: -5.7kg (± 5.3); DSD -4.6kg (± 4.5) Combined intervention: -5.1 (± 2.2)	8 months: Intervention : -3.8kg (± 1.9)

Risk of bias legend: R = Random sequence generation (selection bias); A = Allocation concealment (selection bias); P = Blinding of participants and personnel (performance bias); B = Blinding of outcome assessment (detection bias); I = Incomplete outcome data (attrition bias); S = Selective reporting (reporting bias).

= Low risk = Unclear risk = High risk

Abbreviations: TTT = Ten Top Tips; DSD = Do Something Different; TYL = Transforming Your Life; BMI = Body Mass Index; QOL = Quality of Life; ± = Standard Deviation; IQR = Interquartile range.

Interventions

Studies based their interventions on forming new habits^{17,20,21}, breaking old habits¹⁷, or a combination of both^{18,19} (Table 6.1). One study¹⁷ compared two different interventions; one which formed new habits and the other broke old habits. There were no significant differences in weight loss and weight loss maintenance between these two groups. Therefore, we grouped the intervention results together for the primary and secondary outcome measures. Intervention duration ranged from 8 to 14 weeks and follow-up 6 to 24 months.

Weight change

Primary outcome

After an 8-14 week intervention, participants achieved an overall average weight loss of 2.5kg (range 1.7 to 6.7kg) compared with the 1.5kg mean loss of control participants (range 0.4 to 5.8kg) (Figure 6.2). Weight loss was statistically different between the intervention and control group (MD 1.4kg [95% CI 2.3, 0.5; $P=0.004$]).

On inspection of the meta-analyses, study duration did not appear to influence weight loss results. Mean weight loss varied in studies with the same intervention duration^{17,18,20} (12 weeks; 1.7kg, 6.7kg, 3.3kg, 2.9kg) (Table 6.1).

As expected, there was a statistically significant heterogeneity among studies post-intervention ($I^2 = 71%$). As a sensitivity analysis, the papers by Cleo¹⁷ and Lally²¹ were removed from the forest plot as they were the only 2 studies which used wait-list control groups instead of active-controls. When we removed these 2 studies, the I^2 dropped to 0%. We therefore suspect heterogeneity between studies was due to the difference in the use of active and non-active control groups.

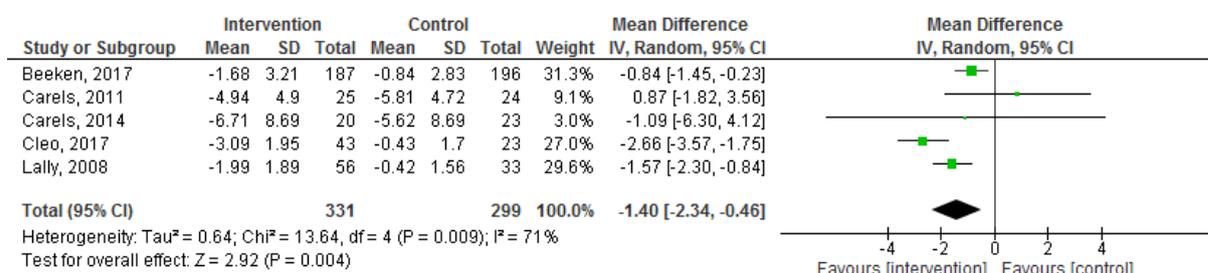


Figure 6.2 Comparing weight loss (kg) at post-intervention between intervention and control groups

Secondary outcomes

Three of the five studies measured weight loss maintenance in both the intervention and control groups at follow-up and were included in a meta-analysis^{19,20,22}. All control groups included in the meta-analysis were active. After 6-24 month follow-up, weight loss maintenance in the intervention group was 3.4kg (range 2.2 to 8.9kg) and 3.1kg (range 3.0 to 4.2kg) in active-controls (Figure S6.1). However, weight loss maintenance was not statistically significant between the intervention and active-control groups (MD 0.1kg [95% CI -2.5, 2.4; $P=0.96$]).

The two studies (Cleo¹⁷, Lally²¹) where only intervention group data were reported at follow-up (and not control group data) achieved mean weight loss maintenance of 5.1kg and 3.8kg after 12 and 8 months follow-up, respectively.

Three of the five studies reported on the proportion of participants achieving clinically beneficial weight loss ($\geq 5\%$ total body weight reduction); two of the three at post-intervention^{17,20} and all three at follow-up^{17,20,21} (Figure S6.2). At post-intervention, 16-35% of participants in the intervention group and 4-8% in the control group had achieved clinically beneficial weight loss. Participants in the intervention group were therefore 2.43 times (RR) more likely to achieve clinically beneficial weight loss than control participants (Figure 6.3). At follow up, 27-65% of participants in the intervention group and 26% in an active-control group had achieved and maintained a reduction of $\geq 5\%$ total body weight (Figure S6.2).

We observed a moderate heterogeneity amongst studies in the follow-up analysis, however this was not statistically significant ($I^2 = 50\%$).

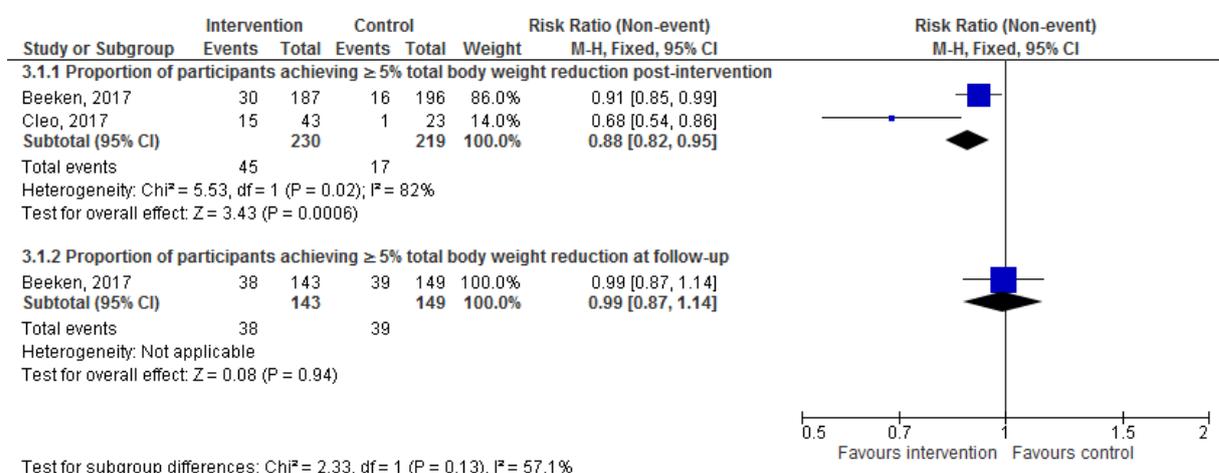


Figure 6.3 Subgroup analysis comparing effect size of the proportion of participants achieving $\geq 5\%$ total body weight reduction at post-follow-up and at follow-up

Subgroup analysis

Analyses were completed for 2 subgroups: active vs non-active control groups and forming habits vs forming + breaking habits. There was a 0.8kg mean difference favouring the intervention group, when comparing habit-based interventions with active controls ($P= 0.01$). The mean difference increased to 2.1kg when comparing habit-based interventions with non-active controls ($P= <0.001$) (Figure 6.4).

Interventions which used forming new habits as the theoretical basis of their intervention^{17,20,21}, showed a statistically significant mean difference when compared with controls (MD 1.4kg; $P= 0.001$), however two of three of these used wait-list controls. Interventions which used forming new habits in combination with breaking old habits did not show a statistically or clinically meaningful difference compared with active-control groups (MD 0.5kg; $P= 0.71$)^{19,22} (Figure S6.3).

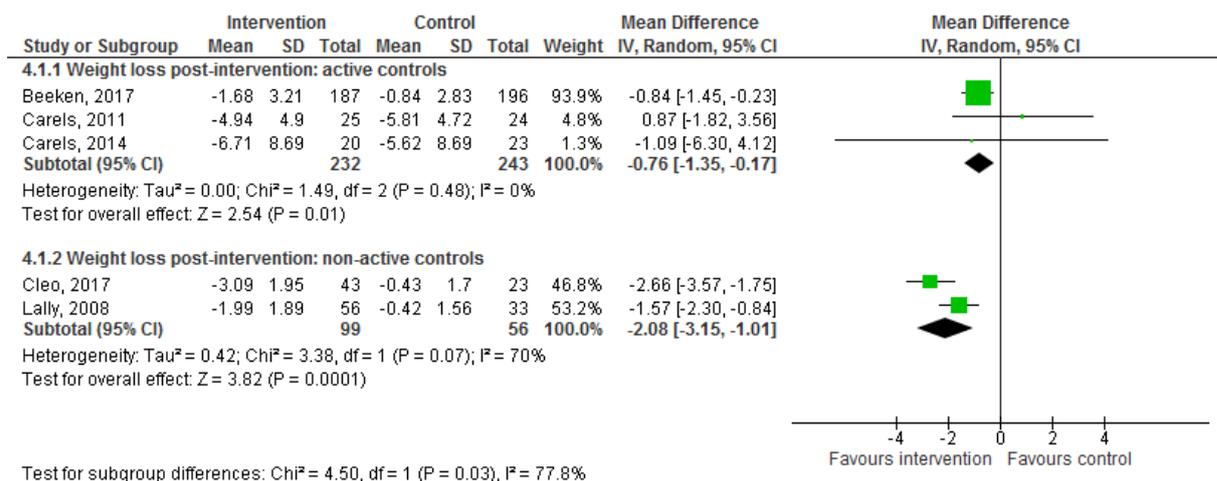


Figure 6.4 Subgroup analysis comparing weight loss (kg) post-intervention between intervention and active vs non-active control groups

Quality of included studies

Four studies were randomised controlled trials¹⁷⁻²⁰ and one was randomised according to intervention commencement date²¹ (Table 6.1). As expected, participants and investigators of all studies were aware of the intervention they were receiving or delivering resulting in all studies rating as 'high risk' of bias for blinding of participants and study personnel. We displayed risk of bias outcomes for random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective reporting (Figure S6.4). A TIDieR intervention summary was completed for each of the 5 studies included in this review (Table 6.2). This summary describes why the

intervention was initiated, what methods and materials were used, and details of intervention fidelity, amongst other intervention information.

Table 6.2 TIDieR intervention summary (Hoffman 2017)

Author Year	Brief name	Recipient	Why	What-materials	What-procedures	Who provided	How (mode of delivery; individual or group)	Where	When and how much	Tailoring	Modification of intervention throughout trial	Strategies to improve or maintain intervention fidelity	Extent of intervention fidelity
Beeken, 2017 ⁽²⁰⁾	- Habit-based advice for weight loss: Ten Top Tips (TTT)	- Adults with obesity (BMI $\geq 30\text{kg/m}^2$)	- Primary care is 'first port of call' for weight control advice - There's a need for simple, effective interventions that can be delivered without specialist skills	- Written materials provided including: self-guided leaflet detailing the intervention and logbook, for self-monitoring target behaviors and weight (www.weightconcern.org.uk/tentoptips)	- 12 week self-guided, intervention - 10 behaviors associated with achieving negative energy balance, improving awareness of food intake and promote routines	- Nurses or health-care assistants working with 14 GPs - Training session provided with a script to enable standardised delivery of interventions	- Baseline face to face individual meeting - Remainder of intervention self-guided with no further clinical contact	- 14 GPs across England recruited through MRC GP Research Framework. - 9 in Southern England, 3 in the Midlands and 2 in the North	- 30 min with nurse or at baseline to explain intervention leaflet - At 3 months, patients mailed 2 nd copy of leaflet and able to request additional copies of logbook - F/up at 6, 12, 18 and 24 months post-intervention with no contact between f/up appointments	- All participants received same intervention	- Not described	- Quality checks involving site visits to observe intervention delivery to ensure compliance	- Intervention fidelity was not formally measured - Participants reported automaticity of target behaviors, suggesting TTT was effective at establishing new habits
Carels, 2011 ⁽¹⁹⁾	- Transforming Your Life (TYL): An environmental modification approach to weight loss	- Adults with overweight or obesity (BMI $\geq 27\text{kg/m}^2$)	- Environmental modification is critical to habit formation and disruption - Compared traditional weight loss program with environmental modification	- Not described	- Information to develop and maintain healthy habits, disrupt unhealthy habits, create environments that encourage goal-related cues	- Licensed clinical health psychologist or psychology doctoral students experienced in leading weight loss interventions	- 90 min, face to face, weekly group sessions	- Not specified, assumed at university clinic; USA	- 14 week program administered in 90 min group sessions, weekly - F/up 6 months post-intervention with no treatment during this period	- All participants received same intervention	- Not described	- Participants submitted daily records of energy intake, physical activity and energy expenditure - Participants shared insights to promote group cohesion and adherence	- Intervention fidelity partially measured: Participants provided, on average, 53.8 (SD = 39.1) of 98 potential diet and exercise diaries over 14 weeks (54.1%)
Carels, 2014 ⁽¹⁸⁾	- Differences in weight loss maintenance using New Perspectives (NP) or Transforming Your Life (TYL) interventions	- Adults with overweight or obesity (BMI $\geq 27\text{kg/m}^2$)	- Healthy habits program (TYL) compared with a novel weight loss program (NP), directed at changing unhealthy relationships with food, body image, and attitudes about weight	- Not described	- Information to develop and maintain healthy habits, disrupt unhealthy habits, create environments that encourage goal-related cues	- Licensed clinical health psychologist and/or graduate students in psychology	- 90 min, face to face, weekly group sessions	- Not specified, assumed at university clinic; USA	- 12 week program administered in 90 min group sessions, weekly - F/up at 6 months post-intervention with no treatment during this period	- All participants received same intervention	- Not described	- Not described	- 43 (73%) participants remained in program (TYL = 20; Control = 23) - Across groups, participants recorded 52.7 (SD = 36.1; 62.7%) out of 84 possible diet and exercise diaries over 12 weeks

Cleo, 2017 ⁽¹⁷⁾	- Habit-based weight loss interventions: Ten Top Tips (TTT) and Do Something Different (DSD)	- Adults with overweight or obesity (BMI $\geq 25\text{kg/m}^2$)	- Habitual behaviors strongly influence health outcomes - Habit based weight-loss studies with data beyond 6 months post-intervention are scarce	- TTT: Written materials provided including: self-guided leaflet detailing the intervention and logbook, for self-monitoring target behaviors and weight (www.weightconcern.org.uk/tentoptips) - DSD implemented via online software (www.dsd.me)	- TTT: 12 week, self-guided, intervention - 10 behaviors associated with achieving negative energy balance, improving awareness of food intake and promote routines - DSD: 9 week intervention to break unhealthy habits	- Dietitian experienced in weight management	- Baseline face to face meeting in groups of 5 - Remainder of intervention was self-guided with supportive weekly phone calls from dietitian	- Bond University, Institute of Health and Sport, Gold Coast, Australia	- TTT and DSD: Participants attended group baseline meeting and contacted via telephone weekly for the intervention period - DSD: Participants received tasks via email and/or text message, 3-4 times per week for the intervention period - F/up at 6 and 12 months post-intervention with no contact between f/up sessions	- TTT: all participants received same intervention - DSD: participants completed questionnaire s assessing personal behaviors and habits and tailored program to each individual	- Interventions delivered as intended	- Researchers followed procedure manuals by original developers and standardized introductory presentations and resources - Weekly phone calls by dietitian discussing barriers and facilitators of program adherence. Problem solving strategies discussed	- Intervention fidelity not formally measured - Dietitian able to monitor through weekly phone calls and weekly self-monitoring tools participants completed
Lally, 2008 ⁽²¹⁾	- Healthy habits: Efficacy of Ten Top Tips (TTT) on weight control	- Adults with overweight or obesity (BMI $\geq 25\text{kg/m}^2$)	- Few behavioural interventions have been underpinned by theory related to habit formation	- Written materials provided including: self-guided leaflet detailing intervention and logbook, for self-monitoring target behaviors and weight (www.weightconcern.org.uk/tentoptips)	- 12 week, self-guided, intervention - 10 behaviors associated with achieving negative energy balance, improving awareness of food intake and promote routines	- Research psychologist	- Baseline face to face meeting, with whole intervention group - Remainder of intervention was self-guided with no further clinical contact	- Health Behavior unit at University College London; UK	- Participants given leaflet at baseline and received no further therapeutic contact. - Weight measured at drop-in sessions at baseline, weeks 4 and 8 and either weekly or monthly for 6 months (to 32 weeks) - F/up was 8 months post-intervention with no contact between intervention and f/up	- All participants received same intervention	- Not described	- Not described	- 46% of participants that completed final qualitative report ($n= 24$) stated all behaviors became habits, 33% reported some were habits and remainder none were habits

Abbreviations: TTT = Ten Top Tips; BMI = Body Mass Index; GPs = General Practitioners; MRC = Medical Research Council; min = minute; f/up = follow up; TYL = Transforming Your Life; NP = New Perspectives; DSD = Do Something Different.

Discussion

Despite our intentions, habits influence a large proportion of our daily behaviours. If we were able to change our eating habits – where, when and why we eat, - we might be able to manage our weight more effectively. Therefore determining if habit-change interventions are effective for weight loss and weight loss maintenance is important. We systematically evaluated the efficacy of habit-based interventions for weight loss and weight loss maintenance in individuals with overweight and obesity. There was a statistically significant difference in weight loss between intervention and control participants after an 8 to 14 week intervention period. Participants in the intervention group were 2.4 times more likely to achieve clinically beneficial weight loss than the control group.

The long-term effects of habit-based interventions on weight loss maintenance were difficult to conclude as the interventions were compared with active-control groups (non-habit based weight loss programs^{19,22} and lifestyle advice with or without community referral²⁰). The two studies which used non-active controls (wait-list) were not included in the follow-up analysis as they did not measure or analyse these data. However, the single-armed results from these two studies show that the participants had in fact achieved weight-loss maintenance^{17,21}.

In the current analyses, forming habits achieves greater weight loss when compared with forming+breaking habit interventions. However, both studies of forming+breaking habits^{18,19} were compared with active controls. Therefore, studies comparing forming+breaking habits compared with non-active controls are required to determine robust measures of outcome.

Our study is strengthened by our procedures. We searched five databases and contacted authors for missing data or unclear practices. We also assessed the quality of the studies using the Cochrane Risk of Bias tool¹⁴. Overall, the risk of bias was well-reported in the studies; however, there were some inconsistencies. One study reported the outcome assessor was not blind to group allocation when conducting post-assessments and two studies did not report on this^{19,22} and were rated as unclear risk for detection bias. Due to the nature of the interventions, it is not possible to blind participants and personnel to treatment allocations, therefore all studies were rated as high risk of bias for blinding. However, the measurement of weight is objective rather than self-reported so the magnitude of bias associated with inadequate blinding of participants is not likely to affect outcomes¹⁴. Finally, knowing an intervention is effective is immaterial if it is not described well for clinicians to use. A key strength of this review was including a TIDieR summary of interventions. This summary provided a description of the main intervention components for each of the included

studies for clinicians to make important judgements about their ability to implement these interventions in their place of work.

The published literature on habit-based weight loss interventions is scant. This systematic review was limited by the small number of published studies, using habit-based interventions for weight management in individuals with overweight and obesity. Interventions which focus on habit-change theory are a new and novel approach to weight management. We anticipate seeing more included studies in future updates of this review. Also, there was a considerable heterogeneity in the included studies. Due to the limited number of studies, meta-regression could not be conducted to explore study variability that might have contributed to the heterogeneity.

The weight loss- weight regain cycle is common. Previous systematic reviews show that after a lifestyle program, commonly diet and exercise, an average of 46-50% of weight loss is regained just 12-months post-treatment^{1,23,24} and much of the rest over the subsequent 3 years²⁵. Habit-based weight loss interventions show better weight loss and weight maintenance success when compared with the lifestyle programs presented in previous systematic reviews. Unlike diet and exercise programs, interventions which are founded on habit-change theory encourage behaviour to become 'second nature'; therefore, the new, healthy behaviours are more resistant to change. More research is required to accurately determine the efficacy of habit-based interventions when compared with non-active control groups long-term.

Conclusions

Habit-based weight loss programs are more effective at achieving clinically beneficial weight loss than lifestyle advice, non-habit based programs and waitlist in the short-term. Habit-based weight loss programs also lead to maintenance of weight loss in the longer-term, but not to a greater extent than non-habit based programs in the three studies included in this review. The results presented in this systematic review are novel and provide a unique perspective from which to derive a new approach to weight management. Longer and more methodologically rigorous studies that are powered to examine at least a 12-month follow-up are required to determine the role of habit formation and disruption on weight loss maintenance.

Acknowledgements: We thank Ms Rebecca Simms for her invaluable assistance in data extraction and analysis. We also thank Mr Justin Clark for conducting our search.

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Supplementary material for Chapter 6

Table S6.1 Descriptive data of excluded studies

Figure S6.1 Comparing weight loss (kg) at follow-up between intervention and control groups

Figure S6.2 Proportion of participants achieving $\geq 5\%$ total body weight reduction at post-intervention and follow-up

Figure S6.3 Subgroup analysis comparing weight loss (kg) between forming habits and a combination of forming and breaking habits

Figure S6.4 Risk of bias summary

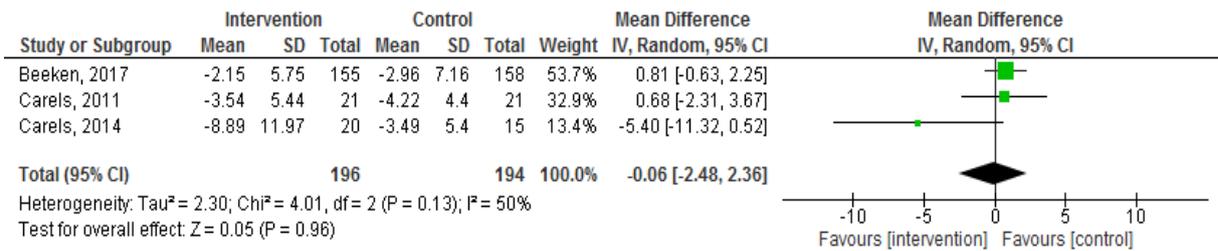
File S6.1 PROSPERO International prospective register of systematic reviews

File S6.2 Search strategy

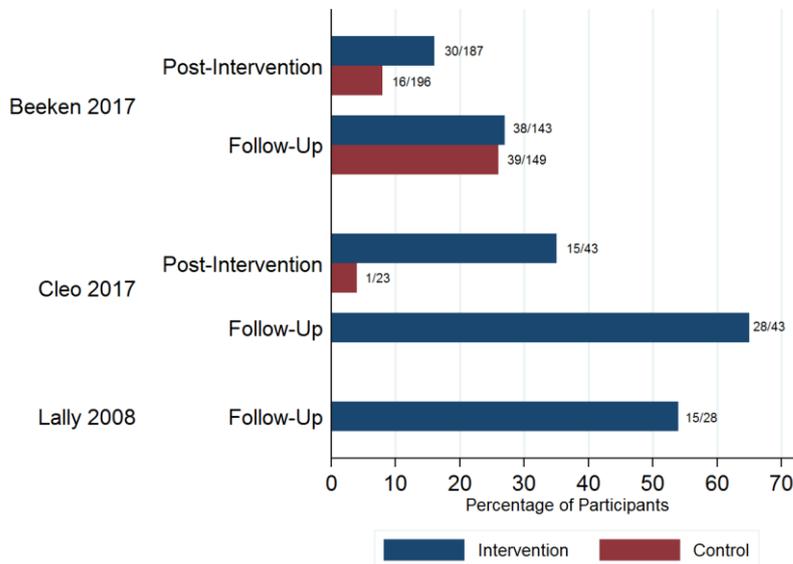
Supplementary Table 6.1 Descriptive data of excluded studies

Study reference	Baseline weight, kg*	Mean age, years	Intervention theory	Duration of intervention (weeks)	Follow-up (months)	Reason for exclusion
Beeken, 2011	Pre-intervention (no data)	Pre-intervention (no data)	Forming habits	12	24	Duplicate
Beeken, 2014	100.8 (±17.2)	59 (IQR 48.7-66.8)	Forming habits	12	24	Duplicate
Fletcher, 2011	29.6kg/m ² (± 4.8)	44.2 (± 7.3)	Breaking habits	4	2	Non-randomised
Kraschnewski, 2010	93.2 (±14.4)	50 (± 10.9)	Lifestyle program	12	nil	Not habit-based
Page, 2008	30kg/m ² (± 5.7)	44.4 (±8.7)	Breaking habits	4	2-3	Non-randomised
Ter Bogt, 2011	88	56 (± 7.7)	Lifestyle program	1 x baseline session	8 (visits) 12 (telephone)	Not habit-based

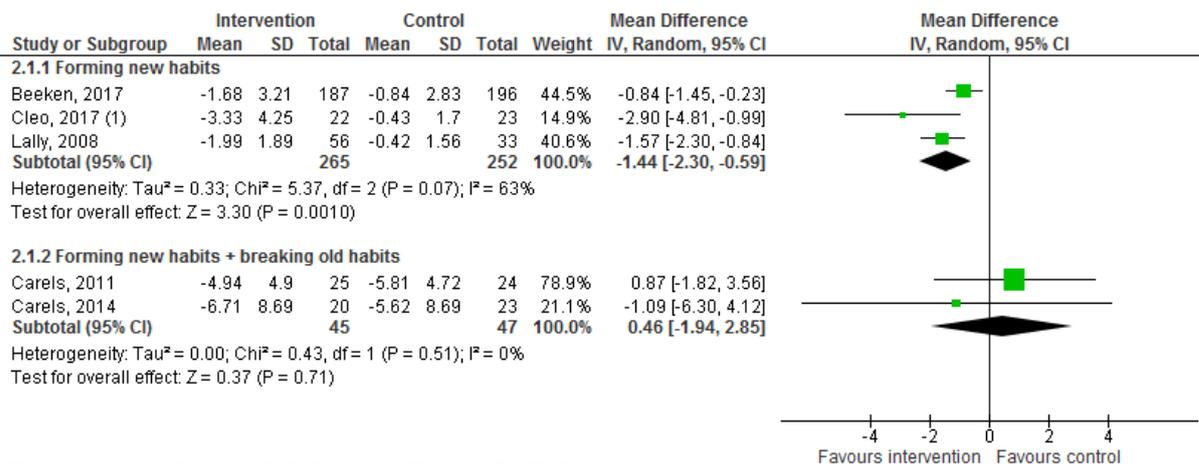
Abbreviations: kg = kilogram; BMI = Body Mass Index; IQR = Interquartile range * = BMI (kg/m²) was used if weight (kg) not reported



Supplementary Figure 6.1 Comparing weight loss (kg) at follow-up between intervention and control groups



Supplementary Figure 6.2 Proportion of participants achieving ≥5% total body weight reduction at post-intervention and follow-up



Test for subgroup differences: Chi² = 2.15, df = 1 (P = 0.14), I² = 53.4%

Footnotes

(1) The data for Cleo 2017, in this Figure relate only to the habit forming intervention, Ten Top Tips (TTT), as reported in the publication.

Supplementary Figure 6.3 Subgroup analysis comparing weight loss (kg) between forming habits and a combination of forming and breaking habits

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Beeken, 2017	+	+	-	+	+	+	+
Carels, 2011	+	?	?	?	+	+	+
Carels, 2014	+	+	?	?	+	+	+
Cleo, 2017	+	+	-	+	+	+	+
Lally, 2008	+	+	-	-	+	+	+

Supplementary Figure 6.4 Risk of bias summary

Supplementary File 6.1 PROSPERO International prospective register of systematic reviews

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for
Health Research

PROSPERO International prospective register of systematic reviews

Review title and timescale

1. Review title

Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.

Efficacy of habit-based weight loss interventions: a systematic review and meta analysis

2. Original language title

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. Anticipated or actual start date

Give the date when the systematic review commenced, or is expected to commence. *02/06/2017*

4. Anticipated completion date

Give the date by which the review is expected to be completed. *08/09/2017*

5. Stage of review at time of this submission

Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

Review team details

6. Named contact

The named contact acts as the guarantor for the accuracy of the information presented in the register record. **Ms Cleo**

7. Named contact email

Enter the electronic mail address of the named contact.

gcleo@bond.edu.au

8. Named contact address

Enter the full postal address for the named contact.

Center for Research in Evidence Based Practice Faculty of Health Sciences and Medicine Bond University 14 University Drive, ROBINA QLD 4226 AUSTRALIA

9. Named contact phone number

Enter the telephone number for the named contact, including international dialing code.

+61 75595 1588

10. Organisational affiliation of the review

Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Bond University

Website address: **<https://bond.edu.au/>**

11. Review team members and their organisational affiliations

Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation
Ms	Gina	Cleo	Bond University
Professor	Paul	Glasziou	Bond University
Professor	Elaine	Beller	Bond University
Professor	Elisabeth	Isenring	Bond University
Dr	Rae	Thomas	Bond University

12. Funding sources/sponsors

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the

individuals or bodies listed should be included.

This review received no funding sources or sponsors GC and EI received no funding with respect to this study. RT and EB are supported by a NHMRC grant (APP1104136, APP1044904). PG is supported by a NHMRC Australian Fellowship grant (GNT1080042).

13. Conflicts of interest

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

Are there any actual or potential conflicts of interest?

Yes

GC has conducted a randomized controlled trial comparing two habit-based interventions for weight loss. Manuscript is under review.

14. Collaborators

Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details
Ms	Rebecca	Sims	Bond University
Mr	Justin	Clark	Bond University

Review methods

15. Review question(s)

State the question(s) to be addressed / review objectives. Please complete a separate box for each question.

- What is the effect of habit-based weight-loss interventions on weight reduction in overweight and obese adults?
- What is the effect of habit-based weight-loss interventions on weight loss maintenance in overweight and obese adults after the conclusion of the study (at last follow-up)?
- What is the proportion of participants achieving clinically important weight loss and weight loss maintenance ($\geq 5\%$ total body weight loss) post-intervention and at last follow-up?

16. Searches

Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

Electronic searches within PubMed, Embase, CINAHL, Cochrane CENTRAL and Web of Science, will be conducted to identify potential studies for inclusion. The search strategy will include only terms relating to or describing habit-based weight loss interventions. There will be no language or date restrictions. The searches will be re-run just before the final analyses and further studies retrieved for inclusion.

17. URL to search strategy

If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

https://www.crd.york.ac.uk/PROSPEROFILES/65589_STRATEGY_20170619.pdf

I give permission for this file to be made publicly available **Yes**

18. Condition or domain being studied

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Overweight and/or obesity

19. Participants/population

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion: Adults (18 years of age and above); overweight or obese by BMI classification ($\geq 25.0\text{kg/m}^2$) Exclusion: Children or adolescents (under 18 years of age).

20. Intervention(s), exposure(s)

Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed

The search strategy will restrict the search to habit-based weight-loss interventions that focus specifically on habit- change as the conceptual theory; therefore, habit-change is the primary strategy for behavior change and weight loss. The inclusion criteria of studies for review are: randomized clinical trials and quasi randomized clinical trials that quantify weight change outcomes in overweight or obese adults (at a minimum for pre-intervention and post- intervention), any year, country or language. If multiple post-intervention follow-up assessments are reported, then the longest follow-up (i.e., longest duration from the conclusion of the intervention) will be used for the purpose of this review.

21. Comparator(s)/control

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).

The comparator is likely to be a waitlist comparison group, usual care group, or an alternative active intervention group.

22. Types of study to be included

Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.

We will include randomized clinical trials and quasi randomised clinical trials which report weight change outcomes. The trial must include an intervention and a control group.

23. Context

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

Trials conducted in any setting and any country will be included.

24. Primary outcome(s)

Give the most important outcomes.

Change in weight (kg)

Give information on timing and effect measures, as appropriate.

Changes in weight from (1) baseline to post-intervention and (2) baseline to last available follow-up.

25. Secondary outcomes

List any additional outcomes that will be addressed. If there are no secondary outcomes enter None. **Clinically beneficial weight change (weight loss = \geq 5% total body weight)**

Give information on timing and effect measures, as appropriate.

Proportion of participants losing \geq 5% total body weight lost at last available follow-up

26. Data extraction (selection and coding)

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources will be screened independently by two reviewers to identify studies that potentially meet the inclusion criteria outlined above. The full text of these potentially eligible studies will be retrieved and independently assessed for eligibility by two review team members. Any disagreements will be resolved through discussion with a third reviewer. A standardized, pre-piloted form will be used to extract data from the included studies for assessment of study quality and evidence synthesis. Extracted information will include: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control conditions; type of study used; recruitment and study completion dates; outcomes and times of measurement; information for assessment of the risk of bias. Two reviewers will extract data independently, discrepancies will be identified and resolved through discussion, consensus, or arbiter. Missing data will be requested from study authors via email at least twice.

27. Risk of bias (quality) assessment

State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the

planned synthesis.

Two independent reviewers will assess the risk of bias in included studies by using the Cochrane Risk of Bias tool (Higgins & Green 2011). This includes: random sequence generation (selection bias); allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessment (detection bias); incomplete outcome data (attrition bias); selective reporting (reporting bias); other sources of bias. Each of these domains will be described as reported in the trial and then assigned a judgement about the adequacy of each item: 'low', 'high', or 'unclear' risk of bias. Disagreements between reviewers will be resolved by discussion, consensus, or arbiter.

28. Strategy for data synthesis

Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.

We anticipate that there will be limited scope for meta-analysis due to heterogeneity of intervention duration and methods. However, where studies have used the same type of intervention and comparator, we will pool the results using a random-effects meta-analysis and calculate 95% confidence intervals and two sided P values for each outcome. We will also provide a narrative synthesis of the findings from the included studies, structured around the type of intervention, target population characteristics, type of outcome and intervention content. We will provide summaries of intervention effects for each study by calculating mean differences for changes in weight. We will describe the proportion of participants who have lost $\geq 5\%$ total body weight from baseline to post-intervention and baseline to last available follow-up.

29. Analysis of subgroups or subsets

Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.

Active vs non-active controls

Review general information

30. Type and method of review

Select the type of review and the review method from the drop down list. **Systematic review**

31. Language

Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.

English

Will a summary/abstract be made available in English? **Yes**

32. Country

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.

Australia

33. Other registration details

Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

34. Reference and/or URL for published protocol

Give the citation for the published protocol, if there is one.

Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available **Yes**

35. Dissemination plans

Give brief details of plans for communicating essential messages from the review to the appropriate audiences. **Outcomes of this review and meta-analysis are expected to be published in a peer-reviewed journal.**

Do you intend to publish the review on completion? **Yes**

36. Keywords

Give words or phrases that best describe the review. (One word per box, create a new box for each term) **weight management; behaviour change; habit-change; habit-based intervention; weight loss intervention; weight loss maintenance; systematic review; forming habits; breaking habits**

37. Current review status

Review status should be updated when the review is completed and when it is published. **Ongoing**

Supplementary File 6.2 Search strategy

We used the following search strategies to search Pubmed to search the Cochrane Central Register of Controlled Trials (CENTRAL), Embase, CINAHL and Web of Science. There were no language or date restrictions.

PubMed search

("Habits"[Mesh] OR "Habits"[tiab] OR Habit[tiab])
 AND
 (Formation[tiab] OR Disruption[tiab] OR Based[tiab] OR Breaking[tiab] OR Break[tiab])
 AND
 ("Weight Loss"[Mesh] OR "Weight loss"[tiab] OR "Weight control"[tiab] OR "Weight reduction"[tiab])
 AND
 ("Patient Education as Topic"[Mesh] OR "Pamphlets"[Mesh] OR "Diet, Reducing"[Mesh] OR "Weight Reduction Programs"[Mesh] OR "Environment Design"[Mesh] OR "Patient education"[tiab] OR Pamphlet[tiab] OR Pamphlets[tiab] OR Leaflet[tiab] OR Leaflets[tiab] OR Dietary[tiab] OR Diet[tiab] OR Diets[tiab] OR Food[tiab] OR Foods[tiab] OR "Weight Reduction Programs"[tiab] OR "Weight Reducing Programs"[tiab] OR "Weight Reduction Program"[tiab] OR "Weight Reducing Program"[tiab] OR "Environment Design"[tiab] OR "Environmental modification"[tiab])
 AND
 ("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR randomized[tiab] OR randomised[tiab] OR placebo[tiab] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR "Epidemiologic Studies"[Mesh] OR "case-control studies"[Mesh] OR "Cohort Studies"[Mesh] OR "case control"[tiab] OR Cohort[tiab] OR "Follow up"[tiab] OR Observational[tiab] OR longitudinal[tiab] OR Prospective[tiab] OR retrospective[tiab] OR "cross sectional"[tiab] OR "Cross-Sectional Studies"[Mesh] OR Investigated[tiab] OR Analysis[tiab] OR Statistics[tiab] OR Data[tiab] OR "statistics and numerical data"[sh] OR "epidemiology"[sh])

Cochrane CENTRAL

([mh Habits] OR Habits:ti,ab OR Habit:ti,ab)
 AND
 (Formation:ti,ab OR Disruption:ti,ab OR Based:ti,ab OR Breaking:ti,ab OR Break:ti,ab)
 AND
 ([mh "Weight Loss"] OR "Weight loss":ti,ab OR "Weight control":ti,ab OR "Weight reduction":ti,ab)
 AND
 ([mh "Patient Education as Topic"] OR [mh Pamphlets] OR [mh "Diet, Reducing"] OR [mh "Weight Reduction Programs"] OR [mh "Environment Design"] OR "Patient education":ti,ab OR Pamphlet:ti,ab OR Pamphlets:ti,ab OR Leaflet:ti,ab OR Leaflets:ti,ab OR Dietary:ti,ab OR Diet:ti,ab OR Diets:ti,ab OR Food:ti,ab OR Foods:ti,ab OR "Weight Reduction Programs":ti,ab OR "Weight Reducing Programs":ti,ab OR "Weight Reduction Program":ti,ab OR "Weight Reducing Program":ti,ab OR "Environment Design":ti,ab OR "Environmental modification":ti,ab)

Embase

('Habit'/exp OR Habits:ti,ab OR Habit:ti,ab)
 AND

(Formation:ti,ab OR Disruption:ti,ab OR Based:ti,ab OR Breaking:ti,ab OR Break:ti,ab)
 AND
 ('weight reduction'/exp OR "Weight loss":ti,ab OR "Weight control":ti,ab OR "Weight reduction":ti,ab)
 AND
 ('Patient Education'/exp OR 'publication'/exp OR 'diet therapy'/exp OR 'weight loss program'/exp OR 'environmental planning'/exp OR "Patient education":ti,ab OR Pamphlet:ti,ab OR Pamphlets:ti,ab OR Leaflet:ti,ab OR Leaflets:ti,ab OR Dietary:ti,ab OR Diet:ti,ab OR Diets:ti,ab OR Food:ti,ab OR Foods:ti,ab OR "Weight Reduction Programs":ti,ab OR "Weight Reducing Programs":ti,ab OR "Weight Reduction Program":ti,ab OR "Weight Reducing Program":ti,ab OR "Environment Design":ti,ab OR "Environmental modification":ti,ab)
 AND
 (random* OR factorial OR crossover OR placebo OR blind OR blinded OR assign OR assigned OR allocate OR allocated OR 'crossover procedure'/exp OR 'double-blind procedure'/exp OR 'randomized controlled trial'/exp OR 'single-blind procedure'/exp OR 'epidemiology'/exp OR 'controlled study'/exp OR 'cohort analysis'/exp OR "case control":ti,ab OR Cohort:ti,ab OR "Follow up":ti,ab OR Observational:ti,ab OR longitudinal:ti,ab OR Prospective:ti,ab OR retrospective:ti,ab OR "cross sectional":ti,ab OR 'Cross-Sectional Studies'/exp OR Investigated:ti,ab OR Analysis:ti,ab OR Statistics:ti,ab OR Data:ti,ab)

CINAHL

((MH "Habits+") OR TI Habits OR AB Habits OR TI Habit OR AB Habit)
 AND
 (TI Formation OR AB Formation OR TI Disruption OR AB Disruption OR TI Based OR AB Based OR TI Breaking OR AB Breaking OR TI Break OR AB Break)
 AND
 ((MH "Weight Loss+") OR TI "Weight loss" OR AB "Weight loss" OR TI "Weight control" OR AB "Weight control" OR TI "Weight reduction" OR AB "Weight reduction")
 AND
 ((MH "Patient Education+") OR (MH "Pamphlets+") OR (MH "Diet, Reducing+") OR (MH "Weight Reduction Programs+") OR TI "Patient education" OR AB "Patient education" OR TI Pamphlet OR AB Pamphlet OR TI Pamphlets OR AB Pamphlets OR TI Leaflet OR AB Leaflet OR TI Leaflets OR AB Leaflets OR TI Dietary OR AB Dietary OR TI Diet OR AB Diet OR TI Diets OR AB Diets OR TI Food OR AB Food OR TI Foods OR AB Foods OR TI "Weight Reduction Programs" OR AB "Weight Reduction Programs" OR TI "Weight Reducing Programs" OR AB "Weight Reducing Programs" OR TI "Weight Reduction Program" OR AB "Weight Reduction Program" OR TI "Weight Reducing Program" OR AB "Weight Reducing Program" OR TI "Environment Design" OR AB "Environment Design" OR TI "Environmental modification" OR AB "Environmental modification")
 AND
 ((MH "Clinical Trials+") OR (MH "Quantitative Studies") OR TI placebo* OR AB placebo* OR (MH "Placebos") OR (MH "Random Assignment") OR TI random* OR AB random* OR TI ((singl* or doubl* or tripl* or trebl*) W1 (blind* or mask*)) OR AB ((singl* or doubl* or tripl* or trebl*) W1 (blind* or mask*)) OR TI clinic* trial* OR AB clinic* trial* OR PT clinical trial OR (MH "Epidemiological Research+") OR (MH "Study Design+") OR TI "case control" OR AB "case control" OR TI Cohort OR AB Cohort OR TI "Follow up" OR AB "Follow up" OR TI Observational OR AB Observational OR TI longitudinal OR AB longitudinal OR TI Prospective OR AB Prospective OR TI retrospective OR AB retrospective OR TI "cross sectional" OR AB "cross sectional" OR TI Investigated OR AB Investigated OR TI Analysis OR AB Analysis OR TI Statistics OR AB Statistics OR TI Data OR AB Data)

Web of Science

(Habits OR Habit)

AND

(Formation OR Disruption OR Breaking OR Break)

AND

("Weight Loss" OR "Weight loss" OR "Weight control" OR "Weight reduction")

AND

("Patient Education as Topic" OR Pamphlets OR "Diet, Reducing" OR "Weight Reduction Programs" OR "Environment Design" OR "Patient education" OR Pamphlet OR Pamphlets OR Leaflet OR Leaflets OR Dietary OR Diet OR Diets OR "Weight Reduction Programs" OR "Weight Reducing Programs" OR "Weight Reduction Program" OR "Weight Reducing Program" OR "Environment Design" OR "Environmental modification")

AND

(Trial OR randomized OR randomised OR placebo OR randomly OR groups OR "Epidemiologic Studies" OR Epidemiological OR "case-control studies" OR "Cohort Studies" OR "case control" OR Cohort OR "Follow up" OR Observational OR longitudinal OR Prospective OR retrospective OR "cross sectional" OR "Cross-Sectional Studies" OR Investigated OR Analysis OR Statistics OR Data)

Chapter 7

General discussion

*“In theory, there is no difference between theory and practice.
But, in practice there is”*

- Yogi Berra

This chapter draws together the findings of all four research studies, and discusses their importance within the broader scope of the overarching thesis aims. Importantly, this chapter elaborates on implications of these findings for directing current clinical practice and future research projects.

As the prevalence of overweight and obesity and corresponding comorbidities such as heart disease and diabetes continue to increase each year, the need for evidence-based, effective treatment has become a priority. Current conventional diet and exercise interventions are effective for short-term weight loss; however, show little evidence for long-term weight loss maintenance (1-3 years)¹. This is a problem as the weight-loss-weight-regain cycle can be detrimental to an individual's physical and emotional health. The key objectives of this thesis were to determine whether habit-based weight loss interventions are effective at achieving weight loss and weight loss maintenance in adults with overweight or obesity. We also explored the acceptability of these programs through the lived experiences of our participants. Finally, we aimed to synthesise the evidence through meta-analysing data from available clinical trials on how habit-based weight loss programs compare with active/non-active control groups and the proportion of participants achieving clinically important weight loss of $\geq 5\%$ of their total body weight.

To achieve these aims, a scoping of the current evidence and an implementation of habit-based programs were required. The four studies presented earlier in this thesis (Chapters 1, 4-6) explored each of these key areas via the focussed research questions posed in the 'Methodology and aims of studies' (p. xii-xxiii). Each individual study makes an important contribution to the evidence-based practice of habit-based weight loss and weight loss maintenance. The thesis as a whole makes a novel contribution to the evidence and has furthered understanding of the efficacy of habit-based weight management, while also highlighting some recurrent themes throughout. By drawing together these research findings, areas for improvement in clinical practice and future directions in the conduct of research have been identified.

The findings from the randomised controlled trial (Chapter 4) indicate that participants in the habit-based programs (Ten Top Tips [TTT] and Do Something Different [DSD]), lost significantly more weight when compared with the wait-list control group. At 12-months post-intervention, participants in both TTT and DSD continued to lose weight with 65% achieving clinically important weight loss. Considering lifestyle interventions report a consistent and substantial regain of the weight lost within the first year following treatment ¹, and that weight loss maintenance is the greatest challenge for weight loss interventions ², our results prove promising. In the systematic review, results from the meta-analysis (Chapter 6) also showed a significant difference in weight loss between groups, favouring habit-based interventions over control. At follow-up, habit-based interventions achieved successful weight loss maintenance, however when compared with active control groups, the difference in weight loss was not

significant. More studies powered to examine at least 12-month follow-up are required to accurately evaluate long-term weight loss maintenance outcomes.

During the qualitative interviews (Chapter 5) conducted with participants in the TTT and DSD interventions, it was evident that participants valued the novelty of the interventions as they shifted focus from diet and exercise (which constitute the foundation of most weight-management programs), to practical every day habit changes. Participants reported the programs were convenient and practical to implement which may have contributed to sustained behaviour change. A major theme which emerged from the interviews was participants' sense of accountability throughout the programs. Accountability is a key factor for successful weight management and its lack is commonly reported as a barrier to achieving weight loss and weight loss maintenance³.

Interestingly, participants in the TTT and DSD interventions reported no self-accountability, only a sense of accountability to the researcher and the study, yet they continued to lose weight 12-months post-intervention and six months after the last follow-up appointment. This was a curious phenomenon which we can only explain through the concept of habit-change theory. TTT and DSD are founded on this concept; participants engaged in behaviours designed to become 'second nature' therefore, are more resistant to change. Once habits are formed, behaviours are performed automatically, without reflective decision making and despite intentions⁴. Hence, interventions that focus on changing the contexts that maintain those habits have a greater probability of long-term success,⁵ without the need for self-accountability⁶.

Key strengths and limitations

The broad and inclusive nature of data collection processes (e.g. including systematic searching, random allocation, and purposive sampling) are strengths across the studies. Consequently, this thesis has a key strength of providing a broad and comprehensive picture of the current state of evidence for habit-based weight-loss interventions. Additionally, the use of rigorous study methodologies and standardised templates (e.g. TIDieR checklist, COREQ checklist, CONSORT checklist and Cochrane Risk of Bias tool) ensures this thesis makes a valuable contribution to the current body of evidence in the field by highlighting the similarities, differences and variety in habit-based weight loss interventions provided within the literature. Lastly, habits and habit-based interventions are new and emerging topics. This

thesis provides a novel and timely insight into the efficacy of these interventions and provides recommendations for their practical application.

A primary limitation in evaluating the findings of this thesis is the limited number of published studies on habit-based interventions. This is a potential barrier to implementing evidence-based practice as it hinders robust exploration of the efficacy and mechanisms of habit-based interventions. Finally, the relationships observed in the meta-analysis and subgroup analysis presented in Chapter 6 (e.g. comparing weight loss between forming habits and a combination of forming and breaking habits) have the potential to be confounded by other factors such as: active and non-active control groups, dose of contact with participants and facilitator qualifications. This is largely because subgroup analyses are not based on randomised comparisons and are therefore observational by nature.

Complexities within literature and evidence

Psychology studies have defined the conceptual theories of habit-change and the sustainable effects of behaviour becoming 'second nature' ^{6,7}; however, eating behaviours are mostly mindless ⁸, multifaceted and are elicited for a variety of reasons. For example, dieters tend to ignore their internal cues, such as being aware of hunger levels and are instead guided by external cues such as images, aromas, or meal times ⁹. More specifically, we make food decisions based on the size of our plate, stress levels, amount of food variety presented, the number people we are eating with, time of day, and many more internal and external reasons, other than physiological hunger ¹⁰.

Although the nature of dietary choices is mostly mindless, according to habit theory, this can be used as a tool to trigger healthy eating. For example, smaller plates trigger early satiety, or the accessibility to fruit triggers fruit consumption. However, we are not always in control of external cues. Therefore, complying with a healthy eating regimen will be influenced by the contexts in which the individual is exposed to and also depend on the individual's habit strength. Individuals with strong habit strength are more likely to be guided by habits rather than by intention when compared with individuals with weak habit strength ¹¹. Consecutively, when behaviours are not well learned or when they are performed in unstable contexts, conscious decision making is likely to influence behaviour rather than habit ¹². Therefore, in order for a new behaviour to become second nature, the context must be stable during the habit acquisition phase (mean time 66 days with a range of 18-254 days) ⁶ and the individual must adhere to consistently repeating the new behaviour until it becomes habitual. This will build habit strength and establish the new behaviour with the triggering context.

Furthermore, external accountability is an important factor in behaviour change ³. When external accountability is absent, there are essentially no consequences to an individual ceasing their diet and exercise plans except for experiencing a sense of failure. We therefore speculate that changing dietary behaviours is unlike changing behaviours which attract external accountability and consequences, such as not fastening a seatbelt in the car has the potential to increasing the risk of injury and potential fines. When there is no external accountability, such as a support person, and no external consequences, perhaps forming a new healthy dietary change is more difficult.

There is a possible oversight in the literature between general habit-change theories which describe the effects of automaticity and sustained behaviour change (narrative literature), and habit-change specifically for dietary behaviour (intervention research). From the available habit-based studies, there are greater amounts of weight loss in the interventions which included regular, face-to-face accountability ^{9,13,14} (weekly meetings or drop-in sessions) compared with those that did not ^{2,15,16}; however there are too many confounding factors to confidently draw the conclusion that regular contact resulted in an improvement in diet and exercise behaviours and therefore, great weight loss. More research is required to specifically assess the mechanisms behind diet and exercise changes using habit-based strategies.

The most important component in this thesis was that the weight loss interventions used (TTT and DSD) and analysed (Transforming Your Life [TYL]), did not include a specific dietary prescription. Yet, overall, participants were able to successfully lose weight and maintain their weight loss. This finding, as well as previous studies, show that for long-term weight loss maintenance of up to 24-months, specific dietary prescription is not particularly effective ¹⁷, and may be somewhat unnecessary. As a dietitian (GC), who has developed countless individually-tailored meal plans, this was both challenging and refreshing. Understanding the various reasons people eat, and individually addressing those reasons using a variety of tools, including habit-change theory, is an invaluable strategy for successful weight-management.

Implications and recommendations for clinicians

The key implications and recommendations have been derived from issues raised in one or more studies in this thesis. These are discussed in detail below.

1. Include contextual cues when goal-setting

Currently, the clinical practice guidelines for the management of overweight and obesity according to the National Health and Medical Research Council (NHMRC) ¹⁸ include: focus on creating an energy deficit achieved by either reducing energy intake, increasing energy expenditure, or both; aim for a weight loss of 5%; implement individualised and supported interventions by self-management principles and regularly review these with a healthcare professional; take into account influences on health behaviours when planning interventions with individuals (e.g. social, physical and psychological factors). However, although the evidence of these behaviour changes show good weight loss success, the long-term maintenance of the weight loss is rare ¹.

Best-practice guidelines would benefit from the addition of habit-change techniques and the establishment of contextual cues to personalise the current advice and increase the chance of long-term weight loss maintenance. As contextual cues must be personalised to each individual's lifestyle and daily routines, it is difficult to offer exact examples such as: *“at 7am on Monday to Friday, go for a 30-minute brisk walk”*. Clinical guidelines should therefore start by briefly explaining the habit cycle (action-routine-reward) and offering examples on how to establish contextual cues. A tool such as the one displayed in Box 7.1 could be used as a guide.

Box 7.1 Creating a new healthy habit using contextual cues

Goal (e.g. 'to eat more fruit')

Plan (e.g. 'when I come home from work, I will have a piece of fruit')

When and where _____

I will _____

Other examples of context-dependent habit-changes include: *“when I serve myself dinner at home, I will fill half my plate with salad or vegetables”*; *“when I am eating or drinking, I will put away any distractions and practice mindfulness”*; *“when I am taking the dog for a walk, I will take a different route from the day before”*, etc.

Forming habits is a natural process and contributes to energy preservation as our brains don't have to consciously think about habitual behaviours and is therefore liberated to consider other things, such as what to make for dinner ¹⁹. Clinicians should work one-on-one with individuals to establish new, personalised healthy habits grounded specifically with contextual cues to support goal setting.

2. Include multiple cues to support the same behaviour

A recent qualitative study on TTT participants showed that linking behaviours to work-day cues such as arriving to work, was successful in forming new habits due to their stability and predictability ²⁰. Individuals embedded their new behaviours in existing routines and the predictability, stability and order of work routines was particularly conducive to integrating new behaviours. In contrast, weekends and holidays where behaviour patterns are less structured, temporarily disrupted habit performance due to the absence of associated cues. Although habits were reinstated on return to work, weekends and holidays led some participants in the study to 'come unstuck' ²⁰.

Because initiation and maintenance of habitual behaviours is context dependent, and contexts vary, interventions could be enhanced by associating the new desired behaviour to a wide range of contexts, or encouraging individuals to form multiple habits that support the same behaviour in different settings (e.g. a weekday habit of cycling to work and a weekend habit of cycling to shops).

3. Small changes make big differences

Although we see a dose-effect in participant's engagement in an intervention and the amount of weight loss achieved ^{21 22}, big or complex changes are more difficult to achieve and sustain when compared with small, simple changes ^{6,7,23}. As an example, most TTT participants in our study and previous studies ²¹ managed an average of 5 out of 10 tips per week. Moreover, changes associated with perceived difficulty, for example, walking 10,000 steps per day, were performed less frequently than simpler tasks such as, packing a healthy snack. Despite the evidence behind the relevance of walking 10,000 steps a day for weight loss ²⁴⁻²⁶ if individuals are struggling to complete the task, then readdressing it is necessary. For example, changing the goal from 10,000 steps per day to '*increase daily steps taken when walking*', and building on the step count each week or month by using a step-count diary. This effect has been observed in previous studies where participants took one and a half times longer to reach a

level of automaticity with exercise behaviours when compared with eating and drinking behaviours (exercise behaviours are considered more complex than eating or drinking) ²⁷.

This proposes that healthy behaviours which are perceived as relatively simple, such as walking, may become a habit more easily than behaviours which are perceived as more complex, such as attending an organised fitness program, as the latter behaviour requires more intentional effort and planning ²⁸. Similarly, changing certain components of an individual's eating habits would be more achievable if the changes happened in small, manageable increments; such as: *'include 1 piece of fruit per day in to your diet'*, compared with a bigger change such as, a pre-set meal plan.

It is important that individuals are not set up to fail by being assigned seemingly complex or unachievable goals. By regularly building on 'tiny habits', an individual is more likely to maintain those changes over a long period of time, subsequently achieving their desired health and weight goals.

4. *Include psychological and social support in weight loss interventions*

A conceptual review on who succeeds at maintaining weight loss summarised that weight maintenance is associated with an internal motivation to lose weight, social support, better coping strategies and ability to handle life stress, self-efficacy, autonomy, assuming responsibility in life, and overall more psychological strength and stability ²⁹. This suggests that individuals require social and psychological support to achieve long-term weight loss maintenance.

Social support often comes in the form of external accountability, to a friend, family member or health care professional. Accountability has been extensively reported as an essential facilitator to weight loss and weight loss maintenance ^{3,13,30,31}. Moreover, as mentioned earlier, the NHMRC clinical practice guidelines for the management of overweight and obesity recommends interventions be individualised, supported and include regular review ¹⁸. Although the evidence strongly favours external accountability, it is not routinely practiced in clinical or research settings especially post-intervention when it is most essential. Interventions should include regular and long-term follow-up to ensure adequate accountability to help maintain weight loss.

For individuals seeking to maintain weight loss, providing psychological support goes beyond the scope of practice of health care professionals who are not psychologists. Unfortunately, psychologists are not the first port of call for individuals wanting to lose weight, but rather

doctors, dietitians and commercial weight loss programs such as Weight Watchers³²⁻³⁴. Perhaps training support people in motivation techniques could be valuable as it would be unrealistic to recommend a psychologist to every individual wanting to lose weight. Motivation techniques can include shared-decision making and motivational interviewing³⁵, goal-setting, promoting a body-positive environment, providing incentives, etc. In summary, a multidisciplinary approach which includes at least a dietitian and psychologist (or support person trained in motivation techniques) might be effective in disrupting the weight-loss-weight-regain cycle.

Unanswered questions for future research

While the above four recommendations emerged from the research in this thesis, it also highlighted several unanswered questions:

1. What are the repeated long-term weight loss maintenance outcomes of habit-based interventions?

Habit-change theory describes habits as behaviours which are elicited with minimal prior deliberation and sustain as long as the triggering cues are continued, thereby sustaining behaviour change^{27,36}. Habit-based interventions therefore have the potential to enable long-term impact on behaviour and health⁶.

Studies in habit-based interventions have emerged in the past decade with only three weight-loss interventions currently available in the literature (TTT, DSD and TYL)^{9,13,16}. Although in this thesis we synthesised available data through meta-analysis, there were no long-term studies comparing habit-based programs with non-active control groups (maximum trial duration 3-months)¹⁵. When looking at weight loss maintenance outcomes from single-armed studies, the data suggest that habit-based interventions are successful at achieving long-term weight loss maintenance, however this was not the case when the interventions were compared with active-control groups. Hence, we conclude that longer and more methodologically rigorous studies that are powered to examine at least a 12-month follow-up are required to build on our assessment of the efficacy of habit-based interventions for long-term weight loss maintenance.

2. What is the efficacy of habit-based interventions when compared with non-active control groups?

Our systematic review and meta-analysis found significant gaps in the literature. To date, there have been only three published studies looking at weight change outcomes of habit-based interventions compared with non-active controls post-intervention ^{2,15,37}, and no studies looking at the long-term outcomes. Three studies compared habit-based interventions with active-controls ^{13,14,16}, however as demonstrated in our post-intervention meta-analysis, comparing active and non-active controls results in significantly different overall effect sizes.

Non-active control group comparisons give reliable baseline data. The issue of long-term waitlist control groups is challenging as longer waiting periods results in increased attrition rates ³⁸. Nevertheless, a study design which considers this expected attrition when carrying out sample size calculations would make this study type more feasible.

3. Do forming new habits or breaking old habits, or a combination of both result in the greatest weight loss and weight loss maintenance?

Although our randomised controlled trial and systematic review aimed to determine if forming new habits or breaking old habits achieved greater weight loss, we are yet to answer this query. According to our randomised controlled trial, there were no statistically significant differences between forming new habits and breaking old habits for weight loss and weight loss maintenance. Conversely, our systematic review which compared forming new habits with the combination of forming+breaking habits showed that forming new habits achieved greater weight loss; however, because the combination interventions were compared with active control groups, a conclusion cannot be made either way with the current published literature. Further studies comparing the conceptual theories of habit-change, whether forming new habits, breaking old habits, or a combination of both are required.

4. What are the underlying mechanisms influencing the relationship between habit change and weight loss?

Despite the growing interest in habit-based strategies, this approach is still scarce and the mechanisms which influence the relationship between habit change and weight loss and loss maintenance are not completely understood. Only one very recent study explicitly explored the potential mechanisms of TTT for weight loss ²¹. Considering habit-based interventions

show significant weight loss and weight loss maintenance with no diet or exercise prescription, understanding how these interventions influence weight loss is essential.

Future studies which focus on the mechanisms influencing the relationship between habit-based strategies and weight loss may provide guidance on the development of more effective weight-management interventions.

A mediator analysis could be performed on current and future studies to help identify the mechanisms which underlie the observed relationship between habit change and weight loss. Alternatively, a factorial design clinical trial could be conducted to test the treatment effects of each intervention task independently. An example of this for TTT, could be a random allocation of tips, where each individual receives 8 of the 10 tips; this would allow the investigator to analyse the effect of each missing/included tip. A mixed methods analysis would also be valuable, where investigators implement a randomised controlled trial using habit-based weight loss interventions and a non-active control group, ensuring qualitative data on barriers and facilitators are collected throughout the study.

5. How can habit-based weight loss interventions be standardised and widely available?

Habit-based weight loss interventions have shown positive weight management outcomes with promising sustained effects. Standardising habit-based interventions and making them more widely available might increase intervention uptake and consequently improve the lives of thousands of people. One potential method would be to develop smartphone applications (apps) in multiple languages, which would be available for download to any person with a compatible phone device. Over the past decade, health and fitness apps have gained popularity in interventions to improve health behaviours. The widespread adoption of mobile phones highlights a significant opportunity to impact health behaviours globally, particularly in low-and middle-income countries where health care may not be as accessible³⁹. A recent systematic review of 23 studies which explored the efficacy of interventions that use apps, showed improvements in health behaviours, specifically for diet and physical activity⁴⁰. Developing, implementing and evaluating apps specifically for habit-based weight loss interventions would be a valuable contribution to standardising and creating a widely available and accessible tool for individuals to use.

Conclusion

This thesis explored the current evidence and efficacy of using habit-based interventions for weight loss and weight loss maintenance. The findings identified key gaps in the literature as well as contributed to shaping the growing evidence on habit-based weight-loss interventions. Finally, this thesis offered important considerations for future strategies, interventions and research studies.

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Addendum

This section of the thesis seeks to clarify and acknowledge both Cancer Research UK (CRUK) and the University College London: Weight Concern (UCL: Weight Concern) as co-developers of the Ten Top Tips (10TT) intervention and all associated intellectual property.

Dr Gina Cleo

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Appendices

Appendix A (pages 206 to 219)

Peer-reviewed journal article, published in the Journal of Human Nutrition and Dietetics in February, 2017.

Cleo G., Isenring E., Thomas R., Glasziou P. (2017) Could habits hold the key to weight loss maintenance? A narrative review. J Hum Nutr Diet. doi: 10.1111/jhn.12456



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NARRATIVE REVIEW

Could habits hold the key to weight loss maintenance? A narrative review

G. Cleo^{1,2} E. Isenring¹ R. Thomas^{1,2} & P. Glasziou^{1,2}

¹Faculty of Health Sciences and Medicine, Bond University, Gold Coast, QLD, Australia

²Centre for Research in Evidence-Based Practice (CREBP), Bond University, Gold Coast, QLD, Australia

Abstract:

Background: Despite the significance placed on lifestyle interventions for obesity management, most weight loss is followed by a weight regain. Psychological concepts of habitual behaviour and automaticity have been suggested as plausible explanations for this overwhelming lack of long-term weight loss success. Interventions, which focus on changing an individual's behaviour, are not usually successful at changing an individual's habits, as they do not incorporate the strategies required to break unhealthy habits and/or form new healthy habits.

Methods: A narrative review was conducted and describes the theory behind habit formation in relation to weight regain, and evaluated the effectiveness of using habits as tools to maintain weight loss. Three specific habit-based weight loss programs are described: '10 Top Tips', 'Do Something Different' and 'Transforming Your Life'.

Results: Participants in these interventions achieved significant weight loss when compared with a control group or other conventional interventions.

Conclusion: Habit-based interventions show promising results in sustaining behaviour change. Weight loss maintenance may benefit from incorporating habit-focused strategies and should be investigated further.

Key words: obesity; overweight; weight maintenance; habits; habit-based intervention

Introduction

Weight loss maintenance

In Obesity, even modest weight loss is associated with significant health benefits, especially when maintained over time ⁽¹⁾. A systematic review and meta-analysis of 26 randomised controlled trials ($n= 2899$ participants) reported a 5-10% reduction in body weight in overweight or obese individuals was associated with significant improvements in LDL cholesterol, total cholesterol, blood pressure, blood glucose and other health indices ^(2, 3). If the lost weight is not regained, these health benefits appear to be sustained ⁽⁴⁾. Weight loss of 10-15% body weight has even greater benefits ⁽⁵⁾. Achieving ideal weight is not essential for an individual to attain these health benefits ⁽⁶⁾.

Among participants from the National Weight Control Registry (NWCR) who have maintained their weight loss for a number of years ($n= 784$), over 90% reported improvement in their overall quality of life, mobility, level of energy, general mood and self-confidence ⁽⁷⁾. Furthermore, a randomised controlled trial of 588 overweight or obese individuals reported reductions in weight at 12 months were associated with improvements in overall wellbeing, depression, anxiety, and ratings of self-control and vitality ⁽⁸⁾. These findings are consistent with previous studies, which investigated the impact of weight change on various factors relating to quality of life ⁽⁹⁾. A cross-sectional longitudinal study ($n= 4601$) showed a significant association between excess weight and lower quality of life scores ⁽¹⁰⁾ and a randomised, parallel group trial of 423 participants showed predictability between lower weight and better quality of life regardless of the weight loss intervention ⁽¹¹⁾.

The first 2-5 years after weight loss is the most vulnerable time for weight regain. Maintaining weight loss during those first few years decreases the risk of successive regain by 50% ⁽¹²⁾. Consequently, individuals who manage to maintain their weight loss for more than 2 years have a significantly greater chance of keeping the weight off long-term ⁽⁷⁾. However, considering the majority of overweight or obese individuals will regain most of the weight lost, understanding and addressing the determinants for weight regain is essential for successful weight loss maintenance interventions. No single theory can fully explain decision making in health behaviour, therefore, considering multiple perspectives is essential ⁽¹³⁾.

Conventional interventions and outcomes

A wide range of interventions are available for treating overweight and obesity. These can be classified into three general categories: surgical, pharmacological and lifestyle.

Bariatric surgery has seen the most success with weight loss maintenance ⁽¹⁴⁾. However only a small number of individuals qualify for surgical interventions due to guideline recommendations that surgical candidates have a body mass index (BMI) of at least 40kg/m² or a BMI between 35-39kg/m² and experiencing at least one serious obesity-related comorbidity. These guidelines are due to the significant risk of morbidity and mortality associated with bariatric surgery ⁽¹⁾.

Pharmacotherapy treatment (such as prescription medication which suppress appetite or inhibit fat absorption) is generally prescribed for no longer than 12 weeks due to adverse side effects

such as insomnia, dizziness, headaches, stomach aches and an increased risk of heart disease and stroke ⁽¹⁵⁾. Consequently pharmacotherapy studies show a general short-term weight reduction and an invariable weight regain due to the short treatment period ⁽¹⁴⁾.

Finally, lifestyle interventions (which constitute the foundation of any weight-management program) present a consistent regain of the weight lost with about 40% regained over the first year following treatment and much of the rest over the following three years ^(1, 14). Understanding and addressing the determinants for weight regain in lifestyle interventions is therefore essential for successful weight loss maintenance interventions.

There is extensive evidence that behaviour can be effectively modified through behaviour change interventions, however evidence for the sustainability of this change is limited ⁽¹⁶⁾. Simply knowing what diet and exercise behaviours are necessary for long-term weight loss success does not equate to a healthy diet or loss of weight. In recent years, studies in psychology have shown strong evidence to suggest that unconscious, automatic processes strongly influence our behaviour ⁽¹⁷⁾. This evidence of unconscious behaviour and automaticity has led to extensive research in the area of habits, the intention-behaviour gap, automaticity and behavioural flexibility. We discuss the theory of these novel determinants, search for weight-loss interventions that use these behaviour change techniques, and evaluate the effectiveness of using these techniques as tools to maintain weight loss in adults.

Habits

According to a systematic review of 100 theoretical explanations for maintenance of behaviour change, the brief theoretical explanation for a habit is when someone is effective in maintaining behaviours which have become habitual and are supported by automatic responses to relevant cues ⁽¹⁶⁾.

Habits are generally formed by repeating a behaviour until it has become more or less automatic ⁽¹⁸⁾. By repeating behaviour in a consistent context, we forge a direct link in memory between the context and response ⁽¹⁹⁾. Therefore, we learn to associate the behaviour triggered by that setting; this process is termed 'context-dependent repetition'. This reinforces a mental context-behaviour association, such that alternative options become less accessible in memory ⁽²⁰⁾; eventually, the mere perception of the context automatically triggers the responding behaviour ^(21, 22). Habit formation involves a gradual shift in cognitive control from intentional to automatic processes ⁽¹⁸⁾. This is why a habit is defined as an action which has been triggered automatically in response to a contextual cue associated with its performance ⁽²³⁾. Approximately 45% of everyday behaviours are repeated in the same location ^(24, 25). Daily life consistently exposes people to numerous cues triggering wanted and unwanted habits.

To illustrate habit formation and how it relates to dietary intake, imagine that each time a person goes home in the evening, they eat a snack. When they first eat the snack, a mental link is formed between the context (getting home) and their response to that context (eating a snack). Every time they subsequently snack in response to getting home, this link strengthens, to the point that getting home prompts them to eat a snack automatically; a habit has been formed ⁽²³⁾.

We make over 200 food decisions per day ⁽²⁶⁾. Most of these decisions appear to be ‘automatic’ or habitual, which means we unconsciously eat without reflection, deliberation or any sense of awareness of what or how much food we select and consume ⁽²⁶⁻²⁸⁾. Therefore, due to the lack of thought required to perform a habit, habitual behaviours override intention ⁽²⁸⁾. The sight of the TV remote control can derail a plan to exercise; the notification of a new email can trigger the common habit of procrastinating on the internet ⁽²²⁾. The ubiquitous effect of habits in everyday behaviour is a key to understanding the struggle people recurrently experience in changing their lifestyles. Failed attempts at changing diet and exercise behaviour are typical ⁽⁸⁾. Such failures are common considering cues such as location and time of day both trigger repetition of usual responses ⁽²²⁾. Lack of will power or poor knowledge of health is not necessarily an indicator for failures to change, but instead may indicate the power of situations to trigger past responses. Although people are free to act in non-habitual ways, everyday demands such as time pressures and distractions reduce the capacity to engage in reflective thought; therefore people tend to rely on eating habits ⁽²⁹⁾. In a qualitative investigation of 11 adults, automatic behaviour patterns were identified as a perceived cause of weight gain ⁽³⁰⁾. Habits keep us operating in the way we have always done, despite our best intentions to act otherwise.

Intention-behaviour gap

Social psychology theories suggest that forming a goal intention (e.g. ‘I intend to eat healthily’) is imperative in promoting behaviour change and goal attainment ⁽³¹⁾. However, a recent meta-analysis ($n= 22$ studies) of healthy eating and physical activity habits showed that the stronger an individual’s habit strength, the less impact their intentions had on their actions ⁽³²⁾. Although individuals develop an intention to change their health behaviour, they might not take any action; this discrepancy is called the “intention-behaviour gap” ⁽³³⁾. A cross-sectional study ($n= 538$) integrated habit strength in the theory of planned behaviour in order to understand participants’ fruit consumption. Findings showed that stronger fruit consumption habits made fruit consumption less intentional ⁽³⁵⁾. Therefore participants with strong habits of fruit consumption ate fruit as a result of their habit to do so, not their intention. In fact, when an individual had low levels of habit strength the intention-fruit consumption relationship was more than twice as strong than when an individual had a high level of habit strength ⁽³⁵⁾.

The same participants were assessed for exercise behaviour, intention and habit strength. Findings indicated that exercise has both a cognitive and an automatic component and that stronger exercise habits make exercise less intentional, with the intention-exercise relationship nearly three times stronger at lower levels of exercise habit strength than at higher levels ⁽³⁵⁾.

Habits are strengthened as behaviour is repeatedly performed in a consistent context ⁽³²⁾ and when behaviour is reinforced by a pleasant experience or reward (i.e. the sweet satisfaction of a chocolate cookie or the comfort of a hearty, warm pudding) ⁽³⁶⁾. In a three-wave observational study of fruit and vegetable (FV) intake in adults ($n= 127$), the researchers hypothesised that the intrinsic reward value of FV consumption would strengthen FV consumption habits. Habit strength was assessed with the Self-Report Behavioural Automaticity Index (SRBAI), an automaticity-specific abbreviation of the Self-Report Habit Index (SRHI) ⁽³⁷⁾. Questionnaires measured participants’ intrinsic reward, intention and self-

efficacy at baseline and after two and four weeks. Results indicated intrinsic reward had a positive indirect effect on habit strength through its influence on the frequency of FV consumption. Further, the relationship between FV consumption and habit was stronger where consumption was considered more intrinsically rewarding. These findings highlight the potential relevance of intrinsic reward to habit and should be considered as a tool in habit-based interventions ⁽³⁸⁾.

People with strong habits are generally not observant to information about the adverse effects of their behaviour ⁽³⁶⁾. To illustrate, Ji and Wood studied college students ($n= 219$) over a week-long period and predicted how often they watched TV or purchased fast food from their behavioural intentions and from their habits ⁽³⁹⁾. The findings showed that students acted on their intentions only when their habit strength was weak or moderate ⁽³⁹⁾. Students with strong habits continued their typical behaviour in purchasing fast food, despite their intentions. Therefore, as habit strength increased, intentional behaviour decreased. In fact, intentions guided actions largely when habits had not been formed. These findings support the theory that habitual behaviour can be triggered independent of an individual's intentions ⁽¹⁹⁾. Consequently, this automatic eating behaviour has been described as the most plausible factor to explain the lack of weight loss maintenance success ⁽⁴⁰⁾.

Automaticity

Once a habit is formed, automaticity is considered to be the 'active ingredient' of that habit ⁽¹⁸⁾. Automaticity can be described as a behaviour which features efficiency, lack of awareness, unintentionality and uncontrollability ⁽⁴¹⁾. Automatic behaviours occur without reflective decision-making processes, ⁽²⁷⁾ and increase with continuous repetition of the behaviour ⁽⁴¹⁾.

The complexity of a particular behaviour impacts the development and strength of automaticity ^(23, 41). In a study of 96 participants who chose an eating, drinking or exercise behaviour to carry out daily in the same context for 12 weeks, the average time participants took to reach automaticity of their chosen behaviour was 66 days, (range of 18-254 days) ⁽³²⁾. Exercise behaviours (considered more complex than eating or drinking) took one and a half times longer to reach a level of automaticity than eating and drinking habits) ⁽⁴¹⁾. In another study, automaticity strength peaked more rapidly for simple actions (e.g. drinking water) than for more elaborate procedures (e.g. doing 50 sit-ups) ⁽²³⁾. Other studies report consistent findings with participants automatically performing lifestyle behaviours after approximately 10 weeks; moreover, participants maintained their new habitual behaviours over 32 weeks and the behaviours increased in automaticity ⁽⁴²⁾.

Automaticity is a powerful tool in positive habit formation as there is a reassurance that doing a new and healthful behaviour will get progressively easier. Therefore, maintaining motivation and consistently undertaking the new behaviour is only necessary until the habit forms and the new behaviour becomes 'second nature' ⁽²³⁾. Lifestyle changes commonly last only a short period of time as individuals generally return to their previous patterns ⁽⁴³⁾. Once a behaviour becomes automatic however, it is more resilient to change than purposeful or intentional behaviours ^(41, 44) and therefore lasts longer and achieves continued or maintained results ⁽⁴⁵⁾.

Habit advice, should therefore include behaviour changes which are simple for individuals to implement as this provides realistic long-term effects ⁽²³⁾. Gardner et al. developed a sample tool for health professionals to use with patients in order to encourage habit formation (Box 1).

Box 1 A tool for patients to encourage habit formation ⁽²³⁾

Box 1. A tool for patients

Make a new healthy habit

1. Decide on a goal that you would like to achieve for your health.
2. Choose a simple action that will get you towards your goal which you can do on a daily basis.
3. Plan when and where you will do your chosen action. Be consistent: choose a time and place that you encounter every day of the week.
4. Every time you encounter that time and place, do the action.
5. It will get easier with time, and within 10 weeks you should find you are doing it automatically without even having to think about it.
6. Congratulations, you've made a healthy habit!

My goal [e.g. 'to eat more fruit and vegetables'] _____

My plan [e.g. 'after I have lunch at home I will have a piece of fruit']
 (When and where) _____ I will _____

Some people find it helpful to keep a record while they are forming a new habit. This daily tick-sheet can be used until your new habit becomes automatic. You can rate how automatic it feels at the end of each week, to watch it getting easier.

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
Monday										
Tuesday										
Wednesday										
Thursday										
Friday										
Saturday										
Sunday										
Done on >5 days, yes or no										
How automatic does it feel? Rate from 1 (not at all) to 10 (completely)										

Habit formation begins with an 'initiation phase', during which the new chosen behaviour and the context in which that behaviour will be performed are selected; for example, 'eating a piece of fruit at breakfast'. Automaticity develops in the subsequent 'learning phase', during which the behaviour is repeated in the chosen context to strengthen the context-behaviour association (self-monitoring through a tick sheet may help ⁽⁴⁶⁾ (Box 1)). Finally, habit formation is accomplished in the 'stability phase', at which the behaviour persists over time with minimal conscious thought or effort ⁽²³⁾. This tool has not been formally tested, however synthesises evidence based on current literature of habit theory ⁽²³⁾.

Behavioural flexibility

Behavioural flexibility has an inverse relationship to automaticity and is a measure of a person's range of behaviours across different situations ⁽⁴⁷⁾. An individual with more behavioural flexibility has a greater behavioural reservoir and behaves in less habitual ways than a person with less behavioural flexibility. Behavioural flexibility is primarily measured using a psychometric instrument labelled the 'FIT Profiler' (Framework for Internal Transformation) ⁽⁴⁷⁻⁵²⁾ which measures core aspects of a person's thinking processes and the nature and flexibility of their behaviours.

In a study sampling over 1,000 people, behavioural flexibility was found to correlate negatively and significantly with BMI ⁽⁴⁹⁾. This finding led the researchers to the novel hypothesis that, if behavioural flexibility is negatively correlated with BMI, then increasing behavioural flexibility would lead to weight reduction ⁽⁵⁰⁾. By doing something different on a daily basis individuals are challenged to break existing habits and increase their behavioural flexibility. This approach avoids the need for sustained willpower and may provide the impetus for positive change by altering the daily habits that trigger overeating and the broader changes needed for positive health behaviour generally ⁽⁴⁷⁾.

Habit change interventions for weight loss maintenance

Breaking unwanted habits can be achieved through restructuring an individual's environment, or programming new responses to their existing environment ⁽³²⁾. Interventions, which focus on changing an individual's behaviour are not usually successful at changing an individual's habits as they do not incorporate the strategies required to break unwanted habits and form new healthful habits ^(42, 53). General health advice is usually based on advising patients on what to change and why (e.g. reduce daily calorie intake to achieve weight loss). Such advice requires conscious, deliberative thoughts ⁽²³⁾. However, motivation and attention to change behaviours wane over time, therefore the effects of behaviour change are typically short-lived ⁽²³⁾. Advice on how to change, whilst engaging automatic behaviours (including efficiency, lack of awareness, unintentionality and uncontrollability ⁽⁴¹⁾) may offer a valuable alternative with potential for long-term impact ⁽²³⁾.

A focused search in PubMed for its generality and PsychInfo for its focus on psychological interventions found three habit-based weight loss interventions: '10 Top Tips' ^(44, 47), 'Do Something Different' ^(47, 40) and 'Transforming Your Life' ^(54, 55). See Table 1 for comparison of intervention methods.

The 10 Top Tips (10TT) is an intervention based on habit formation theory, using written materials to guide participants through a set of simple weight management behaviours with the intention of making those behaviours habitual. For example, participants are required to keep to a meal routine, eat off a smaller plate, eat mindfully and pack a healthy snack. Results from a randomised controlled trial with 104 overweight or obese participants, showed the 10TT intervention produced a statistically significant mean weight loss of 2.0kg at 8 weeks compared to a mean weight loss of 0.4kg in the control group. Moreover, participants in the 10TT intervention continued to lose weight with an average of weight loss of 3.8kg at 32 weeks. The intervention was easily disseminated, low-cost and produced clinically significant

weight loss. Participants in the 10TT study also reported automaticity of some of the healthy habits prescribed in the intervention, therefore sustainability of their weight loss was predicted⁽⁴²⁾.

Semi-structured interviews were conducted at the end of the intervention with a random subsample ($n=10$) of participants in order to gather feedback and explore general experiences. Results showed that behaviour change was initially experienced as cognitively effortful but as automaticity increased, enactment became easier. Most participants reported characteristics of habit: Automaticity, the importance of repetition and “feeling strange” when not doing the behaviour⁽⁵⁶⁾.

Do Something Different (DSD) is a behavioural intervention, which focuses on increasing participants’ behavioural flexibility by breaking daily habits. The authors describe the aim of DSD is to break the distal habits proposed to play a role in unhealthy dietary and exercise behaviours. DSD requires participants to do something different each day and to engage in novel, weekly activities to expand their behavioural repertoire. What makes this intervention particularly novel is that these activities are not food or exercise related. In a longitudinal, two-armed controlled trial of 31 participants, the DSD intervention achieved a gradual and continuous weight loss with a statistically significant mean average of 2.6kg loss over a 4-week period, compared with 0.88kg loss in the control group. Two months post-intervention, DSD participants had continued to lose weight with a total mean weight loss of 5.18kg ($SD = 3.85$), compared with 0.43kg ($SD = 1.94$) loss in the control group⁽⁴⁷⁾; suggesting the changes effected in the DSD intervention were maintained.

A key finding in the study was a dose-response relationship between changes in behavioural flexibility that occurred as a result of the 4 week DSD program and the amount of weight loss observed. This supports the hypothesis that behavioural flexibility may facilitate in weakening poor lifestyle habits and therefore contribute to weight loss⁽⁵⁰⁾.

Transforming Your Life (TYL) is an environmental modification approach to weight loss, which combines promoting healthy habits as well as disrupting unhealthy habits. Individuals were taught to create their personal food and exercise environment in a manner that minimises unhealthy eating and sedentary behaviour cues/choices, maximises healthy eating and exercise-related cues/choices, and encourages automatic responding to goal-related cues⁽⁵⁵⁾. In a 12-week randomised controlled trial, 59 overweight and obese participants were randomised to either TYL or a weight loss program which emphasized reducing unhealthy relationship with food (New Perspectives (NP)). Despite equivalent weight loss at the end of treatment ($Mean = 6.6kg$, $SD = 5.3$), the TYL participants were significantly more effective at maintaining their weight loss with a further average weight loss of 2.2kg ($SD = 4.4$) while NP participants regained an average of 2.1kg ($SD = 7.3$) during the 6-month no-treatment follow-up period⁽⁵⁵⁾.

Although a 6-month follow-up period is relatively brief, the continued weight loss in the TYL program supports the theory that habit-based interventions achieve greater success at maintaining weight loss long-term when compared to traditional behavioural weight loss programs⁽²³⁾.

Table 1 Table of comparison of intervention methods and results

		Do something different (Habit disruption)		Transforming your life (Habit formation & habit disruption)	
		DSD – Study 1 ⁽⁴⁹⁾	DSD – Study 2 ⁽⁴⁶⁾	TYL – Study 1 ⁽⁵³⁾	TYL – Study 2 ⁽⁵⁴⁾
Intervention method and delivery	10 top tips (Habit formation) 10TT ⁽⁴¹⁾	Based on habit formation theory to promote automaticity. Participants attended an information meeting where they were provided with a leaflet, which outlined the 10 tips as well as a daily self-monitoring form. The programme was self-guided at home and no therapeutic contact was provided during the intervention period	Aimed to break distal habits proposed to play a role in unhealthy dietary and exercise behaviours. Participants attended a 2-h group induction session where they were provided with a task booklet, which guided them to do something different every day. The tasks were not diet and exercise related. The intervention was self-guided at home	An environmental modification approach, which combined promoting healthy, habits as well as breaking unhealthy habits. Participants attended weekly, group, 90 min, face-to-face sessions conducted by a licensed clinical health psychologist and/or graduate students in psychology. Sessions included weight assessment and provided a combination of didactic instruction, group and individual in-class activities, and take home assignments	An environmental modification approach, which combined promoting healthy, habits as well as breaking unhealthy habits. Groups of 12–16 individuals met weekly for a 90-min, face-to-face session conducted by a licensed clinical health psychologist and/or graduate students in psychology. Sessions included weight assessment and provided a combination of didactic instruction, group and individual in-class activities, and take home assignments
Control group treatment	Wait list group were offered the intervention after 8 weeks	Participants engaged in daily tasks not expected to influence behavioural flexibility	Provided same intervention as active group with the addition of a diet of their choosing	LEARN weight loss programme, which encourages increasing physical activity and decreasing energy and fat intake	New Perspectives weight loss programme, which emphasises reducing unhealthy relationships with food, body image dissatisfaction and internalised weight bias
AND quality criteria ⁽⁵⁶⁾	Neutral	Positive	Positive	Positive	Positive
Outcomes measured	BMI, satisfaction with life, development of habits – Self-Report Habit Index	Weight	BMI, weight, behavioural flexibility, changes in food consumption and exercise time, anxiety, and depression	Average daily energy intake (kcal), average daily energy expenditure (kcal), average energy expenditure from physical activity, exercise duration, and weight	Weight, BMI, average daily energy intake (kcal), average daily energy expenditure (kcal), Binge Eating Scale, Emotional Eating Scale, several other scales
Trial duration	8-week intervention; 6-month follow-up	4-week intervention; 2-month follow up	4 week intervention; 2-month follow-up	14 week intervention; 6-month follow-up	12-week intervention; 6-month follow-up
Inclusion criteria	BMI ≥ 25 kg m ⁻² , age ≥ 18	BMI ≥ 25 kg m ⁻² , no medical contraindications	BMI 20– \rightarrow 30 kg m ⁻² .	BMI ≥ 27 kg m ⁻² , nonsmokers, free from cardiovascular disease and insulin dependent diabetes	BMI ≥ 27 kg m ⁻² , free from major medical conditions
Mean (SD) baseline weight	89.8 (15.0) kg	Not reported	Not reported	Not reported	109.8 (32.2) kg
Mean (SD) baseline BMI	30.9 (4.5) kg m ⁻²	29.6 (4.8) kg m ⁻²	31.2 (6.5) kg m ⁻²	37.2 (6.7) kg m ⁻²	39.7 (10.3) kg m ⁻²

Table 1. Continued

	10 top tips (Habit formation) 10TT (41)		Do something different (Habit disruption)		Transforming your life (Habit formation & habit disruption)	
		DSD – Study 1 (49)	DSD – Study 2 (46)	TYL – Study 1 (53)	TYL – Study 2 (54)	
Mean (SD) age	40.5 (10.4) years	44.2 (7.3) years	43.7 (9.5) years	47.3 (11.2) years	44.3 (13.2) years	
N	104	31	55	54	59	
Study design	Quasi randomised controlled trial	1 month longitudinal prospective cohort study	3 month longitudinal quasi-controlled trial	Two-armed randomised controlled trial	Two-armed randomised controlled trial	
Mean (SD) weight loss post-intervention	8 weeks: – 2.0 kg	4 weeks: – 2.6 kg	4 weeks: – 1.5 (1.2) kg	14 weeks: – 5.4 (4.8) kg	12 weeks: – 6.6 (5.3) kg	
Mean (SD) weight loss at follow-up from baseline	4 months: – 4.10 kg 8 months: – 3.8 kg	2 months: – 4.5 kg	1 month: – 3.3 (2.3) kg 2 months: – 5.0 (2.7) kg	6 months: – 3.9 (4.9) kg	6 months: – 8.8 (9.7) kg	

AND, Academy of Nutrition and Dietetics; BMI, body mass index; DSD, do something different; n, number of participants; QOL, Quality of Life; 10TT, 10 Top Tips; TYL, transforming your life.

Limitations

There are several limitations to this review. There is currently limited long-term follow up data on habit-based weight loss interventions; therefore this review reflects a maximum 6-month follow-up outcome. Weight loss outcomes at least 12-months post-intervention would provide a more accurate conclusion on the efficacy of habit-based interventions on long-term weight loss maintenance. We also did not discuss the physiological and biological effects on weight regain and obesity as we did not focus on causes of obesity. Rather, we focused on habit-based weight management interventions which may be effective for obesity treatment. The search strategy for this review restricted the search to habit-based interventions that focused specifically on habit-change as the conceptual theory. Although interventions may indirectly change an individual's habits, this study focused only on the interventions where habit-change was the primary strategy for behaviour change and therefore weight loss.

Conclusion and areas for future research

Ample evidence suggests that a significant part of daily eating behaviours consists of habits. In line with this, the concept of habit is increasingly incorporated into studies investigating the behavioural and psychosocial determinants of food choice, yielding evidence that habit is one of the most powerful predictors of eating behaviour and therefore weight loss success ⁽³⁶⁾.

Best intentions are not enough to elicit behaviour change. People with strong habits tend to continue their typical behaviour despite their well-meaning and often well-informed intentions ⁽²⁸⁾ In fact, theory and empirical research suggests that intentions guide actions largely when habits have not yet been formed ⁽²¹⁾ This phenomenon supports the theory that habitual behaviour can be triggered independent of an individual's intentions ⁽⁵⁸⁾. Therefore, a deeper focus on habit-change interventions would be beneficial in order to better inform weight management interventions.

Despite using different methods, the habit-based interventions highlighted in this paper, namely 10TT, DSD and TYL all show significant weight loss results with promising long-term weight loss maintenance. None of the interventions however have published results regarding maintenance of the participants' weight loss longer than six months. For those who adhere to weight loss lifestyle programs, weight loss is often the outcome but typically not for long. Research in weight loss programs would benefit from long-term follow-up periods beyond the immediate and short-term. Additionally, there is currently a dearth of studies focused primarily on habit-change theories for the treatment of obesity. Perhaps a fresh look at habits and the intention behaviour gap will shed some light on this significant problem.

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Transparency Declaration: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained.

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Appendix B (page 221)

National Health and Medical Research Council (NHMRC) Evidence hierarchy: designations of 'levels of evidence' according to type of research question.

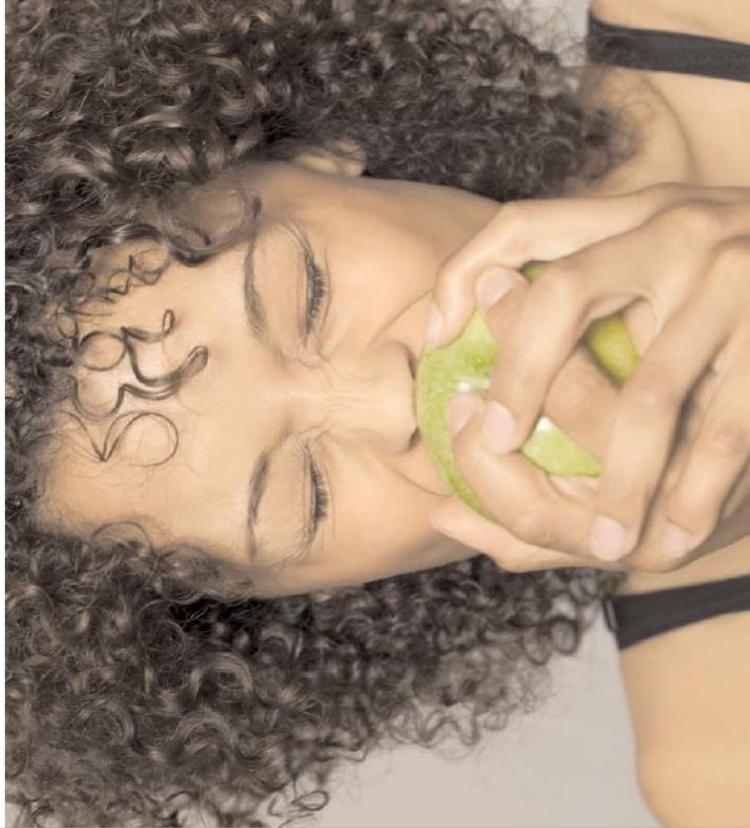
NHMRC Evidence hierarchy: designations of 'levels of evidence' according to type of research question

Level	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening Intervention
I	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> Non-randomised, experimental trial Cohort study Case-control study Interrupted time series with a control group 	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> Non-randomised, experimental trial Cohort study Case-control study
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> Historical control study Two or more single arm study Interrupted time series without a parallel control group 	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> Historical control study Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Source: NHMRC Levels of evidence and grades for recommendations for developers of guidelines 2009

Appendix C (pages 223 to 226)

Ten Top Tips informational leaflet and sample logbook (ticksheet).



ten top tips

weight loss tips based on scientific evidence

ten top tips

This leaflet contains a programme of weight loss tips, all based on scientific evidence. They will help you take in fewer calories and burn more energy through activity. Ten Top Tips are simple habits that everyone can fit into their daily routines and doing all ten over the longer-term will help you lose weight and keep it off.

How can the Ten Top Tips help you control your weight?

The Ten Top Tips programme helps you incorporate lifestyle changes into your daily routine so that they become automatic and easy to maintain. To develop new healthy habits you need to:

- **Plan ahead:** In the first week or two, spend a little time working out in advance how you are going to do the tips. For example work out how to fit five servings of fruit and vegetables and the extra walking into your day.
- **Tracking your progress:** Use tick sheets each day to record if you do each of the tips. Keep this up until the tips have become automatic. Record-keeping increases success in developing healthy habits.

A tear off tick sheet can be found at the back of this leaflet.

Does being overweight matter?

Being overweight affects your health. It can increase the risk of several types of cancer. These include cancers of the bowel, kidney, oesophagus (foodpipe) and womb, as well as breast cancer in women who have been through the menopause. It can also increase the risk of diabetes, high blood pressure, coronary heart disease, osteoarthritis and stroke.

We all know how difficult it is to lose weight and keep it off. The good news is that if you are overweight losing just 5-10% of your body weight and keeping it off will have a positive effect on your health. For most people this will be around 3-10kg or 1/2 - 1 1/2 stone.

(NB. If you are seriously overweight and have other health problems, it may be advisable to seek advice from your Doctor before beginning a weight management programme).

Visit www.reduce therisk.org.uk for further information on all of these tips.



2 Go reduced fat

Choose reduced fat versions of foods such as dairy products, spreads and salad dressings where you can. Use them sparingly as some can still be high in fat.

Handy Hint:

- Change to semi-skimmed milk and save 60 calories/day, amounting to 420 calories over a week (based on consuming 300mls milk/day).

Keep to your meal routine

Try to eat at roughly the same times each day, whether this is two or five times a day.

Handy Hints:

- Pick a pattern that fits in with your own daily routine and stick to it.
- If you are someone who needs snacks, try to snack around the same time each day.
- Try planning when you intend to eat and check at the end of the day if you have achieved this.

Keeping a record has been shown to increase people's success in developing healthy habits

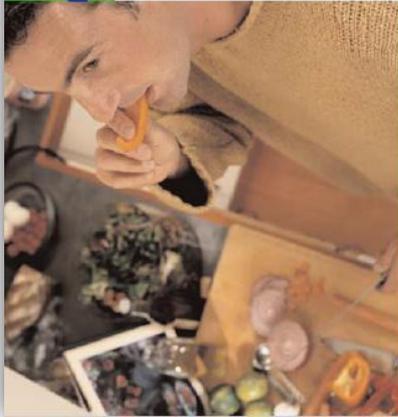
3 Walk off the weight

Walk 10,000 steps (equivalent to 60-90 minutes moderate activity) each day. You can use a pedometer to help count the steps. You can break up your walking throughout the day.

Handy Hints:

- 5000 steps a day extra (40mins walking at a brisk pace), will burn 1240 calories over a week.
- Take the stairs rather than the lift.





5 Look at the labels

Be careful about food claims. Check the fat and sugar content on food labels when shopping and preparing food.

Handy Hints:

- A low fat digestive biscuit has the same number of calories as the standard digestive biscuit at 70 calories. Check the fat and sugar content.
- Order our shopping guide from the Reduce the Risk website: www.reducetherisk.org.uk

4 Pack a healthy snack

If you snack, choose a healthy option such as fresh fruit or low calorie yogurts instead of chocolate or crisps.

Handy Hints:

- Have a banana instead of a snack-size chocolate bar and save 225 calories.
- Take a piece of fruit to work in your bag so that you have it with you for a snack.
- Choose yogurts with less than 100 calories per pot. The calcium will also keep your bones healthy.

Creating a daily routine, keeping track of your progress and planning ahead are key to developing healthier habits to last a lifetime.

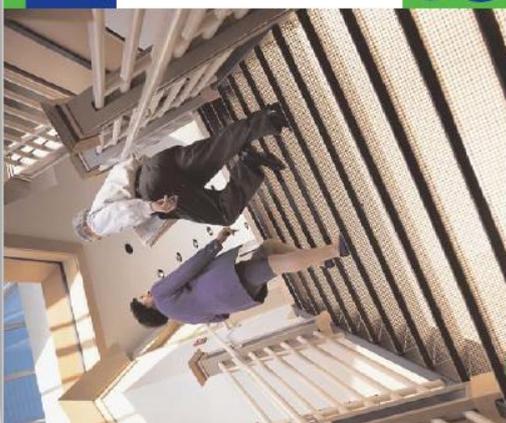
6 Caution with your portions

Don't heap food on your plate (except vegetables). Think twice before having second helpings.

Handy Hint:

- Fill your plate up with lots of vegetables. They are low in calories and will help satisfy your hunger.





7 Up on your feet

Break up your sitting time. Stand up for ten minutes out of every hour.

Handy Hints:

- Standing up on the bus or train burns an extra 70 calories an hour.
- When watching TV try to stand up during the ad breaks and do a few chores (e.g wash the dishes or put the rubbish out).

8 Think about your drinks

Choose water or sugar-free squashes. Unsweetened fruit juice is high in natural sugar so limit it to 1 glass per day (200ml/1/3 pint). Alcohol is high in calories so try to limit the amount you drink.

Handy Hint:

- A pint of standard beer has 2 units of alcohol and 182 calories.

9 Don't forget your 5 a day

Eat at least 5 portions of fruit and vegetables a day (400g in total).

Handy Hints:

- A medium sized apple or banana or 3 serving spoonfuls of peas is 1 portion.
- Try having fruit or vegetables with every meal. This makes it easier to reach the five a day.



frequently asked questions



Should I choose 'diet' foods?

Low calorie foods can be useful for reducing your energy intake but be careful of misleading claims and check the labels. For example low fat biscuits and other sweet foods may be lower in fat but not in calories.

I don't eat any fruit and vegetables.

Do I have to start eating five all at once?

It may work better for you to start eating a smaller number and build up over time. Make sure your plan is clear so you can judge if you achieve it or not each day.

Do I have to make all these changes at once?

The sooner you can build the tips into your life the quicker you'll start to lose weight. But it can be difficult to make all these changes at once. If you prefer you could try a smaller number until you feel confident enough to move on to others. The end goal is to fit all of the tips into your lifestyle.

Should I avoid occasional opportunities to exercise if not part of my normal routine?

It is fine to do more but keep doing your routines as well. This applies to all the tips.

What do I do on days when I am doing something different to my normal routine? for example: when I am away on business or at weekends.

You can develop different routines for the doing the tips during the week and at weekends. If you are away on a trip, do your best to stick to most of the tips and then get back to your normal routine as soon as you return.

What if I lose interest in the tips?

Changing habits of a lifetime is hard work but once the tips become part of your normal routine you will hardly notice doing them. Just like brushing your teeth.

The sooner you can incorporate all the tips into your life the quicker you'll start to lose weight.

Guide to shopping

The following information provides you with some simple advice for understanding food labels.

	per 100g	a lot	a little
Sugars	10g	2g	
Fat	20g	3g	
Saturated fat	5g	1g	
Fibre	3g	0.5g	
Salt	1.25g	0.25g	
Sodium	0.5g	0.1g	

Reproduced with permission from the Food Standards Agency

Look for the following information on food labels to make healthy choices:

Snacks

Less than 3g fat and less than 8g sugar per serving

Breakfast cereals

Less than 5g fat and less than 10g sugar per 100g

Ready meals

Less than 10g fat and less than 350kcal per portion

Pre-packed sandwiches

Less than 6g fat and less than 280kcal per sandwich pack

further information

Visit www.reducehisk.org.uk for further information about the Ten Top Tips and more about the healthy choices that could reduce your risk of cancer.

Visit Weight Concern's website www.weightconcern.org.uk for further information about obesity and weight loss.

For more about cancer visit Cancer Research UK's patient information website www.cancerhelp.org.uk.

About Cancer Research UK

Cancer Research UK is the leading charity dedicated to research on the causes, treatment and prevention of cancer. If you would like to support our work please call 020 7121 6699 or visit our website.

Cancer Research UK
PO Box 123
London
WC2A 3PX
020 7242 0200
www.cancerresearchuk.org

Reg. charity no. 1089464 2006 fief-rt-400

About Weight Concern

Weight Concern is a UK charity committed to researching and developing more effective treatments for obesity. We also train health professionals in techniques to help support people who want to control their weight.

Weight Concern
Brook House
2-16 Torrington Place
London
WC1E 7HN
enquiries@weightconcern.org.uk
www.weightconcern.org.uk

ten top tips tick sheet: Keeping track of your progress

Fill in this tick sheet every day to record whether or not you managed each tip. Keeping a record has been shown to increase people's success in developing healthy habits. Keeping track of your weight is also very useful. Daily weighing has been shown to increase successful weight control. In the notes column you can write details of how you are achieving the tips, and anything that particularly helps you use them. This information will help you plan for the next week.

ten top tips	m	t	w	t	f	s	s	done on 5 days or more?	notes
1. Keep to your meal routine									
2. Go reduced fat									
3. Walk off the weight (No. of steps)									
4. Pack a healthy snack									
5. Learn the labels									
6. Caution with your portions									
7. Up on your feet									
8. Think about your drinks									
9. Focus on your food									
10. Don't forget your 5 a day									
Your weight									

What do you plan to do next week? (e.g. I will write a shopping list to remind myself to buy fruit)

Appendix D (page 228)

List of 'expanders' relevant to the self-classification questionnaire used to personalise the Do Something Different program

List of expanders relating to the self-classification questionnaire in the DoZone

Behaviour	Explanation
Firm	<i>Resolute, stand by what you think, determined</i>
Reactive	<i>Responding automatically, triggered actions</i>
Play it safe	<i>Not trusting, being wary, concerned about risks</i>
Introverted	<i>Inward-looking, not outgoing</i>
Flexible	<i>Open to change, willing and able to adapt</i>
Wary of others	<i>Watchful or cautious, not readily trusting others</i>
Unpredictable	<i>Others don't know what you will do next</i>
Lively	<i>Bubbly, effusive, full of life, animated</i>
Proactive	<i>Take the initiative, foresee and act in advance</i>
Systematic	<i>Planning and considering in advance. Orderly</i>
Trusting	<i>Believing that others are truthful and reliable</i>
Unconventional	<i>Different, willing to stand out</i>
Individually – cantered	<i>Doing your own thing</i>
Definite	<i>Certain, sure</i>
Not lively / Laid back	<i>Apparently lacking in energy, easy going</i>
Extroverted	<i>Outgoing, sociable</i>
Group cantered	<i>Take a team view, go along with the group</i>
Single-minded	<i>Very focused, knowing what and how</i>
Calm/relaxed	<i>Being peaceful and not stressed; without tension</i>
Open-minded	<i>Open to new things, unprejudiced</i>
Predictable	<i>Habitual, people know what you will do next</i>
Spontaneous	<i>Doing things on the spur of the moment</i>
Unassertive	<i>Not putting yourself forward, or asking for what you want</i>
Behave as you wish	<i>Do as you want to, not as others want you to</i>
Gentle	<i>Mild, kindly, subtle</i>
Assertive	<i>Insisting upon your rights, or asking for what you want</i>
Conventional	<i>Traditional, formal, according to normal customs</i>
Risk taker	<i>Risky, act without due regard for consequences</i>
Energetic / driven	<i>Focused, enthusiastic, motivated</i>
Behave as others want you to	<i>Do as others would normally expect you to</i>

Appendix E (page 230)

Recruitment flyer used in the pilot study.

You're invited to participate in a...

4 WEEK WEIGHT LOSS PILOT STUDY



Commencing Tuesday 3rd February 2015

Did Christmas get the better of your waist line?

Email Gina at gcleo@bond.edu.au or call 0432 688 101 for information on a free weight loss intervention

Program running through Bond University as part of a PhD study. Commencing 3rd of February for 4 weeks. Participants must have a Body Mass Index (BMI) of 25kg/m² or above, live on the Gold Coast and have access to their phone and/or email everyday.

LIMITED TO 10 PARTICIPANTS ONLY!!

Email gcleo@bond.edu.au or call 0432 688 101 for participation information and to check your eligibility.

Bond University research ethics approval number: RO1888

Appendix F (pages 232 to 246)

Bond University Research Ethics Committee (BUHREC) application for pilot study.



Bond University Research Ethics Committee (BUHREC)

BUHREC Protocol Number: RO1888B

INSTRUCTIONS AND CHECKLIST BEFORE SUBMISSION TO BUHREC-BONDUNIVERSITY APPLICANTS

To ensure your project is processed without delays, please use this checklist before sending your application:

- Obtain a BUHREC Protocol Number from the Research Ethics Coordinator (5595-4194 or buhrec@bond.edu.au). Add this above. **Note: you should have the project title, principal investigator's name and researcher(s) name(s) when requesting a protocol number.**
- Complete the application form electronically using the form features of Microsoft Word.
- Save the file using the protocol number and the surname of the principal investigator
- Have all items on the application form have been addressed:
 - Provide a detailed, clear purpose of study using non-technical language.
 - Details, duration and length of participation have been addressed.
 - Risks have been outlined.
 - Benefits of this research have been addressed.
 - Signatures of Supervisor, all researchers and the Dean/ Associate Dean of the Faculty.
 - Does the research require further Indemnity Insurance? Yes No**
 - Has this research been registered as a clinical trial?**
If yes, Name of register: ANZCTR. No, state why:
 - All appendices, instruments, explanatory statement are included.
 - Print the **original** of the form, attach all appendices including the explanatory statement(s), instrument(s), stimulus material(s), and consent form(s) and obtain the signatures required in Section F (the Dean or Assoc. Dean from the relevant faculty must sign the application form). Forms without this authorisation will be returned to applicants for completion, (prior to consideration by BUHREC).
- Submit one fully signed **hard** copy and one fully signed **electronic** copy of the application **including all appendices** (scanned items are acceptable) to the Research Ethics Coordinator by e-mail: (buhrec@bond.edu.au).
- You should retain a copy of your application for your own records, which should be stored in a secure place.

Explanatory Statement (ES)

- On Bond letterhead.
- BUHREC protocol number and title added.
- Counselling/ support service has been added as appropriate (check with supervisor).
- Assurance of confidentiality or anonymity is guaranteed.
- Research Ethics Coordinator details (buhrec@bond.edu.au) are added to the Explanatory Statement.
- Principal Researcher and Co/Student researchers' signatures are on the ES.

BUHREC APPLICATION FORM

Revised October 11

1

COMMERCIAL IN CONFIDENCE

SECTION A: SUMMARY RECORD OF RESEARCH PROTOCOL	
APPLICANTS - Type in the grey form fields, replacing existing text. Save document according to instructions, p 13.	
RECORD ITEM	DATA
1. Name of Responsible Institution	Bond University Other:
2. Faculty/School/Institute/Centre	Health Sciences Medicine
3. Principal Researcher/Supervisor	Other
The Principal Investigator will be ultimately responsible for the ethical conduct of the research. In the case of student research the Supervisor exercises this responsibility.	Gina Cleo
	07 5595 1588
	07 5595 1588
	gcleo@bond.edu.au
4. Co-Researcher(s)/Student Researcher(s)	
Co-/Student Researcher 1 (Primary Contact)	Associate Professor
Name	Rae Thomas
Phone	07 5595 5521
Fax	07 5595 1271
Email	rthomas@bond.edu.au
Co-/Student Researcher 2	Professor
Name	Liz Isenring
Phone	07 5595 3337
Fax	07 5595 3524
Email	lisenring@bond.edu.au
Co-/Student Researcher 3	Professor
Name	Paul Glazsiou
Phone	07 5595 5515
Fax	07 5595 1271
Email	pglaszio@bond.edu.au
Co-/Student Researcher 4	
Name	
Phone	
Fax	
Email	
Co-/Student Researcher 5	
Name	
Phone	
Fax	
Email	

RECORD ITEM	DATA
5a. What kind of research is this project?	Student research <input type="checkbox"/> HDR Student <input checked="" type="checkbox"/> Psychology/4 th Year <input type="checkbox"/> Multiple student Research <input type="checkbox"/> Faculty/Centre Research <input type="checkbox"/> (Skip 5b) Class Project / Template <input type="checkbox"/> (Skip 5b) External research <input type="checkbox"/>
5b. Degree Program (such as PG Dip Psyc, HDR Research, MA, PhD, etc)	PhD
If you are a Postgraduate student, is the degree by course- work?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
6a. Project Title (Maximum of 150 Characters)	Habit-based interventions for weight loss maintenance in overweight and obese adults: A Randomised Clinical Trial
7. Expected date of commencement of human data collection <i>Note: Must not be LESS than 30 days from this application.</i>	1 July 2015
8. Expected date of completion of human data collection: <i>Note: Should this date change you must advise BUHREC.</i>	24 December 2016
9. Type of Human Data Collection: Provide details in B2 below.	Question-asking/Survey Anthropometry
11a. Has this project, as presented here, been submitted to any other ethics committee(s)? Eg, research on hospital patients will require approval from that hospital's ethics committee.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> <i>(If No, skip to Q12a)</i>
11b. If Yes, give details of the committee.	Name of Committee Contact Phone Secretariat Address Secretariat e-mail
11c. Has that committee approved the research protocol? If Yes, attach supporting letter.	Yes <input type="checkbox"/> No <input type="checkbox"/> Pending <input type="checkbox"/>
12a. Is the research in this protocol connected in any way with external funding or a grant?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> <i>(If No, skip to Q13)</i>
12b. If Yes, give details of the source of funding.	
13. What type of review are you seeking with this application? (See rules on the BUHREC web site to determine whether your research qualifies for expedited review.)	Full <input type="checkbox"/> Expedited <input checked="" type="checkbox"/>

SECTION B: RATIONALE AND PROCEDURAL DETAILS

1. THEORETICAL RATIONALE

1a. Write a concise, jargon-free explanation about this research. Link your project to a problem or theory identified in the **relevant** literature. If appropriate, state your hypotheses.

Note: Form limits word length to 400. If you run out of room, please edit to fit. You may wish to type in an unprotected Word document, spell check, then past into the form space.

The aim of this research is to implement and assess the feasibility and acceptability of two weight loss interventions that focus on habits and behaviours. Obesity has nearly doubled since 1980 with the prevalence progressively increasing each year. The actual causes of obesity are complex and multifactorial, however are fundamentally described as the imbalance between excessive nutrient intake in relation to an individual's daily energy requirements. We do not simply eat when we feel hunger or our bodies require energy from calories. In fact, studies demonstrate that we are aware of only a fraction of the 200 food decisions we make daily (Wansink, 2007). Studies in psychology have shown evidence to suggest that unconscious, automatic processes strongly influence behaviour. This evidence of unconscious, automatic behaviour has therefore been described as the most plausible explanation for the overwhelming lack of weight loss success (Moldovan & David, 2012). (Where weight loss success is losing 5-10% of body weight and maintaining that weight loss for at least 12 months).

This study will look at two weight loss interventions which focus on habit formation. Both interventions have been implemented on a community level before.

Intervention 1: '10 Top Tips' (Lally, P, 2008) aims to increase habitual performance of healthy lifestyle behaviours such as 'Keep a food diary', 'Switch to low fat food', 'Practice portion control' etc. The tips are provided to the participants in the form of a pamphlet, and a tracking diary is provided for record keeping.

Intervention 2: 'Do Something Different' (Fletcher, B. C, 2011) aims to break daily habits and increase behavioural flexibility by assigning participants a different task to perform each day. Examples of these tasks include: 'Take a different route to work', 'Write a short story', 'Wear something you've never worn before' etc. These tasks are emailed or text messaged to the participants depending on their preference. Both interventions will be 6 weeks in duration.

Data collection will occur twice, once prior to the commencement of the intervention and once at conclusion of the intervention (week 6). Data collected will include: Height, weight, waist circumference, body composition (measured by BodPod), behaviour flexibility questionnaire and a qualitative interview on the acceptability of the intervention. The participants' tracking diaries will also be assessed qualitatively for general eating habits and exercise behaviours. The Pilot study should determine the feasibility and acceptability of the two interventions as well as display weight loss results over a 6 week period.

1b. Include your short list of references here.

Form limits word length to 100. If you run out of room, reduce the number of references.

(1) Wansink, B. S., Jeffery. (2007). Mindless Eating: the 200 Daily Food Decisions We Overlook. *Environmental and Behavior*, 39, 106-123.; (2) Moldovan, A. R., & David, D. (2012). Features of automaticity in eating behavior. *Eat Behav*, 13(1), 46-48.; (3) Lally, P., et al. (2008). "Healthy habits: efficacy of simple advice on weight control based on a habit-formation model." *Int J Obes (Lond)* 32(4): 700-707.; (4) Fletcher, B. C., et al. (2011). "FIT - do something different: A new behavioral program for sustained weight loss." *Swiss Journal of Psychology* 70(1): 25-34.

2. METHODS

2a. Tell us about your participants. (A) Approximately how many people will be involved as participants? (B) What kinds and ages of people will these be? (e.g. (A) $n=200$, (B) school children age 6-9 who are epileptics.)

Form limits word length to 100. If you run out of room, please edit to fit.

((A) $n= 75$

(B) Inclusion criteria: Adults 18-75 years of age, male or female who are overweight or obese as classified by a BMI of 25.0kg/m² or greater, able to consent for themselves, able to speak English, live on the Gold Coast, able to access their email and/or phone every day, able to exercise.

Exclusion criteria: Participating in other weight management programs or taking any medications which affect appetite, metabolism or weight, pregnant, unable to provide consent due to mental incapacity, significantly ill, 220g or over.

2b. Tell us about recruitment. (A) How will participants be recruited? (B) Where will participants be recruited? (C) who will recruit the participants? And (D) How and by whom will the research purpose and process be explained to the participants? A written explanatory statement must be given to participants in every research project; attach your Explanatory Statement to this application.

Form limits word length to 200. If you run out of room, please edit to fit.

(A) We will identify potential participants via a local televised new segment as well as local ABC radio interview. Interested participants can contact me via the provided phone number and email address.

(B) Participants will be recruited from all areas of the Gold Coast.

(C) The primary researcher, Gina Cleo (GC) will be recruiting the participants

(D) GC will explain the research purpose and process both orally and in writing through an explanatory statement which will be sent to all participants via email prior to the initial meeting.

Please see attached explanatory statement (called: Patient information form).

2. METHODS (Continued)

2c. Tell us what you will do with your participants from the start to the end of the study, including (A) how much time you are asking of each participant. If there are treatment and control groups, (B) explain what happens to each. If tests, surveys, or interviews will be used, (C) describe these and (D) attach a copy of the questions and indicate whether or not participants will be anonymous. This is a very important part of the proposal. Please be as clear as possible.

Form limits word length to 400. If you run out of room, please edit to fit.

(A) Participants will be randomly assigned an intervention and asked to attend a 30 minute introduction meeting which will explain the intervention they have been assigned to (10 Top Tips, Do Something Different or a Waitlist). At the Introduction meeting, anthropometry measures (height, weight, waist circumference) will be taken as well as a short series of validated psychometrics including questionnaires regarding: Wellbeing, Depression, Anxiety, Habit Rater and Openess to change (Behaviour Rater). The psychometrics help measure a persons habitual tendencies and attitudes. The meeting will be conducted in an allocated meeting room at Bond University.

Furthermore participants will be asked to come back at the end of the 9-12 week intervention for post-intervention anthropometry measures (weight and waist circumference) and to complete the psychometrics descibed above again. There will also be a simple weight and wasit circumference measurement at 6 and 12 months post intervention. Participants enrolled into the waitlist group will be moved to an intervention after 12 weeks from initial start date- this uses an intention to treat model and ensures all participants are provided with fair and equal opporinity to partiipate in a weight loss intervention.

(B, C) - Weight will be measured using a standard stand-up scale. - Height will be measured using a wall chart. - Waist circumference will be measured using a soft tape-measure. The psychometric questionnaires will be completed online through a secure website which requires a personal login.

(D) All participant information will be organised using first and last name. Due to the nature of face-to-face measurements, the participants will not be anonymous, but will however remain confidential to the 4 researchers involved in this study..

2. METHODS (Continued)

2d. Tell us how you plan to analyse the data you will collect by briefly discussing the statistical tests you will use and why you will use them. *Form limits word length to 200. If you run out of room, please edit to fit.*

Analysis will focus on both quantitative and qualitative measures. Quantitative data will include weight, BMI, waist circumference, serves of fruit and vegetables consumed per day, hours of exercise performed per week and psychometric data including wellbeing, depression, anxiety, habits and openness to change. We will report on mean change between the different time points for each intervention with a focus on weight change at the 12-month follow-up time point. Each intervention group will be analysed separately and a comparison between the interventions will be presented in order to display which intervention group was more successful at losing and maintaining weight loss. The qualitative analysis will be conducted using thematic analysis of one-on-one face-to-face interviews conducted at 6-months post-intervention.

Primary outcome is weight loss maintenance at 12-month follow-up from post-intervention. Secondary outcomes include weight loss at all time points, changes in fruit and vegetable consumption, hours of exercise performance and psychometric measures including wellbeing, depression, anxiety, habit strength and openness to change. Secondary analysis also include proportion of participants achieving $\geq 5\%$ total body weight loss at 12-month follow-up from baseline.

3. DATA STORAGE AND SECURITY

3a. BUHREC requires the following procedures concerning storage of data. Please indicate your agreement to comply with these regulations by ticking both the following items.

- Only the researchers will have access to the original data.
- The data be securely stored in the relevant academic unit at Bond University for five years and be subsequently disposed of securely.

3b. If you have not ticked both the above statements and the above security precautions aren't being followed, how will information be handled to safeguard confidentiality?
Form limits word length to 100. If you run out of room, please edit to fit.

SECTION C: ETHICS SUMMARY	
<p>Instructions: Please respond Yes or No to EVERY item. If you respond Yes on ANY item, please complete the corresponding explanation in Section D. Corresponding explanations in Section D have the same item or question number as the Yes/No items in this section. IMPORTANT: If you answer Yes to ANY item below, you may not qualify for expedited review.</p>	
RECORD ITEM	DATA
1. Is there a potential for power-dependency between researcher/data collection personnel and participants?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
2. Will participants be deceived about the nature of the research?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
3a. Does this research involve minors, collectives or other special groups?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
3b. Research with minors, collectives and special groups requires the use of a consent form which must be attached this application. Have you included the consent form?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> NA <input checked="" type="checkbox"/>
4. Will you need to take any participants alone to a private place to conduct the research?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
5. Will participants' identity be known in any way to you, the researcher(s), or to other participants?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
6a. Will participants' private records be accessed for this research, or will you use existing records or data that is not ordinarily available to the public (e.g. medical records, personal diaries, computer data, or any other information not available in a public library)?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
6b. Will you be able, either directly or indirectly, to match people's names to their data?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> NA <input type="checkbox"/>
7. Is permission required from any organisation(s) that may control access to participants?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

8. Will the research involve the administration of any tests or procedures that can only be used by people with certain qualifications or training?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
9. Are you, the researcher(s), required by law to report any of the findings (eg some infectious diseases, child abuse etc.)?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
10. Is there any risk of physical/psychological stress, inconvenience or discomfort beyond the normal experience of everyday life, in either the short or long term, from participation in the project?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
11. Will you debrief your participants following data collection?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
12. Will inducements be offered?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
13. Have you applied for external funding for this research project?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
14. <i>If you answered Yes to ANY of the above questions, tick Yes here and discuss the risk/benefit ratio of your research at 14 in Section D. If you did NOT answer Yes to ANY of these questions, tick No here.</i>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

SECTION D: Ethics Explanations to Accompany Section C

Instructions: If you responded Yes to ANY item in Section C, you MUST provide an explanation in this section at the corresponding number. IMPORTANT: If you answer Yes to ANY item in Section C, requiring explanation in this section, you may not qualify for expedited review. If you answer NO to an item in Section C, leave the corresponding number in this section blank, or type NA.

1. If you indicated that potential exists for a power/dependency relationship between the recruiter or the researcher and the participants, describe the nature of the relationship, and explain what special precautions will preserve the rights of such people to decline freely from participating, or to withdraw from participation once the research has begun.

Form limits word length to 100.

2. If you indicated that subjects will be actively deceived about the nature or purpose of the research, explain why the real purpose needs to be concealed.

Form limits word length to 100.

3. If you indicated that this research will be conducted with participants who are younger than 18 years of age, please explain what special care is being taken to protect their naivety. Note that all research with minors requires the use of a consent form from parents, guardians or institutional bodies acting en loco parentis. You must attach a copy of the consent form; this application cannot proceed without it.

Form limits word length to 100.

4. If you indicated the need to take one or more participants alone to a private place to conduct the research: (A) What real or potential risk(s) to the researcher or the participant do you foresee and (B) what security methods will be employed? (These may include having a second researcher present or video-taping the session.)

Form limits word length to 100.

(A/B) In order to ensure privacy for the participant whilst taking weight and waist measurement, the measurements will be carried out in a private office or meeting room at Bond University where security staff are available until 10pm each day. There will be two researchers present during the measurement consultation (one to measure and one to record). We foresee no potential risks to the participants, as the researchers are trained health professionals who have worked with patients one on one for years.

5. If you indicated that the identity of participants will be known either to you, the researcher(s) or to other participants: (A) Why must you know the identity of your participants (for example to match pre- and post-test data) and (B) what security measures will be used to protect the privacy of participants? (Measures may include de-identifying data, ensuring that records are stored securely and destroyed at the appropriate time.) Note that written, signed consent of participants may be required to collect personally identifying information.

Form limits word length to 100.

(A) To match pre and post-intervention data without confusion

(B) Data collected will be stored in a secured location at Bond University for a period of five years in accordance with the guidelines set out by the Bond University Human Research Ethics Committee. This data will also be destroyed appropriately as per the guidelines after five years.

6a/b. If you indicated that the private records of participants will be accessed for this research, please explain: (A) what records you intend to use, (B) what permissions are required for this access including names and positions of persons who have given those permissions, and (C) how you have complied with Commonwealth and state or local privacy legislation.
Form limits word length to 100.

7. If you indicated that permission is required from one or more organisation(s) that may control access to participants, please provide: (A) information about the organisation(s) including whether they are Commonwealth Agency (i.e. a Commonwealth government department, an agency established by the Commonwealth, a federal union, the Australian Federal Police, or a federal or ACT court), (B) what you did or will do to seek permissions, and (C) whether permission is pending or has been granted. Note: you must provide BUHREC with written approval(s) before this application will be granted ethics clearance.
Form limits word length to 100.

8. If you indicated that the research involves administration of tests or procedures that can only be used by people with certain qualifications or training, please: (A) identify the test(s), (B) what qualifications are required and (C) the name(s) of the qualified person(s) who will administer these for your study.
Form limits word length to 100.

9. If you indicated that you, the researcher(s), are required by law to report aspects of the findings to authorised agencies, please explain: (A) to whom you must report, (B) which findings would require reporting and (C) how you can protect the safety of the participants and/or society in reporting such data (or avoiding such data collection)? Note: You must advise participants of this requirement in the Explanatory Statement and, in most cases, will be required to obtain their written, signed consent to collect data of this nature.

Form limits word length to 100.

10. If you indicated that risk(s) beyond the normal experience of everyday life may result from participation in the project, please: (A) explain the nature of this risk including its duration and severity, (B) what you will do to minimise or alleviate this risk to participants, (C) what you will do should participants experience such stress, inconvenience or discomfort during the research and (D) what resources you will refer them to. Notes: In such cases, it is often advisable to make available the telephone counselling number for Lifeline and similar agencies in the Explanatory Statement. These risks should normally be outlined on the explanatory statement and consent form. This application cannot obtain full approval without an attached explanatory statement.

Form limits word length to 100.

11. If you indicated that you will debrief your participants following data collection, explain the debriefing procedures you intend to use.

Form limits word length to 100.

12. If you indicated that inducements will be offered, provide details of: (A) the nature of the inducement, (B) which participants receive the inducement and under what conditions (if any) and (C) the necessity of the inducement to your project. Note: Inducements MUST be offered equitably and must NOT coerce or unduly entice participation.

Form limits word length to 100.

13. You indicated that you have applied for external funding in relation to this project. Indicate (A) the source of funding, (B) the status of the application (granted, pending or denied) and (C) whether the funding poses conflicts of interest for the researcher that may affect the interests of the participants.

Form limits word length to 100

14. By answering Yes to this item in Section C, you have indicated to BUHREC that your research proposal involves some level of risk to participants. Overall this risk may be very small or it may be very great. In the following space, please weigh the potential benefits of your research with the potential risks.

Form limits word length to 200.

The potential benefits of this research for the researchers and other health professionals in the field, include an improved understanding of how habits affect weight loss and weight regain. This research will also enhance work towards developing successful weight loss interventions, which focus on the maintenance of lost weight and understanding the roles of habits and automaticity. The potential benefits to participants includes: weight loss, changing unwanted habits, lifestyle improvements and improvements in self-management behaviours. The questionnaires in this study have been validated and frequently used in research; they do not contain sensitive information and are not known to cause emotional or psychological discomfort. Therefore potential risks to the participants are estimated by the researchers to be minimal and only include possible emotional distress for which clear strategies are in place to mitigate this. The potential benefits therefore, seem to vastly outweigh any risks posed.

SECTION E: DECLARATION

The following declaration is made by the signatories in Section F as an Agreement pertaining to this research project. The points in this declaration are mainly drawn from the NHMRC National Statement on Ethical Conduct in Research Involving Humans. Please tick each box AFTER you have read and agreed with each statement.

- I/we, the undersigned, accept responsibility for the conduct of the research detailed above. If any changes to the protocol are proposed after the approval of the Committee has been obtained, then BUHREC will be informed immediately of any matter that may warrant review of ethical approval of the protocol, including: (a) serious or unexpected adverse effects on participants; (b) proposed changes in the protocol; or (c) unforeseen events or adverse occurrences that might affect continued ethical acceptability of the project.
- I/we accept that if BUHREC imposes any conditions upon their approval of this research, the research can only proceed after such conditions have been satisfied and after notification of compliance with such conditions has been made to BUHREC.
- I/we accept that where BUHREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, BUHREC may withdraw approval. I/We accept that this research must not continue if ethical approval is withdrawn.
- In the preparation for and conduct of this research, the researcher(s) shall give every respect and consideration to participants' rights, beliefs, perceptions, customs and cultural heritage both individual and collective.
- I/we accept that at least annually (and more often if specified by BUHREC), reports must be submitted from Principal Researchers on matters including: progress to date or outcome in the case of completed research; secure maintenance of records; and compliance with any conditions of approval.
- I/we accept that BUHREC may recommend and/or adopt any additional appropriate mechanism for monitoring this research, including random inspections of the data, research sites and signed consent forms, and/or interviews of research participants (with prior consent).
- I/we accept that the National Health and Medical Research Council (NHMRC) may, from time to time conduct audits through the Australian Health Ethics Committee to ensure compliance with this declaration and statement contained in this questionnaire.

Appendix G (pages 248 to 252)

Participant information form and Registration form



Participant Information Sheet and Consent Form:

Project Title: *Maintaining weight loss: a look at habits.*

Researchers:

Student Researcher: Miss Gina Cleo

Contact Phone: 0420 937 932

Contact Email: gcleo@bond.edu.au

Along with Professors: Roger Hughes, Liz Isenring, Paul Glasziou and Rae Thomas

Why is the study being conducted?

My name is Gina Cleo (dietitian) and I am currently completing a Doctor of Philosophy at Bond University under the supervision of Professors Roger Hughes (dietitian), Liz Isenring (dietitian), Paul Glasziou (general practitioner) and Rae Thomas (psychologist).

We are conducting a research investigation into successful weight loss maintenance, with a specific interest in how habits affect our eating behavior.

What do I need to do?

As part of this study, you will be invited to complete a 9-12-week study of a weight management program designed to help establish healthy lifestyle behaviours. We will hold a 30 minute introductory meeting to introduce you to the intervention which you have been randomly assigned to.

There are two potential interventions including:

Intervention #1: Aims to increase habitual performance of 10 healthy lifestyle behaviours such as 'Keep a food diary', 'Switch to low fat food', 'Practice portion control' etc. The tips are provided to you in the form of a pamphlet, and a tracking diary is provided for record keeping. You are required to perform the 10 tips everyday for the 12 week intervention duration.

Intervention #2: Aims to break daily habits and increase behavioural flexibility by assigning you a different task to perform each day. Examples of these tasks include: 'Take a different route to work', 'Write a short story', 'Contact a long lost friend or family member' etc. These tasks are

emailed or text messaged to you 2-4 times per week for the 9 week intervention duration. A login for an online tracking diary will be provided in order to self-monitor your progress.

Pre and post intervention measures obtained for both interventions include weight, height, waist circumference, basic demographic details, and other diagnostic questionnaires which assess wellbeing (8 item questionnaire), thoughts and feelings (8 item questionnaire), habits (12 item questionnaire) and lifestyle behaviours (8 item questionnaire). After the intervention is complete, there will be a 3, 6, and 12 month follow up measuring only weight and waist circumference- these meetings will be about 15-20 minutes each.

We anticipate the total time required from you during your participation in this study to be no more than two hours over the 9-12 week period- this includes pre-intervention introductory meeting (30 minutes), all diagnostics pre and post intervention (1 hour) and the post-intervention measurements (30 minutes- 10 minutes each).

How will participants be selected?

Participants must be over the age of 18 years, have a Body Mass Index (BMI) of 25kg/m² or above and live on the Gold Coast.

How will this research be used?

The data collected during this study will assist us in assessing the different results achieved using two different habit-focused weight loss interventions. We hope to gather quantitative data of your weight loss results as well as general health and wellbeing. The potential benefits to yourself include: losing weight, changing unwanted habits, forming new healthful habits, lifestyle improvements, and improvements in self-management behaviours.

Your participation in this study will enhance work towards developing successful weight loss interventions, which focus on the maintenance of lost weight and understanding the role of habits and automaticity.

What are the risks?

The questionnaires in this study have been validated and frequently used in research; they do not contain sensitive information and are not known to cause emotional or psychological discomfort. However, if you experience distress from participation in this research, please contact a Queensland community support officer on 13 HEALTH (13 43 25 84) for professional guidance and advice.

Am I free to withdraw?

Participation in this study is **completely voluntary** and you may withdraw at any time without risking any negative consequences. If you choose to withdraw your participation in this study, the information you have provided will be immediately destroyed.

What if I want to more information about the study?

For additional information about the project, contact Gina Cleo, gcleo@bond.edu.au

What if I want to make a complaint?

Should you have any complaints concerning the manner in which this research is being conducted please make contact with: Bond University Human Research Ethics Committee, c/o Bond University Office of Research Services. Bond University, Gold Coast, 4229

Tel: +61 7 5595 4194

Fax: +61 7 5595 1120

Email: buhrec@bond.edu.au

How do I express consent?

By completing and returning the consent form below you have consented to participation in the research project: *'Weight loss maintenance: a look at habits'*

How will my confidentiality be protected?

All the data collected in this study will be treated with complete **confidentiality** and not made accessible to any person outside of the researchers working on this project. Although the data will be analysed as a cohort, individual results can also be used to correlate qualitative and quantitative data. Data will be stored in a secured location at Bond University for a period of five years in accordance with the guidelines set out by the Bond University Human Research Ethics Committee.

Will participating cost me anything?

No, participating in the study is completely free of any charges.

By signing below, I confirm that I have read and understood the information package, and in particular I have noted that:

- I understand that providing my contact details to the researchers is entirely voluntary;
- I understand that I will be contacted by the researchers following the voluntary provision of my contact details;
- I understand that my participation in this research is entirely voluntary and that I am free to withdraw from this research at any time, without comment or penalty;
- I have had any questions answered to my satisfaction and understand that if I have any additional questions I can contact the research team;
- I have been informed that the confidentiality of the information I will provide will be safeguarded, my opinions will be treated as personal information, and my privacy respected;
- I understand that I can contact the Manager, Research Ethics, Office of Research Services, Building 1C, Level 4, Bond University (phone 07 55 954 194 or buhrec@bond.edu.au) if I have any concerns about the ethical conduct of the project; and
- I agree to participate in this study.

Signature:

Date:

My contact details (for follow up):

Name:

Contact Phone:

Contact Email:

Please return this form to the researchers by either:

Email to: gcleo@bond.edu.au

Post to:

Gina Cleo

School of Health Sciences

Bond Institute of Health and Sport

2 Promethean Way, Robina,

QLD 4226, Australia



Participant Registration

Date _____

First Name: _____ Family Name: _____

Phone: (h/w) _____ (m) _____

Email: _____

DOB: _____ Age: _____

Suburb you live in: _____ State: _____ Post Code: _____

Occupation: _____ Marital status: _____

Education level: Did not complete school. Completed school.

University degree. Doctoral.

Do you have any current health concerns? _____

Please list any current Medications &/or Supplements: _____

If you are a woman, are you pregnant? YES NO

Are you currently on any weight loss programs or weight loss medication? YES NO

How many hours per week do you exercise? _____

Type of exercise performed: _____

How many serves of fruit do you eat per day on average? (Where 1 serve is 1 medium piece of fruit/ 2 small pieces) 0 1 2 3+

How many serves of vegetables do you eat per day? (Where 1 serve is 1 cup of salad/ ½ cup of vegetables): 0 1 2 3 4 5+

Thank you

For Researcher:

Height (cm): _____ Weight (kg): _____ BMI: _____

Waist circumference (cm): _____

Participant has signed consent

"It always seems impossible until it's done."

- Nelson Mandela