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Understanding how meal replacements could be used within an established weight loss program to manage cravings and boost early weight loss

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Executive summary

Overview

Weight loss can be challenging and there isn't one weight loss approach that is appealing or effective for everyone. Previous work from the Diet Types Survey has suggested that individuals with higher craving tendencies do not lose as much weight on the CSIRO Total Wellbeing Diet as other personality types, such as those who love preparing and trying new foods (referred to as "Foodies"). From a secondary analysis of the CSIRO Total Wellbeing Diet program, we also know that members who lose the most weight in the first 3 weeks, go on to lose three times more weight overall compared to those members who do not do as well over the same period.

The use of meal replacements may offer a safe and effective temporary strategy to elicit faster, initial weight loss, before transitioning to a healthy, whole foods, diet. For this research we were interested to understand whether the use of meal replacements provides an alternative and effective entry point to the CSIRO Total Wellbeing Diet to help members, particularly the subgroup who struggle with cravings, achieve successful weight loss.

This research includes:

- A brief, narrative review of literature around the impact of meal replacements on cravings and longer-term eating habits;
- An online survey of people with higher craving tendencies to better understand the challenges they experience when trying to lose weight; and
- A pilot study to assess the feasibility, acceptability, and practicality of starting the CSIRO Total Wellbeing Diet with 3 weeks of meal replacements.

Part I: The literature review

- Findings from the review of literature suggests that people who are overweight or obese tend to experience greater food cravings, and people with cravings may struggle more with weight management.
- Energy restriction to lose weight seems to be associated with reduced food cravings, regardless of the method of restriction (food-based energy restricted diet, or use of meal replacement products).
- Meal replacements may offer a safe and effective temporary strategy to elicit faster, initial weight loss, before transitioning to a healthy food-based diet.
- More research is needed to examine:
 - The effectiveness of energy restriction, in the form of meal replacements, for people who struggle with cravings to understand the level of weight loss they can achieve using meal replacements; and

- Whether the use of meal replacements within a weight loss program helps to reduce the experience of cravings for people who are trying to lose weight.

Part II: The online survey

A sample of 330 people who had previously completed the CSIRO Diet Types survey and were classified as having higher craving tendencies completed a new online survey for this study. Cravings were positively associated with survey respondents' BMI and were often cited as a barrier to weight management.

Previous attempts at managing their weight

- About half of the survey respondents said the most difficult things when trying to manage their weight were 'struggle to control cravings' and 'controlling intake around tempting foods'.
- Most respondents (82%) agreed that it would be easier to lose weight without cravings. Around 7 out of 10 respondents also agreed it would be easier to lose weight without temptations present (73%), that it was a constant struggle to resist tempting foods (67%) and a constant struggle to resist their cravings (66%).

Cravings and weight management

- Over the past month, all respondents had experienced a craving for at least one food. At baseline, no respondents had never 'given in' to their cravings over the past month. Chocolate, biscuits, cake, potato chips and ice cream were the top five most craved foods from the Food Craving Inventory.
- 74% of participants indicated that they had both a clear trigger food and situation that they found particularly difficult. Situations included afternoons, after lunch and after dinner, as well as during work, stress and social situations.
- There was a weak positive relationship between BMI and high fat food cravings, suggesting that as BMI increases so does cravings for high fat-style foods.
- Six out of 10 respondents did not feel they could resist tempting foods when they were present and 68% did not feel they had the strength to control their cravings.
- Participants had tried a range of strategies to reduce their cravings, but also felt that most strategies were largely unsuccessful. The only strategy that most people were favourable toward was not buying certain foods with 56% agreeing this was successful.
- When presented with scientifically evaluated ways to reduce cravings, acceptance-based therapy/thinking appeared to be most preferred.

Use and attitudes towards meal replacements

- About two-thirds of respondents had tried a meal replacement or shake diet before. About a third of whom thought it was helpful for losing weight, but less than 10% felt it was successful in helping keep weight off. Using meal replacements was liked for being convenient (73%), easy (58%) and requiring no cooking (43%).

- When asked about the worst part of using meal replacements, lack of solid food was the most common response (48%), along with boredom (47%), hunger (36%), taste (36%) and difficult to maintain (35%).

Part III: The pilot study

A pilot study was designed to assess the feasibility, acceptability, and practicality of starting the CSIRO Total Wellbeing Diet program with 3 weeks of partial meal replacements, as well as to examine the short-term weight loss results. An invitation to participate went out to nearly 5,000 obese adults who had previously completed the CSIRO Diet Types survey and were classified as having higher craving tendencies. A final sample of 80 participants were included in the analysis. At the end of 3 weeks, participants were encouraged to transition to a healthy balanced diet, that was following the standard CSIRO Total Wellbeing Diet, for another 3 weeks. It was recommended but not mandatory to transition at week 3 and participants could choose to continue with meal replacements. Participants were required to pay the standard \$199 for the 12-week Total Wellbeing Diet membership and were provided meal replacement shakes and a set of Wi-Fi enabled scales free of charge. Evaluation surveys were completed at baseline, weeks 3 and 6. Weight loss was assessed each week but reported here at week 3 (point of recommended transition) and week 6 (end of trial). Participants were also asked about their hunger, cravings, and experience of any adverse events on a weekly basis throughout the trial.

Who started the program and why?

- Most enrolled participants (n=80) were female (91%) and aged between 31-65 years. Seven out of 10 participants lived in middle to higher income areas. The average BMI was 37.4 kg/m² and by design, all participants were classified as obese.
- Participants' main reasons for signing up to the study were associated with weight (81% interested in losing weight, 58% feeling overweight) or their perceived readiness to start a weight loss program (74% ready to commit, 60% felt in the right headspace).

Participants' expectations

- During the study, the proportion of participants who agreed they would enjoy the program increased (66% at baseline v. 87% at week 6). Participants' rating of their confidence in overcoming barriers and following the program changed from 93% at baseline to 74% at week 6.
- Participants expected to lose around 1 kg each week during the study and their confidence that the program would help them achieve their weight loss goals was consistently high throughout the study (88% at baseline v. 89% at week 6).

Weight loss results

- Across all participants who enrolled (n=80), the average weight loss was 3.1 kg (3.1% of their starting weight) in the first 3 weeks and 4.0 kg (3.9% of their starting weight) after 6 weeks using baseline observation carried forward to estimate average weight loss. 44% of all participants who started the program recorded clinically meaningful weight loss (≥5% of their starting body weight) after 6 weeks.

- About 7 out of every 10 enrolled participants completed the study and provided a weight at week 6 (completion rate: 55 out of 80, 69%). For completers (55 participants), the average weight loss was 4.1 kg in the first 3 weeks, and 5.9 kg after 6 weeks (equivalent to 5.6% of their starting body weight). Nearly two-thirds of completers (35 out of 55, 64%) recorded clinically meaningful weight loss at week 6. Seven out of 10 participants felt positive about their weight change during the study.
- At week 3, 84% of participants who completed the survey rated their compliance with the program as 6 out of 10 or greater, and after 6 weeks, 67% of participants rated their compliance with the program as 6 out of 10 or greater.
- Common reasons impacting compliance were similar to those seen in other weight loss trials including, social situations, holidays, general work/life stress and perceived lack of motivation.

Self-reported adverse events

- Participants were asked about their experience of adverse events in the weekly pulse surveys. 57 participants reported at least one adverse event over the 6-week study period. In week 1, 64% of participants (44 out of 69) who completed the week 1 pulse survey reported a symptom, which decreased to 32% (18 out of 56 participants) in week 3 and 23% (11 out of 47 participants) in week 6. The most common adverse events were increased gas (reported on n=63 occasions), constipation (n=41), headaches (n=35) and bloating (n=31). Most adverse events were rated as mild. Two participants experienced adverse events which were assessed as moderate (n=1) or severe (n=1) and probably related to participation in the trial.
- The duration of symptoms varied. About one third reported that their symptoms lasted for less than 1 week, and nearly half reported their symptoms persisted throughout the 6-week program.

Participants' hunger and food cravings

- Participants' confidence in their ability to control their weight by resisting overeating in certain tempting situations increased during the study by 19% from baseline. The greatest increase was seen in resisting eating when feeling sad or anxious (negative emotion) and watching television or reading.
- Throughout the program, all participants experienced cravings, but the proportion of participants who indicated that they had never 'given in' to their cravings increased during the study from no one at baseline, to 30% of participants at week 3, and 13% of participants at week 6.
- The proportion of participants who reported that they had never 'given in' to their cravings was slightly higher among the participants who achieved $\geq 5\%$ weight loss.
- In relation to cravings, 80% of participants at week 3 and 74% of participants at week 6 reported that they felt they were better in control of their cravings.
- The proportion of participants who agreed they felt hungry over the past week decreased over the study period from 49% in week 1 to 17% in week 6.

Experience and evaluation of meal replacements

- When asked about their motivation for trying this meal replacement trial, the most common responses were trust in CSIRO (79%) and expected weight loss results (77%).
- At the end of week 3, 88% of participants felt positive about meal replacement shakes. The most common reasons participants liked using meal replacements were the convenience (98%) and ease (93%). Integration with family meals (38%), boredom (25%) and gastrointestinal upsets (23%) were reported as the worst things about using meal replacement shakes among the participants at week 3.

Transitioning to a healthy balance diet

- Participants were encouraged to transition to a healthy balanced diet, following the standard CSIRO Total Wellbeing Diet, at the end of week 3. Only 11% of participants decided to stop having meal replacements at this point.
- At week 6, 47% of participants who completed the survey reported to have transitioned to the CSIRO Total Wellbeing Diet. Of those that had transitioned, 68% continued using meal replacements in some way – mostly once per day or 2-3 times per week.
- Reasons for transitioning included feeling like it was time or that they were ready to follow a food-based diet program, they missed or were craving solid food, and one person reported side effects and that they weren't satisfied with the shakes.

Evaluation of the program as a whole

- In week 3, 84% of participants (47 out of 56) who completed the survey gave a score of 6 or more out of 10 for their experience on the program, and this remained high at 87% of participants (46 out of 53) in week 6.
- The best things about the program, selected by more than half the participants at weeks 3 and 6 were: it's convenience/ease, weight loss results, learning about healthy foods, and reduction in cravings.
- The worst things about the program were integration with family meals, selected by about half of the participants, and gastrointestinal upsets, selected by about a third of participants.
- Participants were asked to rate their experience on this program compared with their previous dieting attempts. Nine out of ten participants who completed the survey (n=49 out of 53, 92%) recorded a response to the program of 6 or higher out of 10, with one-quarter (n=14 out of 53, 26%) giving the maximum score of 10 indicating it could not be better.
- Most participants (87%) said they would recommend the program to their friends who were interested in losing weight.

Conclusion

The review of scientific literature provides strong support for the use of meal replacements to achieve weight loss and for any form of dietary restriction to improve individuals experience of

cravings. There has not been much focus in the existing literature on people who experience higher levels of craving specifically, and whether meal replacements may be useful for this group both in terms of their experience of cravings and in achieving weight loss.

The survey conducted here in 330 people provides further insight into the experience of those with higher cravings. Many were familiar with their own personal triggers and struggles with resisting temptation. Four out of 5 agreed it would be easier to lose weight without cravings. Two-thirds had tried meal replacements amongst many other strategies, but generally did not feel that meal replacements alone were successful in the long-term due to boredom and lack of solid food.

The pilot study suggested that the use of meal replacements within an established whole foods weight loss program helped to decrease cravings and feelings of hunger, increased confidence around managing cravings, and helped members who have higher craving be successful in achieving early weight loss.

A transition to a whole food weight loss plan was recommended at week 3 but 11% of participants reported to have transition at this point. When and how people chose to transition onto a whole food diet varied among participants of this study and therefore, this recommendation may need to be more tailored to allow people to transition in a way that suits them and when they feel ready. Taken with the survey results, it is likely this transition is needed when participants become bored of not having solid foods or when they start to integrate their meals with family meal preparation. Insight from the survey also suggested that people with higher craving tendencies tended to identify with strategies that limit access to craved foods. Most had tried a range of strategies but only felt that not buying certain items was promising. There was also a theme around reductionist thinking with many participants identifying their own lack of willpower as an issue and as blaming themselves for giving into cravings which suggests that it may be important to explore emotional and psychological factors for this group in future research.

Reported adverse events experienced over the 6 weeks, particularly those associated with gastrointestinal function, were expected and in line with previous studies and considered acceptable. However, it will be important to provide additional advice and guidance around managing digestive changes when meal replacements are used.

Inclusion of meal replacements as an alternative entry for the CSIRO Total Wellbeing Diet could assist in achieving early weight loss and reducing cravings for those people who experience higher level of cravings. It is important to understand this subgroup of dieters because they appear to have greater difficulty losing weight and report a higher number of lifetime dieting attempts. We cannot currently comment on the appropriateness of this approach for those who do not report higher levels of cravings. However, the literature review suggests that meal replacements can be effective for weight loss and craving reduction in broader samples.

More thorough investigation, including evaluation of this program in a larger sample over a longer period, is needed to understand the weight loss results and acceptability of the program alterations in a more diverse sample, and to better understand when and how to best support the transition off meal replacements and onto a whole foods diet. Future research should also compare those with higher cravings to other personality types, or those of different levels of obesity, to understand whether meal replacements, used within the context of an established weight loss program, is more beneficial for certain groups of the population.

Part I Literature Review



Background

Overweight and obesity are preventable lifestyle conditions characterised by the excessive accumulation of adipose tissue, driven by an interplay of individual, environmental and societal factors [1]. Despite global efforts to manage overweight and obesity [2] rates are continuing to rise; in 2016, nearly two billion adults were considered overweight (39%) or obese (13%) globally, as defined by Body Mass Index (BMI) [3]. Having a high BMI increases the likelihood of developing other non-communicable diseases including cardiovascular diseases, type II diabetes, and some cancers [4].

Bodyweight regulation is multifactorial and complex, influenced by a collection of biological, behavioural and environmental variables that control energy intake and expenditure [5, 6]. However, this rapid, population-level weight-gain is largely attributable to the imbalance between energy intake and energy expenditure, and encouraged by the obesogenic environment which has evolved [7].

A range of strategies to manage obesity exist, including pharmaceutical agents and bariatric surgery, but given that the lifestyle causes of obesity are modifiable, it is argued that they should be the primary target for intervention [2]. Strategies to control obesity using lifestyle interventions to promote weight reduction through caloric restriction, the addition of prescribed exercise, or a combination of both, have proven to be effective methods of weight loss in the short-term (<1 year) [8-10]. However, a high degree of individual variability in success exists [11].

Food cravings and weight management

Food cravings are positively associated with BMI, and are estimated to account for 7–11% of variance in eating behaviour and body weight [12, 13]. A food craving is defined as an intense desire to consume a particular food or type of food that is difficult to resist, typically energy-dense foods such as sweets or fast food [14, 15]. Obese individuals are reported to have higher frequencies of food cravings than healthy-weight individuals, as well as higher intakes of foods that they crave [12, 16-18].

Individuals interested in losing weight may assume that limiting their food intake will increase their food cravings [19]. However, the research findings are mixed regarding dietary restriction and cravings. Some studies report an increase [20-22] or no change [23], but the majority of evidence suggests that cravings decline during periods of energy restriction [18, 24-34]. For example, Chao et al. [18] investigated the effect of a 14-week group lifestyle modification program on food cravings and food addiction. Participants (n=178) were prescribed an energy restricted, portion-controlled diet (1,000-1,200 kcal/day). Food cravings significantly declined from pre- to post-intervention, and participants with more frequent food cravings at baseline lost less weight than those with the least frequent food cravings (7.6% versus 9.1% of initial body weight, respectively).

A variety of tools are used to assess food cravings examining different craving constructs, such as state versus trait cravings [13], or are not adapted for use in different countries. Coupled with

different study designs and different intervention components, this makes meaningful collation of findings difficult. A comprehensive review of food cravings questionnaires available for use suggested that the Food Cravings Inventory (FCI) questionnaire is among the most widely used self-report tools [35]. The FCI measures the frequency of cravings for specific foods during the previous month, which can be separated into high fat, sweet, carbohydrate-rich, and high fat fast foods.

Meal replacements and weight loss

Failure to achieve reasonable weight loss during the first weeks of an intervention is an important predictor of drop-out, especially among obese participants [36]. One dietary approach to facilitate faster weight loss is the utilisation of meal replacement products. These products, typically provided as shakes, bars, or pre-packaged meals, offer a safe and effective therapy for obesity management, through energy restriction, portion control, as well as improved satiety and stimulus control by limiting dietary variety [37-44], and are often promoted to obese individuals in the lead up to bariatric surgery to reduce the risk of complications [45-47]. Meal replacements may be used as total diet replacement, i.e., as the exclusive source of nutrition, or as a partial meal replacement, i.e., consumed in conjunction with other foods.

Meal replacement products are widely available, and some are prescribed as part of commercial weight loss programs. Laudenslager et al. [48] synthesised the evidence for the safety and efficacy of commercial lifestyle programs, including meal replacement programs, for eliciting long-term weight loss (12-months) among obese individuals. Commercial offerings from Jenny Craig, Nutrisystem, Health Management Resources, Medifast and OPTIFAST were among the meal replacement programs reviewed. The components and outcomes of the programs are summarised in Table 1. In RCTs evaluating weight loss at 12-months, participants achieved weight reductions ranging between 7.1 and 10.9% (Jenny Craig), 4.2 and 7.8% (Medifast), and 8.6 and 10.5% (OPTIFAST).

Table 1 Components and outcomes of commercial weight loss programs with meal replacements

| Program | Components | | | | Relative monthly costs | 12-month weight loss in RCTs | Delivery modalities tested in RCTs† | Ongoing RCTs |
|--------------------------------------|---|-------------------------------|---------------------------------|--|------------------------|------------------------------|-------------------------------------|--------------|
| | Diet | Exercise | Behavioural strategies | Support | | | | |
| Jenny Craig [49-52] | Low-calorie meal replacements | Encourages increased activity | Self-monitoring Goal setting | Group sessions; 1-on-1 counselling; online community forum | ≥\$100 | 7.1–10.9% | In-person‡; virtual | Yes |
| Nutrisystem [49, 50, 52] | Low-calorie meal replacements | Exercise plans | Self-monitoring | 1-on-1 counselling; online community forum | <\$100 | No 12-month outcomes | Virtual | Yes |
| Health Management Resources [49, 53] | Low-calorie or lower-calorie meal replacements | Encourages increased activity | Goal setting | Group sessions; telephone coaching; medical supervision | ≥\$100 | No 12-month outcomes | In-person; virtual | Unknown |
| Medifast [31, 49, 54, 55] | Very-low-calorie or low-calorie meal replacements | Encourages increased activity | Self-monitoring | 1-on-1 counselling; online coaching | ≥\$100 | 4.2–7.8% | Virtual‡ | Unknown |
| OPTIFAST [49, 52, 56] | Very-low-calorie or low-calorie meal replacements | Encourages increased activity | Problem-solving | 1-on-1 counselling; group support; medical supervision | ≥\$100 | 8.6–10.5% | In-person‡ | Unknown |

Adapted from “Commercial Weight Loss Programs in the Management of Obesity: an Update” by M. Laudenslager, Z.W. Chaudry, S. Rajagopal, S. Clynes and K.A. Gudzone, 2021, *Current Obesity Reports*, 10, p. 92 [48].

Note: For each program described, the authors captured evidence from several sources including a previously published systematic review as well as an updated MEDLINE keyword search using the program name to identify randomized controlled trials in adult subjects. Similar to the prior systematic review, the authors did not include trials performed in special populations such as cancer survivors or patients post-bariatric surgery. The authors also searched program websites for citations and contacted all programs via email to request results. Finally, the authors searched clinicaltrials.gov to identify ongoing randomized controlled trials of programs. The authors used program website to identify information about components included. †Virtual delivery modality may consist of a remote web-based platform, online components, and/or telephone delivery of services. ‡Modalities with demonstrated weight loss efficacy greater than comparator at 12 months in an RCT published in a peer-reviewed publication.

To date, three landmark clinical trials have utilised meal replacements as part of a lifestyle intervention in diabetes management, the Look AHEAD, DIRECT, and PREVIEW studies. The findings of these trials have been reviewed by Noronha et al. [57] and summarised in Table 2. The Look AHEAD intervention was a partial meal replacement program [58], whereas the DIRECT and PREVIEW studies were total meal replacement diets for the weight loss phase [59, 60], and all three studies included a food-reintroduction phase to facilitate the maintenance of lost weight.

To date, 'Look AHEAD' is the largest randomised controlled trial, with >5,000 overweight/obese participants enrolled. All participants assigned to the intensive lifestyle intervention (replacing two meals with a liquid shake) who completed the program achieved clinically significant weight loss ($\geq 5.5\%$ of starting body weight). Compared to a usual care group, participants in the intensive lifestyle intervention lost more weight after one year (0.7% of initial weight versus 8.6%, respectively). The relationship between the use of meal replacements and weight loss was also examined. Participants with the highest use (quartile) of meal replacements were found to have four times greater odds of reaching weight loss goals of 10% initial body weight than did participants in the lowest use quartile [58]. The PREVIEW study used meal replacement products in an 8-week weight loss phase (as a total meal replacement diet), before participants were randomised to a 148-week weight maintenance phase of either diet or exercise intervention. Out of the 2,326 participants enrolled in the PREVIEW study, 1,857 (~80%) achieved $\geq 8\%$ weight loss (average, 11%) during the first eight weeks of the trial. Those participants were followed for three years for a weight maintenance phase. At three years, some weight was regained, but, on average, a 5% reduction from participants' starting weight was recorded [60]. The DIRECT study [59] used a similar model; during the initial total diet replacement weight loss phase (12-20 weeks in duration), on average, participants who completed the program lost 14.5 kg, compared with 3.0 kg for non-completers.

Table 2 Summary of large-scale RCTs incorporating meal replacements as part of a comprehensive lifestyle intervention

| Study [reference] | Design | Subjects | Interventions | Results |
|-------------------------|---|--|---|--|
| Look AHEAD [58, 61, 62] | Multi-centre, randomized controlled trial | 5,145 overweight /obese patients with Type 2 Diabetes (T2D) | Intensive lifestyle intervention (ILI) involved a caloric target of 1,200-1,800 kcal/day, use of meal replacement (MR) products (weeks 3 to 19 only), and >175 minutes of moderate-intensity physical activity per week Diabetes support and education (DSE) involved group sessions focused on diet, exercise and social support | <p>2^o outcomes (ILI vs. DSE):</p> <ul style="list-style-type: none"> - ↓ very-high-risk Chronic kidney disease incidence - ↓ mild or greater depression symptoms - ↓ odds of Non-alcoholic fatty liver disease - ↑ remission of obstructive sleep apnoea <p>Weight loss & 1^o outcome: participants who achieved >10% weight loss had 21% lower risk of the 1^o outcome (composite of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for angina) compared with participants who had stable weight or weight gain MR use: at year 1, participants in the highest quartile of MR use had greater odds of reaching the 7% and 10% weight loss goal than did participants in the lowest quartile of MR use.</p> |
| DIRECT [59] | Open-label, cluster randomized trial | 298 overweight /obese patients with T2D from 49 primary care practices | Intervention involved total diet replacement using formula diet for 3–5 months, stepped food reintroduction for 2–8 weeks, and structured support for long-term weight loss maintenance Control group involved best practice care by guidelines | Diabetes remission: 46% of participants in the intervention group achieved diabetes remission vs. 4% of participants in the control group MR use: total diet replacement using formula diet resulted in weight loss of 14.5 kg in participants that engaged with the intervention (completers) vs. 3 kg in non-completers |
| PREVIEW Study [60] | Randomized trial with 2x2 factorial design (two diets and two physical activity programs) | 2,326 adults with prediabetes | Participants completed an 8-week weight loss phase which involved a low-energy diet consisting of meal replacement products Those who achieved weight loss of >8% continued on to the weight maintenance phase (148 weeks) consisting of a combination of one of two diets (high or moderate protein) with one of two physical activity (high or moderate intensity) programs | 1,857/2,326 (79.8%) participants achieved >8% weight loss during the 8-week weight loss phase No significant differences were observed in 3-year T2D incidence between diets, physical activity, or their combination Overall incidence of T2D was very low (3.1%), especially when compared to previous diabetes prevention studies (10.5%-15.8%) |

Adapted from "Meal Replacements for Weight-Related Complications in Type 2 Diabetes: What Is the State of the Evidence?" by J.C. Noronha, C.W.C. Kendall, and J.L. Sievenpiper, 2022, *Frontiers in Endocrinology*, 13 [57].

A recent systematic review and meta-analysis assessed the effects of meal replacement-based diets compared with food-based diets on weight loss [38]. Twenty-four interventions, reported across 22 studies involving 1,982 overweight or obese participants were included (Table 3). The percentage of energy intake from meal replacements varied between 21% and 100% (i.e., total meal replacement diet protocol). The calorie contents of the meal replacements ranged between 270 and 1,200 kcal/day.

Overall, it was reported that meal-replacement based low-energy diets were superior to food-based low-energy diets for weight loss (Figure 1). There was no restriction in the duration of the interventions included in the meta-analysis; studies ranged from 2 weeks to 52 weeks (average ~15 weeks). Findings from the meta-regression also suggest that the greatest effect was seen when participants received $\geq 60\%$ of their total daily energy intake from meal replacement products.

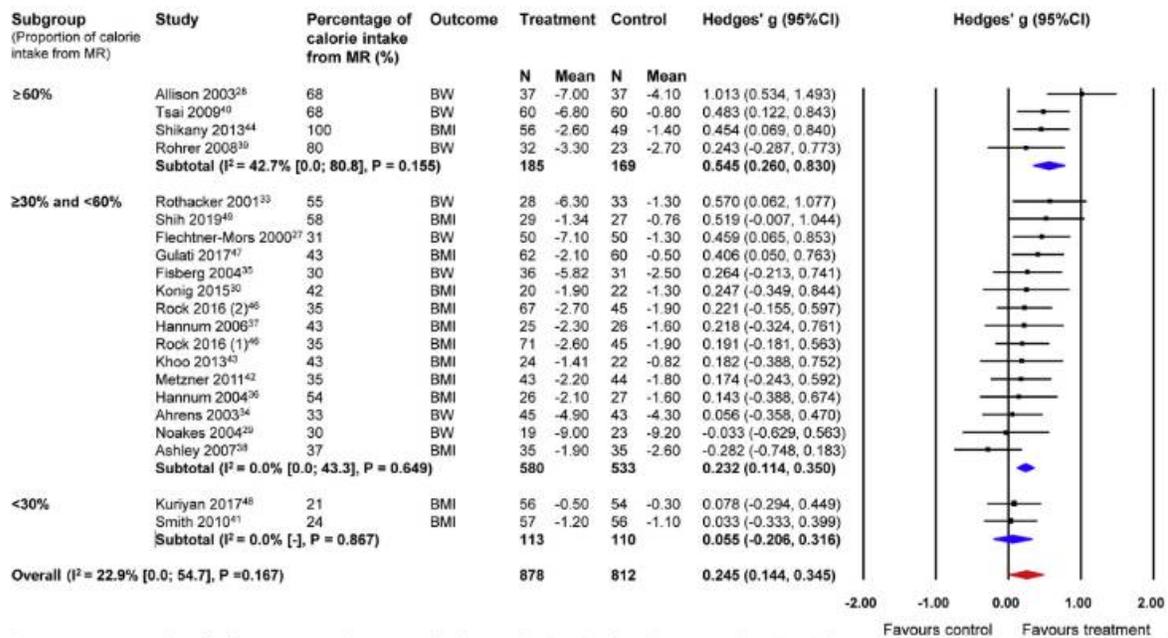


Figure 1 Forest plot of effect size on change in body weight (BW) or body mass index (BMI) between meal replacement (MR)-based and conventional low-energy diets

Reproduced from "The Effect of Meal Replacement on Weight Loss According to Calorie-Restriction Type and Proportion of Energy Intake: A Systematic Review and Meta-Analysis of Randomized Controlled Trials" by J. Min, S-Y. Kim, I-S. Shin, Y-B. Park and Y-W. Lim, 2021, *Journal of the Academy of Nutrition and Dietetics*, pp. 1555-1557 [38].

Table 3 Characteristics of studies included in the systematic review and meta-analysis by Min et al. [38]

| First author, year, country | Age (y) | Female (%) | Initial BMI | Sample size randomised / analysed | Duration (weeks) | Type of MR | # meals replaced | MR, kcal/day (%) | Adverse events |
|------------------------------------|----------------|-------------------|--------------------|--|-------------------------|--|-------------------------|-------------------------|--|
| Flechtner-Mors, 2000, Germany | 45.2 | 79.0 | 33.6 | 100/100 | 12 | Liquid formula | 2 | 420 (31) | NR |
| Rothacker, 2001, US | 36.9 | 100.0 | 28.9 | 75/61 | 52 | Powdered mixes plus skim milk | 3 | 1,320 (100) | None |
| Ahrens, 2003, US | 47.7 | 87.4 | 29.3 | 95/88 | 12 | Liquid formula | 2 | 220 (16) | NR |
| Allison, 2003, US | 50.2 | 80.0 | 34.3 | 100/74 | 12 | Powdered mixes plus water | 2 | 800 (68) | Gas/indigestion, constipation, taste: abnormal, lethargy |
| Fisberg, 2004, Brazil | 36.0 | 93.6 | NR | 78/67 | 12 | Liquid formula or powdered mixes plus milk | 2 | 420 (30) | Transitory elimination of flatus |
| Hannum, 2004, US | 37.1 | 100.0 | 31.6 | 60/53 | 8 | Pre-packaged foods | 2 | 733 (54) | NR |
| Noakes, 2004, Australia | 48.1 | 41.8 | 32.5 | 66/42 | 24 | Liquid formula and bars | 2 | 430 (30) | NR |
| Hannum, 2006, US | 38.1 | 0 | 31.4 | 60/51 | 8 | Pre-packaged foods | 2 | 733 (54) | NR |
| Ashley, 2007, US | 38.2 | 100.0 | 29.3 | 96/70 | 52 | Liquid formula or bars | 2 | 440 (37) | None |
| Rohrer, 2008, US | 47.2 | 80.0 | 36.3 | 63/55 | 4 | Pre-packaged foods | 3 | - (100) | NR |
| Tsai, 2009, Taiwan | 43.2 | 85.8 | 32.4 | 120/120 | 12 | Powdered mixes plus water | 2.3 | 800 (68) | Diarrhea, gas/indigestion, losing sleep |
| Smith, 2010, US | 28.2 | 32.7 | 33.1 | 113/113 | 24 | Liquid formula or bars | 2 | 380 (24) | NR |
| Metzner, 2011, Germany | 49.7 | 100.0 | 31.2 | 105/87 | 12 | Liquid formula, soups or bars | 2 | 415 (35) | Diarrhea |
| Khoo, 2013, Singapore | 40.5 | 0 | 32.7 | 48/46 | 12 | Liquid formula | 2 | 640 (43) | None |
| Shikany, 2013, US | 40.0 | 88.3 | 40.9 | 120/105 | 26 | Liquid formula and pre-packaged foods | 3 | 1,000 (100) | NR |
| König, 2015, Germany | 49.0 | 57.1 | 32.7 | 50/42 | 6 | Powdered mixes | 2 | 460 (42) | NR |

| | | | | | | | | | |
|-------------------------|------|------|------|---------|----|---|---|----------|---------------------------------------|
| Fuller, 2016, Australia | 42.3 | 53.9 | 30.4 | 76/76 | 6 | Whole-grain products | 2 | NR | Gastrointestinal adverse effects |
| Rock, 2016 (a), US | 46.4 | 58.6 | 33.1 | 117/116 | 12 | Pre-packaged foods including high protein | 2 | 266 (35) | NR |
| Rock, 2016 (b), US | 46.7 | 59.8 | 33.4 | 112/112 | 12 | Pre-packaged foods | 2 | 266 (35) | NR |
| Gulati, 2017, India | 37.5 | 57.4 | 30.4 | 122.122 | 12 | Powdered mixes | 2 | 642 (43) | None |
| Kuriyan, 2017, India | 31.0 | 100 | 29.1 | 110/110 | 2 | - | 2 | 288 (21) | NR |
| Shih, 2019, Taiwan | 38.1 | 51.8 | 24.8 | 60/56 | 8 | Powdered mixes | 2 | 781 (58) | No serious adverse effects |
| Kim, 2005, Korea | 24.4 | 100 | 25.6 | 66/54 | 4 | Powdered mixes including herbal extract | 2 | 270 (45) | Constipation, powerlessness, vomiting |

Adapted from "The Effect of Meal Replacement on Weight Loss According to Calorie-Restriction Type and Proportion of Energy Intake: A Systematic Review and Meta-Analysis of Randomized Controlled Trials" by J. Min, S-Y. Kim, I-S. Shin, Y-B. Park and Y-W. Lim, 2021, *Journal of the Academy of Nutrition and Dietetics*, pp. 1555-1557 [38].

Meal replacements and cravings

Some studies have examined changes in food cravings following an energy-restricted diet intervention including meal replacement products.

Moldovan et al. [31] investigated the effects of a 12-week meal replacement program on weight loss and food cravings in a sample of 77 obese (BMI >35 to 50 kg/m²) adults. Participants (82% female) were randomised to receive Medifast meal replacements with phentermine (37.5 mg/day) or without (placebo). Meal replacements were five nutritionally balanced, low-fat, portion-controlled Medifast meals, plus one self-prepared meal consisting of a lean protein source and three servings of vegetables, daily [54]. Total calories for the plan were estimated at 900-1,100 kcal/day. Food cravings for 28 specific foods were assessed by the FCI, and situational states and stable traits of general food cravings were assessed by the General Food Cravings-State, and General Food Cravings-Trait, respectively.

Following the 12-week intervention, participants in both groups experienced significant weight loss (8.8% and 12.1% of initial body weight in the placebo and phentermine groups, respectively). Cravings for all food groups and trait and state food cravings decreased in both groups; however, there was a greater reduction in cravings for fats and sweets in the phentermine group compared with the placebo group. Per cent weight loss was positively correlated with changes in total food cravings, cravings for sweets, and state food cravings. Considering food cravings have been directly linked with obesity [15], eating behaviours [14], and adherence to diet protocols [63], this study provides some evidence that use of meal replacement meals as part of a lifestyle intervention may be an effective method for eliciting weight loss and reducing food cravings. Lack of a follow-up period means longer term effects remain unknown.

Bowen et al. [30] compared a high-protein, partial meal replacement program with or without alternate day fasting on weight loss, psychological, nutritional and behavioural markers. The dietary protocol involved one meal (dinner) of lean protein and low-energy vegetables, and a prescribed number of meal replacements (Impromy™) and snacks between meals. Participants assigned to the alternate day fasting group followed the same dietary protocol for three days, consumed two meals replacements and low energy vegetables (dinner) for three days, and one day of *ad libitum* intake. The energy intake for the dietary restriction and alternate day fasting groups were estimated at 35,000 kJ/week, and 32,200 kJ/week (equivalent to ~8,333 kcal/week and 7,619kcal/week), respectively. During the intervention, participants met with a dietitian every two weeks until week 16.

Following the 16-week intervention, there was a significant reduction in body weight, fat mass, visceral adipose tissue, and fat-free mass in both groups – that is partial meal replacements with or without alternate day fasting. Food cravings were assessed by the Food Cravings-Trait questionnaire. Consistent with the findings of Moldovan et al. [31], at week 16, trait food cravings decreased in both groups. The 16-week intervention was followed by eight weeks of a weight maintenance food-based dietary protocol (i.e., no meal replacements), which was tailored to individuals' energy requirement for weight maintenance. Both groups were instructed to follow to

follow the same weight maintenance diet. Weight loss was maintained between the energy restriction phase and weight maintenance phase. This suggests that the use of meal replacements for weight loss, in the context of use in this study, did not result in rebound weight gain when participants were no longer taking them during the weight maintenance phase, at least at the 6-month timeframe. Cravings were not assessed at week 24. During the 8-week weight maintenance phase, participants were not offered dietetic counselling, so these findings are independent of additional support.

Martin et al. [26] investigated changes in food cravings during low (5,024 kJ/day) and very low (3,349 kJ/day) energy diets (equivalent to ~1,196 kcal/day and 797 kcal/day, respectively). Participants randomised to the low energy diet (n=39) followed a food-based meal plan, and participants in the very-low energy diet group (n=59) consumed five servings of a meal replacement (Health Management Resources), supplemented with one or two nutrition bars as desired (Phase 1, ~12 weeks), followed by a refeeding period (Phase 2, ~6 weeks). In a stepwise fashion, servings of the meal replacement were reduced, while servings of foods from different food groups were increased until participants' meal plans consisted entirely or almost entirely of whole foods. Food cravings (FCI) were assessed at baseline, week 6, and week 12 of Phase 1, and again at the end of Phase 2 (~week 18). Food cravings decreased in both groups, and a greater reduction was reported in the very low energy (liquid) diet group compared with a food-based low-calorie diet group. Changes in food cravings in the very low energy diet group at week 6 were sustained at weeks 12 and 18, suggesting food cravings did not rebound with resumption of solid food intake.

Kahathuduwa et al. [28] examined the effects of a 3-week total meal replacement intervention versus an iso-caloric typical diet on food-cue reactivity, food cravings and weight among obese adults (n=32). Participants randomised to the typical diet group were instructed to limit their dietary intake to 1,120 kcal/day for three weeks by controlling portion sizes and calorie monitoring of foods they typically consume. No other dietary advice or recommendations were provided. Those randomised to the total meal replacement condition were provided with Optifast™800 meal replacement sachets (170 kcal/sachet) and were instructed to consume seven sachets (consumed as shakes) per day. Greater weight loss was reported in the total meal replacement group compared with food-based diet restriction. At week 3, total food cravings (FCI) declined in the total meal replacement group (only). Cravings for sweet and starchy foods were reduced in both the total meal replacement and food-based diet restriction groups.

Clinical considerations regarding meal replacements

Despite their efficacy in eliciting acute weight loss, the prescription of meal replacement products for overweight and obese patients is thought to be underutilised by health care professionals [46, 47]. Barriers to prescription of meal replacement products include experience with poor dietary compliance, perceived inability to sustain long-term weight loss, cost, and safety, particularly regarding psychological impact of weight cycling and long-term weight regain [46, 47].

While meal replacement products are generally well-tolerated, mild gastrointestinal upsets are common [48]. Compared with food-based diets, higher rates of adverse events have been

reported among those using meal replacements [56, 64]. However, among the 22 studies included in Min and colleagues' systematic review and meta-analysis [38] which investigated the effect of meal replacements on weight loss, only half (n=11) reported information on adverse events. Five (of the 11 studies) reported no serious adverse events, and six reported mild adverse events, such as constipation, diarrhoea and gastrointestinal symptoms.

Summary and conclusions

The key findings of this review include:

- People who are overweight or obese tend to experience greater food cravings.
- Food cravings are related to eating behaviour, and the relationship of these factors with body weight varies between individuals.
- Energy restriction to lose weight seems to be associated with reduced food cravings, regardless of the method of restriction (food-based energy restricted diet, or use of meal replacement products).
- Meal replacements may offer a safe and effective temporary strategy to elicit faster, initial weight loss, before transitioning to a healthy food-based dietary pattern.
- Meal replacement products are reported to be underutilised by health care professionals, attributable to their perceived inability to sustain long-term weight loss and safety concerns.

Previous literature offers little insight into causal mechanisms regarding craving, weight loss and weight status. There is suggestion that people who are obese struggle more with cravings, and that people with cravings struggle more with weight management. Despite the established benefits of energy restriction for the experience of cravings, few weight loss interventions have specifically evaluated this in people who struggle with cravings. Based on the literature presented, more research is needed to examine how effective energy restriction in the form of meal replacements is for people who identify as struggling with cravings – that is whether the use of meal replacements within a weight loss program helps to reduce the experience of cravings and thereby leads to greater weight loss for this segment of the population.

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Part II Online Survey



Background and aims

The CSIRO Diet Types survey (What's Your Diet Type? | CSIRO Total Wellbeing Diet) is a short questionnaire which provides individuals with feedback on their 'dieting personality' (2017-csiro-diet-types-report.pdf (digitalwellness.com)). Secondary analysis of these data suggested that individuals with higher craving tendencies (classified as "Cravers") don't lose as much weight on the CSIRO Total Wellbeing Diet compared to other personality types, such as those who love preparing and trying new foods (classified as "Foodies"). In fact, analysis has shown that Cravers do not do as well as other diet types on a few aspects of the program.

In an analysis of over 19,000 people who had completed the CSIRO Diet Types survey and the CSIRO Total Wellbeing Diet, Cravers lost 15% less weight on the program after 12 weeks than Foodies, and 6% less than the average weight loss of all members. This difference in weight loss started to emerge between weeks 3 and 6 of the program and continued to diverge through to the end of 12 weeks (Figure 2). Cravers were also about 4kg heavier than Foodies when they started the CSIRO Total Wellbeing Diet, and among the heaviest subgroup of the people who start the program. This suggests that people who report they struggle with cravings may benefit from additional support, and possibly a different style of program, to lose weight.

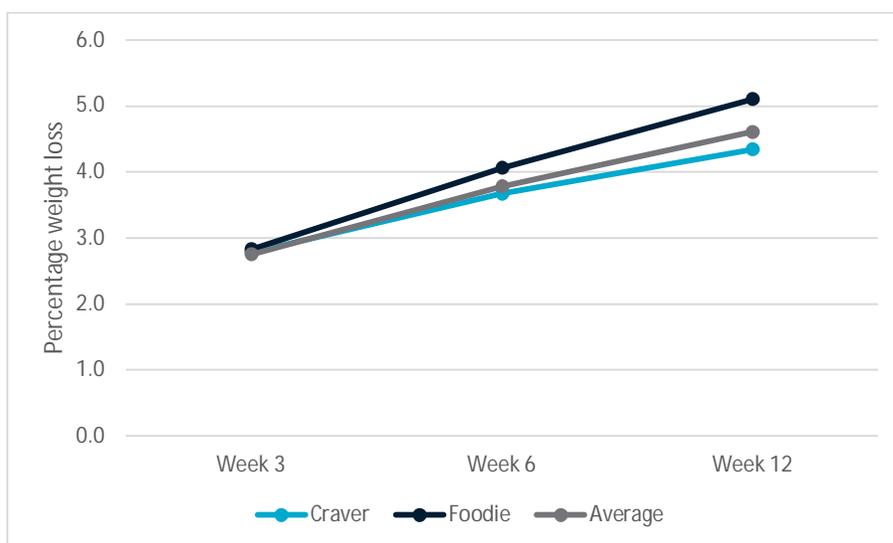


Figure 2. Weight loss (as a percentage of baseline weight) by diet type

We were interested to better understand the challenges people with cravings experience when trying to lose weight. To explore this, a sample of people were invited to complete an online survey asking about their cravings, dieting history and strategies they use to manage their cravings and weight.

People were recruited from an existing database of people who had previously completed the CSIRO Diet Types survey and were classified as having higher craving tendencies. Recruitment was limited to those aged 18 years and older and who had not previously been members of the CSIRO Total Wellbeing Diet online program. The study was reviewed and approved by the CSIRO Health and Medical Human Research Ethics Committee (2022_044_LR). The following sections describe the results of this survey.

Characteristics of the sample

A total of 330 people completed the online survey, with a distribution from Australian states that was broadly representative of the Australian population. Most respondents were female (90%), aged between 31-70 years. The average Body Mass Index (BMI) of people who completed the survey was 32.9 kg/m², and 21% were classified as overweight and 60% as obese according to BMI categories (Table 4).

This sample had a mix of weight loss experience with 30% reporting 1-5 attempts to actively manage their weight in their lifetime, 26% reporting 6-10 attempts, and 22% reporting more than 25 attempts to actively manage their weight.

Table 4. Demographic characteristics of the sample of people who completed the survey

| | | Count | Percentage |
|---|---------------------|-------|-------------|
| | Total | 330 | 100.0% |
| Gender | Male | 33 | 10.0% |
| | Female | 297 | 90.0% |
| Age group | 18-30 years | 7 | 2.1% |
| | 31-50 years | 85 | 25.8% |
| | 51-70 years | 209 | 63.3% |
| | 71 years+ | 29 | 8.8% |
| Level of education | High school | 49 | 14.8% |
| | Tafe/diploma | 104 | 31.5% |
| | Bachelor's degree | 77 | 23.3% |
| | Post-graduate study | 97 | 29.4% |
| State of residence | ACT | 14 | 4.2% |
| | NSW | 88 | 26.7% |
| | QLD | 60 | 18.2% |
| | SA | 39 | 11.8% |
| | VIC | 88 | 26.7% |
| | WA | 37 | 11.2% |
| Mean weight (kg) (+-SD) [†] | | | 89.8 (23.1) |
| Mean BMI (kg/m ²) (+-SD) [†] | | | 32.9 (7.9) |
| Weight status [†] | Normal weight | 54 | 16.4% |
| | Overweight | 68 | 20.6% |
| | Obese | 198 | 60.0% |
| | Not reported | 10 | 3.0% |
| Previous attempts to manage weight | Never | 5 | 1.5% |
| | 1-5 times | 99 | 30.0% |
| | 6-10 times | 85 | 25.8% |
| | 11-25 times | 70 | 21.2% |
| | More than 25 times | 71 | 21.5% |

Note: †, some values for height (n=7) and/or weight (n=5) were not reported; final numbers included in mean weight calculation, n=325; final numbers included in mean BMI calculation and weight status classification, n=320; data will cell counts <5 not shown.

Challenges in managing weight

To understand weight management challenges, respondents were asked to choose the thing/s they consider most difficult when it comes to managing their weight (they could select up to 3 from a list). 'Struggle to control cravings' and 'controlling intake around tempting foods' were the two most common difficulties, each selected by around half of the survey respondents (Figure 3).

About a quarter of respondents selected 'high stress levels', 'feeling tired', 'lack of drive', 'too many temptations', and 'limited changes in weight', in their top 3 challenges in managing their weight.

'Feeling tired' (31% vs 15%), 'limited changes in weight' (24% vs 13%) and 'lack of drive' (25% vs 15%) were more commonly selected in the top 3 challenges for obese compared to normal weight respondents. Conversely, 'controlling intake around tempting foods' (61% vs 40%) and 'eating out' (19% vs 8%) were more commonly selected in the top 3 challenges for normal weight respondents (Table 5).

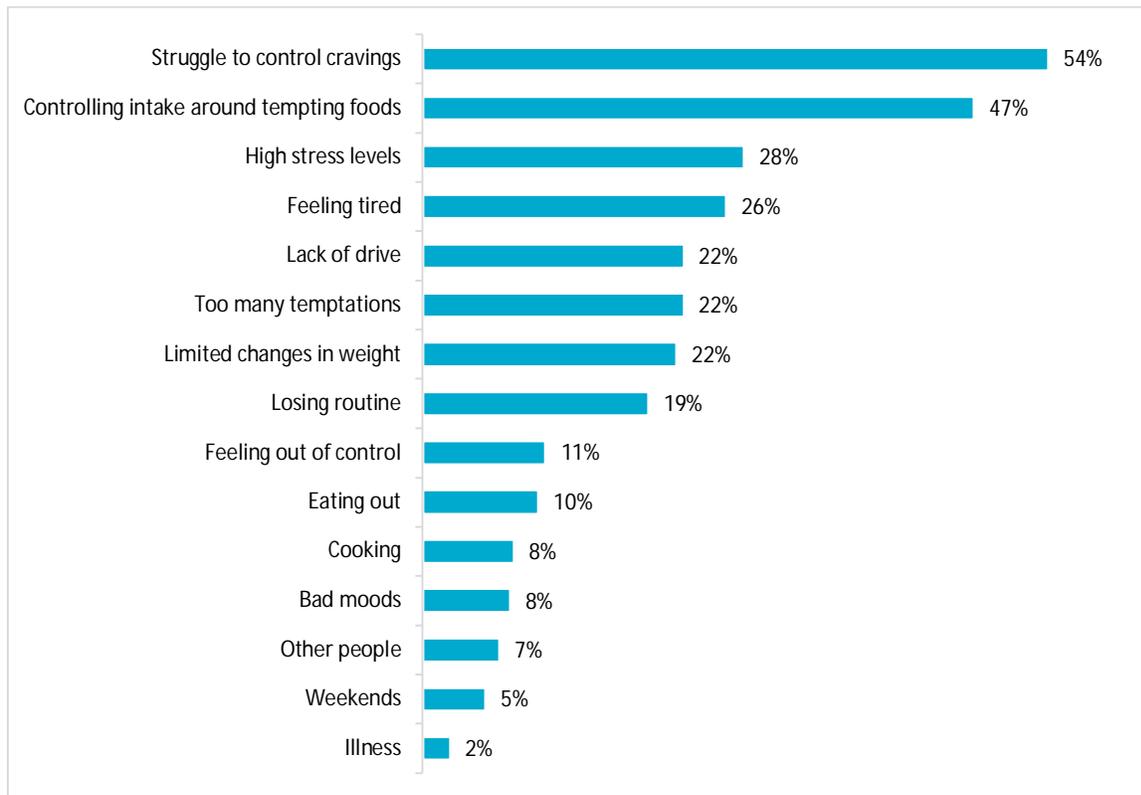


Figure 3 The most common weight management challenges

Table 5 The most common weight management challenges by weight status

| | Normal weight (n,%) | Overweight (n,%) | Obese (n,%) | Total (n,%) |
|--|----------------------------|-------------------------|--------------------|--------------------|
| Struggle to control cravings | 31, 57% | 35, 51% | 105, 53% | 177, 54% |
| Controlling intake around tempting foods | 33, 61% | 39, 57% | 80, 40% | 156, 47% |
| High stress levels | 12, 22% | 22, 32% | 57, 29% | 91, 28% |
| Feeling tired | 8, 15% | 15, 22% | 62, 31% | 86, 26% |
| Too many temptations | 16, 30% | 17, 25% | 39, 20% | 74, 22% |
| Limited changes in weight | 7, 13% | 14, 21% | 47, 24% | 72, 22% |
| Lack of drive | 8, 15% | 12, 18% | 49, 25% | 74, 22% |
| Losing routine | 12, 22% | 12, 18% | 38, 19% | 64, 19% |
| Feeling out of control | 7, 13% | 6, 9% | 21, 11% | 35, 11% |
| Eating out | 10, 19% | 6, 9% | 16, 8% | 33, 10% |
| Cooking | 2, 4% | 7, 10% | 16, 8% | 26, 8% |
| Bad moods | 5, 9% | 6, 9% | 14, 7% | 25, 8% |
| Other people | 3, 6% | 5, 7% | 14, 7% | 22, 7% |
| Weekends | 2, 4% | 2, 3% | 14, 7% | 18, 5% |
| Illness | 0, 0% | 1, 1% | 7, 7% | 8, 2% |

Respondents rated their level of agreement to 10 statements related to their ability to control or resist temptations. Most respondents (82%) agreed that it would be easier to lose weight without cravings (Figure 4 and Table 6).

Generally, respondents also had a high level of agreement to statements relating to their struggle with resisting temptation and cravings. For example, 73% of respondents agreed it would be easier to lose weight without temptations present, 67% agreed that it is a constant struggle to resist tempting foods and 66% felt it was a constant struggle to resist their cravings. In contrast, respondents did not feel they could resist tempting foods with 61% disagreeing they could resist tempting foods when they were present and 68% disagreeing that they had the strength in controlling their cravings.

Table 6 Agreement and disagreement with statements about cravings

| Statement | Mean (SD) | Rating ≤3 (number, %) “Disagreed” | Rating ≥5 (number, %) “Agreed” |
|--|------------------|--|---|
| It would be easier for me to lose weight without cravings | 5.9 (1.6) | 32, 10% | 272, 82% |
| It would be easier for me to lose weight with less temptations present | 5.5 (1.6) | 39, 12% | 241, 73% |
| Compared to other people my age and gender, I struggle more with controlling the amount I eat when I snack | 5.2 (1.7) | 57, 17% | 221, 67% |
| It is a constant struggle for me to resist tempting foods | 5.0 (1.8) | 77, 23% | 220, 67% |
| It is a constant struggle for me to resist my craving | 5.0 (1.8) | 80, 24% | 218, 66% |
| Compared to other people my age and gender, I struggle more with resisting temptation | 4.8 (1.6) | 61, 18% | 186, 56% |
| Compared to other people my age and gender, I struggle more with having thoughts about eating | 4.8 (1.7) | 69, 21% | 182, 55% |
| Compared to other people my age and gender, I snack more often | 4.6 (1.8) | 87, 26% | 175, 53% |
| I can resist tempting foods when they are present | 3.1 (1.6) | 202, 61% | 71, 22% |
| No matter how strong, I can control my cravings | 2.9 (1.6) | 225, 68% | 58, 18% |

Note: Participants were asked to rate their level of agreement on a scale of 1 (strongly disagree) to 7 (strongly agree); a score of ≤3 was considered disagreement with the statement, a score ≥5 was considered agreement with the statement.

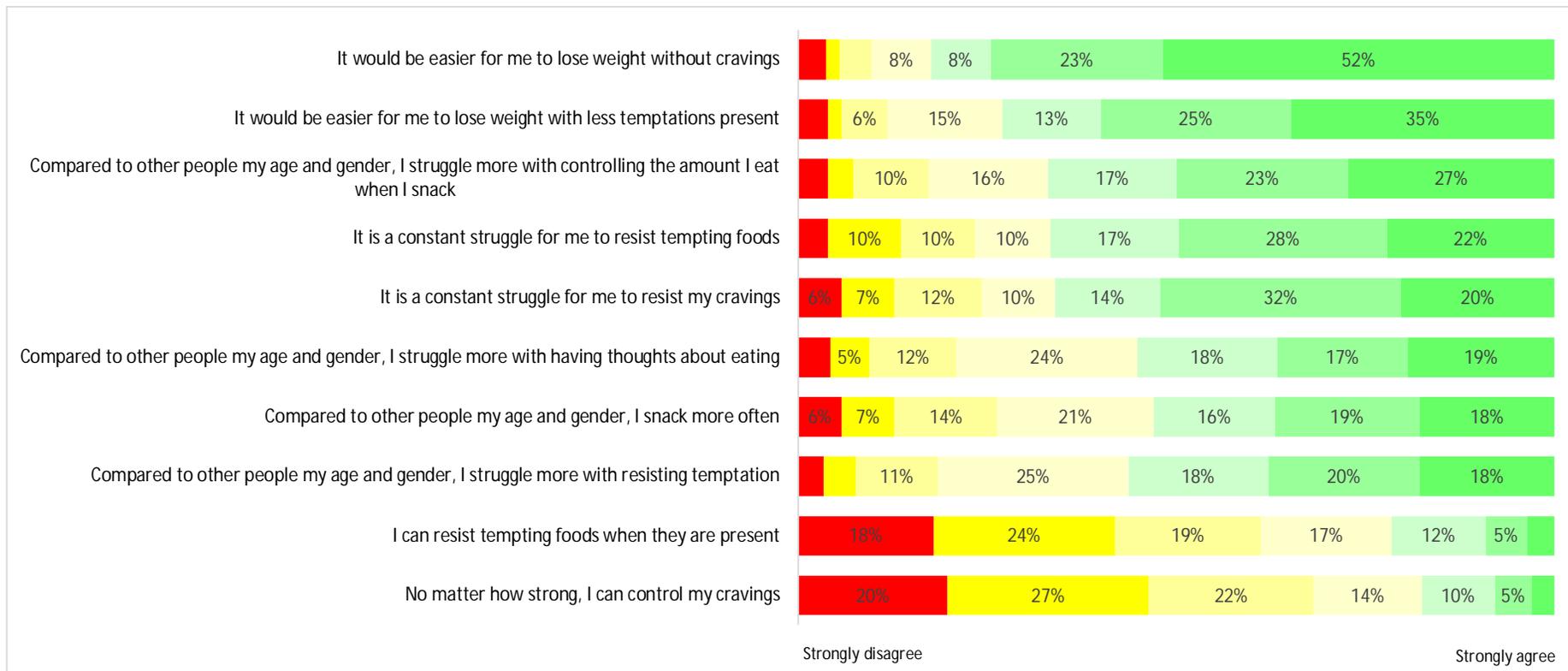


Figure 4 Level of agreement with statements about cravings

Note: Participants were asked to rate their level of agreement on a scale of 1 (strongly disagree) to 7 (strongly agree); red shading indicates a level of disagreement with the statement, grey shading indicates a neutral score, green shading indicates a level of agreement with the statement. Values for percentages less than 5 are not displayed in the figure.

Food cravings

People were asked to complete the Food Craving Inventory (FCI). In the first part of the FCI ('subjective' component), people were asked to record the frequency they experienced cravings for 28 listed foods over the past month, ranging from never to always/almost every day. The FCI groups this list of foods into four subscales: (1) high fat foods, (2) sweet foods, (3) carbohydrate-rich foods, and (4) high fat fast foods.

All respondents reported that they had experienced a craving for at least one of the 28 foods listed in the FCI over the past month (Table 7). Almost all respondents had a craving for carbohydrate-rich foods (99%). Most respondents also had cravings for sweets (98%), fast foods (95%), and high fat foods (87%).

Higher levels of cravings were rated for sweets (1.5 ± 0.7) and fast foods (1.5 ± 0.8), followed by cravings for carbohydrates (1.3 ± 0.7), then high fat foods (0.7 ± 0.6). Chocolate, biscuits, cake, chips, and ice cream were the top five most craved foods from the FCI. (Figure 5).

Table 7 Percentage of the sample and mean food craving scores by craving type, as assessed by the Food Craving Inventory

| | n, % | Mean (SD) [§] |
|----------------------|-----------|------------------------|
| Total food craving | 330, 100% | 1.2 (0.5) |
| Carbohydrate craving | 325, 99% | 1.3 (0.7) |
| Sweet craving | 324, 98% | 1.5 (0.7) |
| Fast food craving | 314, 95% | 1.5 (0.8) |
| Fat craving | 285, 87% | 0.7 (0.6) |

Note: Participants were asked to rate how often they have experienced a craving for the 28 foods in the FCI over the past month on a scale of never (0), rarely (1), sometimes (2), often (3) and always/almost every day (4). [§] Data presented are the summed scores for each craving type, divided by the number of foods in each sub-scale. Higher scores reflect higher levels of food cravings.

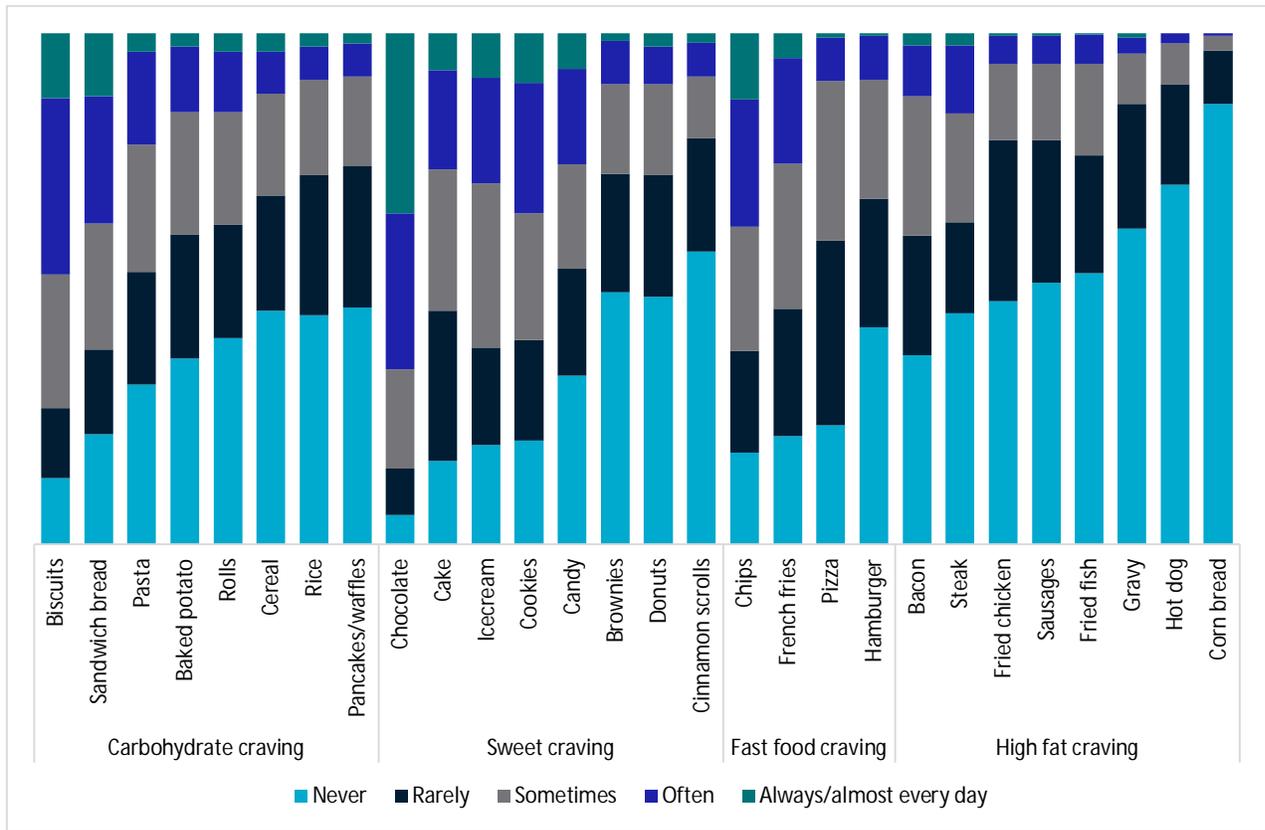


Figure 5 Percentage of sample craving each of the foods in the Food Craving Inventory over the past month

Cravings for different types of foods were all significantly associated with each other, and with total cravings. There was a weak positive relationship between BMI and total cravings, high fat cravings and cravings for fast foods, suggesting, to some extent, that people with a higher BMI have greater cravings generally, and also greater cravings for high fat and fast foods (Table 8).

Table 8 Correlation between BMI and food cravings

| | BMI | Fat craving | Sweet craving | Carbohydrate craving |
|-----------------------------|--------|-------------|---------------|----------------------|
| Total craving | 0.135* | | | |
| High fat craving | 0.243* | - | | |
| Sweet craving | -0.034 | 0.217* | - | |
| Carbohydrate craving | 0.083 | 0.514* | 0.489* | - |
| Fast food craving | 0.171* | 0.545* | 0.252* | 0.489* |

Note: *, correlation significant (at the p<0.05 level).

In the second part of the FCI ('behavioural component'), respondents were asked to record how often over the past month (from never to always/almost every time) that they have 'given in' and consumed the particular food/s they craved.

All respondents reported to have 'given in' to their cravings at some point in the last month (i.e., they had eaten one of the foods in the FCI that they craved over the past month; Table 9). Cravings for high fat foods had the greatest proportion of respondents who had never 'given in' to those cravings (14%). Cravings for carbohydrate rich and sweet foods had the lowest proportion of respondents who had never 'given in' to those cravings (9% and 8%, respectively).

Table 9 Number that had never 'given in' to cravings more than once in the past month and mean food craving scores, as assessed by the Food Craving Inventory

| | n, % | Mean (SD) [§] |
|------------------------------|---------|------------------------|
| Total who had never given in | 0, 0% | 1.0 (0.5) |
| Carbohydrate craving (n=325) | 7, 2% | 1.1 (0.7) |
| Sweet craving (n=324) | 6, 2% | 1.3 (0.8) |
| Fast food craving (n=314) | 25, 8% | 1.2 (0.9) |
| Fat craving (n=285) | 39, 14% | 0.5 (0.5) |

Note: Participants were asked to rate how often they gave in to their cravings and ate those foods over the past month on a scale of never (0), rarely (1), rarely (once or twice) (2), sometimes (3) and always/almost every day (4). [§] Data presented are the summed scores for each craving type, divided by the number of foods in each sub-scale. Higher scores reflect higher levels of food cravings.

Trigger foods and situations

When asked if they had specific things that triggered their cravings, 84% indicated that they had a triggering food and 85% indicated that they had a triggering situation, and 73% indicating they had both a triggering food and situation.

When asked to specify a food, most people listed a discretionary option. Participants reported a mixture of savoury (for example potato chips) and sweet discretionary foods with chocolate being the most frequent (others included cakes and ice cream). Cheese, bread (sometimes white bread specifically), and peanut butter were the only foods from the five healthy 'core' food groups mentioned as trigger foods (Figure 6).

In terms of situations, afternoons, after lunch and after dinner were frequently mentioned, as well as a reference to work, stress and social situations (Figure 7).

Experience with meal replacements

About two-thirds of respondents (67%) had tried a meal replacement or shake diet before, of whom, most had used meal replacement shakes occasionally (44%) or used them as a partial meal replacement program with whole foods (39%). Only 17% of the respondents had tried a full meal replacement program (Table 10).

Table 10 Previous experience trying meal replacements

| | | Count | Percentage |
|-----------------------------------|----------------------------------|-------|------------|
| Experience with meal replacements | Have not tried meal replacements | 109 | 33.0% |
| | Have tried meal replacements | 221 | 67.0% |
| | The occasional shake | 98 | 44.3% |
| | Hybrid | 86 | 38.9% |
| | Full MR program | 37 | 16.7% |

Note: numbers may not add to 100% due to rounding; MR, meal replacements.

Among the respondents who had tried meal replacements before, when asked how successful they felt, 26% felt they were previously successful during a meal replacement diet (that is scored ≥ 5 on a 7-point scale, 7=extremely) and 31% felt meal replacements were helpful to lose weight. In contrast, only 7% of respondents felt meal replacements were successful in helping them keep weight off (Table 11).

Of those who had not tried meal replacements in the past, only 9% felt they would be successful during a meal replacement diet and 14% felt they would be successful in losing weight with meal replacements.

Table 11 Self-reported success or perceived success of meal replacement diets for those who had and had not tried meal replacements in the past

| | | Mean (SD) | Rating ≥ 5 (number, %) |
|--|--|-----------|--------------------------------|
| <i>Of those who have tried meal replacement shakes</i> | | | |
| How successful ... | did you feel during this diet | 3.1 (1.9) | 57, 26% |
| | do you think it was at helping you lose weight | 3.2 (2.0) | 69, 31% |
| | do you think it was at helping keep weight off | 1.9 (1.4) | 16, 7% |
| <i>Of those who have not tried meal replacement shakes</i> | | | |
| How successful do you think ... | you would be during a meal replacement diet | 2.3 (1.6) | 10, 9% |
| | you would be at losing weight if you used meal replacements | 2.8 (1.7) | 15, 14% |
| | you would be at keeping weight off if you used a meal replacement diet | 2.2 (1.4) | 9, 8% |

Note: numbers may not add to 100% due to rounding. Participants were asked to rate their level of success (actual or perceived) on a scale of 1 (not at all) to 7 (extremely); a score of ≥ 5 was considered 'successful'.

Respondents who had tried meal replacements in the past were asked what they liked best about them. The top 3 responses related to the convenience of meal replacements. The most common reason respondents liked using meal replacements was that they were convenient (73%), followed by easy (58%) and required no cooking (43%). About a quarter of respondents selected 'weight loss results' as a reason they liked meal replacements (Figure 8).

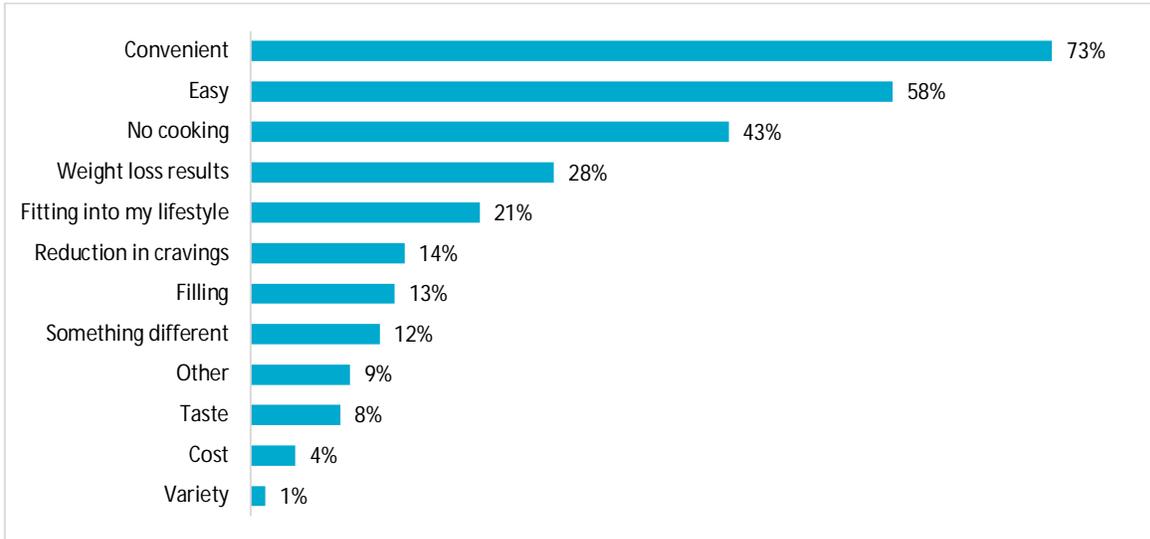


Figure 8 Most common positive attributes about using meal replacement shakes

When asked about the worst part of using meal replacements, lack of solid food was the most common response selected by almost half of the survey respondents – both those who had and had not tried meal replacements in the past (Figure 9). Boredom, hunger, taste and difficult to maintain were also commonly reported as the worst thing about using meal replacements.

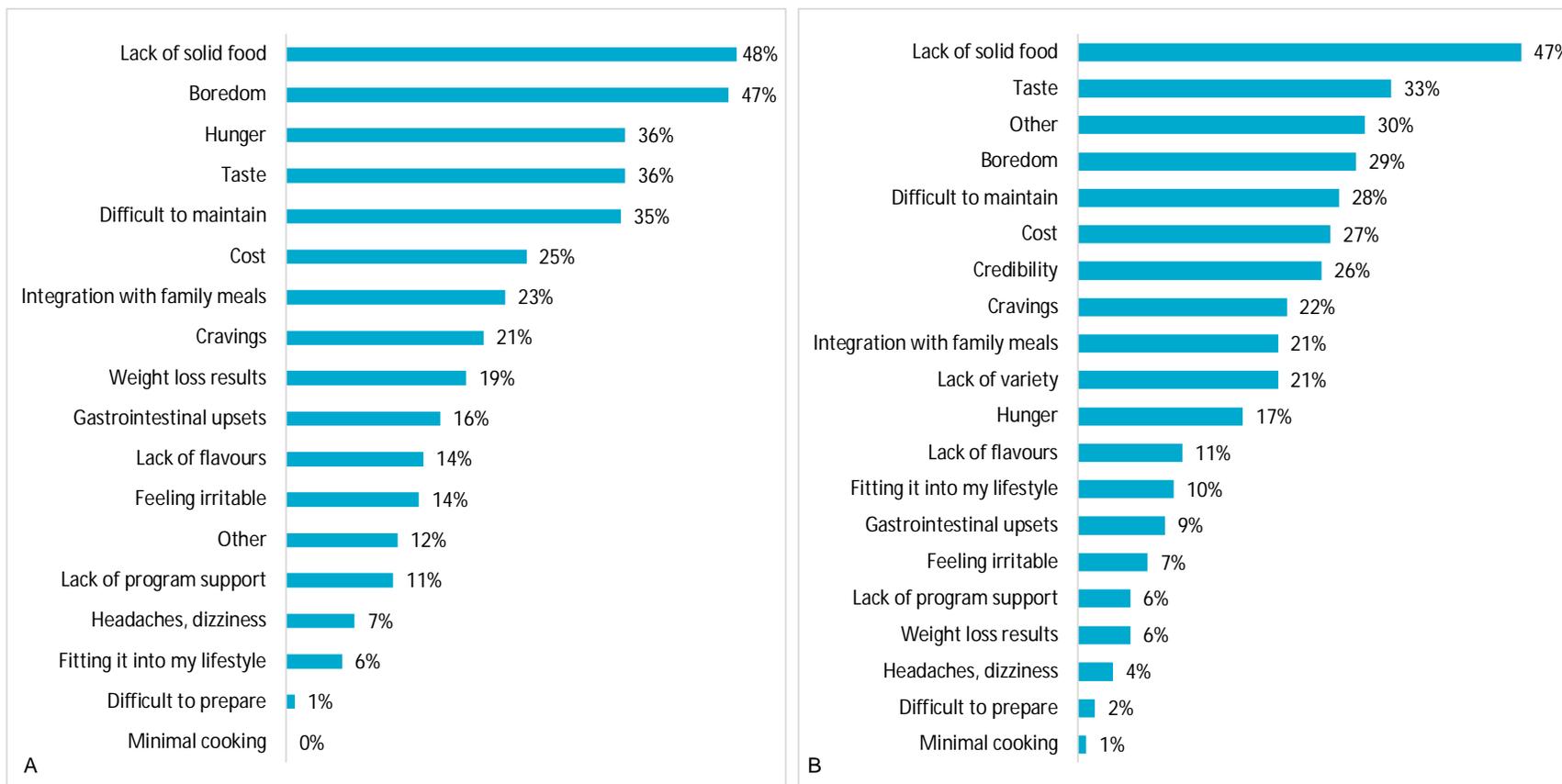


Figure 9 Most common negative attributes about using meal replacement shakes reported by respondents who (A) had tried meal replacements or (B) had not tried meal replacements in the past

Snacking behaviours

Most respondents reported they typically consumed 3 meals each day and had 1-3 snacks between meals (Table 12). It was most common for respondents to report they would struggle with thoughts about eating (37%) and willpower (31%) if they had to stop eating snacks (Figure 10).

Table 12 Number of meals and snacking occasion per day

| | | Count | Percentage |
|---|-------------------------|-------|------------|
| Snacking occasions between meals each day | Never | 13 | 4% |
| | Once per day | 93 | 28% |
| | 2 times per day | 129 | 39% |
| | 3 times per day | 67 | 20% |
| | 4 or more times per day | 28 | 9% |
| Main meals consumed each day | No main meals | 0 | 0% |
| | 1 meal | 23 | 7% |
| | 2 meals | 95 | 29% |
| | 3 meals | 210 | 64% |

Note: data will cell counts <5 not shown.

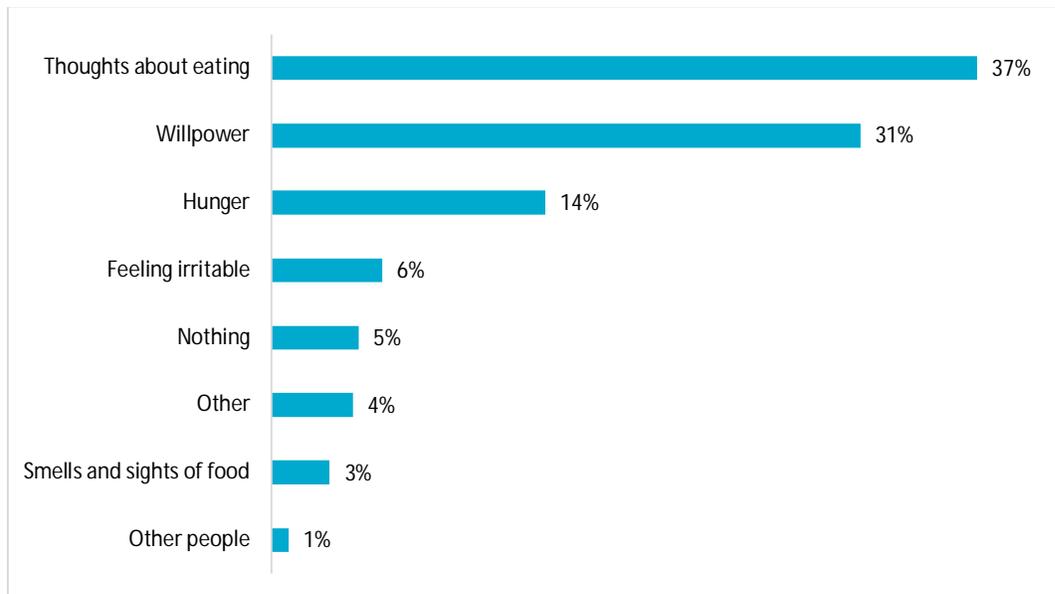


Figure 10 The most common challenges to stop eating snacks

When respondents were asked about using strategies to reduce their food intake generally, most people had tried all the strategies listed. The most common strategies respondents had tried were not buying certain items (98%), limiting intake to smaller portions (96%), and using their willpower (94%; Figure 11 and Table 13).

In terms of how successful respondents felt these strategies were to reduce food intake, not buying certain items was the highest rated strategy (56% rating 5 or above). For the other most common strategies, 32% of respondents felt changing the way they cooked and 29% felt limiting intake to smaller portions were successful strategies for reducing their food intake. Fewer than one-third of respondents rated the other strategies as successful.

Table 13 Strategies to reduce intake, the frequency of the sample who had tried the strategy and the perceived rating of success

| Strategy | Strategy tried [†] | | Success rating [§] | | |
|--|-----------------------------|-----------|-----------------------------|--------------------------|--------------------------|
| | Have tried (number, %) | Mean (SD) | Mean (SD) | Rating ≤3 (number, %) | Rating ≥5 (number, %) |
| Not buying certain items | 322, 98% | 5.5 (1.5) | 4.6 (2.0) | 92, 28% | 185, 56% |
| Limiting intake to smaller portions | 318, 96% | 4.7 (1.6) | 3.5 (1.7) | 158, 48% | 95, 29% |
| Pure willpower | 309, 94% | 4.9 (1.7) | 2.7 (1.6) | 218, 66% | 47, 14% |
| Avoiding or cutting out snacks | 300, 91% | 4.3 (1.8) | 3.1 (1.8) | 189, 57% | 69, 21% |
| Substituting for similar items that are healthier | 299, 91% | 4.4 (1.8) | 3.6 (1.7) | 142, 43% | 93, 28% |
| Beating myself up for being weak | 293, 89% | 5.1 (2.1) | 2.6 (2.0) | 221, 67% | 57, 17% |
| Ignoring it | 271, 82% | 3.9 (2.0) | 2.4 (1.7) | 211, 64% | 31, 9% |
| Changing the way I cook | 268, 81% | 4.0 (2.0) | 3.9 (1.8) | 107, 32% | 107, 32% |
| Trying to change the way I think about it | 256, 78% | 3.7 (2.1) | 2.9 (1.6) | 169, 51% | 43, 13% |
| Trying to change the way I feel about it | 245, 74% | 3.4 (2.0) | 2.9 (1.6) | 165, 50% | 37, 11% |
| Hiding the food away | 244, 74% | 3.5 (2.1) | 2.7 (1.6) | 175, 53% | 32, 10% |
| Setting aside specific occasions to have foods I crave | 230, 70% | 3.2 (2.0) | 3.0 (1.7) | 150, 45% | 50, 15% |
| Talking to other people about it | 214, 65% | 2.9 (1.9) | 2.8 (1.7) | 150, 45% | 31, 9% |
| Having certain foods on some but not all days | 211, 64% | 3.2 (2.0) | 3.0 (1.6) | 138, 42% | 42, 13% |
| Asking other people to stop offering me certain foods | 205, 62% | 3.0 (2.1) | 2.8 (1.7) | 147, 45% | 34, 10% |

Note: †, Participants were asked to rate how much they have tried these strategies on a scale of 1 (never) to 7 (always); §, Respondents who had tried that strategy were asked to rate how successful they felt the strategy/ies were on a scale of 1 (not at all) to 7 (extremely).

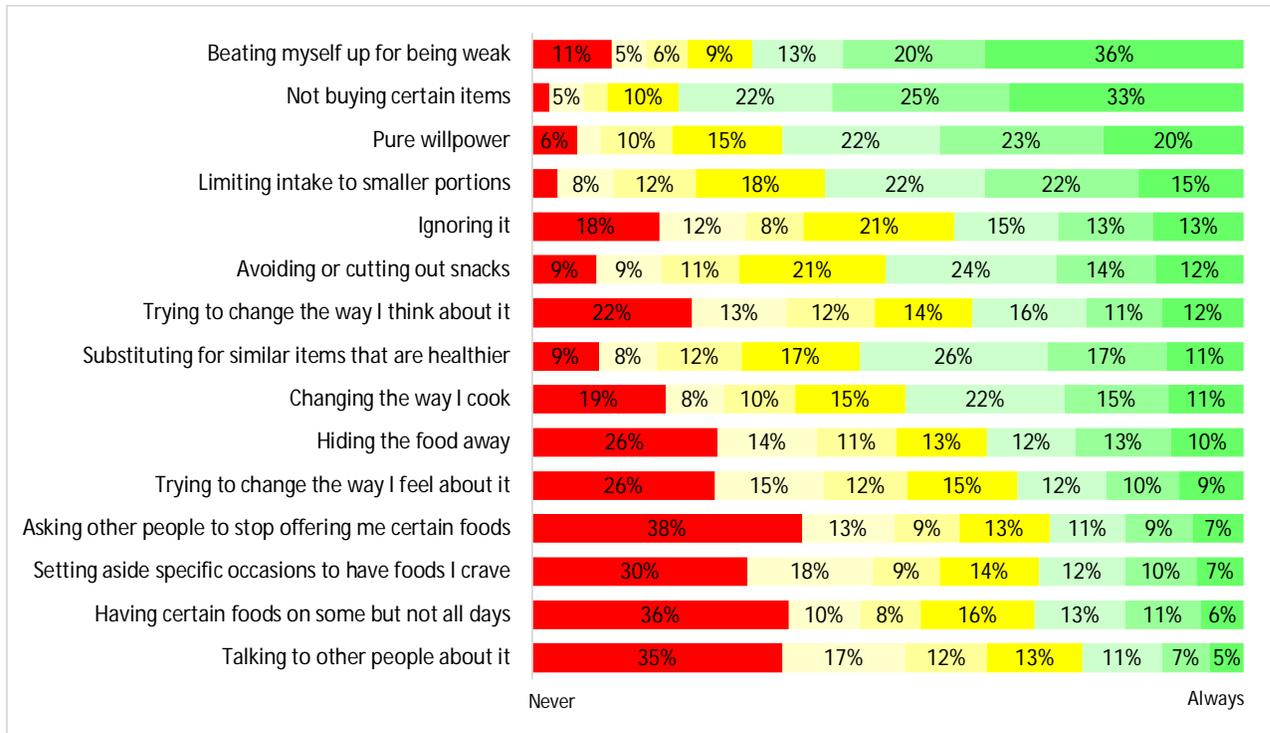


Figure 11 Percentage of respondents who had tried strategies to reduce intake

Note: Participants were asked to rate how much they have tried the strategies on a scale of 1 (never) to 7 (always); red shading indicates ‘never’. Values for percentages less than 5 are not displayed in the figure.

Techniques

People were asked to rate their feelings toward nine existing techniques reported in the scientific literature which have been suggested to reduce cravings or help people better resist temptation.

'Acceptance thinking' relates to accepting thoughts for what they are without feeling the need to stop them or act on them. 'Acceptance thinking' and 'Substituting tempting foods with healthy foods' were the most appealing techniques, as rated by respondents (Table 14).

Respondents were asked to rate their perceived level of ease in following each technique, and their willingness to try each technique on a scale of 1 (not at all) to 7 (extremely). Generally, techniques with higher appeal also had higher ratings for their ease and willingness. 'Acceptance thinking', 'Days free from tempting foods' and 'Substituting tempting foods with healthy foods' were rated as the top techniques across the three domains. About half of the survey respondents would be willing to try (score ≥ 5) each technique, regardless of its appeal or perceived ease.

Table 14 Appeal, ease and willingness to try existing techniques

| Technique | Appeal* | Easy | Willing |
|--|------------|--------------------------------|--------------------------------|
| | Mean (SD) | Rating ≥ 5 (number, %) | Rating ≥ 5 (number, %) |
| Acceptance thinking | 22.1 (5.4) | 155, 47% | 225, 68% |
| Substituting tempting foods with healthy foods | 22.0 (5.9) | 159, 48% | 206, 62% |
| Days free of tempting foods | 20.9 (6.4) | 171, 52% | 216, 65% |
| Mindful eating | 19.8 (6.1) | 121, 37% | 187, 57% |
| Halving my portions | 19.7 (6.6) | 132, 40% | 189, 57% |
| Disrupting images of foods in your mind | 18.3 (7.4) | 119, 36% | 150, 45% |
| Stopping all thoughts of tempting foods | 18.4 (6.8) | 92, 28% | 149, 45% |
| Complete abstinence | 17.6 (6.6) | 84, 25% | 163, 49% |
| Pre-exposure | 14.5 (6.0) | 41, 12% | 141, 43% |

Note: *, Appeal score was calculated from the sum of 5 factors including: (1) bad \rightarrow good; (2) not enjoyable \rightarrow enjoyable; (3) useless \rightarrow useful; (4) harmful \rightarrow beneficial; and (5) unmotivating \rightarrow motivating on a 5-point scale. Higher score indicates more positive response to the technique.

Summary

In this online survey, we were interested to better understand the challenges people with higher cravings experience when trying to lose weight. A sample of 330 people who had previously completed the CSIRO Diet Types survey and were identified as having higher craving tendencies responded to the invitation and completed the survey.

- About half of the survey respondents said the most difficult things to manage their weight were 'struggle to control cravings' and 'controlling intake around tempting foods'.
- Most respondents (82%) agreed that it would be easier to lose weight without cravings. Around 7 out of 10 respondents also agreed it would be easier to lose weight without temptations present (73%), that it was a constant struggle to resist tempting foods (67%) and it was a constant struggle to resist their cravings (66%).
- Six out of 10 respondents did not feel they could resist tempting foods when they were present and 68% did not feel they had the strength to control their cravings.
- Three-quarters of participants had both trigger foods and situations that they found difficult to manage. Trigger foods tended to be salty, fatty or sweet discretionary options and trigger situation tended to be after lunch or after dinner, as well as work, stress and social situations
- Over the past month, all respondents had experienced a craving for at least one food and had given in to their cravings on at least one occasion. Chocolate, biscuits, cake, chips and ice cream were the top five most craved foods from the Food Craving Inventory.
- There was a weak positive relationship between BMI and high fat cravings and for fast food cravings, suggesting that people with a higher body weight have greater cravings for higher fat foods.
- About two-thirds of respondents had tried a meal replacement or shake diet before. About a third of those thought it was helpful for losing weight, but less than 10% felt it was successful in helping keep weight off. The most common reason respondents liked using meal replacements was that they were convenient (73%), easy (58%) and required no cooking (43%).
- Of those who had not tried meal replacements in the past, few (15%) felt they would be successful in losing weight with meal replacements.
- When asked about the worst part of using meal replacements, lack of solid food was the most common response, along with boredom, hunger, taste and difficult to maintain.
- Survey respondents had tried a range of different strategies in their attempts to reduce their food intake. Not buying certain items, eating smaller portions, using their willpower, avoiding or cutting out snacks and substituting with similar healthier items were the strategies that were most commonly tried – 9 out of 10 respondents had tried these strategies. However, when asked how successful these strategies were at reducing food intake, not buying certain items was the highest rated strategy. 56% of respondents felt

not buying certain items was a successful strategy to reduce their food intake, compared to 29% for eating smaller portions and 14% for using their willpower.

Previous analysis of CSIRO Total Wellbeing Diet members has shown that people with higher craving tendencies start the program heavier than other members and do not lose as much weight on the program. Therefore, in this survey we were specifically interested in the challenges people with higher craving tendencies experience when trying to lose weight, and to better understand the strategies they have tried to lose weight. However, it is likely most people face a range of challenges when trying to lose weight and so in future research it would be interesting to survey a more diverse group of people to ascertain whether there are important differences between personality types in terms of the perceived barriers and challenges experienced when embarking on a weight loss journey.

Part III Pilot Study



Background and methods

Previous analysis suggested that those who had reported higher craving tendencies on the CSIRO Diet Types survey, lost 15% less weight on the CSIRO Total Wellbeing Diet program after 12 weeks than another personality type “Foodies” (those people with a high involvement and connection with food), and 6% less than the average weight loss of all members. The review of literature also found the people with higher craving tendencies report a reduction in cravings during early weight loss, and from the online survey conducted people with higher cravings appeared to identify with strategies that limit access to craved foods. Therefore, this pilot study focused on testing an alternative program in a subgroup of members who had previously reported higher cravings.

A pilot study was designed to assess the feasibility, acceptability, and practicality of starting the CSIRO Total Wellbeing Diet program with 3 weeks of partial meal replacements and one healthy, balanced meal per day. The aim of this study was to assess the amount of weight loss participants could achieve over the initial 3 weeks of the program through this alternative entry to the CSIRO Total Wellbeing Diet. We also wanted to assess attitudes towards this blended program, ease of following the program, and any changes in cravings and perceived control over their eating behaviours participants experienced. The study was reviewed and approved by the CSIRO Health and Medical Human Research Ethics Committee (2022_044_LR).

Individuals from an existing database (owned by Digital Wellness) of people who had previously completed a health-related survey hosted on the CSIRO Total Wellbeing Diet platform and consented to being contacted for future research were invited to participate.

Individuals were invited to participate if they:

- Were aged between 18 and 65 years
- Had a Body Mass Index (BMI) of $>30\text{kg}\cdot\text{m}^2$
- Were generally healthy and not been diagnosed with diabetes or chronic kidney disease
- Had completed the CSIRO Diet Type Survey in the previous 9 months and were classified as having higher craving tendencies
- Had not previously/were not currently members of the CSIRO Total Wellbeing Diet

To be involved, participants needed to be willing to sign up and pay for the standard CSIRO Total Wellbeing Diet program (\$199 for 12 weeks) as well as be willing to consume meal replacement shakes which were provided free-of-charge for the study. The meal replacement shakes along with a set of Wi-Fi enabled scales were sent to participants after they enrolled in the pilot trial (total estimated value \$350). Participants were enrolled after they provided consent and completed a baseline screening questionnaire. All enrolled participants were advised to complete an initial 3-week block of a partial meal replacement program. Depending on an individual's estimated energy requirement, they were instructed to have 2 meal replacement shakes and 1 healthy, balanced main meal (for example, this protocol will be for individuals with a lower energy requirement such as women) or 3 meal replacement shakes and 1 healthy, balanced main meal (protocol for larger women and men, for example). Fruit (2 servings per day) and vegetables (unlimited) snacks were also offered. Meal replacement shakes were offered in 4 flavours: chocolate, coffee, strawberry, and vanilla.

Following this first 3-week block, individuals were encouraged to transition to the standard CSIRO Total Wellbeing Diet menu plan. They were also given the choice to continue using meal replacements.

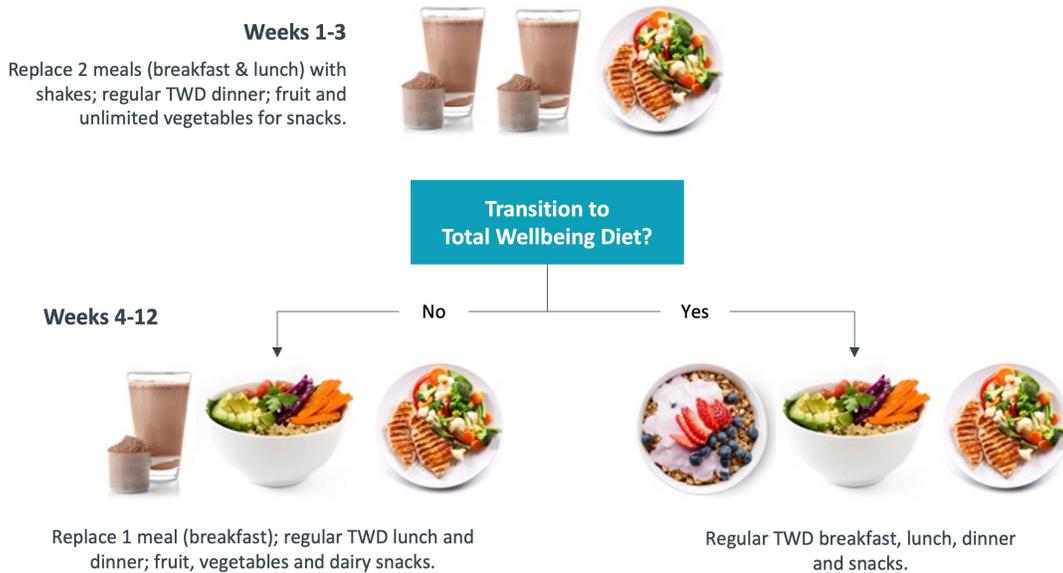


Figure 12 Summary of the diet protocol

The primary outcomes of the pilot trial were collected at baseline, week 3 and week 6 and included:

- Weight loss collected weekly using Wi-Fi enabled smart scales.
- Weight loss self-efficacy and cravings measured using previously validated surveys.

Additional data were also collected as part of the baseline, week 3 and week 6 surveys on:

- Baseline: Participant characteristics such as gender, age, reasons for wanting to start a diet program, dieting attempts, other dieting experience and weight loss expectations
- Week 3 and 6: Participant experience during the program, including taste and acceptance of meal replacements, compliance to the program and usability of the CSIRO Total Wellbeing Diet platform while having meal replacements and transitioning off them.

Program experience and adverse events were tracked weekly in short surveys (called Pulse surveys). The pulse surveys asked participants to rate their agreement with the following on a scale of 1 (strongly disagree) to 5 (strongly agree):

- I felt hungry
- I felt I was able to manage my cravings
- I felt it was easy to stick to the program
- I felt happy with my weight change

Participants were also asked to report any occurrence of adverse events including any gastrointestinal upsets or dizziness each week.

Characteristics of the sample

An invitation to participate in the pilot study was sent to 4,628 individuals. The expression of interest was open for 10 days, during which time 288 individuals expressed interest in the study, and 89 were formally enrolled in the study (31% of those who expressed an interest). Nine participants were excluded from the final analysis, leaving a total of 80 participants (90% of those who formally enrolled in the study; Figure 13).

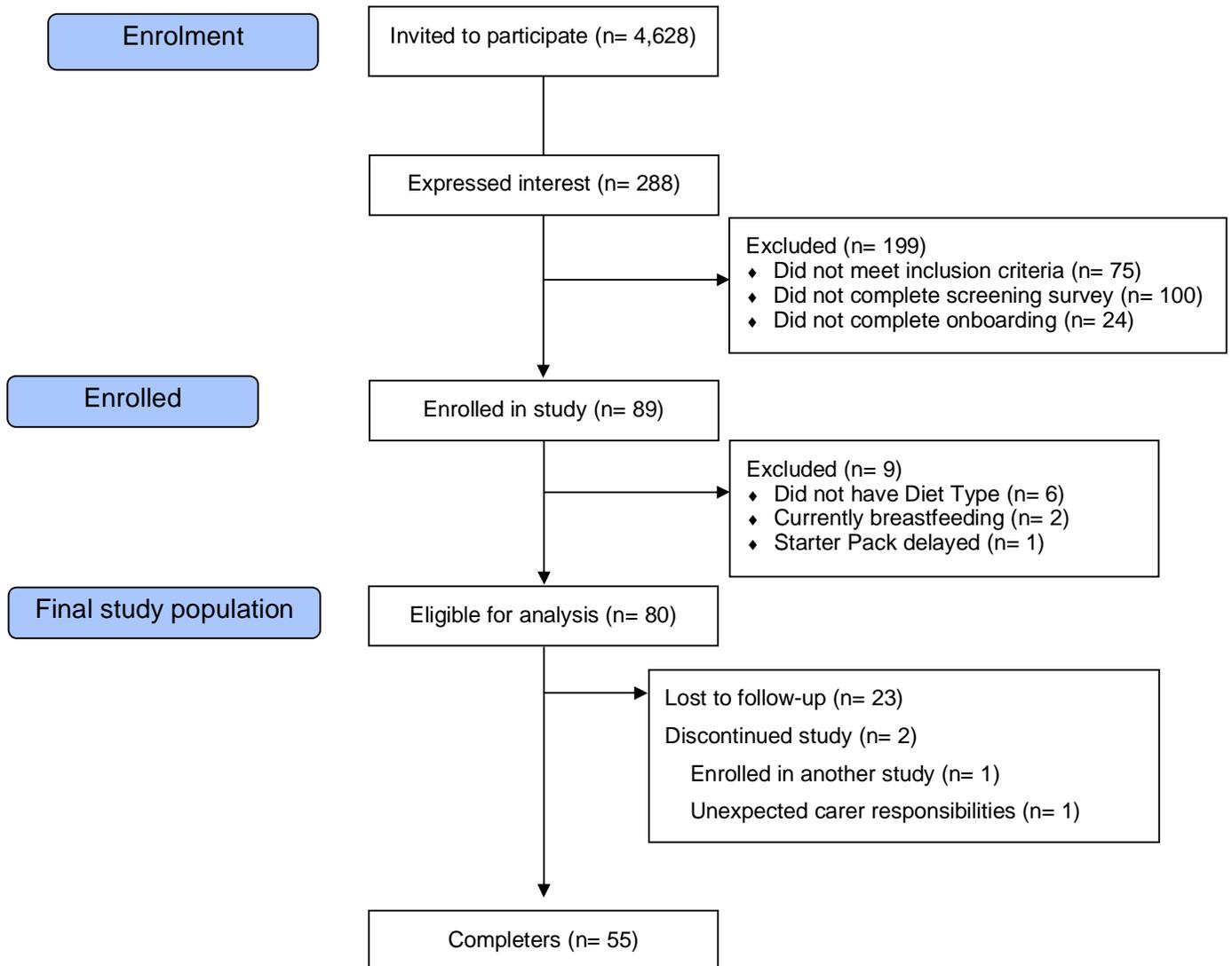


Figure 13 CONSORT 2010 Flow Diagram

Most enrolled participants (n=80) were female (91%), aged between 31-65 years. Half the participants resided in New South Wales (30%) or Victoria (21%), and the remainder in Queensland, South Australia, or Western Australia. Seven out of 10 participants lived in middle to higher income areas.

The average Body Mass Index (BMI) was 37.4 kg/m². By design, all participants were classified as obese, with 43% classified as Class I obese, 26% as Class II, and 31% as Class III (Table 15).

Table 15 Demographic characteristics of the sample of people who completed the pilot study

| | | Count | Percentage |
|--|------------------------|-------|--------------|
| | Total | 80 | 100.0% |
| Gender | Male | 7 | 8.8% |
| | Female | 73 | 91.3% |
| Age group | 18-30 years | 6 | 7.5% |
| | 31-50 years | 37 | 46.3% |
| | 51-65 years | 37 | 46.3% |
| State of residence | NSW | 24 | 30.0% |
| | QLD | 13 | 16.3% |
| | SA | 10 | 12.5% |
| | VIC | 17 | 21.3% |
| | WA | 11 | 13.8% |
| Index of Relative Socio-economic Disadvantage | 1 (most disadvantaged) | 10 | 12.5% |
| | 2 | 14 | 17.5% |
| | 3 | 25 | 31.3% |
| | 4 | 14 | 17.5% |
| | 5 (most advantaged) | 17 | 21.3% |
| Mean weight (kg) (±SD) [†] | | | 102.8 (21.0) |
| Mean BMI (kg/m ²) (±SD) [†] | | | 37.4 (6.2) |
| Weight status | Obese Class I | 34 | 42.5% |
| | Obese Class II | 21 | 26.3% |
| | Obese Class III | 25 | 31.3% |

Note: [†], data presented as Mean (Standard Deviation). Data will cell counts <5 not shown.

Interest in the study

When asked about the main reasons for not signing up to CSIRO Total Wellbeing Diet in the past, about half of the sample selected 'not ready to commit' (54%) and 'did not have the head space' (45%). About a third (34%) selected cost as one of the main reasons for not signing up in the past.

Participants were asked about the main reasons they volunteered for this study. The most common reason selected by eight out of ten participants was 'interested in losing weight' (81%). Being 'ready to commit' (74%) and 'feel in the right head space' (60%) were also highly rated, as was feeling overweight (58%) and interested in the research (55%) and new program (51%) (Figure 14).

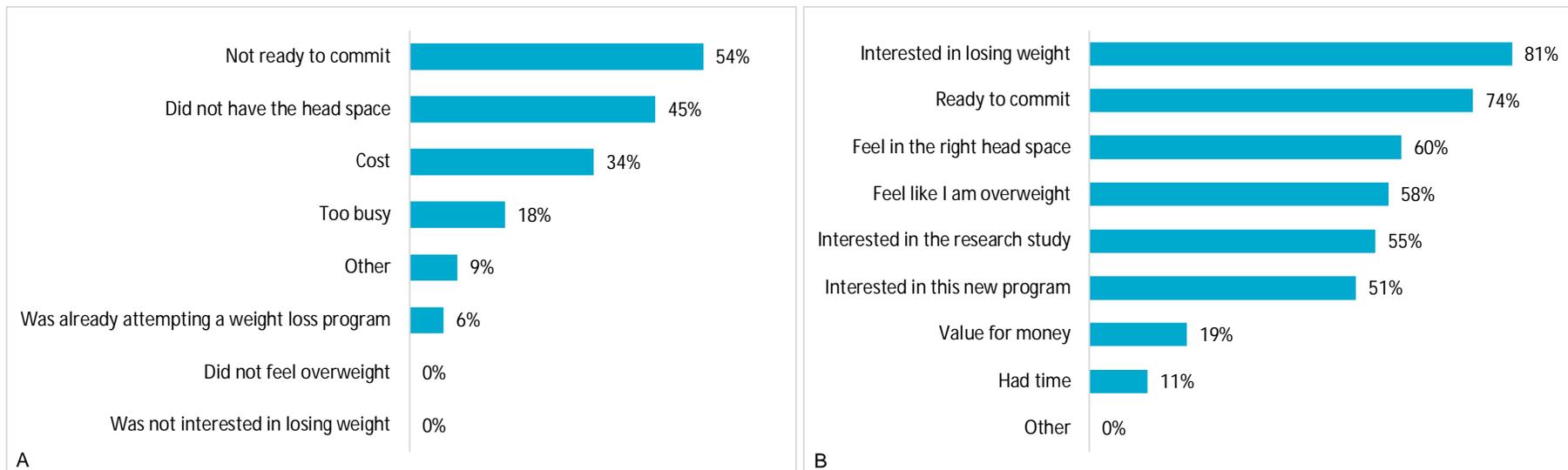


Figure 14 Main reasons for (A) not signing up to TWD and (B) participating in the pilot study

Expectations at the start and during the program

Participants were asked about their expectations around weight loss, and their confidence in the CSIRO Total Wellbeing Diet to support them with their weight loss goals on three occasions during the program: at baseline, and in weeks 3 and 6.

During the study, the proportion of participants who agreed they would enjoy being on the program increased (66% at baseline v. 87% at week 6; Table 16). The proportion of participants who agreed they were confident overcoming barriers and following the program was 93% at baseline and 74% at week 6. At baseline, 84% of participants agreed they would get good weight loss results, and this remained high throughout the trial with 74% agreeing they would get good weight loss at week 6.

Participants' confidence that the program would help them achieve their weight loss goals was consistently high throughout the study (88% at baseline v. 89% at week 6).

Overall, participants expected to lose around 1 kg each week. At baseline, participants expected to lose an average of 7.6 kg over the first 6 weeks program. The average expected weight loss in the first 3 weeks was 4.5 kg. When asked at the end of week 3, participants expected to lose an additional 3.3 kg, on average, during the following 3 weeks.

Table 16 Agreement and disagreement with statements about expectations of the program and weight loss

| Statement | Baseline (n=80) | | Week 3 (n=56) | | | Week 6 (n=53) | | |
|--|--------------------|-----------|--------------------|-----------|----------------|--------------------|-----------|----------------|
| | "Agreed" (n, %) | Mean (SD) | "Agreed" (n, %) | Mean (SD) | Δ Mean (SD) | "Agreed" (n, %) | Mean (SD) | Δ Mean (SD) |
| I am confident the program will help me to achieve my weight loss goals | 70 (88%) | 5.6 (1.0) | 47 (84%) | 5.8 (1.4) | 0.2 (1.6) | 47 (89%) | 5.9 (1.4) | 0.3 (1.7) |
| I will enjoy being on the program for the next 3 weeks | 53 (66%) | 5.3 (1.3) | 47 (84%) | 5.7 (1.2) | 0.5 (1.5) | 46 (87%) | 5.8 (1.4) | 0.5 (1.7) |
| I will get good weight loss results over the next 3 weeks | 67 (84%) | 5.6 (1.0) | 45 (80%) | 5.4 (1.3) | -0.3 (1.5) | 39 (74%) | 5.3 (1.6) | -0.3 (1.8) |
| I am confident I can overcome barriers and follow the program for the next 3 weeks | 74 (93%) | 5.9 (0.9) | 43 (77%) | 5.7 (1.3) | -0.2 (1.6) | 39 (74%) | 5.6 (1.6) | -0.3 (2.0) |
| In the next 3 weeks, how much weight do you expect to lose? (kg) | n/a | 4.5 (2.9) | n/a | 3.3 (1.8) | | n/a | 2.6 (1.2) | |
| In the next 6 weeks, how much weight do you expect to lose? (kg) | n/a | 7.6 (3.0) | - | - | - | - | - | - |

Note: Participants were asked to rate their level of agreement on a scale of 1 (strongly disagree) to 7 (strongly agree); a score ≥ 5 was considered agreement with the statement; n/a, not applicable. Δ , change score calculated as week 3 / week 6 score minus baseline score.

Weight change during the program

Most participants recorded their weight at weeks 3 (n=63 of 80, 79%) and 6 (n=55 of 80, 69%).

Weight change was calculated at weeks 3 and 6 from participants' starting weight. Where participants did not record their weight at one of the evaluation time points, a value of 0 was imputed (indicating no weight change from their starting weight, also referred to as baseline observation carried forward). On average, participants lost 3.1 kg (3.1% of their starting weight) in the first 3 weeks of the program and 4.0 kg (3.9% of their starting weight) after 6 weeks (Table 17). Of everyone that started the program, 44% (n=35 of 80) recorded clinically meaningful weight loss ($\geq 5\%$ of their starting body weight) at week 6 of the program, however 25 of 80 participants (31%) did not provide a week 6 weight.

Weight loss was also evaluated for the subsample of completers, that is, those who recorded their weight at week 6 (n=55). The average starting BMI of completers was not statistically different to the average BMI of the starting sample. On average, completers lost 5.9 kg after 6 weeks (5.6% of their starting body weight). Nearly two-thirds of completers (35/55, 64%) recorded clinically meaningful weight loss at week 6 (Table 18).

During the program, participants were also asked to rate their weight loss on the program on a scale of 0 (completely awful) to 10 (couldn't be better). In week 3, the average rating was 7.0 ± 2.4 out of a possible 10, and 75% of participants gave ratings of 6 or higher. Ratings were similar at week 6; the average rating was 6.8 ± 2.6 , with 73% of participants giving scores of 6 or higher.

Table 17 Weight loss during the program for all participants who enrolled in the program (n=80), by starting weight status

| | Starting weight | | Week 3 | | Week 6 | | | |
|------------------------|-----------------|---------------|------------------------|----------------------|---------------|------------------------|----------------------|------------------------------|
| | Weight | Weight | Weight loss | | Weight | Weight loss | | |
| | Mean (SD), kg | Mean (SD), kg | Mean Δ (SD), kg | % of starting weight | Mean (SD), kg | Mean Δ (SD), kg | % of starting weight | $\geq 5\%$ body weight (n,%) |
| All | 102.8 (21.0) | 97.9 (17.7) | -3.1 (2.4) | -3.1% | 97.5 (17.6) | -4.0 (3.6) | -3.9% | 35, 44% |
| Obese Class I (n=34) | 87.9 (9.4) | 85.8 (9.5) | -2.4 (1.7) | -2.7% | 85.6 (8.8) | -3.1 (2.8) | -3.4% | 10, 29% |
| Obese Class II (n=21) | 102.1 (9.9) | 96.7 (10.4) | -3.5 (2.7) | -3.4% | 95.7 (9.2) | -4.3 (3.9) | -4.2% | 11, 31% |
| Obese Class III (n=25) | 123.6 (21.9) | 115.5 (16.4) | -3.9 (2.6) | -3.2% | 114.7 (17.4) | -5.0 (2.7) | -3.9% | 14, 40% |

Note: Δ , change score calculated from baseline.

Table 18 Weight loss during the program for participants who completed the program (n=55), by starting weight status

| | Starting weight | | Week 3 | | Week 6 | | | |
|------------------------|-----------------|---------------|------------------------|----------------------|---------------|------------------------|----------------------|------------------------------|
| | Weight | Weight | Weight loss | | Weight | Weight loss | | |
| | Mean (SD), kg | Mean (SD), kg | Mean Δ (SD), kg | % of starting weight | Mean (SD), kg | Mean Δ (SD), kg | % of starting weight | $\geq 5\%$ body weight (n,%) |
| All | 103.4 (18.5) | 99.4 (17.8) | -4.1 (1.9) | -3.9% | 97.5 (17.6) | -5.9 (2.8) | -5.6% | 35, 64% |
| Obese Class I (n=24) | 89.9 (8.8) | 87.0 (9.1) | -3.0 (1.5) | -3.3% | 85.6 (8.8) | -4.4 (2.4) | -4.9% | 10, 42% |
| Obese Class II (n=13) | 102.7 (9.4) | 97.7 (8.7) | -5.0 (1.7) | -4.9% | 95.7 (9.2) | -7.0 (2.4) | -6.8% | 11, 85% |
| Obese Class III (n=18) | 121.7 (17.4) | 117.5 (16.9) | -4.9 (1.8) | -4.0% | 114.7 (17.4) | -7.0 (2.7) | -5.8% | 14, 78% |

Adverse events

Each week, participants were asked if they experienced any gastrointestinal upsets in the past week. In total, 57 participants reported adverse events during the program on at least one occasion over the 6 weeks (total 127 reported ailments). The most common upsets were gas (reported on n=63 occasions), constipation (n=41), headaches (n=35) and bloating (n=31). Most adverse events were assessed as mild, that is, an event that was easily tolerated by the participant, causing minimal discomfort, and not interfering with everyday activities. Two participants experienced adverse events that were assessed as moderate or severe and probably related to the trial. In one instance, this caused severe dizziness resulting in the participant to collapse, and lead them to seek medical advice.

The number of ailments reduced during the study. In week 1, 64% of participants reported an ailment, which decreased to 32% in week 3 and 23% in week 6 (Table 19 and Figure 15).

Participants were also asked about gastrointestinal upsets at the weeks 3 and 6 in the evaluation survey. In these surveys, 61% reported that they had experienced upsets in the first three weeks of the program, and at week 6, 47% reported they had experience upsets during the program.

Of those that had completed the week 6 survey and reported symptoms (n=25 of 53), about one third reported that their symptoms lasted for less than 1 week (28%), 12% reported they lasted for 1-2 weeks, 16% for 3-4 weeks and 4% for 4-5 weeks. Four in 10 participants reported these symptoms persisted throughout the program.

Table 19 Ailments reported in the weekly pulse surveys

| | Week 1 (n=69) | Week 2 (n=66) | Week 3 (n=56) | Week 4 (n=52) | Week 5 (n=49) | Week 6 (n=47) |
|------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| n, % reporting ailment | 44, 64% | 26, 39% | 18, 32% | 14, 27% | 14, 29% | 11, 23% |
| Bloating (n, %) | 8, 12% | 6, 9% | 9, 16% | 4, 8% | 2, 4% | 2, 4% |
| Gas (n, %) | 16, 13% | 12, 18% | 12, 21% | 8, 15% | 9, 18% | 6, 13% |
| Stomach pain (n, %) | 7, 10% | 2, 3% | 2, 4% | 3, 6% | 2, 4% | 1, 2% |
| Constipation (n, %) | 9, 13% | 11, 17% | 6, 11% | 5, 10% | 4, 8% | 6, 13% |
| Diarrhoea (n, %) | 9, 13% | 3, 5% | 2, 4% | 4, 8% | 3, 6% | 1, 2% |
| Headache (n, %) | 23, 33% | 5, 8% | 3, 5% | 2, 4% | 0, 0% | 2, 4% |
| Dizziness (n, %) | 10, 14% | 1, 2% | 2, 4% | 1, 2% | 2, 4% | 1, 2% |

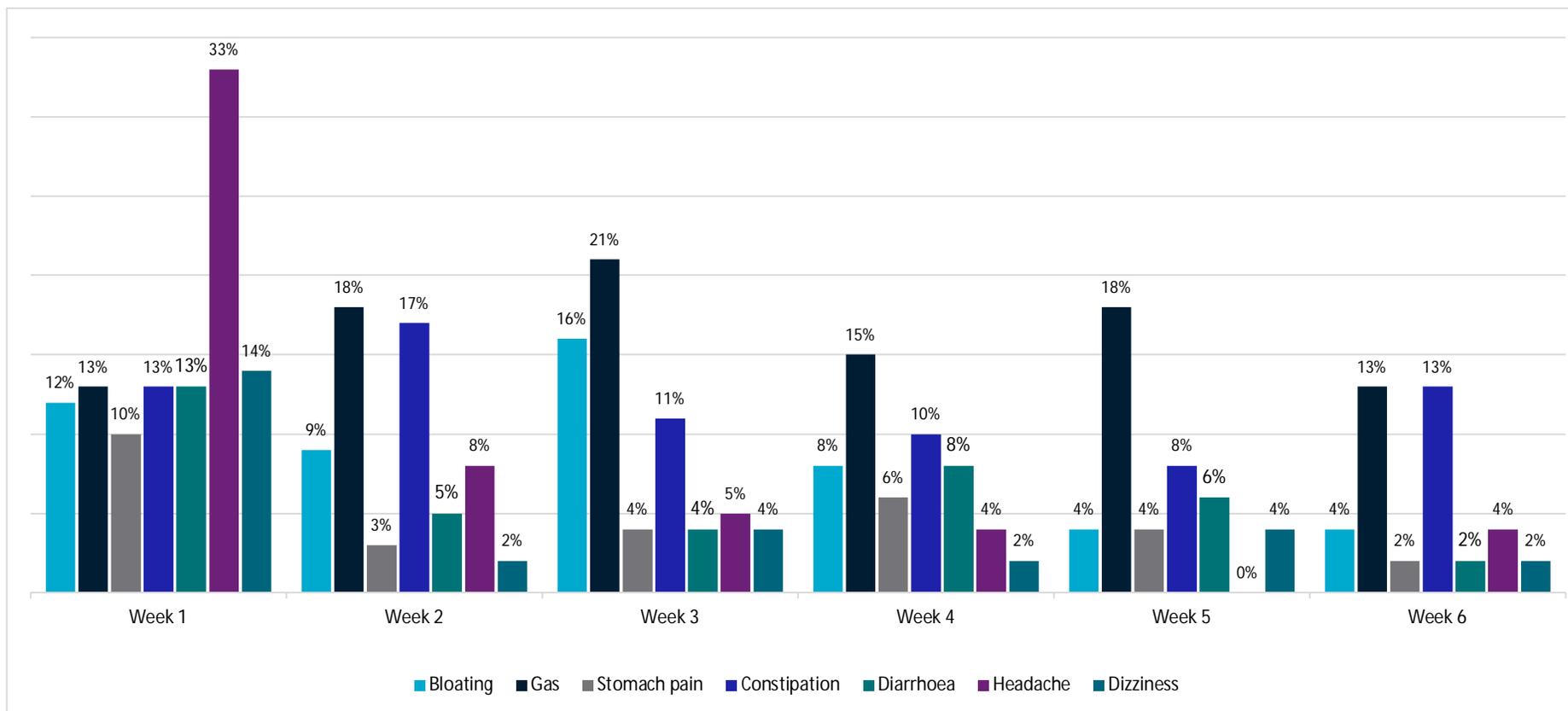


Figure 15 Percentage of participants reporting ailments during the study via the weekly pulse surveys

Self-reported compliance with the program

At weeks 3 and 6, participants were asked how well they felt they had been following the program in the last 3 weeks on a scale of 0 (not at all) to 10 (perfectly). In week 3, the average rating was 7.5 ± 2.3 out of a possible 10, and 84% of participants reporting a compliance of 6 out of 10 or greater in the previous 3 weeks. In week 6, the average rating had decreased from week 3 to 6.5 ± 2.8 , with 67% of participants reporting a compliance of 6 out of 10 or greater.

Participants who selected a compliance rating of 5 or less were asked to describe key barriers they felt were preventing them from following the program. Difficulty following the program in social situations or holidays, due to work/life stresses, and a general lack of motivation were the most common barriers cited. Feeling hungry and having cravings were also cited, but less frequently (less than 10% of participants).

Weight loss self-efficacy

Participants were asked to complete the weight efficacy lifestyle (WEL) questionnaire at baseline and again at week 6. The WEL questionnaire includes 20 statements to measure individuals' confidence in being able to control their weight by resisting overeating in certain tempting situations, using a 10-point scale ranging from 0 (not confident) to 9 (very confident).

Overall, participants' weight loss self-efficacy increased by about 19% during the program, indicating participants were more confident in their ability to resist overeating in certain tempting situations at week 6 compared with baseline (mean change +21.6 points out of 180; Table 20).

On average, scores across all 20 statements increased at week 6, compared with baseline. The greatest difference was seen in the subscales evaluating participants' negative emotion score (+5.4 points out of 36, equivalent to 28.7% increase from baseline), availability score (+4.6 points out of 36, 22.9% increase from baseline) and positive activities score (+5.1 points out of 36, 19.6% increase from baseline). That is, participants' confidence in resisting eating when feeling sad or anxious (negative emotion) and confidence in resisting eating when watching television or reading) increased the most during the study. The subscale with the smallest change was the 'physical discomfort' score (+2.5 points out of 36, equivalent to a 10% increase from baseline), which refers to resisting eating when fatigued or in pain.

Table 20 Participant's confidence in their ability to resist the desire to eat

| | Baseline (n=80) | Week 6 (n=53) | |
|--|-----------------|---------------|-------------|
| | Mean (SD) | Mean (SD) | Δ Mean (SD) |
| Weight loss self-efficacy (total score, /180) | 114.4 (33.9) | 137.2 (30.8) | 21.6 (38.3) |
| Negative emotion score (/36) | 18.8 (8.1) | 24.1 (9.3) | 5.4 (11.4) |
| Availability score (/36) | 20.1 (8.5) | 25.5 (7.2) | 4.6 (9.4) |
| Social pressure score (/36) | 24.4 (7.2) | 28.8 (6.1) | 3.9 (7.0) |
| Physical discomfort score (/36) | 25.0 (7.2) | 27.5 (7.5) | 2.5 (7.8) |
| Positive activities score (/36) | 26.0 (7.5) | 31.3 (4.4) | 5.1 (7.0) |

Note: Higher score reflects stronger weight loss self-efficacy. Δ, change score calculated as week 6 score minus baseline score.

Food cravings

Participants were asked to complete the Food Craving Inventory (FCI) at baseline, week 3 and week 6. In the first part of the FCI ('subjective' component), people were asked to record the frequency they experienced cravings for 28 listed foods over the past month, ranging from never to always/almost every day. The FCI groups this list of foods into four subscales: (1) high fat foods, (2) sweet foods, (3) carbohydrate-rich foods, and (4) high fat fast foods.

On each occasion the FCI was administered, all participants reported that they had experienced a craving for at least one of the 28 foods listed in the FCI over the past month (Table 21).

At baseline, all participants had a craving for carbohydrate-rich foods and for sweets. Cravings for fast foods were experienced by 95% of participants, and 91% for high fat foods. Higher levels of cravings were rated for fast foods (1.7 ± 0.7) and sweets (1.5 ± 0.6), followed by cravings for carbohydrates (1.2 ± 0.7), then high fat foods (0.9 ± 0.6).

Cravings decreased during the program. At week 3, on average, total craving scores had halved from baseline (1.2 at baseline v. 0.6 at week 3), which was sustained at week 6 (Table 21).

Chocolate, chips, French fries and biscuits were among the top 5 most craved foods from the FCI on each occasion the FCI was administered. At baseline, cookies scored in the top 5, but were replaced by sandwich bread at week 3 and week 6.

Table 21 Percentage of the sample and mean food craving scores by craving type, as assessed by the Food Craving Inventory

| | Baseline (n=80) | | Week 3 (n=56) | | Week 6 (n=53) | |
|--------------------|----------------------|------------------------|---------------|------------------------|---------------|------------------------|
| | n, % | Mean (SD) [§] | n, % | Mean (SD) [§] | n, % | Mean (SD) [§] |
| Total food craving | 80, 100% | 1.3 (0.5) | 56, 100% | 0.6 (0.3) | 53, 100% | 0.6 (0.4) |
| Craving Types | Carbohydrate craving | 80, 100% | 52, 93% | 0.7 (0.5) | 47, 89% | 0.6 (0.5) |
| | Sweet craving | 80, 100% | 53, 95% | 0.6 (0.4) | 49, 93% | 0.7 (0.5) |
| | Fast food craving | 76, 95% | 52, 93% | 0.9 (0.6) | 50, 94% | 0.9 (0.7) |
| | Fat craving | 73, 91% | 47, 84% | 0.4 (0.4) | 40, 75% | 0.4 (0.4) |

Note: Participants were asked to rate how often they have experienced a craving for the 28 foods in the FCI over the past month on a scale of never (0), rarely (1), sometimes (2), often (3) and always/almost every day (4). [§] Data presented are the summed scores for each craving type, divided by the number of foods in each sub-scale. Higher scores reflect higher levels of food cravings. Δ , change score calculated from baseline.

In the second part of the FCI ('behavioural component'), participants were asked how often over the past month (from never to always/almost every time) they had 'given in' and consumed the particular food/s they craved.

At baseline, all participants had 'given in' to their cravings and eaten at least one of the foods in the FCI on at least one occasion over the past month (Table 22). The proportion of participants who had never given into their cravings in the past month increased from 0% at baseline to 30% in week 3 and 13% in week 6.

Table 22 Percentage of the sample who had never 'given in' to their cravings and mean food craving scores by craving type, as assessed by the Food Craving Inventory

| | Baseline | | Week 3 | | Week 6 | |
|------------------------------|-----------------|------------------------|---------------|------------------------|---------------|------------------------|
| | n, % | Mean (SD) [§] | n, % | Mean (SD) [§] | n, % | Mean (SD) [§] |
| Total who had never given in | 0, 0% | 1.0 (0.5) | 17, 30% | 0.2 (0.2) | 7, 13% | 0.3 (0.3) |
| Craving Types | | | | | | |
| Carbohydrate craving | 3, 4% | 1.0 (0.7) | 27, 49% | 0.1 (0.2) | 13, 28% | 0.3 (0.3) |
| Sweet craving | 0, 0% | 1.3 (0.7) | 21, 40% | 0.2 (0.3) | 17, 35% | 0.3 (0.4) |
| Fast food craving | 2, 3% | 1.5 (0.8) | 24, 46% | 0.3 (0.4) | 16, 32% | 0.5 (0.5) |
| Fat craving | 3, 4% | 0.7 (0.5) | 17, 36% | 0.2 (0.2) | 16, 40% | 0.2 (0.3) |

Note: Participants were asked to rate how often they gave in to their cravings and ate those foods over the past month on a scale of never (0), rarely (1), rarely (once or twice) (2), sometimes (3) and always/almost every day (4). [§] Data presented are the summed scores for each craving type, divided by the number of foods in each sub-scale. Higher scores reflect higher levels of food cravings. Percentages calculated using the number of participants who experienced a craving at the respective timepoint as the denominator.

Food cravings and weight loss

Among those who had completed the week 6 survey and recorded a weight (n=49), changes in food cravings were similar regardless of weight loss success. That is, participants who lost <5% of their starting body weight had a similar reduction in total cravings to those who lost $\geq 5\%$ of their starting body weight (Table 23). However, the proportion of participants who had never 'given in' to their cravings was slightly higher among the participants who achieved $\geq 5\%$ weight loss. That is, participants who lost greater amounts of weight were more likely to never give in to their cravings. The greatest difference was seen for high-fat food cravings; 50% of participants who lost $\geq 5\%$ body weight had never given in to those cravings, compared with 25% of participants who lost <5% body weight (Table 24).

Table 23 Percentage of the sample and mean food craving scores by craving type at week 6 as assessed by the Food Craving Inventory, by weight loss success

| | Total | | Carbohydrate | | Sweet | | Fast Food | | Fat | |
|------------------------|----------|-------------|--------------|-------------|---------|-------------|-----------|-------------|---------|-------------|
| | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) |
| All (n=49) | 49, 100% | -0.7 (0.6) | 43, 88% | -0.7 (0.8) | 45, 92% | -0.8 (0.6) | 46, 94% | -0.8 (0.8) | 36, 73% | -0.4 (0.5) |
| <5% body weight (n=16) | 16, 100% | -0.7 (0.6) | 13, 81% | -0.7 (0.8) | 14, 88% | -0.9 (0.7) | 15, 94% | -0.9 (0.8) | 12, 75% | -0.4 (0.5) |
| ≥5% body weight (n=33) | 33, 100% | -0.7 (0.6) | 30, 91% | -0.7 (0.7) | 31, 94% | -0.8 (0.6) | 31, 94% | -0.9 (0.8) | 24, 73% | -0.5 (0.5) |

Note: Data presented are for participants who completed the week 6 survey and recorded a weight at week 6. Participants were asked to rate how often they have experienced a craving for the 28 foods in the FCI over the past month on a scale of never (0), rarely (1), sometimes (2), often (3) and always/almost every day (4). ⁵ Data presented are the summed scores for each craving type, divided by the number of foods in each sub-scale. Higher scores reflect higher levels of food cravings. Δ, change score calculated from baseline.

Table 24 Percentage of the sample who had never 'given in' to their cravings and mean food craving scores by craving type at week 6 as assessed by the Food Craving Inventory, by weight loss success

| | Total | | Carbohydrate | | Sweet | | Fast Food | | Fat | |
|------------------------|--------|-------------|--------------|-------------|---------|-------------|-----------|-------------|---------|-------------|
| | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) | n, % | Δ Mean (SD) |
| All (n=49) | 7, 14% | -0.8 (0.5) | 13, 30% | -0.9 (0.7) | 17, 38% | -0.9 (0.7) | 16, 35% | -1.3 (0.7) | 15, 42% | -0.5 (0.5) |
| <5% body weight (n=16) | 2, 13% | -0.6 (0.7) | 2, 15% | -0.7 (1.0) | 3, 21% | -0.8 (0.6) | 4, 27% | -1.3 (0.7) | 3, 25% | -0.3 (0.5) |
| ≥5% body weight (n=33) | 5, 15% | -0.9 (0.5) | 11, 37% | -1.0 (0.6) | 14, 45% | -1.0 (0.7) | 12, 39% | -1.4 (0.8) | 12, 50% | -0.6 (0.5) |

Note: Data presented are for participants who completed the week 6 survey and recorded a weight at week 6. Percentages calculated using the number of participants who experienced a craving at the respective timepoint as the denominator.

Experience with meal replacements before and during the program

About two-thirds of participants (70%) had tried a meal replacement or shake diet before starting this program. Of these, most participants had used meal replacement shakes occasionally (64%) or used them as a partial meal replacement program with whole foods (29%). Only 7% of the respondents had tried a full meal replacement program (Table 25).

Table 25 Previous experience trying meal replacements

| | | Count | Percentage |
|-----------------------------------|----------------------------------|-------|------------|
| Experience with meal replacements | Have not tried meal replacements | 24 | 30.0% |
| | Have tried meal replacements | 56 | 70.0% |
| | The occasional shake | 36 | 64.0% |
| | Hybrid | 16 | 29.0% |
| | Full MR program | 4 | 7.0% |

Note: numbers may not add to 100% due to rounding; MR, meal replacements.

Before starting the program, participants who had previously tried meal replacements were asked about their motivation for trying meal replacement shakes in the past. 'Convenient/easy' (59%) and 'expected weight loss results' (54%) were the top 2 reasons participants selected for trying meal replacements in the past.

Participants were also asked about their motivation for trying this meal replacement program now. The top 2 responses were 'trust in CSIRO' (79%) and 'expected weight loss results' (77%; Figure 16). 'Program support' (57%) and 'convenient/easy' (45%) were also selected by about half of participants.

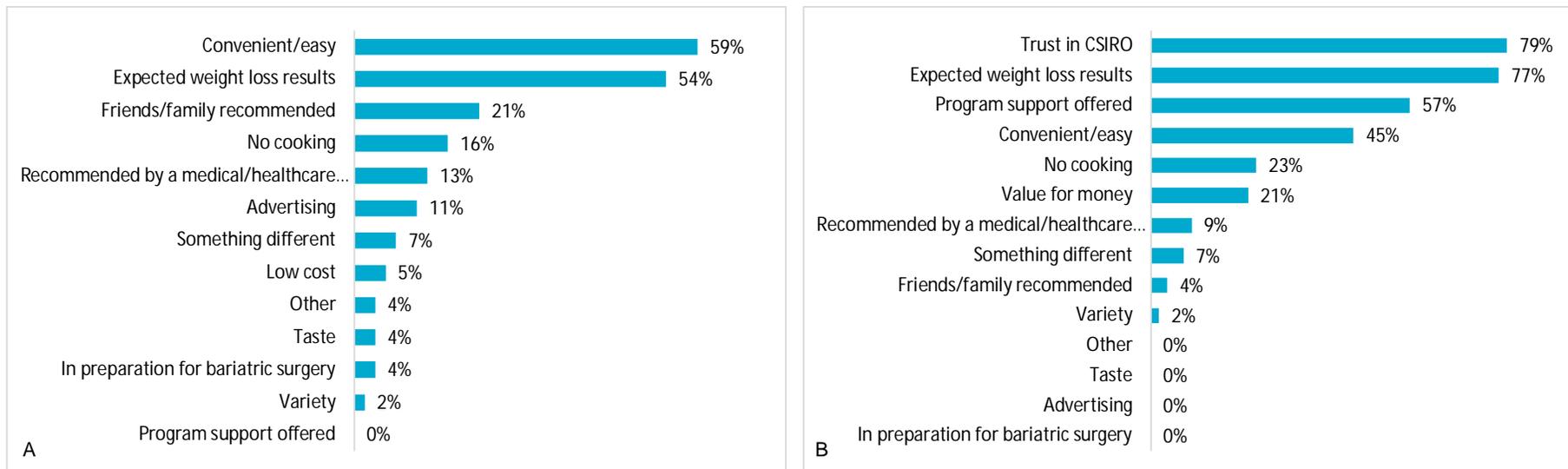


Figure 16 Main reasons for trying meal replacement shakes (A) in the past, and (B) now

At the end of week 3, participants were asked to rate the meal replacement shakes on a scale of 0 (completely awful) to 10 (couldn't be better). The average rating was 8.2 ± 2.0 out of a possible 10, and 88% of participants gave scores 6 or greater for meal replacement shakes at the end of week 3.

Participants were asked what they liked best about using meal replacement shakes. The most common reasons participants liked using meal replacements were 'convenient' (98%), and 'easy' (93%). About half of the participants selected 'weight loss results' (55%), 'no cooking' (50%) and 'reduction in cravings' (50%).

Participants were also asked about the worst part of using meal replacement shakes. 'Integration with family meals' (38%) was the most common response selected by about a third of participants (Figure 17). Boredom and gastrointestinal upsets were selected by about a quarter of participants. Reasons described under 'other' related to the taste (particularly the sweetness) of the shakes, difficulty integrating in their lives, such as social situations and shopping, and not having access to low fat milk at their workplace. One participant cited difficulty transporting the (pre-made) shakes.

Participants rated their liking for each flavour on a 5-point scale (1, really disliked to 5, really liked). Chocolate was the most popular flavour, 'liked' (score of ≥ 4) by 77% of participants, followed by vanilla (76%), coffee (71%). Strawberry was the least liked flavour by participants (63%).

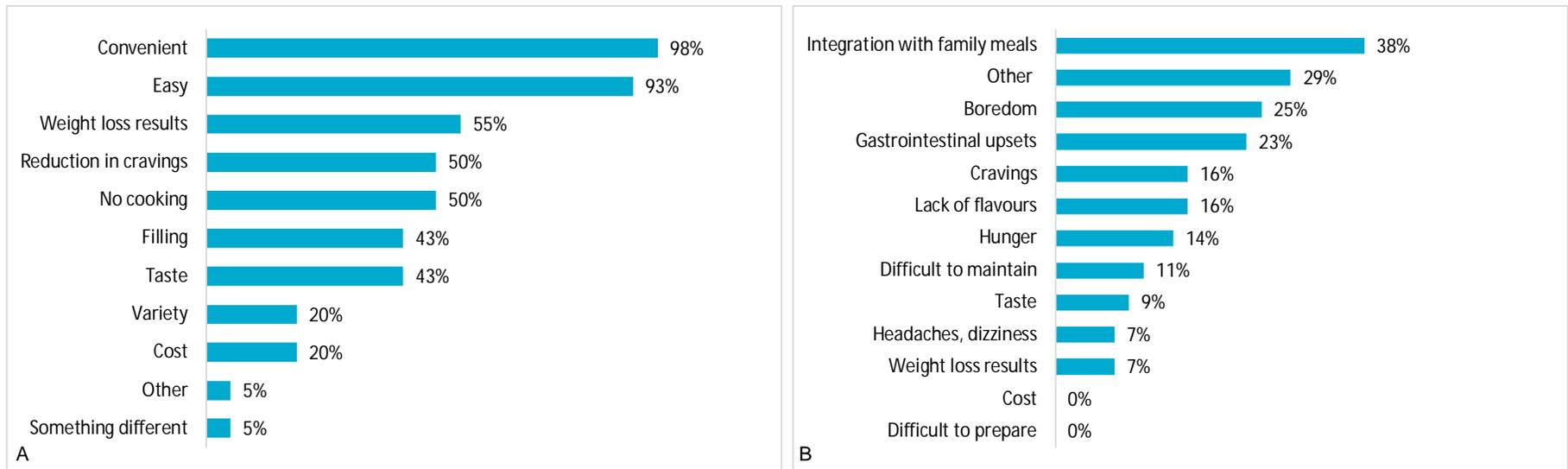


Figure 17 The (A) best and (B) worst parts about using meal replacements shakes, as rated by participants in week 3

Pathway to CSIRO Total Wellbeing Diet

Participants were encouraged to transition to a healthy balanced diet, following the standard CSIRO Total Wellbeing Diet, at the end of week 3. At this time, 89% of participants chose not to transition and stick with meal replacements at this point.

During their third week of the study, participants were asked if they would like an additional supply of meal replacements. About two-thirds (64%) of participants requested more meal replacements, and the number they requested ranged from 7 to 60 shakes.

Of the participants who decided to transition at the end of week 3 (n=6 of 56 (11%) participants who completed the week 3 survey), they indicated they felt it was time or that they were ready to follow a food-based diet program, they missed or were craving solid food, and one reported side effects and that they weren't satisfied with the shakes.

At week 6, 47% of (n=25 of 53 participants who completed the week 6 survey) participants reported to have transitioned to the CSIRO Total Wellbeing Diet. Of those that had transitioned, 68% reported to have continued using meal replacements in some way.

Participants decided to transition at the end of week 6 because they felt it was time or they were ready to follow a food-based diet program, because the program defaulted to the CSIRO Total Wellbeing Diet, so they just followed the program, they ran out of shakes, were hungry or craving solid food, or to fit into their lifestyle or they were bored.

Those who continued to use meal replacements after they had transitioned tended to have a meal replacement shake once per day or 2-3 times per week.

The reasons selected for not transitioning at week 6 included the ease and convenience, enjoyment of the structure of the shakes, wanting to do it for a little bit longer, for continued weight loss, hadn't been following the diet well, not mentally ready, lack of support at home, and had additional meal replacement shakes to use up.

Program evaluation

Pulse surveys

Participants were asked to rate their level of agreement to statements about their satisfaction on the program at the end of each week. The number of participants who completed the weekly 'pulse' surveys decreased over the course of the study from 69 (86%) participants in week 1, to 47 (59%) in week 6.

The proportion of participants who agreed that they 'felt hungry' decreased over the study period (49% of 69 participants who complete the pulse survey in week 1 v. 17% of 47 participants who completed the pulse survey in week 6). The proportion of participants who 'felt happy with my [their] weight change' decreased over the study period (81% in week 1 v. 51% in week 6). Levels of agreement to statements related to the ease of sticking to the program and ability of manage cravings was consistent across the six-week study period (Figure 18 and Table 26).

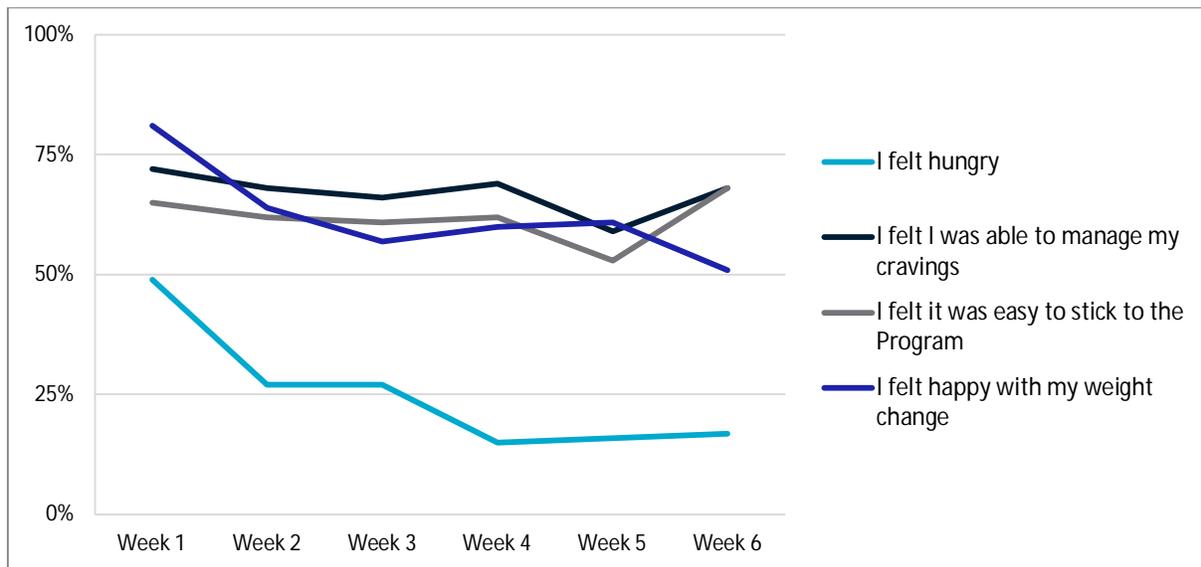


Figure 18 The percentage of participants who 'agreed' to statements about their satisfaction on the program each week during the study

Table 26 Level of agreement to statements about their satisfaction, as rated by participants each week during the study

| | Week 1 (n=69) | | Week 2 (n=66) | | Week 3 (n=56) | | Week 4 (n=52) | | Week 5 (n=49) | | Week 6 (n=47) | |
|---|----------------------|---------------|----------------------|---------------|----------------------|---------------|----------------------|---------------|----------------------|---------------|----------------------|---------------|
| Thinking back over the past week | "Agreed" (n, %) | (Mean, SD) |
| <i>I felt hungry</i> | 34, 49% | 3.2 (1.1) | 18, 27% | 2.8 (0.9) | 15, 27% | 2.7 (1.0) | 8, 15% | 2.5 (1.0) | 8, 16% | 2.6 (1.0) | 8, 17% | 2.4 (0.9) |
| <i>I felt I was able to manage my cravings</i> | 50, 72% | 3.7 (1.0) | 45, 68% | 3.8 (1.0) | 37, 66% | 3.7 (1.0) | 36, 69% | 3.7 (1.0) | 29, 59% | 3.5 (1.1) | 32, 68% | 3.6 (1.2) |
| <i>I felt it was easy to stick to the Program</i> | 45, 65% | 3.7 (1.1) | 41, 62% | 3.7 (1.0) | 34, 61% | 3.6 (1.0) | 32, 62% | 3.7 (1.0) | 26, 53% | 3.5 (1.0) | 32, 68% | 3.6 (1.1) |
| <i>I felt happy with my weight change</i> | 56, 81% | 4.1 (0.9) | 42, 64% | 3.7 (1.0) | 32, 57% | 3.6 (1.1) | 31, 60% | 3.6 (1.0) | 30, 61% | 3.6 (1.0) | 24, 51% | 3.4 (1.1) |

Note: Participants were asked to rate their level of agreement on a scale of strongly disagree (1), disagree (2), neutral (3), agree (4), strongly agree (5). Higher score indicates higher level of agreement; a score ≥ 4 was considered agreement with the statement.

Program content

In week 3, about half of the participants (52%) read or reviewed the CSIRO Total Wellbeing Diet online program content every day, and about a third (32%) read or reviewed the content every other day. The frequency that participants read the content decreased during the study. In week 6, about a third of participants (38%) read or reviewed the program content every day, and 23% of participants reported that they reviewed the content every other day. The remainder of participants reviewed the content weekly (28%), or less often than weekly (9%), and 2% did not read the content.

Participants were also asked about their perception of the program content. In general, most participants agreed they felt confident following the program after reviewing program materials, and that the program content was easy to understand (Table 27). Overall, 79-91% of participants agreed with the statements about the program and its content (including the meal plan and concept of food groups) being easy to follow and clearly explained at week 3, and 77-94% agreed with these statements at week 6. In relation to cravings, 80% of participants and 74% of participants felt they were better in control of their cravings at weeks 3 and 6, respectively.

Seven in ten participants were satisfied (rated 5 or more out of 7) with their weight change at week 3 and 66% at week 6. In relation to program content about making it easy to transition off the meal replacements and onto the Total Wellbeing Diet, 34% of participants agreed with this statement at week 3 and 63% agreed with this statement at week 6.

CSIRO Total Wellbeing Diet platform

Individuals could access the CSIRO Total Wellbeing Diet platform via a website and/or an app. Participants in this study accessed the CSIRO Total Wellbeing Diet platform mostly via the app (43%), or a combination of the website and app (40%).

Participants were also asked about their experience with using the CSIRO Total Wellbeing Diet platform. Most participants agreed that the platform, including the weight and food trackers, were easy to use in both week 3 and 6 (between 76% and 93% of participants agreed with these statements) (Table 27). Participant agreement with the platform as a tool to ease transitioning off the meal replacements went from 41% at week 3 and 65% at week 6.

Table 27 Program Evaluation: participants experience with the CSIRO Total Wellbeing Diet program content and platform

| | Week 3 | | Week 6 | |
|--|-----------------|-----------|-----------------|-----------|
| | "Agreed" (n, %) | Mean (SD) | "Agreed" (n, %) | Mean (SD) |
| Statements about the program content | | | | |
| I felt confident in following the program after reviewing the program materials (tutorial and/or meal plan)* | 47, 84% | 5.9 (1.4) | 47, 94% | 6.1 (1.0) |
| The program content (weekly tutorials) was easy to understand* | 49, 91% | 6.1 (1.2) | 46, 94% | 6.2 (1.0) |
| The concept of food groups was clearly explained* | 50, 91% | 6.1 (1.3) | 46, 92% | 6.2 (1.1) |
| The meal plan was easy to follow | 48, 86% | 5.9 (1.4) | 45, 85% | 5.8 (1.2) |
| The meals were easy to prepare | 50, 89% | 5.9 (1.3) | 45, 85% | 5.7 (1.3) |
| I enjoyed this program | 44, 79% | 5.5 (1.5) | 44, 83% | 5.8 (1.3) |
| I found the program easy to follow | 46, 82% | 5.7 (1.5) | 41, 77% | 5.5 (1.4) |
| I feel better in control of my cravings | 45, 80% | 5.4 (1.5) | 39, 74% | 5.6 (1.6) |
| I am satisfied with my weight change | 40, 71% | 5.2 (1.7) | 35, 66% | 5.1 (2.0) |
| I found it easy to transition off the meal replacements to Total Wellbeing Diet* | 12, 34% | 4.0 (1.5) | 25, 63% | 4.9 (1.6) |
| Statements about the program platform | | | | |
| I found the weight tracker easy to use* | 51, 93% | 6.2 (1.1) | 45, 88% | 6.1 (1.3) |
| I found it easy to use the platform* | 50, 89% | 6.0 (1.3) | 42, 80% | 5.8 (1.4) |
| I found the food tracker easy to use for tracking my intake* | 41, 76% | 5.7 (1.7) | 39, 78% | 5.6 (1.6) |
| I found it easy to transition off meal replacements to Total Wellbeing Diet* | 12, 41% | 4.4 (1.6) | 26, 65% | 5.0 (1.7) |

Note: Participants were asked to rate their level of agreement on a scale of strongly disagree (1) to strongly agree (7). Higher score indicates higher level of agreement; a score ≥ 5 was considered agreement with the statement. *, indicates questions had the option to respond 'not applicable'; for these questions, the per cent agreement was calculated from the subsample of participants who selected a score of 1-7.

General evaluation

During the program, participants were asked to rate their experience on the program on a scale of 0 (completely awful) to 10 (couldn't be better). Ratings were similar at weeks 3 and 6. The average rating was 7.8 ± 2.0 out of a possible 10, and 7.8 ± 1.8 for weeks 3 and 6, respectively. In week 3, 84% of participants reported scores of 6 or greater regarding their experience, and 87% of participants in week 6.

Participants were asked to select the best and worst things about the program at weeks 3 and 6. The best things about the program, selected by more than half the participants at weeks 3 and 6 were: it's 'convenience/ease', 'weight loss results', 'learning about healthy foods', and 'reduction in cravings'. There were some differences between weeks 3 and week 6. In week 6, a greater proportion of participants selected 'reduction in cravings' (75% v. 50%), 'program tools and support' (64% v. 41%), 'taste' (62% v. 41%), and 'filling' (45% v. 30%), compared with week 3 (Figure 19).

The worst things about the program were integration with family meals, selected by about half of the participants, and gastrointestinal upsets, selected by about a third of participants. There were some differences between weeks 3 and week 6. In week 6, a greater proportion of participants selected 'difficult to maintain' (19% v. 13%), 'cost' (17% v. 11%), and 'difficult to prepare' (11% v. 2%), compared with week 3 (Figure 20).

At the end of the study, participants were asked if they would recommend the program to their friends who were interested in losing weight. Most participants who completed the survey (87%) said they would recommend the program, and the remainder of participants (13%) said they were unsure. No-one said they would not recommend the program to their friends.

Seven out of 10 participants thought this program worked better for them, as individuals with higher craving tendencies, and 2 out of 10 felt it was about the same as other programs. Participants who felt this program worked better compared with other programs cited reasons related to the (positive) impact on their cravings and hunger, they were learning about how to eat and how much to eat, and their weight loss results helped them stay on track. Other reasons selected by participants, albeit fewer participants, were related to the convenience and not having to decide what to eat, they enjoyed the shakes and their convenience, and were enjoying the program support and content.

When asked about the impact of the program on their cravings, most participants who felt this program worked better than other programs reported that their cravings had reduced (either in frequency or intensity), or they felt they were able to better control/resist them. Participants who felt this program was about the same as other programs reported there was either no change in their cravings, or that their cravings decreased initially, but had returned. Less than 10% of participants thought the program was worse than other programs and reported that the current program had no impact on their cravings (i.e., they still have cravings).

Participants were also asked to rate their experience on this program compared with their previous dieting attempts on a scale of 1 (completely awful) and 10 (could not be better). Nine out of ten participants (n=49 out of 53, 92%) recorded a positive response to program (score of ≥ 6), and one-quarter of participants (n=14, 26%) gave a score of 10.

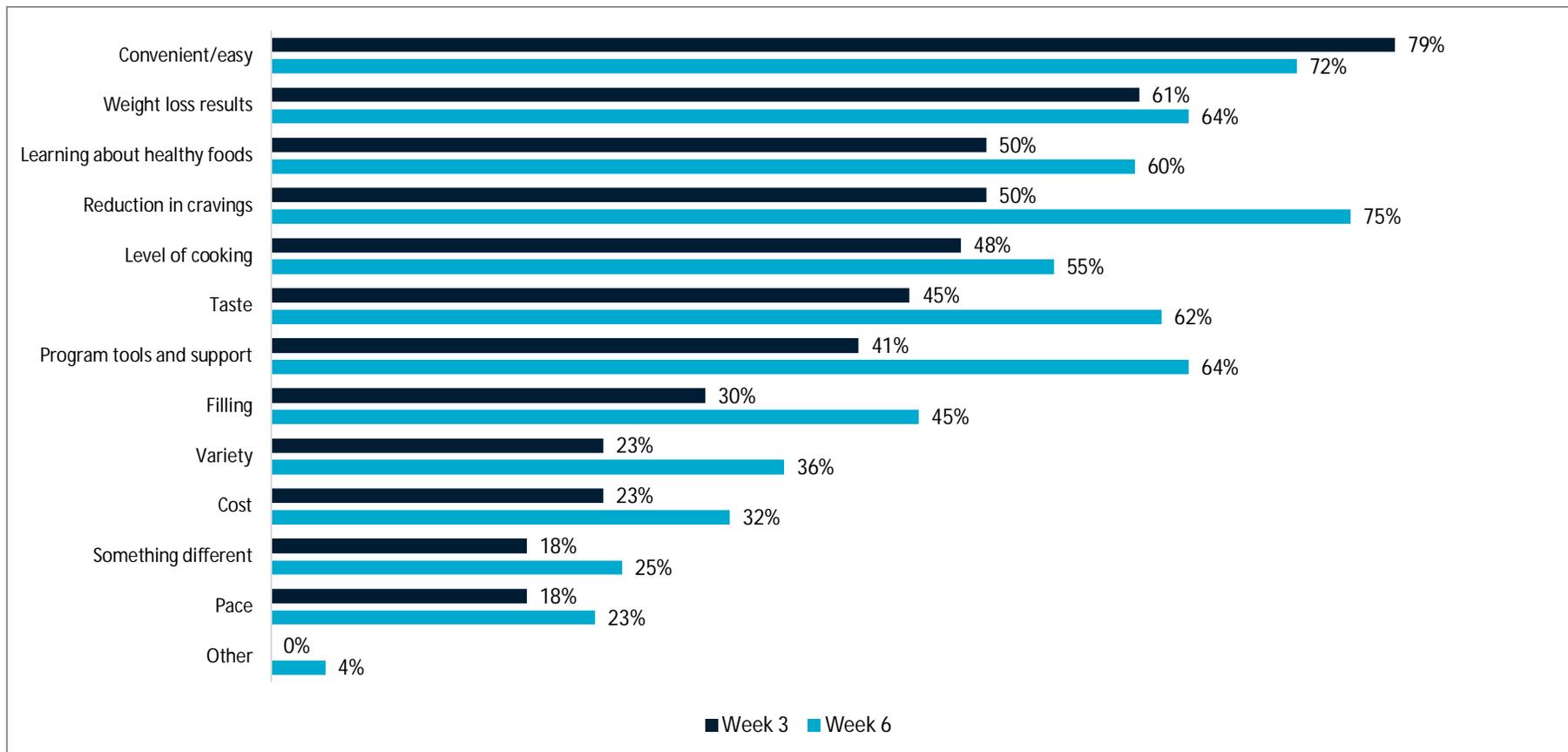


Figure 19 The best things about the program, as rated by participants at week 3 (n=56) and week 6 (n=53)

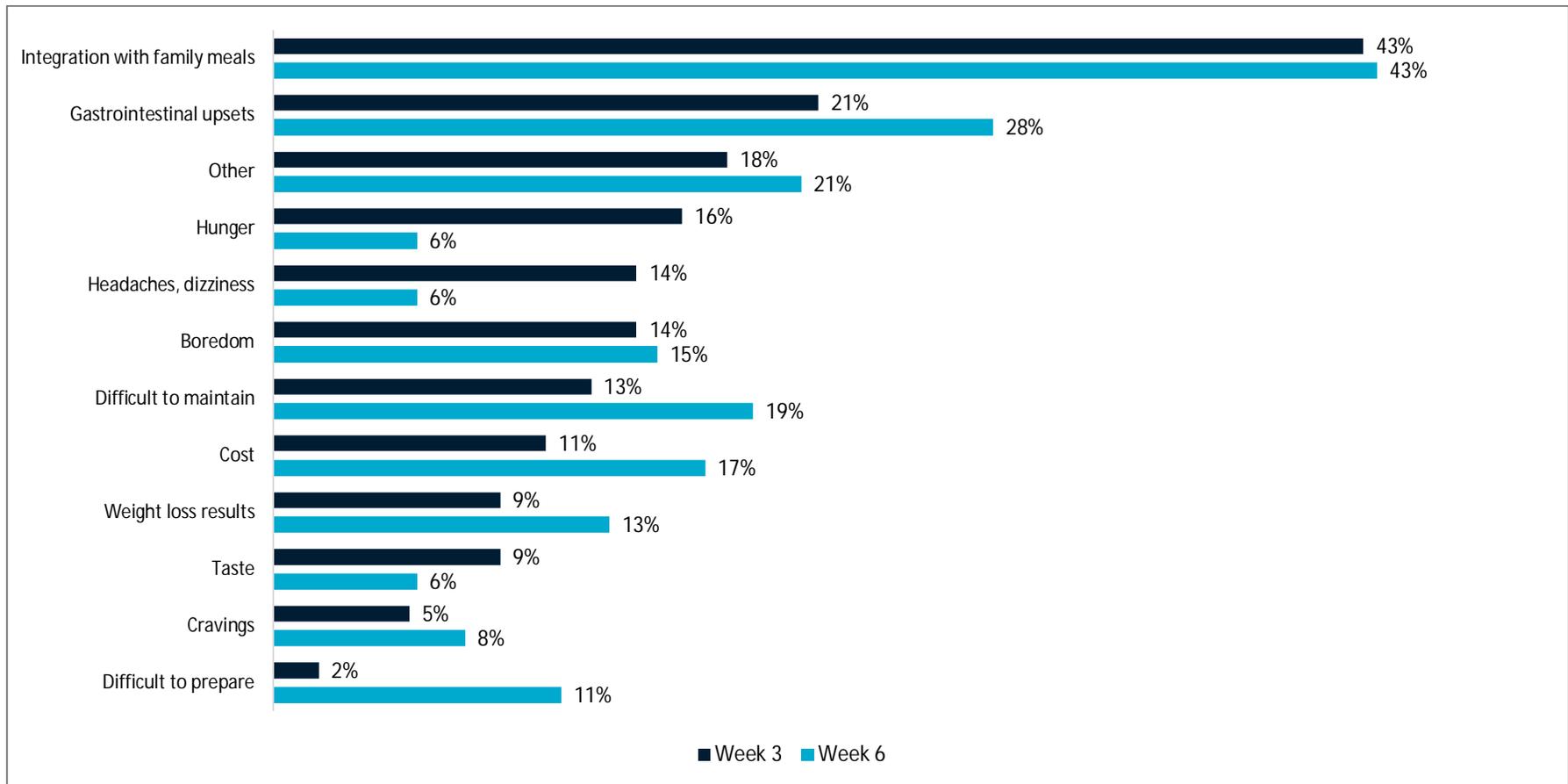


Figure 20 The worst things about the program, as rated by participants at week 3 (n=56) and week 6 (n=53)

Summary

This pilot study was conducted to assess the feasibility, acceptability, and practicality of starting the CSIRO Total Wellbeing Diet program with 3 weeks of partial meal replacements and one healthy, balanced meal. The invitation to participate in the study went out to nearly 5,000 obese adults who had previously completed the CSIRO Diet Types survey and were classified as having higher craving tendencies. The invitation to participate was open for 10 days, during which time 288 individuals expressed interest in the study and 89 were formally enrolled (recruitment rate = 31%). Nine individuals were excluded from the analysis, leaving a total sample size of 80 participants.

Who started the program and why?

- Participants were mostly female (91%), aged between 31-65 years (93%) and lived in NSW or Victoria (51%). All participants were classified as obese, with an average starting weight of 103kg (BMI=37.4).
- Participants' main reasons for signing up to the study were associated with weight (81% interested in losing weight, 58% feeling overweight) or their perceived readiness to start a weight loss program (74% ready to commit, 60% felt in the right headspace).

Participants' expectations

- During the study, the proportion of participants who agreed they would enjoy being on the program increased (66% at baseline v. 87% at week 6). Participants' rating of their confidence in overcoming barriers and following the program changed from 93% at baseline to 74% at week 6.
- Participants expected to lose around 1 kg each week during the study and their confidence that the program would help them achieve their weight loss goals was consistently high throughout the study (88% at baseline v. 89% at week 6).

Weight loss results

- Across all participants enrolled (n=80), the average weight loss was 3.1 kg (3.1% of their starting weight) in the first 3 weeks and 4.0 kg (3.9% of their starting weight) after 6 weeks. 44% of all participants who started the program recorded clinically meaningful weight loss ($\geq 5\%$ of their starting body weight) at week 6 of the program.
- About two-thirds of enrolled participants completed the study and provided a weight at week 6 (completion rate: 55 of 80, 69%).
- In this subsample of 55 participants who completed the study, the average weight loss was 4.1 kg in the first 3 weeks, and 5.9 kg after 6 weeks (equivalent to 5.6% of their starting body weight). Nearly two-thirds of completers (35/55, 64%) recorded clinically meaningful weight loss at week 6. Seven out of 10 participants felt positive about their weight change during the study.

- Most participants rated their compliance in following the program as 6 or more out of 10, with 84% in week 3 and 67% at week 6 giving this rating. Social situations, holidays, general work/life stress and lack of motivation were the common reasons given that impacted participants compliance with the program.

Self-reported adverse events

- In the weekly surveys, 57 participants reported at least one adverse event over the 6-week study period. In week 1, 64% of participants reported a symptom, which decreased to 32% in week 3 and 23% in week 6. The most common adverse events were increased gas (reported on n=63 occasions), constipation (n=41), headaches (n=35) and bloating (n=31).
- The duration of reported symptoms varied. About one third reported that their symptoms lasted for less than 1 week, and nearly half reported their symptoms persisted throughout the 6-week program. While most adverse events were rated as 'mild', two participants experienced adverse events which were assessed as moderate (n=1) or severe (n=1) and probably related to participation in the trial. In one instance, this caused severe dizziness which required medical advice.

Participants' hunger and food cravings

- Participants' confidence in their ability to control their weight by resisting overeating in certain tempting situations increased during the study by 19% from baseline. The greatest increase was seen in resisting eating when feeling sad or anxious (negative emotion) and watching television or reading.
- Throughout the program, all participants experienced cravings, but the proportion of participants who indicated that they had never 'given in' to their cravings was no one at baseline (0%), 30% at week 3, and 13% at week 6.
- The proportion of participants who had never 'given in' to their cravings was slightly higher among the participants who had lost more weight (that is those who achieved $\geq 5\%$ weight loss compared to those who achieved $< 5\%$).
- Also in relation to cravings, 80% of participants at week 3 and 74% of participants at week 6 reported that they felt they were better in control of their cravings.
- The proportion of participants who agreed they felt hungry over the past week decreased over the study period from 49% in week 1 to 17% in week 6.
- Seven out of 10 participants thought this program worked better for them, as individuals with higher craving tendencies. Participants who felt this program worked better compared with other programs cited reasons related to the impacts on their cravings and hunger (positive impacts), they were learning about how to eat and how much to eat, and their weight loss results helped them stay on track.

Experience and evaluation of meal replacements

- 7 out of 10 participants had tried a meal replacement or shake diet before starting this study. Convenience and expected weight loss results were the main reasons cited for trying meal replacements in the past. Participants were also asked about their motivation for

trying this meal replacement trial. The most common responses were trust in CSIRO (79%) and expected weight loss results (77%).

- At the end of week 3, 88% of participants felt positive about meal replacement shakes. The most common reasons participants liked using meal replacements were the convenience (98%) and ease (93%). Integration with family meals (38%), boredom (25%) and gastrointestinal upsets (23%) were reported as the worst things about using meal replacement shakes among these participants.

Transitioning to a healthy balance diet

- Participants were encouraged to transition to a healthy balanced diet, following the standard CSIRO Total Wellbeing Diet, at the end of week 3. Only 11% of participants transitioned and decided to stop having meal replacements at this point.
- At week 6, 47% of participants reported to have transitioned to the CSIRO Total Wellbeing Diet. Of those that had transitioned, 68% continued using meal replacements in some way – mostly once per day or 2-3 times per week.
- Reasons for transitioning at week 3 included feeling like it was time or that they were ready to follow a food-based diet program, they missed or were craving solid foods, and one person reported side effects or that they weren't satisfied with the shakes. Additional reasons for transitioning at week 6 included the program defaulted again to the CSIRO Total Wellbeing Diet so they just followed the program, they ran out of shakes, to fit into their lifestyle, or they were bored.
- The reasons for not transitioning at week 6 included the ease and convenience, enjoyment of the structure of the shakes, wanting to do it for a little bit longer, for continued weight loss, hadn't been following the diet well, not mentally ready, lack of support at home, and had additional meal replacement shakes to use up.

Evaluation of the program as a whole

- Levels of agreement to statements related to the ease of sticking to the program and ability to manage cravings was consistent across the study period. Generally, weight loss slows down gradually with time. Consistent with this, the proportion of participants who 'felt happy with their weight change' decreased over the study period (81% in week 1 v. 51% in week 6).
- In week 3, 84% of participants who completed the survey reported feeling positive about their experience on the program, and 87% of participants in week 6. The best things about the program, selected by more than half the participants at weeks 3 and 6 were: it's convenience/ease, weight loss results, learning about healthy foods, and reduction in cravings. There were some differences between weeks 3 and week 6. In week 6, a greater proportion of participants selected reduction in cravings (75% at week 6 v. 50% at week 3), program tools and support (64% v. 41%), taste (62% v. 41%), and filling (45% v. 30%) as the best things about the program.
- The worst things about the program were integration with family meals, selected by about half of the participants, and gastrointestinal upsets, selected by about a third of participants.

- Participants were asked to rate their experience on this program compared with their previous dieting attempts. Nine out of ten participants who completed the survey (n=49 out of 53, 92%) recorded a positive response to program (score of $\geq 6/10$), and one-quarter (n=14, 26%) gave a maximum score of 10. Most participants who completed the survey (87%) said they would recommend the program to their friends who were interested in losing weight.

Evaluation of the platform and its content

- Participants in this study accessed the CSIRO Total Wellbeing Diet platform mostly via the app (43%), or a combination of the website and app (40%).
- Overall, 79-91% of participants agreed with the statements about the program and its content (including the meal plan and concept of food groups) being easy to follow and clearly explained at week 3, and 77-94% agreed with these statements at week 6.
- The delivery of program content was targeted to the week of the program. In relation to program content making it easy to transition off the meal replacements and onto the CSIRO Total Wellbeing Diet, 34% of participants agreed with this statement at week 3 and 63% agreed with this statement at week 6.
- Most participants agreed that the platform, including the weight and food trackers, were easy to use in both week 3 and 6 (between 76% and 93% of participants agreed with these statements). At week 3, 41% of participants agreed that the platform made it easy to transition off the meal replacements to the CSIRO Total Wellbeing Diet, and this increased to 65% at week 6.

Conclusion

This pilot study was designed to assess the feasibility, acceptability, and practicality of starting the CSIRO Total Wellbeing Diet program with 3 weeks of partial meal replacements, and also to examine the weight loss achieved by participants. The study has shown that meal replacements, combined with a prescribed meal and snacks, can be effective for weight loss in the short term. The recommendation to transition to the CSIRO Total Wellbeing Diet was at 3 weeks, however most participants appeared to be ready to transition off meal replacements and onto a whole foods diet between weeks 3 and 6. Many participants reported to continue using the shakes once per day or a few times per week because of their ease and convenience. Participants felt the program content was easy to follow and clearly explained, however greater support is needed for a more tailored transition off meal replacements and onto a healthy diet. Most of the benefits (such as convenience) and downfalls (such as side effects) of meal replacements echoed those identified in the online survey by people who had previously tried meal replacements and therefore were unlikely specific to this format.

This was a small pilot study designed to assess the feasibility of incorporating meal replacements into an established whole foods weight loss program in a group of obese people with higher craving tendencies. The results of this study represent people who completed the surveys and provided data. It is likely that these individuals were more successful than those who dropped out, and this should be considered when interpreting the results. Future research should explore the effectiveness and acceptability of the inclusion of meal

replacements as an alternative entry for the CSIRO Total Wellbeing Diet to achieve early and longer-term weight loss with a larger cohort of Australians. This larger sample would also allow for a greater understanding in how different members choose to transition onto a whole foods diet and to compare different types of personalities, or levels of obesity, to better understand if this program adaption is more suitable for certain groups of people.

