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The Feasibility and Acceptability of a Pragmatic Food-Based Very-Low-Energy Intervention in Adults with Obesity: A Pilot Single-Arm Intervention Study

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Abstract

Background/Objectives: The objective of this study was to evaluate the feasibility, acceptability, weight loss response, safety and preliminary clinical outcomes of a pragmatic 8-week food-based very-low-energy intervention in adults with obesity. **Methods**: In this prospective, single-arm study, 10 adults eligible for very-low-energy diet (VLED) therapy completed an 8-week food-based intervention targeting approximately 800 kcal/day with an accepted intake range up to 1000 kcal/day. Participants planned, purchased and prepared all foods, supported by dietary self-monitoring and fortnightly dietitian consultations. The primary feasibility outcomes were acceptability and weight loss response. The secondary outcomes included recruitment, retention and engagement. The exploratory outcomes included anthropometric measures, blood pressure, nutritional and biochemical markers, dietary quality, nutritional adequacy and adverse events. **Results**: All participants completed the intervention. Nine of 10 (90%) Food Acceptability Questionnaire (FAQ) scores met their prespecified item-level acceptability thresholds, while 90% (95%CI 55.5 to 99.7%) of participants achieved ≥5% weight loss. Mean weight loss was 10.8%. Attendance at study visits was 100% (95% CI 69.2 to 100%). Participants completed 93 ± 13% of expected food diary days with mean daily energy intakes of 842 ± 70 kcal/day. Statistically significant improvements were observed in anthropometric measures, blood pressure, total and LDL cholesterol and dietary quality. No clinically concerning changes in micronutrient or safety parameters were observed. Adverse events were predominantly mild to moderate. **Conclusions**: This pragmatic 8-week food-based very-low-energy intervention demonstrated encouraging feasibility outcomes, although challenges associated with eating out warrant further attention. Further evaluation in larger controlled trials is needed to assess its comparative effectiveness relative to traditional meal replacement VLEDs and longer-term outcomes.

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Keywords: obesity; very-low-energy diet; very-low-calorie diet; weight loss; food-based diet; meal replacement; dietary self-management; feasibility; acceptability; nutritional adequacy

1. Introduction

Obesity remains a major public health challenge worldwide and is associated with increased risk of cardiometabolic diseases, reduced quality of life and high healthcare burden [1–4]. Dietary and behavioural interventions are foundational to obesity management.

Very-low-energy diets (VLEDs), also known as very-low-calorie diets (VLCDs), are defined as diets providing <800 kcal/day (<3300 kJ/day) and are among the most effective dietary approaches for short-term rapid weight loss. They may be recommended for individuals who do not achieve adequate outcomes with conventional energy-restricted diets [5]. Traditional VLEDs typically replace all usual meals with three or four commercially formulated meal replacement products for 8 to 16 weeks [6], with allowances for non-starchy vegetables (2 cups/day), unsaturated oils (1 tsp/day) and calorie-free fluids (2 L/day) [6]. Following the intensive phase, transition to an eating pattern for weight maintenance occurs where the number of meal replacements is gradually reduced and meals of conventional food are reintroduced [6].

The meal replacement approach is valued for its convenience, structure and predictability, and is frequently perceived as easier to adhere to than initially anticipated [7,8]. The products are formulated to be nutritionally complete and are well-established to be safe and effective. However, much of the food-related decision-making required in everyday life is minimised during the programme as meal planning, shopping, meal preparation and portion estimation are largely replaced by consumption of pre-portioned ready-to-eat products, or foods requiring minimal preparation [9].

While this simplicity may facilitate adherence, it may also provide fewer opportunities to develop food selection and dietary self-management skills relevant to longer-term weight maintenance [8]. Qualitative studies have reported that transition from meal replacements back to conventional foods can be challenging, with some individuals describing anxiety regarding food choices and losing the sense of safety and control provided by the structured VLED [7]. Re-initiation of meal replacements is also used as a strategy to manage weight regain [10,11], potentially reinforcing reliance on product-dependent strategies rather than supporting the development of sustainable, long-term dietary behaviours. These challenges highlight the potential value of approaches that support the development of dietary self-management skills during, rather than only after, active weight loss.

A food-based approach is a potential alternative model to traditional meal replacement VLEDs. Unlike meal replacement VLEDs, implementation using conventional foods introduces greater variability in actual energy intake and requires individuals to undertake dietary behaviours throughout the intervention, including food selection, meal planning, portion estimation and food preparation. Dietary modelling suggests that food-based diets designed to provide approximately 800 kcal/day can achieve comparable energy and macronutrient composition to traditional meal replacement VLEDs while providing a greater variety of dietary fibre [12]. By embedding dietary self-management behaviours during active weight loss, a food-based approach may provide more opportunities for the acquisition of transferable skills relevant to longer-term weight management [13].

However, evidence on the feasibility, acceptability, clinical implementation and micronutrient adequacy of food-based alternatives to traditional meal replacement VLEDs remains limited. Secondary analyses of commercially available food-based VLED menus have identified potential inadequacies in the provision of several micronutrients. But

whether these theoretical inadequacies translate into compromised micronutrient status when such diets are implemented in practice remains uncertain [12]. Existing studies evaluating food-based VLEDs in practice have focused on specific clinical populations [14–16] or have relied on commercially prepared meal programmes [17,18] rather than diets based on self-selected conventional foods. Furthermore, previous studies have not comprehensively evaluated both micronutrient intake and biomarker-assessed micronutrient status in individuals following food-based VLEDs [14–18]. Consequently, it remains unclear whether adults with obesity can successfully implement a food-based VLED within their usual living environment without relying on commercial products or services, while maintaining adequate micronutrient intake and status.

Therefore, the primary aim of this study was to evaluate the feasibility of a pragmatic 8-week food-based very-low-energy intervention in adults with obesity, with acceptability and weight loss response included as pragmatic indicators of successful implementation. Secondary aims were to examine recruitment, retention, engagement, safety and preliminary clinical outcomes, including anthropometric measures, blood pressure, cardiometabolic, micronutrient and general safety biomarkers, dietary quality and nutritional adequacy. These findings were intended to inform intervention refinement and sample size estimation for a future controlled trial.

2. Materials and Methods

2.1. Study Design

This prospective single-arm study was designed to assess the feasibility and acceptability of implementing a pragmatic food-based very-low-energy intervention targeting approximately 800 kcal/day, with an accepted intake range up to 1000 kcal/day, over 8 weeks. The protocol was approved by the University of Melbourne Human Research Ethics Committee (reference number 2025-31540-67275-3) and was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12625001026415). Informed consent was obtained from all study participants. Manuscript reporting was guided by the Consolidated Standards of Reporting Trials (CONSORT) extension for pilot and feasibility trials [19]. No important changes to the study design, eligibility criteria, intervention procedures, assessments or outcome measures were made after trial commencement.

2.2. Participants

Eligibility criteria were based on the recommendations for VLED therapy according to the Australian Obesity Management Algorithm [5].

The inclusion criteria were age 18–65 years and a body mass index (BMI) ≥ 30 kg/m^2, or BMI > 27 kg/m^2 with at least one weight-related cardiometabolic comorbidity. The exclusion criteria included pregnancy or planned pregnancy, lactation, recent (<3 months) myocardial infarction, cerebrovascular events or unstable angina, porphyria or unstable psychiatric conditions.

Participants were recruited through university-based channels including digital mailing lists, printed flyers, social media and word-of-mouth. Interested individuals completed online and telephone screening to determine eligibility. Telephone screening was conducted sequentially according to the submission date and time of the online screening form. Eligible participants attended a baseline visit, where eligibility was confirmed and written electronic informed consent was obtained using the REDCap e-consent framework [20].

The study was conducted at the University of Melbourne Human Nutrition research clinic in Parkville, Victoria, Australia. All screening and study visits were conducted by a single researcher (S.W.Y.P.). Participant flow is summarised in Figure 1.

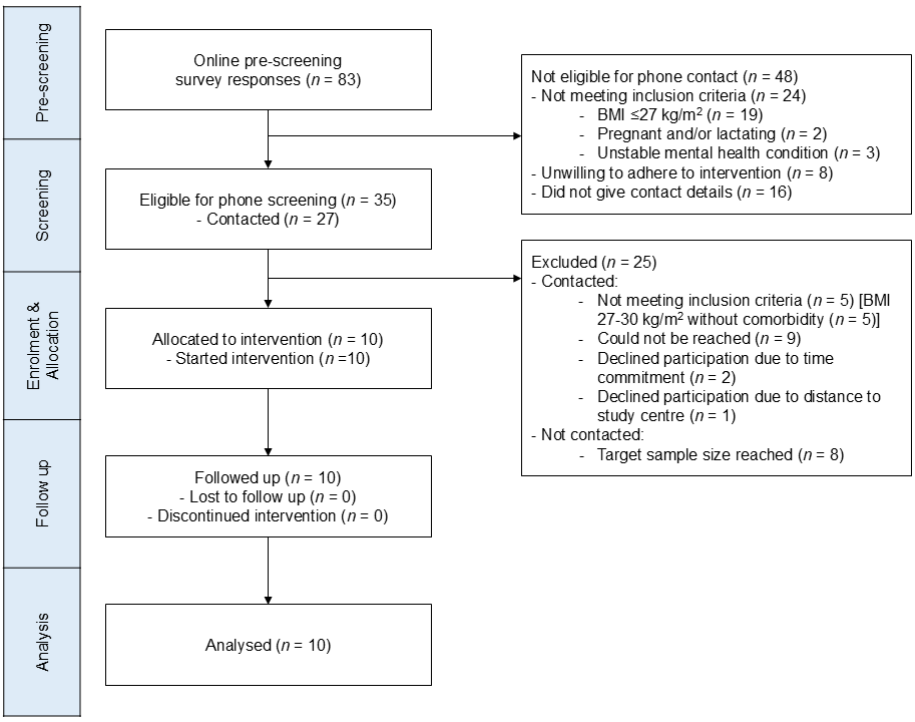


Figure 1. Modified CONSORT flow diagram for participant recruitment, screening, enrolment, and follow-up.

2.3. Intervention Design

The intervention was a pragmatic, 8-week, food-based very-low-energy intervention designed to reflect the duration and intensity of traditional meal replacement VLED programmes, while recognising that implementation using conventional foods requires participants to engage in food-related behaviours such as planning, purchasing, preparing and portioning foods, and introduces unavoidable variability in estimated energy intake.

Participants were instructed to aim for an energy intake of approximately 800 kcal/day using conventional foods. Structured behavioural and regular dietetic support was provided to facilitate adherence. In recognising the practical challenges of achieving this target in participants' usual living environments, reported energy intakes up to 1000 kcal/day were considered within the acceptable implementation range, provided participants continued to aim for the prescribed energy target of approximately 800 kcal/day.

Participants were required to plan, purchase, prepare and portion all foods and meals. No mandatory meal plans or recipes were prescribed. Instead, participants were provided with guidance to distribute food intake across two to three meals per day as a practical framework to achieve the energy target. Participants were encouraged to self-select foods and meals within this framework and were directed to commercially available recipe books and online meal ideas as needed. No meal replacement products or prepared meals were provided. Strict portion control was encouraged, and participants were instructed to weigh foods where practical.

The dietary prescription was based on the Australian Dietary Guidelines [21] and included structured food group targets, with flexibility in food selection within each food group. The food groups and recommended daily serving targets were: (1) proteins (including lean meat, poultry, fish, eggs, tofu, nuts and seeds and low-fat cheese), 2 serves; (2) non-starchy vegetables (including legumes/beans), 2 serves; (3) fruit, 2 serves; (4) dairy (low fat milk and yoghurt), 2 serves; and (5) carbohydrates (grains, cereals and starchy vegetables), 0–2 serves. The recommended daily serve of water and unsweetened fluids was ≥2 L per day. Foods high in added sugars, fats and oils including spreads, sauces

and condiments, and discretionary items such as confectionery, cakes, biscuits, pies and sausages were discouraged in line with the Australian Dietary Guidelines [21].

Behavioural support components were informed by established behaviour change techniques from the Behaviour Change Technique Taxonomy v1 [22], including self-monitoring of behaviour, goal setting, feedback on behaviour, instruction on how to perform the behaviour and problem solving. Dietary self-monitoring included using a mobile application (Easy Diet Diary; Xyris Software, Brisbane, Australia), with dietary data accessible to researchers in real-time, and reviewed using FoodWorks.online [23]. Participants received standardised written resources and attended consultations with an Accredited Practising Dietitian (S.W.Y.P.) at baseline and weeks 2, 4, 6 and 8. Consultations included review of dietary records, individualised feedback, dietary education and counselling.

Participants were advised to take a daily multivitamin and mineral supplement during the intervention to support micronutrient adequacy. A list of commercially available supplements considered appropriate based on their labelled micronutrient composition was provided and participants were instructed to select a product from this list. Participants were encouraged to meet national physical activity guidelines of 150–300 min/week of moderate-intensity activity [24].

Further details regarding intervention delivery including dietary prescription, behavioural and monitoring components, and written materials provided to participants are found in Supplementary Section S1.

2.4. Procedures

The study data were collected and managed using REDCap electronic data capture tools hosted by the University of Melbourne [25,26].

2.4.1. Anthropometry and Blood Pressure

Height was recorded at baseline. Body weight and body fat percentage were measured using a digital scale (TANITA InnerScan® Body Composition Monitor BC-587, Tanita Corporation, Tokyo, Japan) at each visit. Waist circumference was measured against the skin at the smallest horizontal narrowing found between the bottom of the rib cage and the iliac crest [27]. Hip circumference was measured at the widest point of the buttocks. Blood pressure and heart rate were measured in duplicate using an automated monitor (OMRON Digital Automatic Blood Pressure Monitor HEM-907, OMRON HEALTHCARE Co., Ltd., Muko, Japan) following 5 min seated rest; the mean of two readings was recorded.

2.4.2. Biomarkers

Fasting blood samples were collected at baseline and week 8. Analyses included glucose, lipid profile, liver tests and micronutrients (iron, zinc and selenium). Safety parameters included full blood examination and routine biochemistry. Urinary iodine concentration was assessed from fasting urine samples at baseline and week 8. Samples for zinc, selenium and iodine were stored at −80 °C prior to analysis; all other analyses were performed on the day of collection by accredited hospital pathology services.

2.4.3. Dietary Assessment

Baseline dietary intake was estimated from two 24 h dietary recalls, collected in accordance with standard dietetic practice. During the intervention, participants recorded all food, beverage and supplements consumed daily using Easy Diet Diary, with additional notes or images recorded where required. Food records were reviewed at each visit and analysed using AusFoods and AusBrands databases accessed via Foodworks.online [23]. Baseline 24 h recall data were entered into FoodWorks.online by the study researcher-dietitian to estimate

dietary intake [23]. For each fortnightly assessment (weeks 2, 4, 6, and 8), dietary intake was estimated by averaging intake across all completed food diaries within that fortnight.

2.4.4. Diet Quality

Diet quality was assessed using the Healthy Eating Index for Australia (HEIFA-2013) [28]. HEIFA-2013 scores were calculated at baseline and week 8 using dietary intake data derived from the respective assessment methods described above. Scores range from 0 to 100, with higher scores indicating greater alignment with the Australian Dietary Guidelines. A reference HEIFA-2013 score was calculated for a sample menu of the present intervention to contextualise participant scores. Food group allocation followed the AUSNUT 2023 dataset [29], with mixed dishes disaggregated into constituent ingredients [28,29].

2.4.5. Acceptability

Acceptability was assessed using the 10-item Food Acceptability Questionnaire (FAQ) [30,31], scored on a 7-point ordinal scale. Higher scores indicate greater acceptability, except in item 4, which is reverse scored. The FAQ is a recognised instrument used to assess diet acceptability and has been previously tested for reliability in populations with overweight and obesity [32]. The questionnaire also captured participants' perceived benefits and adverse symptoms experienced during the preceding two weeks. FAQ domains were mapped against the Theoretical Framework of Acceptability [33] to support the interpretation of acceptability findings.

2.4.6. Adverse Events

Adverse events were assessed at each visit using a checklist of common symptoms associated with hypocaloric diets, with additional events recorded using an adapted instrument for adverse events from the REDCap shared library [34].

2.5. Outcome Measures

2.5.1. Feasibility Outcomes

Primary feasibility outcomes were evaluated against prespecified targets relating to food acceptability and weight loss.

The prespecified acceptability target required FAQ scores ≥ 4 for all items, except item 4 ("How boring are these foods?"), for which scores ≤ 4 were considered acceptable due to the reversed scale. Each FAQ item was assessed against its respective threshold.

The prespecified weight loss target was ≥5% weight loss at week 8, a threshold associated with clinically meaningful weight loss and improvements in cardiometabolic health [35]. Weight loss response was assessed as the proportion of participants achieving $\geq 5\%$ weight loss from baseline to week 8. Weight loss response was included as a feasibility target to assess whether the intervention demonstrated sufficient preliminary performance in achieving its intended weight loss outcome to warrant further evaluation in a larger, controlled clinical trial.

Secondary feasibility outcomes included recruitment rate (mean number of participants recruited per month), retention (proportion of participants who completed the week 8 visit; mean enrolment duration) and engagement. Engagement was assessed by attendance at scheduled study visits, completion of self-monitoring (defined as the proportion of completed food diary days relative to enrolment duration), mean daily energy intake, and the proportion of completed food diary days with estimated energy intake ≤ 800 kcal/day and $\leq$1000 kcal/day.

2.5.2. Exploratory Clinical Outcomes

Changes from baseline to week 8 were explored for anthropometric measures (body weight, BMI, fat mass percentage, waist and hip circumferences), blood pressure, lipid profile, liver function, glucose, micronutrient status (iron studies, zinc, selenium, iodine) and dietary quality (HEIFA-2013 score). Nutritional adequacy at each timepoint was evaluated against Australian Nutrient Reference Values, specific to the participants' age and sex. The proportion of participants with mean intakes below the Estimated Average Requirement (EAR) was calculated using the cut-point method [36]. For nutrients without EAR values, mean intakes were compared with Adequate Intake (AI) values.

2.5.3. Data Analysis

As this was a pilot feasibility study, a sample size calculation was not performed. A sample size of 10 participants was selected to estimate uncertainty around primary feasibility parameters and outcome variability to inform subsequent trial design [19,37,38], while remaining appropriate for an initial feasibility evaluation.

Descriptive summary statistics were used to summarise baseline characteristics and feasibility outcomes. Continuous variables are presented as mean ± standard deviation (SD) for normally distributed variables, median (IQR) for non-normally distributed values, and categorical variables as frequency counts and percentages. FAQ scores are reported as median (IQR), maximum and minimum due to their ordinal nature. Confidence intervals (95% CI) for feasibility proportions were calculated using the exact binomial (Clopper–Pearson) method.

Within-participant changes for anthropometric measures, blood pressure, biomarker outcomes and HEIFA-2013 scores were assessed for normality using the Anderson–Darling test and visual inspection of histograms. Paired sample *t*-tests were used for normally distributed data and the Wilcoxon signed-rank test for non-normally distributed data. Effect sizes (Cohen's *d*) were reported for parametric analyses. Statistical significance was set at $p < 0.05$. All analyses were performed using Minitab® Statistical Software (LLC, version 20.4) [39].

3. Results

3.1. Participant Characteristics

Selected baseline participant characteristics are presented in Table 1. Of 83 individuals who expressed interest, 35 completed the online screening questionnaire and were awaiting telephone screening. Telephone screening was conducted sequentially according to the submission date and time of the online screening form. Of these, 27 were contacted for telephone screening, while the remaining eight were not contacted because the target sample size of 10 had been reached. All 10 enrolled participants completed the study (Figure 1).

Table 1. Baseline participant characteristics ($n = 10$).

Characteristic [a]	All ($n = 10$)	Males ($n = 5$)	Females ($n = 5$)
Age (years)	39 ± 13	31 ± 4	47 ± 14
Weight (kg)	107.5 ± 20.0	116.5 ± 24.7	98.5 ± 9.4
BMI (kg/m^2)	36.9 ± 5.0	37.6 ± 6.6	36.2 ± 3.3
Waist circumference (cm)	114.4 ± 13.0	117.3 ± 16.8	111.4 ± 8.8
Hip circumference (cm)	122.6 ± 10.0	122.6 ± 10.5	122.5 ± 10.8
Waist-to-hip ratio	0.93 ± 0.06	0.95 ± 0.06	0.91 ± 0.06
Body fat (%)	41.3 ± 9.4	35.7 ± 9.2	46.8 ± 6.2
Ethnicity			
Caucasian/European	7 (70%)	3 (60%)	4 (80%)

Table 1. *Cont.*

Characteristic [a]	All (n = 10)	Males (n = 5)	Females (n = 5)
East/Southeast Asian	2 (20%)	1 (20%)	1 (20%)
South American	1 (10%)	1 (20%)	0 (0%)
Highest level of education			
Year 12 or below	0 (0%)	0 (0%)	0 (0%)
Diploma	2 (20%)	1 (20%)	1 (20%)
Bachelor degree	5 (50%)	3 (60%)	2 (40%)
Post-graduate degree	3 (30%)	1 (20%)	2 (40%)
Medical conditions			
Hypertension	1 (10%)	0 (0%)	1 (20%)
Dyslipidaemia	4 (40%)	1 (20%)	3 (60%)
Hepatic steatosis	2 (20%)	1 (20%)	1 (20%)
Polyendocrine Metabolic Ovarian Syndrome	-	-	1 (20%)
Medical conditions, number per participant			
0 medical conditions	3 (30%)	2 (40%)	1 (20%)
1 medical condition	4 (40%)	3 (60%)	1 (20%)
2+ medical conditions	3 (30%)	0 (0%)	3 (60%)
Medication use			
No medications	7 (70%)	5 (100%)	2 (40%)
Antihypertensives	1 (10%)	0 (0%)	1 (20%)
Statins	3 (30%)	0 (0%)	3 (60%)

[a] Data are presented as mean ± SD or number and proportion of participants, n (%).

Participants had a mean ± SD age of 39 ± 13 years and BMI of 36.9 ± 5.0 kg/m^2. Most participants (n = 7, 70%) had at least one weight-related comorbidity. No participants reported starting, discontinuing or changing the dose of any concomitant medications during the intervention.

All participants had completed post-secondary education and were either employed or not seeking employment. Most participants reported primary or shared responsibility for food shopping, planning and meal preparation and described food preparation as enjoyable.

3.2. Feasibility Outcomes

3.2.1. Food Acceptability

All feasibility outcomes are summarised in Table 2. At the item level, nine of 10 (90%) FAQ items met their prespecified acceptability thresholds. Item 7, which assessed the difficulty of maintaining the diet when eating out, did not meet the threshold at any assessment timepoint, indicating a persistent acceptability challenge in this context throughout the intervention. Median scores for item 7 were 3 (IQR 1.75–3.25, range 1–5) at week 2; 2.5 (IQR 1.75–3.0, range 1–3) at week 4; 2 (IQR 2–3, range 1–3) at week 6; and 2 (IQR 1.0–2.25, range 1–4) at week 8 (Figure 2). Overall diet satisfaction (item 10) remained high throughout the intervention, with 90% of participants reporting scores ≥ 5 at week 8.

Table 2. Summary of feasibility outcomes.

Domain/Outcome	Description of Metric	Result (Outcome)
Primary outcomes		
Food acceptability	Median FAQ score ≥ 4 [a]	9 of 10 (90%) items achieved prespecified threshold across all timepoints (weeks 2, 4, 6 and 8) • Item 7 (difficulty eating out) did not meet the prespecified threshold across all timepoints (weeks 2, 4, 6 and 8)

Table 2. *Cont.*

Domain/Outcome	Description of Metric	Result (Outcome)
Weight loss response	Weight loss ≥ 5% from baseline to week 8	90% (95% CI 55.5 to 99.7%) participants achieved prespecified criterion • 1 (10%) participant lost 3.9% of initial body weight
Secondary outcomes		
Recruitment	Recruitment rate (mean number of participants recruited per month)	6 participants per month
	Reasons for declining participation	Total 3 declined • 2 due to time commitment • 1 due to travel distance to study centre
Retention	Retention rate	100% (95% CI 69.2 to 100%) participants completed week 8 visit
	Mean enrolment duration	8 weeks between enrolled date and last contactable date
Engagement	Visit attendance rate	5 (100%) scheduled visits attended per participant
	Food diary completion rate (% days completed of enrolled duration)	52 ± 7 (93 ± 13%) completed food diary days per participant
	Mean energy intake per day	842 ± 70 kcal/day (range 723–940 kcal/day)
	Energy intake ≤ 800 kcal/day	24 ± 11 days (46 ± 20% of completed diary days)
	Energy intake ≤ 1000 kcal/day	46 ± 6 days (89 ± 7% of completed diary days)

[a] Question 4 ("How boring are these foods?") was reverse scored, where a score of ≤4 applied.

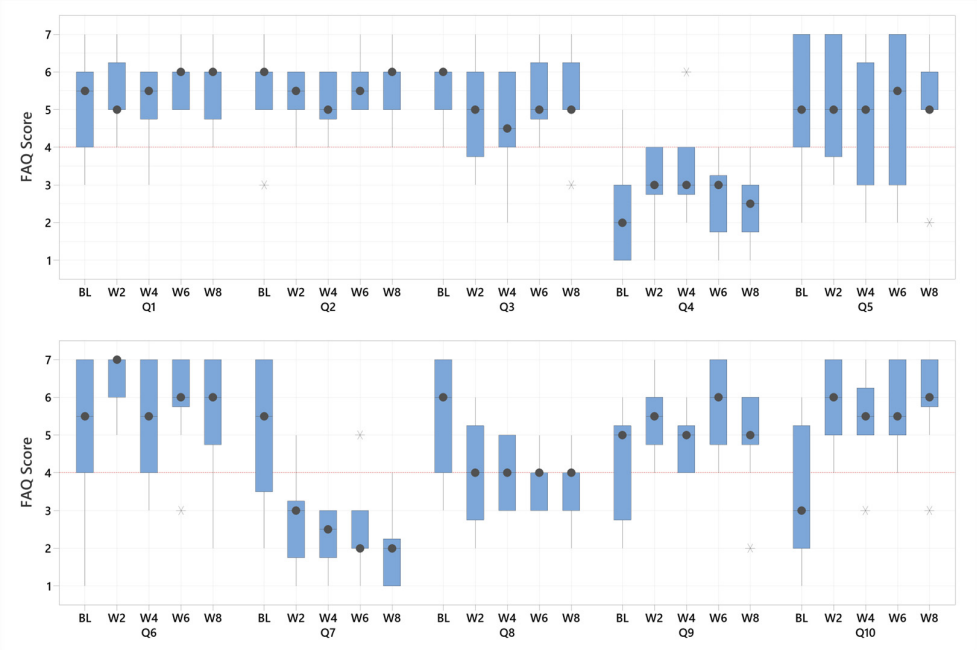


Figure 2. A boxplot of Food Acceptability Questionnaire scores showing median, IQR, minimum and maximum scores (n = 10). Note. The solid dots indicate the median. The blue boxes indicate IQR. The whiskers indicate minimum and maximum scores. The asterisks (*) indicate outliers. The red dotted line at 4 represents a priori criteria to define an 'acceptable' diet. Median scores ≥ 4 indicate an acceptable diet (≤4 for Q4 due to the reverse scale). BL, baseline; W2, week 2; W4, week 4; W6, week 6; W8, week 8. Q1. How well do you like these foods? (1 = not at all, 7 = extremely.) Q2. How well do you like the taste of these foods? (1 = not at all, 7 = extremely.) Q3. How appealing or unappealing do you find the appearance of these foods? (1 = extremely unappealing, 7 = extremely appealing.) Q4. How boring are these foods? (1 = not at all, 7 = extremely.) Q5. How easy or difficult has it been for you to prepare these foods? (1 = extremely difficult, 7 = extremely easy.) Q6. How easy or difficult

has it been for you to purchase these foods? (1 = extremely difficult, 7 = extremely easy.) Q7. How easy or difficult has it been for you to maintain your current diet at restaurants? (1 = extremely difficult, 7 = extremely easy.) Q8. How much effort does it take for you to stay on this diet? (1 = more effort than is possible, 7 = no effort at all.) Q9. How satisfied or dissatisfied do you feel after eating a meal on this diet? (1 = extremely dissatisfied, 7 = extremely satisfied.) Q10. Overall, how satisfied or dissatisfied are you with this diet? (1 = extremely dissatisfied, 7 = extremely satisfied.)

The number of reported symptoms and perceived benefits peaked at week 2 and declined or remained stable thereafter. Participants reported heterogeneous responses, including both improvements and adverse experiences related to energy levels, sleep quality and digestion (Supplementary Section S2).

3.2.2. Weight Loss Response

Nine of 10 (90%; 95% CI 55.5 to 99.7%) participants achieved ≥5% weight loss from baseline to week 8 (Figure 3). Among these participants, weight loss ranged from 7.5% to 18.2% of initial body weight (7.5–19.9 kg). The remaining participant achieved a weight loss of 3.9% (4.5 kg).

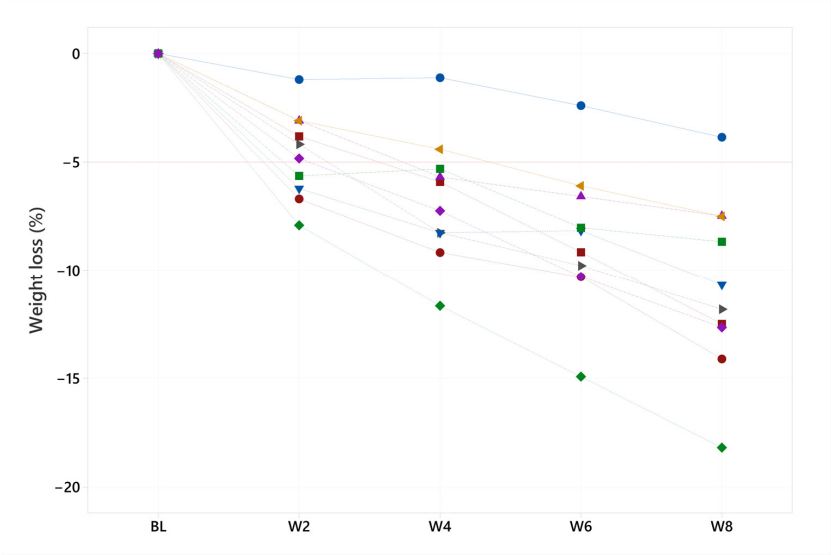


Figure 3. Percentage weight loss achieved per participant at baseline, weeks 2, 4, 6 and 8. Note. Red dotted line indicates the threshold for clinically meaningful weight loss.

3.2.3. Recruitment

The online screening form was available for 112 days (3 October 2025 to 23 January 2026) and yielded 83 responses. Of these, 35 were eligible for telephone screening, and 27 individuals were approached sequentially according to the submission date and time of the online screening form. The remaining eight were not contacted because the target sample size had been reached.

Of the 27 individuals contacted for telephone screening, five were ineligible, nine could not be reached by telephone after two attempts and three declined participation due to time commitments ($n = 2$) and distance to the study centre ($n = 1$) (Figure 1). Ten participants were enrolled between 8 October 2025 and 26 November 2025, over a period of 49 days, corresponding to a recruitment rate of approximately six participants per month.

3.2.4. Retention

All participants completed the week 8 visit (retention rate 100%; 95% CI 69.2 to 100%). Mean duration from enrolment to final study visit was 8 weeks.

3.2.5. Engagement

All participants attended all scheduled study visits. Completion of self-monitoring was also high with participants completing 52 ± 7 food diary days (93 ± 13% of enrolled duration). Among the completed food diaries, mean energy intake was 842 ± 70 kcal/day (range 723–940 kcal/day). Approximately half (46 ± 20%) of the recorded days were ≤800 kcal/day, while most (89 ± 7%) were ≤1000 kcal/day.

3.3. Clinical Outcomes

The baseline, week 8 and change values for anthropometric measures, blood pressure and selected biomarkers are summarised in Table 3. Reductions were observed in all anthropometric measures (body weight, BMI, body fat percentage, waist and hip circumferences) and blood pressure. The mean percentage weight change was −10.8% of initial body weight (95% CI −13.6 to −7.9, Cohen's $d = -2.7$, $p < 0.001$) (Table 3). Total, LDL and HDL cholesterol decreased. No clinically significant changes were observed in fasting glucose or micronutrients. Additional biomarkers (including full blood examination and routine biochemistry) are presented in Supplementary Section S2.

Table 3. Baseline, week 8, and change in anthropometric, blood pressure and selected biomarker outcomes ($n = 10$).

Variable	Baseline [a]	Week 8 [a]	Paired Difference [b]	*p*-Value [c]	Effect Size [d]
Weight (kg)	107.5 ± 20.0	96.0 ± 18.4	−11.5 (−14.8, −8.1)	<0.001	−2.5
Weight change (% of initial)	N/A	N/A	−10.8 (−13.6, −7.9)	<0.001	−2.7
BMI (kg/m^2)	36.9 ± 5.0	33.0 ± 4.8	−4.0 (−5.0, −2.9)	<0.001	−2.6
Waist circumference (cm)	114.4 ± 13.0	105.4 ± 12.0	−9.0 (−11.9, −6.0)	<0.001	−2.2
Hip circumference (cm)	122.6 ± 10.0	114.6 ± 10.0	−8.0 (−10.1, −5.9)	<0.001	−2.7
Body fat (%)	41.3 ± 9.4	36.3 ± 8.8	−5.0 (−7.1, −2.8)	<0.001	−1.7
Systolic blood pressure (mm Hg)	118 ± 6	112 ± 6	−5.6 (−8.5, −2.7)	0.002	−1.4
Diastolic blood pressure (mm Hg)	80 ± 8	73 ± 7	−6.8 (−10.1, −3.5)	<0.001	−1.5
Glucose (mmol/L)	5.2 ± 0.5	5.0 ± 0.4	−0.2 (−0.5, 0.2)	0.34	−0.3
Total protein (g/L)	75.7 ± 4.8	75.3 ± 3.7	−0.4 (−3.0, 2.2)	0.74	−0.1
Albumin [†] (g/L)	43.0 (40.0, 44.3)	44.0 (42.0, 45.3)	1.0 (−0.3, 2.3)	0.19	N/A
Total cholesterol (mmol/L)	5.2 ± 0.7	4.4 ± 0.9	−0.8 (−1.2, −0.4)	<0.001	−1.5
Triglycerides (mmol/L)	1.3 ± 0.5	1.2 ± 0.5	−0.1 (−0.4, 0.2)	0.34	−0.3
HDL cholesterol (mmol/L)	1.3 ± 0.3	1.2 ± 0.3	−0.2 (−0.3, −0.1)	0.008	−1.1
LDL cholesterol (mmol/L)	3.4 ± 0.7	2.8 ± 0.8	−0.6 (−0.9, −0.3)	0.002	−1.3
Ferritin (µg/L)	230.1 ± 150.8	235.0 ± 155.1	4.9 (−32.2, 42.0)	0.77	0.1
Zinc (µmol/L)	12.9 ± 2.6	13.8 ± 4.1	0.9 (−1.0, 2.9)	0.31	0.3
Selenium (µmol/L)	1.6 ± 0.1	1.8 ± 0.2	0.2 (0.03, 0.3)	0.02	0.9
Urinary iodine [†] (µmol/L)	0.9 (0.6, 1.3)	1.0 (0.6, 2.1)	0.2 (−0.6, 0.5)	0.76	N/A

[†] Non-normally distributed variable. [a] Data are presented as mean ± SD for normally distributed values and median (IQR) for non-normally distributed values. [b] Paired differences from baseline are expressed as mean change (95% CI) for normally distributed values, and median change (IQR) for non-normally distributed values. [c] Paired sample *t*-tests were used for normally distributed variables and Wilcoxon signed-rank tests for non-normally distributed variables. [d] Effect sizes are reported as Cohen's *d* for parametric analyses. N/A Not applicable.

3.4. Dietary Quality

HEIFA-2013 scores increased by 10.8 points (95% CI 1.2 to 20.4, Cohen's $d = 0.6$, $p = 0.03$) from baseline to week 8. This improvement was primarily driven by reductions in discretionary foods ($d = 2.5$), sodium intake ($d = 2.3$) and percentage energy from saturated fat ($d = 0.9$; all $p < 0.02$; Table 4). Scores for total cereal and grain intake decreased ($d = -4.3$, $p < 0.001$), reflecting reduced total grain intake during energy restriction, but without significant change in wholegrain cereal intake ($d = -0.6$; $p = 0.08$).

Table 4. The total and component scores of the Healthy Eating Index for Australian Adults (HEIFA-2013) at baseline, weeks 2, 4, 6 and 8 ($n = 10$).

Assessed Component	Max Score	Intervention Score [a]	Baseline Score	Week 2 Score	Week 4 Score	Week 6 Score	Week 8 Score	Paired Difference in Scores [b]	*p*-Value [c]	Effect Size [d]
Discretionary foods, serves per day	10	10	1.5 ± 3.4	10 ± 0	9.5 ± 1.6	10 ± 0	10 ± 0	8.5 (6.1, 10.9)	<0.001	2.5
Vegetables, total serves per day	5	2	3.8 ± 1.4	3.5 ± 1.3	3.6 ± 1.3	3.6 ± 1.3	3.7 ± 1.3	−0.1 (−1.3, 1.1)	0.86	−0.1
Vegetables, variety	5	5	1.7 ± 0.9	1.6 ± 0.8	2 ± 0.8	1.7 ± 0.9	2.2 ± 0.6	0.5 (−0.4, 1.4)	0.24	0.5
Fruit, total serves per day	5	3.75	1.3 ± 1.6	2.3 ± 1.5	1.8 ± 1.2	1.6 ± 1.2	1.6 ± 1.8	0.4 (−1.5, 2.2)	0.66	0.1
Fruit, variety	5	5	1 ± 2.1	2 ± 2.6	2.5 ± 2.6	2 ± 2.6	2.5 ± 2.6	1.5 (−0.9, 3.9)	0.19	0.4
Cereals, total serves per day	5	0–2.5	4.6 ± 0.6	0.4 ± 0.6	1.2 ± 0.8	0.8 ± 0.8	0.8 ± 0.8	−3.8 (−4.5, −3.1)	<0.001	−4.3
Cereals, wholegrain serves per day	5	0–4	2 ± 2.6	0.3 ± 0.7	0.4 ± 0.5	0.2 ± 0.4	0.3 ± 0.7	−1.7 (−3.6, 0.2)	0.08	−0.6
Meat and alternatives, serves per day	10	10	9 ± 3.2	7.6 ± 3.1	5.8 ± 2.9	7.2 ± 2.9	7.2 ± 2.9	−1.8 (−5.0, 1.4)	0.24	−0.7
Dairy and alternatives, serves per day	10	8	0.2 ± 0.6	0.4 ± 0.8	0.4 ± 0.8	0.6 ± 1.3	0.6 ± 1.3	0.4 (−0.2, 1.0)	0.17	0.3
Proportion of water consumed relative to total beverages	5	5	3.9 ± 1.9	4.2 ± 1.8	4.1 ± 1.7	4.4 ± 1.1	4.6 ± 0.7	0.7 (−0.9, 2.3)	0.35	0.3
% total energy from saturated fat	5	5	1.3 ± 1.8	3.5 ± 1.7	3 ± 2	3.3 ± 2.1	3.8 ± 2.1	2.5 (0.4, 4.6)	0.02	0.9
Polyunsaturated and monounsaturated fats/oils, serves per day	5	0	4.8 ± 0.8	0.9 ± 1	1 ± 1.3	0.8 ± 1.1	1.3 ± 1.3	−3.5 (−4.4, −2.6)	<0.001	−2.7
Sodium, mg per day	10	0	0 ± 0	8.5 ± 3.4	8 ± 3.5	9 ± 2.1	8 ± 3.5	8.0 (5.5, 10.5)	<0.001	2.3
Added sugars, % total energy	10	10	4.4 ± 5.3	6.3 ± 4.9	5.3 ± 5.1	5 ± 5.3	3.3 ± 4.7	−1.9 (−6.8, 2.9)	0.39	−0.1
Alcohol, standard drinks per day	5	5	5 ± 0	5 ± 0	5 ± 0	5 ± 0	5 ± 0	0.0 ± 0.0	N/A	N/A
Total HEIFA-2013 score	100	69–75	43.9 ± 12	56.4 ± 8.4	53.5 ± 10.7	55.1 ± 9.8	54.7 ± 11.8	10.8 (1.2, 20.4)	0.03	0.6

[a] The score for the dietary intervention is lower than the maximum score due to the 800 kcal/day target. The diet limits vegetables to 2 serves per day, fruit to 2 serves per day, grains and cereals to 0–2 serves per day, and dairy to 2 serves per day; does not allow added fats and oils; and does not restrict added sodium in cooking or at the table. [b] Paired differences from baseline (week 8 minus baseline) are expressed as mean change (95% CI). [c] Paired sample *t*-tests were used to explore within-participant differences from baseline to week 8. [d] Effect sizes are reported as Cohen's *d*. N/A Not applicable.

3.5. Nutritional Adequacy

Participants were advised to consume a daily multivitamin and mineral supplement during the intervention, and supplement use was recorded alongside dietary intake. Although a list of recommended supplements was provided, four (40%) participants reported using a supplement outside of the recommended list. Micronutrient intake from supplements was estimated using the nutrient composition declared on each product's label, allowing the contribution from each supplement to be quantified according to its specific micronutrient content. Total nutrient intake estimates incorporated contributions from both dietary sources and reported supplement use.

Overall, the proportion of participants with intakes below the EAR was ≤50% for most nutrients, although several exceptions were noted. Calcium intake remained below recommended levels despite reported supplement use, with 90% of participants below the EAR at baseline (mean shortfall −182 ± 176 mg/day) and all participants recording intakes below the EAR at one or more timepoints. The number and proportion of participants with intakes below the EAR for each nutrient are presented in Supplementary Section S2. The magnitude of difference from the EAR is presented in Supplementary Section S2. Mean energy and nutrient intakes at each timepoint are presented descriptively in Supplementary Section S2.

3.6. Adverse Events

Symptoms reported during the intervention were mostly mild to moderate in severity. There was one report of severe decreased exercise tolerance at week 2, and severe muscle cramps at week 6; neither symptom persisted (Supplementary Section S2).

The most common symptoms were constipation and decreased exercise tolerance. Lethargy, weakness, fatigue, light-headedness, dizziness, diarrhoea, cold intolerance and dry skin were also frequently reported.

One participant experienced abdominal pain following consumption of a large, high-fat meal that exceeded the prescribed energy target. Subsequent investigation resulted in a diagnosis of cholelithiasis, which has a recognised association with weight loss.

4. Discussion

This study aimed to assess the feasibility of a pragmatic food-based very-low-energy intervention using self-selected conventional foods. Our findings demonstrated encouraging feasibility outcomes, with 100% participant retention and 90% of participants achieving the prespecified weight loss response. However, the prespecified item-level acceptability threshold was met by nine of 10 (90%) of the FAQ items, with item 7 identifying a persistent challenge in maintaining the diet when eating out. No serious adverse events considered related to the intervention prescription occurred. Exploratory analyses identified weight loss and improvements in cardiometabolic outcomes that were broadly consistent with findings reported for traditional meal replacement VLED interventions [9,35,40]. Together, these findings indicate that the intervention showed promise in terms of recruitment, retention, engagement and weight loss response, although acceptability was not consistently demonstrated across all FAQ items. The challenges associated with eating out warrant further consideration before progression to a future controlled evaluation of this intervention.

Importantly, this feasibility study demonstrated that implementing this intervention in usual living environments necessitated a pragmatic approach to energy prescription and monitoring that accounts for the inherent variability associated with selecting, preparing and estimating the energy content of everyday foods. The intervention targeted approximately 800 kcal/day while accepting reported intakes up to approximately 1000 kcal/day, reflecting the expected variability in food composition, portion estimation and estimated energy intake

under real world conditions. This pragmatic range also provided flexibility to accommodate social occasions and day-to-day fluctuations in food intake. Occasional deviations above the prescribed target were anticipated and offset by lower intakes on other days, such that mean reported energy intake remained aligned with the intended very-low-energy prescription.

Acceptability was high across nine of 10 FAQ domains. When interpreted through the Theoretical Framework of Acceptability [33], the consistently high ratings for liking, taste, appearance and overall satisfaction observed suggest favourable affective attitudes towards the intervention (Supplementary Section S3). The notable exception was maintaining the diet when eating out, indicating that external food environments imposed a burden on participants. This aligns with qualitative evidence identifying restaurants and social eating contexts as challenging for weight management due to reduced control over food choice, portion sizes and practical barriers to obtaining and using nutrition information [41,42].

The flexibility of the dietary framework, which allowed participants to self-select foods within structured energy and food group targets may have contributed to both acceptability and engagement. Similar findings have been reported across diverse food-based dietary interventions where greater flexibility appears to facilitate integration into participants' usual daily routines, dietary and cultural practices and enhance long-term acceptability [43,44]. Although meal replacement VLEDs are often appreciated for their simplicity and convenience [8], qualitative studies have also identified taste fatigue, limited flavour and texture variety and challenges in social situations [7,8], suggesting that flexibility may be an important determinant of acceptability across different delivery models.

An important feature of the present intervention was that clinically meaningful weight loss response was achieved despite participants implementing all dietary behaviours, including planning, purchasing, preparing and portioning foods within their usual living environments. Unlike meal replacement VLEDs, which minimise many food-related decisions during the intensive weight loss phase [9], this intervention required participants to repeatedly practise dietary self-management behaviours. To support implementation, the intervention incorporated evidence-based behaviour change strategies including self-monitoring, action planning, goal setting, feedback and problem solving [22,45,46], delivered through regular dietitian consultations. Participants were also aware that their food diaries were accessible in real-time by the researcher-dietitian, which may have supported self-monitoring and reinforced self-regulation [22] by fostering a sense of accountability. The behavioural and dietetic support components may have contributed to participant adherence and retention, and feasibility findings should be interpreted as reflecting the delivery of a multicomponent intervention programme comprising combined effects of the severe energy restriction with intensive professional support, rather than the dietary model alone. Together, these findings suggest that the behavioural complexity inherent in implementing a food-based very-low-energy intervention does not necessarily preclude high acceptability or clinically meaningful weight loss when appropriate support is provided. However, further research is needed to determine whether this model remains feasible and acceptable under routine clinical practice conditions where access to behavioural and dietetic support may be less intensive or unavailable.

HEIFA-2013 scores increased among participants, even though the theoretical intervention menu could not achieve the maximum possible score. This increase was primarily driven by reductions in discretionary food intake, sodium and saturated fat, indicating greater alignment with these components of the Australian Dietary Guidelines during weight loss. These findings are consistent with previous behavioural weight loss studies incorporating dietary counselling, energy prescription and self-monitoring [47,48]. However, the interpretation of HEIFA-2013 scores in the context of intensive energy restriction warrants caution. As HEIFA-2013 assesses adherence to the Australian Dietary Guidelines,

it does not account for the constraints that a prescribed energy intake may impose on the achievement of recommended serves across food groups. In the present study, the recommended serves for fruit and dairy and alternatives were difficult to achieve, potentially constraining the maximum attainable score. Consequently, an increase in total HEIFA-2013 score should be interpreted as improved alignment with certain components of the Australian Dietary Guidelines, rather than indicating an improvement across all dimensions of dietary quality. Future comparative studies should investigate whether food-based very-low-energy interventions produce different changes in dietary quality compared with traditional meal replacement approaches, and whether these changes are sustained in the longer term.

Nutritional adequacy was maintained for most nutrients, although all participants recorded calcium intake below the EAR at one or more timepoints despite reported multivitamin and mineral supplement use. However, supplements consumed generally provided little or no calcium, meaning calcium intake was derived predominantly from food sources. Low calcium intake is common in Australia with recent national data indicating that approximately 64% of adults do not meet recommended intakes [49]. The substantial energy restriction imposed by the intervention, through reduced in portion size, may further limit calcium intake. Future iterations of the intervention should consider incorporating strategies to improve calcium adequacy, such as greater emphasis on calcium-rich or calcium-fortified foods or calcium-containing supplements.

Lastly, participants reported several adverse symptoms known to be associated with rapid weight loss including severe decreased exercise tolerance, severe muscle cramps, and one diagnosis of cholelithiasis. While no serious intervention-related adverse clinical outcomes were observed over 8 weeks, these symptoms suggest detailed clinical monitoring is needed in future trials.

This study has several limitations. Firstly, this was a small, single-arm feasibility study of short duration, precluding conclusions regarding long-term effectiveness or weight maintenance. The absence of a comparator group means that the observed changes cannot be attributed solely to the intervention.

Dietary intake was self-reported and may be subject to measurement error and reporting bias, despite instruction to weigh foods. Diet quality was assessed using different assessment methods at baseline and week 8. Differences in reporting and measurement error may have influenced the HEIFA-2103 scores. Therefore, changes in diet quality should be interpreted cautiously, as some observed differences may reflect difference in dietary assessment methods rather than changes in dietary intake alone. Supplement choice was not fully standardised, which may have contributed to the variability in micronutrient intake.

All participants in the final sample were self-selected and highly motivated, all had post-secondary education, and most had some responsibility for food shopping and preparation within their household and enjoyed food preparation. Participants were also reimbursed for travel expenses. These characteristics may limit the generalisability to broader populations in routine clinical practice, particularly given the practical demands of independently planning, purchasing, preparing and portioning and monitoring food intake. Accordingly, the feasibility of this approach may not translate directly to individuals with lower health literacy, fewer food preparation skills, socioeconomic constraints or limited access to dietitian support.

Given the small sample size of 10 participants, all clinical analyses were exploratory and should be interpreted as hypothesis-generating. As no adjustment for multiple comparisons were performed, statistically significant findings should not be interpreted as confirmatory evidence of intervention effects.

Furthermore, although designed for implementation in participants' usual environments, the intervention was delivered under research conditions with regular dietitian support, and all screening, intervention delivery and outcome assessments were conducted by a single, unblinded researcher-dietitian (S.W.Y.P.). This introduces a potential source of assessment (non-blinding) bias and may limit the generalizability of the findings to standard clinical, community or primary healthcare settings. Future studies may benefit from incorporating theory-informed acceptability measures from the Theoretical Framework of Acceptability [33] to provide a more comprehensive understanding of factors influencing acceptability.

5. Conclusions

In conclusion, this study demonstrated encouraging preliminary feasibility and tolerability of a pragmatic 8-week food-based very-low-energy intervention using self-selected conventional foods within participants' usual living environments. In this small, selected sample, the intervention was implementable under closely supported research conditions with high retention, engagement, and a high proportion of participants achieving the prespecified weight loss response. These findings support further investigation of this approach in adult weight management settings but do not establish broader clinical feasibility or safety of the approach. The prespecified item-level acceptability threshold was not met for all FAQ items, highlighting the need to address challenges associated with eating out. By requiring participants to engage with food selection and preparation during active weight loss, this approach offers a model to investigate whether behaviourally supported practice of dietary self-management skills contributes to longer-term weight maintenance. Larger controlled trials are needed to determine comparative effectiveness relative to traditional meal replacement VLEDs, evaluate safety and adverse events, assess longer-term outcomes, and incorporate strategies to support eating out and optimise calcium adequacy.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/nu18223775/s1. Supplementary Section S1: Description of the Intervention; Supplementary Section S2: Additional data tables and figures; Supplementary Section S3: Mapping of the Food Acceptability Questionnaire and Theoretical Framework of Acceptability [12,14,17,21–24,30,33,50–55].

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Abbreviations

The following abbreviations are used in this manuscript:

ACTRN	Australian New Zealand Clinical Trials Registry
AI	Adequate Intake
BMI	Body Mass Index
CONSORT	Consolidated Standards of Reporting Trials
EAR	Estimated Average Requirement
FAQ	Food Acceptability Questionnaire
IQR	Interquartile Range
HEIFA	Healthy Eating Index for Australia
RDI	Recommended Dietary Intake
SD	Standard Deviation
TFA	Theoretical Framework of Acceptability
VLED	Very-Low-Energy Diet

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