

Improving diet quality of people living with obesity: Protocol for a randomized controlled trial to build effective dietetic service delivery using technology in a primary health care setting

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Abstract

Background: Almost a third of Australian adults are living with obesity, yet most cannot access medical nutrition therapy from dietitians i.e., the health professionals trained in dietary weight management services. Across the health system, primary care doctors readily identify people who may benefit from weight management services but there are limited referral options in the community. Dietitians are trained to provide evidence informed dietary treatment of overweight and obesity but are underutilized and under-resourced. The chat2 (Connecting Health and Technology 2) trial will test combining new technologies for dietary assessment with behavior change techniques to improve outcomes for people living with obesity.

Objective: To compare the effectiveness of a one-year digital dietary intervention with standard care on body weight reduction and improved diet quality, in adults living with obesity delivered by dietitians in a primary care setting.

Methods: This randomized controlled trial (RCT) will compare a 1-year digital tailored feedback dietary intervention with a control group in 430 adults living with obesity (body mass index (BMI) ?30 to ? 45 kg/m²). The primary outcomes measured at a baseline, six and 12 months, are changes in body weight and diet quality score (DQS). A four-day image-based dietary assessment tool (mobile Food Record; mFR) will be used to measure DQS. Secondary outcomes include dual-energy

absorptiometry (DXA) body composition, total cholesterol, triglyceride, low-density lipoprotein (LDL), high-density lipoprotein (HDL), glycated hemoglobin (HbA1c) and fasting glucose. The intervention group will receive eight video counselling sessions with a trained dietitian delivered over 12 months to support dietary behavior change and relapse prevention. Both groups will receive feedback on their clinical chemistry and DXA scans at each timepoint.

Results: Participant recruitment commenced in July 2023 and will end in August 2024. Data analysis will commence in 2025, with the anticipated publication of results in 2026.

Conclusions: If found to be effective, the results of this RCT will support the delivery of effective evidence-based weight management advice using new technologies. By improving community access to high quality dietetic services, it will ensure more effective utilization of the dietetic workforce to improve outcomes for people living with obesity. Clinical Trial: Australian New Zealand Clinical Trials Registry ACTRN12622000803796.

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Original Manuscript

Protocol

Improving diet quality of people living with obesity: Protocol for a randomized controlled trial to build effective dietetic service delivery using technology in a primary health care setting.

Abstract

Background:

Almost a third of Australian adults are living with obesity, yet most cannot access medical nutrition therapy from dietitians i.e., the health professionals trained in dietary weight management services. Across the health system, primary care doctors readily identify people who may benefit from weight management services but there are limited referral options in the community. Dietitians are trained to provide evidence informed dietary treatment of overweight and obesity but are underutilized and under-resourced. The chat2 (Connecting Health and Technology 2) trial will test combining new technologies for dietary assessment with behavior change techniques to improve outcomes for people living with obesity.

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Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12622000803796.

Keywords: obesity; diet; diet quality; digital behavioral interventions; health behavior change; mHealth; eHealth; mobile food record; telemedicine; weight management.

Introduction

The high and increasing prevalence of obesity across the world is a major challenge for health care

delivery and confers substantial burden to individuals and the healthcare sector. The effects of obesity are widely recognized as one of the leading health concerns, affecting all age and socioeconomic groups [1]. For example in Australia, overweight and obesity and dietary risks collectively account for nearly half of the 38% of the preventable burden of disease, with overweight and obesity the leading contributor to non-fatal burden [2]. In tandem, direct health-care costs associated with obesity-related conditions such as cardiovascular disease, respiratory disease, type 2 diabetes, and some cancers are rising with an unequal distribution with level of socioeconomic disadvantage [3, 4]. Almost a third (31%) of Australian adults are living with obesity, yet most are unable to access weight management services. An urgent priority for health service delivery is to identify the most cost-effective approach to delivering evidence-based weight management.

Primary care is a critical component of addressing obesity and requires a person-centered approach to treatment [5]. This includes changing the weight-stigmatizing narrative amongst health professionals working with people living with obesity [6]. Treatment guidelines for obesity are evaluated by the person's BMI and the severity of obesity-related complications [5]. Intensive interventions involving very low energy diets, pharmacology or bariatric surgery are indicated with BMI ≥ 40 kg/m² and obesity related complications [5]. Whereas, for people with BMIs between 30-40 kg/m² without complications, supervised lifestyle interventions to achieve 10% initial weight loss are recommended [5]. However, unfortunately in Australia, there are limited referral options for weight management in the community. Publicly supported bariatric surgery waiting lists are long and triaged to those with a BMI ≥ 40 kg/m² with obesity related complications, and while recently pharmacological treatments have been increasingly used in the treatment of obesity [7], issues with availability and cost limits access to these pharmacological treatments. In addition, not everyone has access to or wishes to choose the pharmacological pathway. Therefore, continued research on behavioral lifestyle interventions is needed as they remain the first line treatment for people living with obesity [7].

Lifestyle modification is a fundamental component of weight management. The most effective interventions to date have used behavioral strategies to support people to achieve energy reduction [8]. Guidelines for comprehensive weight management interventions identify the importance of personal counselling to achieve a clinically significant 5 % weight loss to confer health benefits, including lowering blood pressure or delaying progression to type 2 diabetes [9]. In a review of primary care interventions for obesity, intensive counselling (≥ 12 sessions per year), delivered face-to-face, by phone, or electronically, produced weight loss of four to seven kilograms (kg) compared to low dose counselling (≤ 12 sessions per year) without behavioral strategies resulted in only modest losses of one to two kg [8] supporting the value of higher intensity behavioral interventions.

Behavioral interventions for weight management are complex and may include a range of components and modes of delivery. Factors associated with greater effectiveness include changes in diet, provision of meal replacements and whether the program was delivered by a dietitian or psychologist [10]. A systematic review of weight management interventions demonstrated that those provided by a dietitian resulted in improvements of BMI and other cardiometabolic outcomes compared with control conditions [11]. Behavioral strategies of these weight management interventions, however, were not explored. Teasing out the behavioral components of interventions is important to discover the most effective behavior change techniques. In a review of behavioral interventions in type 2 diabetes frequent feedback and support was associated with weight reduction [12].

To date, few studies have examined the combined effectiveness of behavior change techniques with new cutting-edge digital technologies and medical nutrition therapy (MNT). Digital technologies are

effective in supporting weight loss, particularly when combined with personalized feedback [13]. One of the challenges for dietitians in working with individuals living with obesity is the ability to easily and accurately assess diet and dietary behaviors; an important component of personalized advice. Another consideration is people's willingness to record their dietary intake. An image-based dietary record app with time and date stamp data, termed the mobile food record (mFR) has been shown to be feasible for dietary assessment and feedback, a key component for changing dietary behaviors [14, 15]. The content of the images is confirmed either by the participant or by novel automated methods using computer vision and machine learning techniques under development [16, 17]. An additional technological intervention feature is the use of video conferencing. Improving access to weight management advice, through video conferencing, may assist people in managing their weight, but is yet to be fully evaluated. This study will provide the first test of these digital technologies in people living with obesity in Australia. The study is designed on key components of effective weight management interventions that includes behavioral strategies guided by the Capability Opportunity Motivation (COM-B) model [18], and the behavior change techniques; self-monitoring, goal setting, and individually tailored feedback on dietary behaviors [15, 19-21]. The objective is to compare the effectiveness of a one-year digital dietary intervention on body weight reduction and improved diet quality, in adults living with obesity delivered by dietitians in a primary care setting, to a control group.

Methods

Study Design

The chat2 study is a 1-year RCT. Consenting participants will be randomized (1:1) to an intervention or minimal intervention control group (Figure 1). Assessments will occur at 0, 6 and 12 months with the primary outcome assessed at 12 months. The project protocol has been approved by the Curtin University Human Research Ethics Committee (approval number HRE2022-0059) and the Department of Health WA Human Research Ethics Committee (PRN: RGS0000005490). The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622000803796).

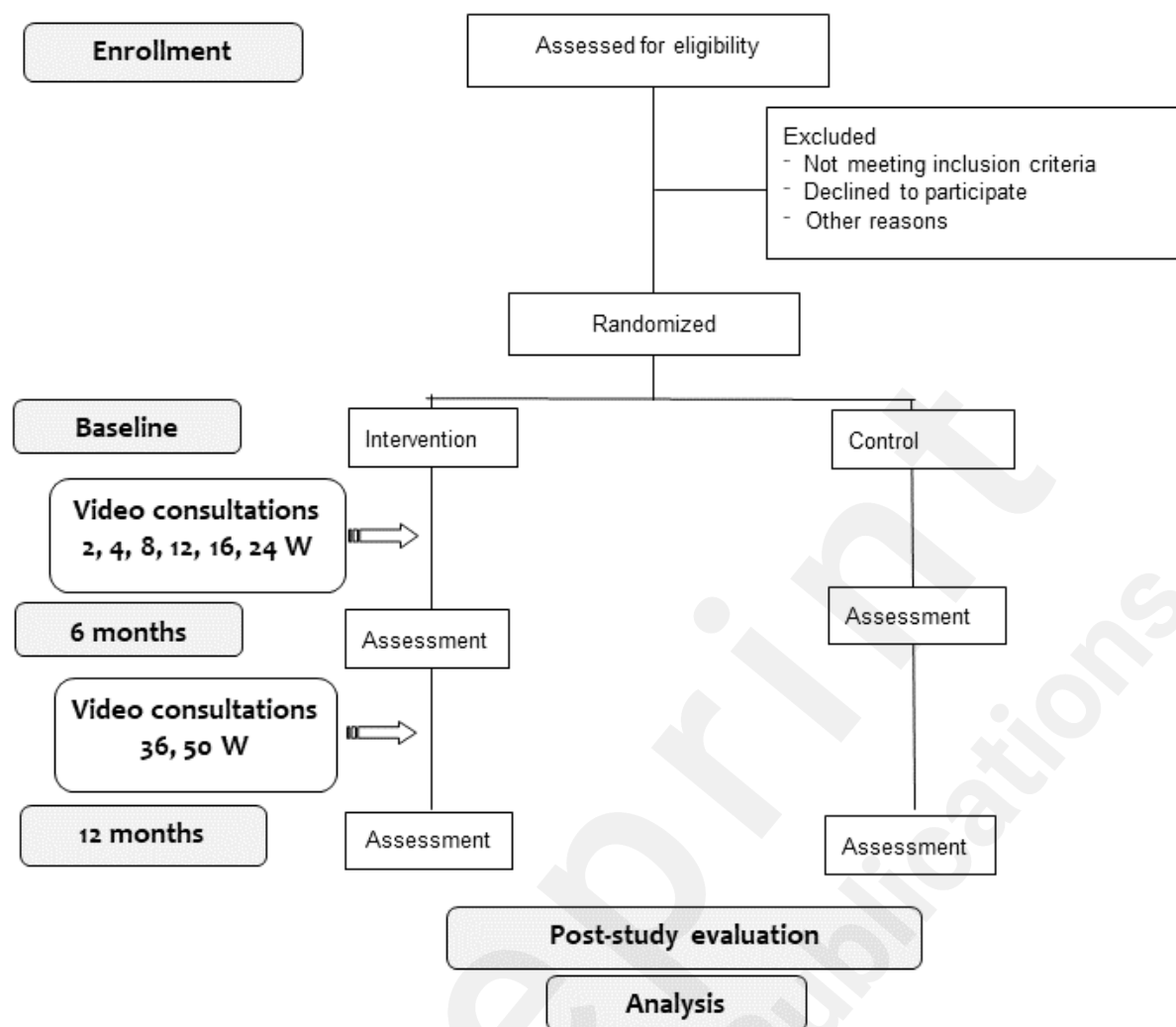


Figure 1. Study design with randomization to two groups: intervention and control groups. W refers to study weeks.

Consumer engagement

Engaging with health consumers alongside doctors and health professionals in weight management is a novel and strategic approach to this complex health issue. Using a systems approach provides opportunities for people with lived experience, health professionals and policy makers to work together to take positive action to address the complex issue of weight management. A systems science group model building approach was used to develop the East Metropolitan Health Service (EMHS) Obesity Prevention Strategy, to co-create a shared understanding of the complex issue of obesity, its causes and consequences, and feasible solutions [22]. Health service executives, clinicians, allied health, and representatives from community service providers, government and non-government agencies identified the gap in services for people living with obesity and prioritized action to address this.

This intervention design was developed in partnership with EMHS and informed by the Western Australian (WA) Healthy Weight Action Plan, led by the WA Health Department's partnership with the WA Primary Health Alliance and the WA Health Consumers' Council [23]. This partnership ensured that peoples' lived experiences were central in the research. Since 2018, the WA Health

Consumers' Council has conducted several engagement activities to ensure the voices of people with lived experience of overweight and obesity were key drivers of change. A review of weight-management services by this group identified gaps in service delivery, including the lack of supported behavior change programs for weight management, absence of clear referral pathways, and limited access to a skilled workforce in weight-management care. The current study will recruit a panel of health consumers who have lived experience of overweight and obesity as members of the project advisory board to ensure that their perspective and voice is considered at all stages of the project. Their role will include reviewing all study materials, including ethics documents, study website design and recruitment strategies and materials. In addition, the project team and consumers will work to ensure the trial is respectful, recognizing that participants are likely to have experienced the negative consequences of weight stigma on their health [6].

Setting

The study setting will target recruitment in the EMHS catchment, one of four publicly funded health service areas in Perth, Western Australia (WA). EMHS is responsible for the maintenance and improvement of the wellbeing and health of 725,000 people, approximately a third of the population of WA, residing within its catchment. This is achieved through the provision of an extensive health network including tertiary, secondary, specialist, community, and population health services. The EMHS catchment has the highest prevalence of overweight/obesity, in the Perth metropolitan area, where 77 % of adults live with overweight or obesity (43 per cent live with obesity) [24, 25].

Recruitment

Participants will be recruited by letters sent to individuals randomly selected from the electoral roll in Perth to provide representation across all socio-economic status groups. Electoral roll recruitment is a feasible and effective recruitment method previously used by the research team [15]. The mail out will be staggered so that recruitment occurs over 12 to 18 months with a target of 25 participants per month. This will ensure adequate resourcing and staffing for the study. Other recruitment methods will supplement the mail out and will include EMHS hospital sites displaying posters and recruitment postcards, newsletters sent to primary care doctors, practice managers, EMHS, and university newsletters and unaddressed mailbox delivery to residential street points in suburbs located in the EMHS catchment area. Quota sampling will ensure equal numbers between study groups and gender. After receiving the letter of invitation, those who wish to take part in the study will contact the research team by email, mobile telephone (text or voice), or the study website where they will be directed to the information statement, and an online screening questionnaire.

To be eligible, participants must be aged 18-65 years, have a self-reported BMI ≥ 30 to ≤ 45 kg/m², own a mobile telephone with internet access, and be able to attend the study center in metropolitan Perth for all four visits. Participants will be excluded on the basis of serious illness or medical conditions including diabetes requiring insulin, medical dietary restrictions (e.g. low potassium diet for renal failure), receiving counselling from a dietitian, had or planned to have surgical intervention for weight management in the next year, severe heart conditions (e.g. cardiac failure requiring fluid restriction, a stroke or myocardial infarction in the previous six months), severe life limiting illness receiving palliative treatment (e.g. cancer, cirrhosis, pulmonary disease or heart failure), currently taking or plan to take weight loss medication in the next 12 months, pregnancy or breastfeeding, or planning to become pregnant or breastfeed in the next year, receiving treatment for an eating disorder, or unable to participate in telehealth dietary consultations.

Randomization

Block randomization will be used with allocation concealment from the active research team via the

use of sealed opaque envelopes. The randomization will be in blocks of four, with stratification by gender (male, female, other) where participants will be assigned to either the intervention or minimal intervention control groups (1:1). Sequence generation will be conducted prior to the commencement of the study by a statistician using a randomization table created in Stata (version 18, StataCorp, College Station, TX). The electronic file will be kept in a secure password-protected server by the statistician. Randomization will occur at the second study visit to assign participants to either the intervention or control groups. On opening the randomization envelope, the participant will inform the research staff which group they are allocated to. Due to the nature of the intervention, it is not possible to blind participants or researchers to the intervention group post allocation but the primary outcome is objective (body weight).

Data-collection procedures

Eligible participants will be notified via email and invited to attend two baseline in-person visits one week apart. Prior to the first visit, participants will be asked to complete an online questionnaire (including ethnicity, education, employment, postcode, alcohol use, smoking, physical activity, eating and dietary habits, motivation, and weight loss history), as detailed in Table 1. At the baseline visit, participants will be asked to fast overnight prior to a blood test, whole-body composition DXA scan and measured height and weight. They will receive training on how to record their dietary intake by taking images using the mFR. They will be asked to return approximately one week later, where they will receive a copy of their DXA scan and blood tests. They will be interviewed by the research dietitian to clarify the content of their mFR images, and probe for missing data. Participants will undergo randomization to the intervention or control groups. The assessments will be repeated for both groups at six and twelve months (Table 1). Participants will be asked to keep an Adverse Events Diary (for example, hospital admissions, illness or changes to medications) for the duration of the study that will be reviewed at the six- and twelve-month study assessment visits. Participants will be encouraged to discuss their involvement with their primary care doctor, who will be notified by the research team that their patient has volunteered and provided with blood test results, information about the trial, and contact details of the research team via a secure facsimile.

Both intervention and control group participants will be provided with a study booklet with information on healthy eating from the Australian Dietary Guidelines (ADG) website [26]. This will include healthy eating information on food groups, serving sizes, links to recipes, and label reading.

Table 1. Frequency of assessment variables for the chat2 study intervention, and control groups.

Variables	Group	Baseline	6 months	12 months
Weight – height, weight (measured at clinic visit)	I ^a , C ^b	Yes	Yes	Yes
Body composition – whole body Dual-X-ray-Absorptiometry (DXA) Scan of regional/total body fat (including visceral body fat)	I ^a , C ^b	Yes	Yes	Yes
Adverse events diary	I ^a , C ^b	Yes	Yes	Yes
Dietary intake – four-day mFR	I ^a , C ^b	Yes	Yes	Yes
mFR usability to assess user feedback and method preference [14, 27]	I ^a , C ^b	Yes	Yes	Yes
Blood sample – total cholesterol, triglyceride, LDL/HDL cholesterol, fasting glucose, glycated	I ^a , C ^b	Yes	Yes	Yes

hemoglobin.				
Health status EQ-5D, a 5-item scale to assess utility and health-related quality of life [28]	I ^a , C ^b	Yes	Yes	Yes
Sociodemographic and personal characteristics assessed via questions on sex, age, eating behavior, educational level, country of birth, ethnicity, socioeconomic status, financial status	I ^a , C ^b	Yes	Yes	Yes
18-item food insecurity [29]	I ^a , C ^b	Yes	—	—
Self-report Habit Index Score [30]	I ^a , C ^b	Yes	Yes	Yes
Creature of Habit questionnaire [31]	I ^a , C ^b	Yes	Yes	Yes
Self-reported physical activity assessed via The International Physical Activity Questionnaire (short form) [32]	I ^a , C ^b	Yes	Yes	Yes
Depression, anxiety, stress scale, with 21 self-report items to assess severity of depression, anxiety, and stress [33]	I ^a , C ^b	Yes	Yes	Yes
Weight-loss history, an 8-item tool to assess previous weight loss history [34]	I ^a , C ^b	Yes	—	—
The Health Care Climate Questionnaire [35]	I ^a	—	—	Yes
Personalized Nutrition Questionnaire (PNQ) [21]	I ^a	Yes	Yes	Yes

^aI: intervention.

^bC: control.

Dietary assessment and analysis

Participants will be provided with access to the mFR application on their mobile device to record their dietary intake at baseline, six and twelve months (Figure 2) [16, 36]. They will be asked to take “before eating” and “after eating” images of all foods/beverages consumed over four consecutive days, including one weekend day. The mFR app communicates with a dedicated cloud-based server for the storage and processing of images via Wi-Fi or 4G/5G network. A fiducial marker is included in the image to allow improved accuracy for quantifying dietary intake [37-39]. Participants will label the content of their images, referred to as mini labels. When the participant starts typing the word, a list of foods will appear where they can select from a list of approximately 800 food and beverages items. These labels link to a food composition database (not visible to the participant) with the food code, detailed description, energy and nutrient composition [40]. These mini labels will be linked to a code for estimating food group serves to enable a food-based assessment. At the study visit, the research dietitian will review the images with participants through the Web and probe for food and beverage items not recorded (Figure 2). The data from the mFR will be entered into a purpose-built Microsoft Access database platform to assess the food group serves.

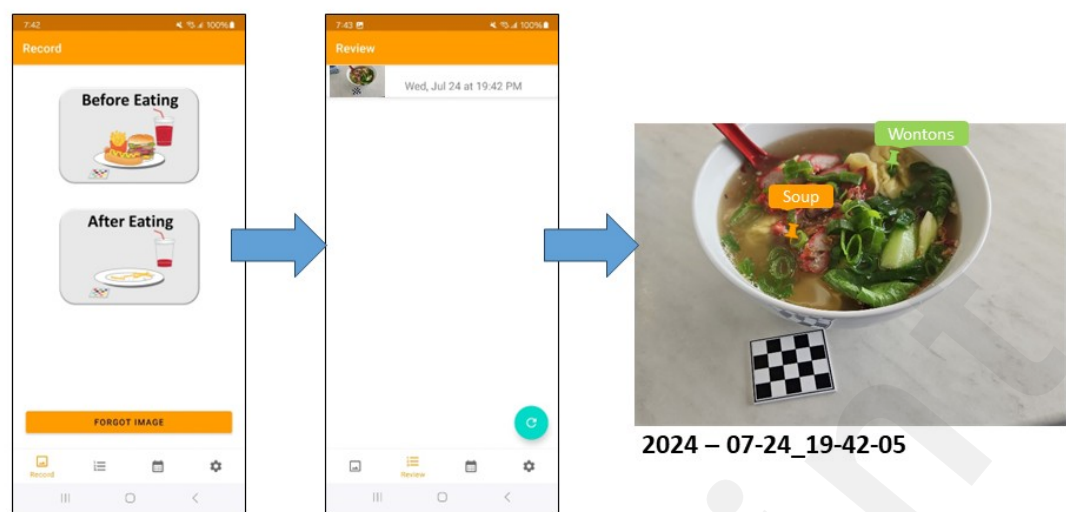


Figure 2. Review process for viewing a labeled eating occasion with colored labels identifying the foods and time and date stamp displayed.

Diet Quality Scoring (DQS)

Analysis of the four-day mFR will be undertaken by the research dietitian and a food-based DQS will be calculated (Table 2). In addition to energy reduction, this study will assess diet quality, as there is emerging evidence that diet quality, particularly reduced ultra-processed foods have a role in energy balance [41, 42]. The 11-component DQS is based on the Australian Dietary Guidelines (ADG) [26] and adapted from two food-based indexes developed for Australian adults [43, 44]. The DQS uses a continuous weighting system based on increments of food group serves, or proportions of total intake for behaviors without set recommendations, such as variety of fruits and vegetables. For core food groups such as fruits and vegetables, the maximum weighting assigned to the item is determined by the ADGs recommended daily serves. To achieve weight reduction consistent with study goals, discretionary foods, and beverages will be split into separate components. Reverse scoring is assigned for discretionary (energy-dense, nutrient-poor) foods, sugar-sweetened beverages, and alcoholic beverages, where a maximum score of 10 points is achieved with zero serves. The DQS at baseline and 6 months will be provided to the study dietitians to be relayed to intervention group participants in the video consultations.

Table 2. Diet Quality Scoring calculated from average daily serves based on the Dietary Guidelines for Australia. Total maximum score of 100 points from 11 components.

Item Description	Minimum score	Composite scores	Maximum score
Fruit			
	0 to < 0.5 serves (0 points)	≥0.5 to < 1.0 serves (2.5 points) ≥1.0 to <1. 5 serves	≥2 serves (10 points)

		(5 points) ≥1.5 to <2.0 serves (7.5 points)	
Vegetables and legumes/beans			
	0 to < 1.0 serves (0 points)	≥ 1.0 to < 2.0 (2 point) ≥2.0 to < 3.0 serves (4 points) ≥3.0 to <4.0 serves (6 points) ≥4.0 to <5.0 serves (8 points)	≥5 serves (10 points)
Variety of fruits			
	0 type (0 points)	1 type (1 point) 2 types (2 points) 3 types (3 points) 4 types (4 points)	5 or more types (5 points)
Variety of vegetables			
	0 type (0 points)	1 type (1 point) 2 types (2 points) 3 types (3 points) 4 types (4 points)	5 or more types (5 points)
Lean meat, poultry, fish, eggs, nuts, seeds, legumes/beans (women)			
	>2.5 serves or < 0.5 serves (0 points)	≥0.5 to < 1.0 (2 points) ≥1.0 to < 1.5 (4 points) ≥1.5 to < 2.0 (6 points) ≥2.0 to <2.5 (8 point)	2.5 serves (10 points)
Lean meat, poultry, fish, eggs, nuts, seeds, legumes/beans (men)			
	>3 serves or < 1.0 serves (0 points)	≥1.0 to < 1.5 serves (2 points) ≥1.5 to <2.0 serves (4 points) ≥2.0 to < 2.5 serves (6 points)	3 serves (10 points)

		≥2.5 to < 3.0 serves (8 point)	
Milk, yoghurt, cheese and/or alternatives			
	(<0.5 serves = 0 points)	≥ 0.5 < 1.0 serves (2 points) ≥ 1 to < 1.5 serves (4 points) ≥ 1.5 to < 2.0 serves (6 points) ≥ 2 to < 2.5 serves (8 points)	≥ 2.5 serves (10 points)
Grain (cereal) foods, mostly wholegrain and/or high cereal fiber varieties			
	<1.0 serves or > 6.0 serves (0 points)	≥1.0 to < 2.0 serve (1 point) ≥2.0 to < 3 serves (2 points) ≥3.0 to < 4 serves (5 points) ≥4.0 to < 5 serves (6 points) ≥5.0 to < 6 serves (8 points)	6.0 serves (10 points)
Discretionary foods			
	≥2.75 serves (0 points)	≥1.75 to <2.75 serves (2 points) ≥0.75 to <1.75 serves (4 points) > 0 to < 0.75 serves (8 points)	0 serves (10 points)
Sugar-sweetened beverages			
	≥2 serves (0 points)	≥1.25 to <2 serves (2 points) ≥0.5 to <1.25 serves (4 points) > 0 to < 0.50 serves (8 points)	0 serves (10 points)
Alcoholic beverages			
	≥2 serves (0 points)	≥1.25 to <2 serves	0 serves

		(2 points) ≥0.5 to <1.25 serves (4 points) > 0 to <0.50 serves (8 points)	(10 points)
Plain water			
	< 1 cup (0 points)	≥ 1 to 3 cups (2 points) ≥ 3 to 5 cups (6 points) ≥ 5 to < 8 cups (8 points)	≥ 8 cups (10 points women) ≥ 10 cups (10 points men)

Intervention features

The intervention features, content and behavior change techniques to be implemented are shown in Table 3. The selection of intervention features and strategies is guided by the COM-B model [18]. The COM-B model identifies behavioral targets when developing interventions and focuses on three factors required to change behavior: capability, opportunity, and motivation. Performing a behavior requires individuals to be capable or have physical and psychological abilities (e.g. nutrition knowledge, cooking skills). Opportunity includes both practical and social aspects (e.g. access to healthy foods, supportive environments and social norms). Whilst motivation comprises automatic drivers like habits as well as beliefs, emotions, impulses, reflective processes such as intentions and planning. Behavior change techniques will include feedback, self-monitoring, feedback on performance, goals/planning, repetition, and substitution/habit formation [20].

Table 3. Overview of the study goals and intervention features, content and behavior change techniques.

Goal	How to achieve	Behavior change techniques [20]
1. Achieve a reduction in body weight by at least 5% in 12 months		
	1. Avoid or limit discretionary foods, sugary drinks and alcohol. 2. Eating less at meals and snacks (except for vegetables and salad) 3. Eating less often (avoid snacking – except for vegetables and salads)	Feedback - Diet Quality Score from mFR ^a
2. Improve diet quality score (DQS)		
	1. Eat from each of these five food groups with more variety	Feedback and self-monitoring - Diet Quality Score from mFR

	(especially vegetables and fruit) every day: <ul style="list-style-type: none"> • Vegetables and legumes/beans, including different types and colors, and legumes/beans • Fruit – choose fresh fruit as much as possible. • Grains (cereal) foods, mostly wholegrain and /or high cereal fiber varieties. • Lean meats and poultry, fish, eggs, tofu, nuts, and seeds, and legumes/beans (e.g. kidney beans, chickpeas, lentils and other beans). • Milk, cheese, yoghurt and /or alternatives, mostly reduced fat. 2. Drink more plain water (no added flavors) 2.1-2.6 L/day (8-10 cups)	
3. Behavior change		
	1. Find your motivation 2. Plan to make changes 3. Set SMART ^c goals 4. Build healthy habits	1. Questionnaire for current barriers and enablers to eating behavior change and some goals (PNQ ^b). 2. Goals and Planning – action planning, commitment, goal setting, problem solving. 3. Goals and planning – action planning, commitment, goal setting problem solving, coping planning, implementation intentions. 4. Repetition and substitution – habit formation.

^a mFR mobile food record.

^b PNQ personalized nutrition questionnaire.

^c SMART Specific, Measurable, Achievable, Relevant, and Time-Bound.

Intervention group

Participants allocated to the intervention group will be offered eight video consultations (approximately 20 to 45 minutes based on intervention stage) with a dietitian for the first six months (at 2, 4, 8, 12, 16, 24 weeks) to provide support and guidance for unhelpful behaviors (e.g., emotional eating) and additional maintenance calls (relapse prevention and coping planning) at 9 and

12 months (8 in total). This number of individual contacts was chosen as a balance between recommendations [9] and practical service delivery costs. Prior to selected telehealth consultations participants complete the Personalized Nutrition Questionnaire (PNQ) to identify and prioritize self-perceived factors impacting on their eating behaviors [21]. The PNQ is a tool designed to support the dietitian during consultations by collecting information on barriers prior to the session. Based on the COM-B framework [18], the PNQ has been used with a variety of groups to support dietitian-led telehealth consultations [45-47]. The MNT consultation will cover dietary feedback focusing on their diet quality score, goal setting, and behavioral strategies. Feedback will be formulated from analysis of the mFR and will focus on key dietary messages (Table 3). The content will address each participant's personal barriers to changing dietary behaviors, reinforce capability, motivation, and guide adoption of health-enhancing habits.

Control Group

The control group will complete all measures, and will be provided with a standard care study booklet using information from the Australian Dietary Guidelines website [26]. At the end of the study, control group participants will receive personalized feedback on their outcomes, including their dietary feedback report.

Dietetics training and consultations

Research dietitians will undertake 8 hours of in-person training, prior to their consultations with participants. The training will include approximately two hours of self-paced recorded online training in the dietitian's own time and six hours of online or in-person workshops. The training will include current evidence-based practice for people living with obesity, addressing weight bias/stigma, study design, ethics, mFR technology/study systems, documentation and fidelity of implementation adherence. Study dietitians will complete online training in motivational interviewing in health care [48]. The behavior change training conducted by the health psychology team will be guided by the COM-B Model, and embedded with behavior change techniques [49]. A follow-up booster session will be conducted midway through the intervention. Standard guides will be developed for each of the eight consultation sessions by the research team. Dietitians will use the consultation guide for each session, record attendance and contact participants for missed sessions. The style of communication will be consistent with self-determination theory and motivational interviewing principles [15, 50, 51]. Fidelity of implementation adherence will be guided by a conceptual framework for implementation fidelity [52] (i.e. adherence to the guide as prescribed, quality of delivery) and will be assessed for dietitians using measures of fidelity and engagement [53]. Practice management software for allied health professionals [54] will be used to manage appointments, document attendance, record treatment notes, access anthropometry, DQS, PNQ and blood test results. Study dietitians will document each of the eight sessions according to the Nutrition Care Process: Nutrition Assessment, Nutrition Diagnosis, Nutrition Intervention, Nutrition Monitoring and Evaluation [55, 56]. They will also document behavior change techniques implemented according to COM-B [20].

Process evaluation

A process evaluation will be undertaken to evaluate the implementation and impact of the intervention (i.e. fidelity, dose and reach) using the UK Medical Research Council evaluation framework [57]. Additional components relevant for digital interventions will assess acceptability, engagement, effectiveness and sustainability. A questionnaire will be used to evaluate participants' perception of the intervention (i.e., dietetic video consults, feedback, usefulness of advice, suitability, and relevance to age group). Both intervention and control participants will evaluate their perceptions of intervention features (i.e., receiving results of blood tests, and whole body DXA

scans).

Post-study qualitative interviews

At the completion of the study, approximately 20 qualitative interviews will be conducted with intervention and control participants using video conferencing. The interviews aim to assess participant experiences, the intervention impact and perceptions of various strategies and study materials. The questions will also examine intervention features influencing participants' motivation, capability and opportunity to change their eating behaviors. Recruitment will be purposeful to include both those experiencing weight loss and no weight loss. Discussions will be audio-recorded and transcribed verbatim by a professional transcription service. Thematic analysis using NVivo software will be used to analyze transcripts. Analysis will involve thoroughly reading interview transcripts and writing notes, coding relevant sections of the transcripts, generating themes from coded data based on observed patterns, reviewing, clarifying, and labelling generated themes, and presenting findings [58].

Statistical Analysis

The primary outcome is a change in weight at 12 months for both groups. Secondary outcome variables are changes in DQS, body fat (DXA derived), total cholesterol, triglyceride, LDL/HDL cholesterol, fasting glucose and HbA1c. It is hypothesized that at 12 months the intervention group will achieve at least a 5% reduction in body weight. Data on change in outcome variables in each of the two groups will be compared using general linear models after adjusting for covariates. Assumptions of the analyses will be assessed by examining residuals. Data will be transformed if assumptions of the analyses are not satisfied. Possible covariates will include age, sex, country of birth, ethnicity, highest education level, socioeconomic index for area, and baseline value of the variable analyzed. P-values < .05 will be considered statistically significant. Effect size of differences between groups will be expressed as adjusted mean difference and associated 95% CIs. Data on change in outcome variables post-intervention and follow-up time points will also be converted into binary categorical variables and analyzed using multivariable logistic regression and generalized estimating equations. Odds ratio and associated 95% CIs will be reported.

Sample size

A sample size of 342 participants (n=171 per group) will have 90% power to detect a difference in change between arms of at least 5% of body weight at 12 months. between groups, using a conservative estimate of standard deviation, at 90% power and 5% level of significance. Assuming 20% of participants are not followed up, this would necessitate 430 (215 in each group) participants to be recruited. Difficulties in obtaining sufficient number of participants in weight management trials is well documented [11]. Assuming an 8% change in weight and 20% dropout would require 170 participants. Estimates of means and standard deviations, including percentage dropout, were obtained from existing trial data for this study's power calculation.

Economic Evaluation

A stepped cost-effectiveness analysis of the two arms (intervention with control) will be conducted. The economic evaluation will consider the relative costs and outcomes of the intervention from the health and social care perspective. For the final step, to facilitate a cost-utility analysis, the EQ-5D will be administered to capture quality of life [28]. The five-level version more sensitively captures changes in health-related quality of life. Incremental quality-adjusted life years will be estimated for both groups. Incremental costs, collating the time needed to provide tailored advice, medication and self-estimated weekly food expenditure will allow economic evaluation from the perspective of the health system and the broader society (by considering all costs). Univariate and multivariate

sensitivity analyses will be undertaken. In particular, the impact of different methods of extrapolating costs and outcomes beyond the horizon of the trial will be assessed. The costing model will include resources required to assess ongoing maintenance of the mFR, including changes because of upgrades to operating systems. The major cost of the intervention is likely to be the provision of dietetic counselling (research personnel and research platform costs). This will be estimated by recording time spent deconstructing the mFR data, and then interpreting data and constructing appropriate feedback.

Results

Participant recruitment commenced in July 2023 and will end in August 2024. Recruitment will be staggered over 12 to 14 months. Data analysis will commence in 2025, with the anticipated publication of results in 2026.

Discussion

Principal Outcomes

This RCT will compare the effectiveness of a one-year digital tailored dietitian-delivered feedback dietary intervention with standard care in adults living with obesity (BMI ≥ 30) in a primary care setting. Specifically, this project addresses a gap in dietetics service for the delivery of telehealth weight management care in the community. A key outcome of this research is to improve the primary care referral pathway for patients living with obesity by improving community access to high quality dietetic services. This includes resourcing dietitians with a digital platform, incorporating an image-based dietary assessment and tailored feedback system. This research could the capability and capacity of dietitians by improving the effectiveness of dietetics weight management services, resourcing dietitians with an innovative, time saving digital platform that will provide a comprehensive state-of-the-art technology in dietary assessment, and feedback. This study will provide the first test of the technology alongside dietetic counselling conducted by videoconferencing in people living with obesity in Australia.

Clinical practice guidelines for the management of obesity have focused on reducing energy intake [59]. Whilst this approach is effective, the 'thinking beyond calories' concept indicates that various dietary components and patterns may negatively affect energy balance leading to obesity [60] and recidivism post-intervention. This novel concept is supported by a cross-over trial where inpatients were fed ad libitum either an ultra-processed or an unprocessed diet [41]. Energy intake was greater during the ultra-processed diet, suggesting improving diet quality and reducing consumption of ultra-processed foods, may play an important role in energy balance. Dietitian led-interventions lead to statistically significant changes, but the effect sizes do not always show clinically significant improvements in health outcomes [11]. This may be due to the inconsistent use of behavior change techniques in dietitian-lead interventions. Their focus on education alone may be insufficient to facilitate behavior change [61]. For dietary interventions, the inclusion of behavior change techniques are more effective for improving health outcomes [62]. However, many studies to date have not specified the behavioral theory used, nor have they measured changes in psychological variables. This study will address this gap through the comprehensive assessment of both dietary and psychological parameters, to comprehensively test the effectiveness of behavior change strategies for weight management.

Strengths and Limitations

A strength of the study is the intervention design comparing a dietitian-led intervention with a minimal intervention control. The intervention is underpinned by the COM-B model delivered by

dietitians trained in behavior change techniques [49]. Additionally, the study will use the electoral roll, a compulsory enrolment system for Australians aged over 18 years, for recruitment of participants to provide representation across socio-economic groups. A limitation is the self-selecting sample, meaning that the findings may not be generalizable to the wider population or priority groups. Further, there may be challenges in recruiting volunteers to meet recruitment targets and ensuring representation from a diverse background for socioeconomic status and ethnicity.

Conclusions

This research aims to improve outcomes for people living with obesity and addresses a gap in telehealth dietetics services for the delivery of weight management care. This RCT will compare a 12-month digital tailored feedback dietary intervention with standard care in people living with obesity where the feedback uses new cutting-edge technologies to automate an otherwise lengthy process. Consistent with a patient-centered model of care, the chat2 intervention incorporates video counselling by trained dietitians to support dietary behavior change and relapse prevention. This model of care will build capacity for dietitians to deliver effective evidence-based weight management advice using new technologies, potentially creating a paradigm change in the management of obesity, a common condition that is associated with a substantial disease burden.

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Conflicts of Interest

PA is an investigator on a publicly funded trial in which Nestle have donated food products to support treatment costs.

Abbreviations

ADG: Australian Dietary Guidelines

BMI: Body mass index

chat2: Connecting Health and Technology 2

COM-B: capability, opportunity, motivation, and behavior model

DXA: dual-energy absorptiometry

mFR: Mobile Food Record

DQS: Diet Quality Scoring

HbA1c: glycated hemoglobin

HDL: high-density lipoprotein
MNT: medical nutrition therapy
LDL: low-density lipoprotein
PNQ: Personalized Nutrition Questionnaire
RCT: randomized controlled trial

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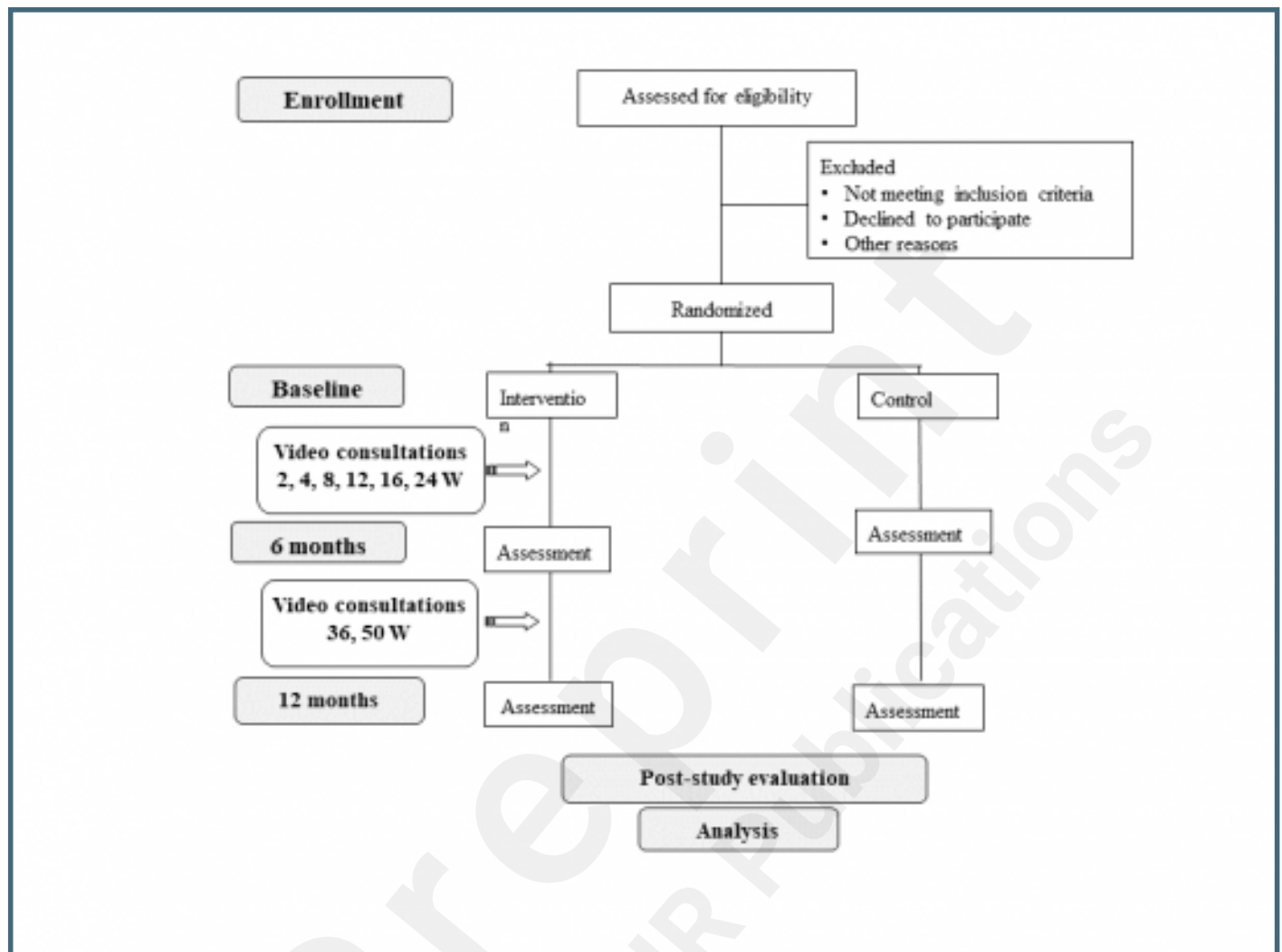
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Supplementary Files

Figures

Study design with randomization to two groups: intervention and control groups. W refers to study weeks.



Review process for viewing a labeled eating occasion with colored labels identifying the foods and time and date stamp displayed.



TOC/Feature image for homepages

Mobile food record app with review process for labeled eating occasion for the chat2 study.

