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BMJ Open Examining the efficacy of a multicomponent m-Health physical activity, diet and sleep intervention for weight loss in overweight and obese adults: randomised controlled trial protocol

Mitch J Duncan,^{1,2} Wendy J Brown,³ Tracy L Burrows,^{1,4} Clare E Collins,^{1,4} Sasha Fenton,^{1,2} Nicholas Glozier,⁵ Gregory S Kolt,⁶ Philip J Morgan,^{1,7} Michael Hensley,⁸ Elizabeth G Holliday,⁹ Beatrice Murawski,^{1,2} Ronald C Plotnikoff,^{1,7} Anna T Rayward,^{1,2} Emmanuel Stamatakis,¹⁰ Corneel Vandelanotte¹¹

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For numbered affiliations see end of article.

Correspondence to

Dr Mitch J Duncan;
mitch.duncan@newcastle.edu.au

ABSTRACT

Introduction Traditional behavioural weight loss trials targeting improvements in physical activity and diet are modestly effective. It has been suggested that sleep may have a role in weight loss and maintenance. Improving sleep health in combination with physical activity and dietary behaviours may be one strategy to enhance traditional behavioural weight loss trials. Yet the efficacy of a weight loss intervention concurrently targeting improvements in physical activity, dietary and sleep behaviours remains to be tested.

Methods and analysis The primary aim of this three-arm randomised controlled trial is to examine the efficacy of a multicomponent m-Health behaviour change weight loss intervention relative to a waitlist control group. The secondary aims are to compare the relative efficacy of a physical activity, dietary behaviour and sleep intervention (enhanced intervention), compared with a physical activity and dietary behaviour only intervention (traditional intervention), on the primary outcome of weight loss and secondary outcomes of waist circumference, glycated haemoglobin, physical activity, diet quality and intake, sleep health, eating behaviours, depression, anxiety and stress and quality of life. Assessments will be conducted at baseline, 6 months (primary endpoint) and 12 months (follow-up). The multicomponent m-Health intervention will be delivered using a smartphone/tablet 'app', supplemented with email and SMS and individualised in-person dietary counselling. Participants will receive a Fitbit, body weight scales to facilitate self-monitoring, and use the app to access educational material, set goals, self-monitor and receive feedback about behaviours. Generalised linear models using an analysis of covariance (baseline adjusted) approach will be used to identify between-group differences in primary and secondary outcomes, following an intention-to-treat principle.

Ethics and dissemination The Human Research Ethics Committee of The University of Newcastle Australia

Strengths and limitations of this study

- The efficacy of a technology-delivered intervention targeting improvements in physical activity, diet and sleep behaviours on weight loss in adults is unknown.
- Detailed assessment of physical activity, dietary intake and patterns, and sleep provides the opportunity to examine how these behaviours change during the intervention.
- Outcome data will contribute to knowledge regarding the combined influence that physical activity, diet and sleep behaviours have on weight loss.
- Collection and analysis of usage data from the intervention app provides the opportunity to examine how usage is related to behaviour change and weight loss in a multiple behaviour intervention.
- Limitations include participants being excluded due to diagnosed sleep disorder or engaging in shift work.

provided approval: H-2017–0039. Findings will be disseminated via publication in peer-reviewed journals, conference presentations, community presentations and student theses.

Trial registration number ACTRN12617000735358; UTM1111-1219-2050.

INTRODUCTION

Globally, the prevalence of overweight and obesity has increased between 1980 and 2013, and currently, in Australia, 63% of adults are overweight or obese.^{1,2} Being overweight or obese increases the risk of developing coronary heart disease and type 2 diabetes

mellitus.³ For individuals who are overweight or obese, weight loss of >5% is associated with clinically significant reductions of risk of ill health.⁴ Traditionally, behavioural weight loss interventions recommend overweight or obese individuals increase physical activity, improve dietary quality and reduce energy intake to create an energy deficit of 2500 kilojoules per day.⁴ Self-management approaches are recommended that provide individuals with the necessary education and behavioural strategies to support relevant lifestyle changes.^{4 5} Although interventions targeting physical activity and diet are effective, the magnitude of weight loss is modest, with meta-analyses reporting average weight loss of 2.70–3.79 kg.^{6 7} Consequently, the efficacy of behavioural weight loss interventions needs to be improved.

One potential way to enhance the efficacy of traditional weight loss interventions may be to target concurrent improvements in sleep health.⁸ Good sleep health is characterised by a duration, quality and timing of sleep that leaves a person satisfied with their sleep and alert during the day.⁹ Several epidemiological studies have demonstrated associations of sleep disturbance and shorter or longer than recommended sleep duration with weight gain or overweight and obesity, suggesting that sleep health may influence weight regulation.^{10–12} However, associations between sleep duration and weight are often non-linear.¹⁰ Experimental studies manipulating sleep duration or quality have demonstrated that short sleep duration and poor quality sleep alter biological and hormonal factors, inhibiting an individual's ability to regulate food intake and reducing physical activity levels the subsequent day.^{13–16} Furthermore, studies have shown that poorer sleep quality, sleep disturbances or the presence of sleep disordered breathing at baseline in traditional weight loss interventions are associated with reduced weight loss.^{17–19} Physical activity and sleep quality also share a bidirectional relationship,^{20 21} and physical activity, dietary and sleep behaviours have been shown to co-occur.^{22 23} These observations suggest that targeting improvements in sleep health in combination with physical activity and diet, as part of a multibehaviour intervention, could enhance weight loss.¹³

One such multicomponent weight loss intervention reported that participants in the physical activity, diet and sleep health group had significantly greater weight loss than participants in the physical activity and diet group.²⁴ However, the sleep component of the intervention did not commence until week 4 of the 12-week intervention, this may have limited changes in sleep health and the corresponding impact on weight loss, due to a shorter intervention duration. Furthermore, this study was delivered face to face, which limits scalability and did not examine the longer term (>3 month) efficacy of the enhanced intervention.²⁴ Consequently, there is a need for more research to examine the efficacy of weight loss interventions that target improvements in sleep health to enhance understanding of the potential benefit of improving sleep as part of behavioural weight loss interventions, particularly for sustained weight loss.

Due to the considerable proportion of the adult population that are overweight or obese, insufficiently physically active (45%), have poor diet quality (94%), sleep shorter or longer than recommended (29%–40%) and report poor sleep quality (19%–38%), feasible, scalable and effective weight loss interventions are required.^{2 23 25} e-Health and m-Health interventions provide a potentially scalable intervention platform, and although meta-analyses report they can achieve significant weight loss (–2.70 kg), it is acknowledged that their efficacy needs to be improved.⁶ Improving sleep health in combination with physical activity and dietary behaviours may be one strategy to achieve this, yet the efficacy of an m-Health weight loss intervention concurrently targeting improvements in physical activity, dietary and sleep behaviours remains to be tested. The primary aim of this study is to examine the efficacy of a multicomponent m-Health behaviour change weight loss intervention relative to a waitlist control group. The secondary aims are to compare the relative efficacy of a physical activity, dietary behaviour and sleep intervention (enhanced intervention), compared with a physical activity and dietary behaviour only intervention (traditional intervention), on the primary outcome of weight loss and secondary outcomes of waist circumference, glycated haemoglobin (HbA1c) physical activity, diet quality and intake, sleep health, eating behaviours, severity of depression, anxiety and stress symptoms and health-related quality-of-life. It is hypothesised that both the enhanced and the traditional interventions will achieve a statistically significant reduction in weight relative to the waitlist control. The secondary hypothesis is that the enhanced group will achieve greater weight loss than the traditional intervention. Potential moderators (eg, participant sociodemographics) and mediators (eg, physical activity, diet and sleep) of intervention efficacy will also be examined.

METHODS

Trial design

The Move, Eat & Sleep study is a randomised controlled trial with three parallel groups. The primary outcome is weight loss at the 6-month postbaseline assessment (primary time point), and the study also includes a 12-month postbaseline follow-up assessment (figure 1). Both active interventions are multicomponent m-Health multibehaviour change interventions, which participants will have access to throughout the entire study period.

The intervention groups are:

1. Waitlist control: asked to maintain current weight, physical activity, dietary intake and behaviours and sleep health.
2. Traditional group: targeting change in physical activity, and dietary intake and behaviours.
3. Enhanced group: targeting change in physical activity, dietary intake and behaviours and sleep health behaviours.

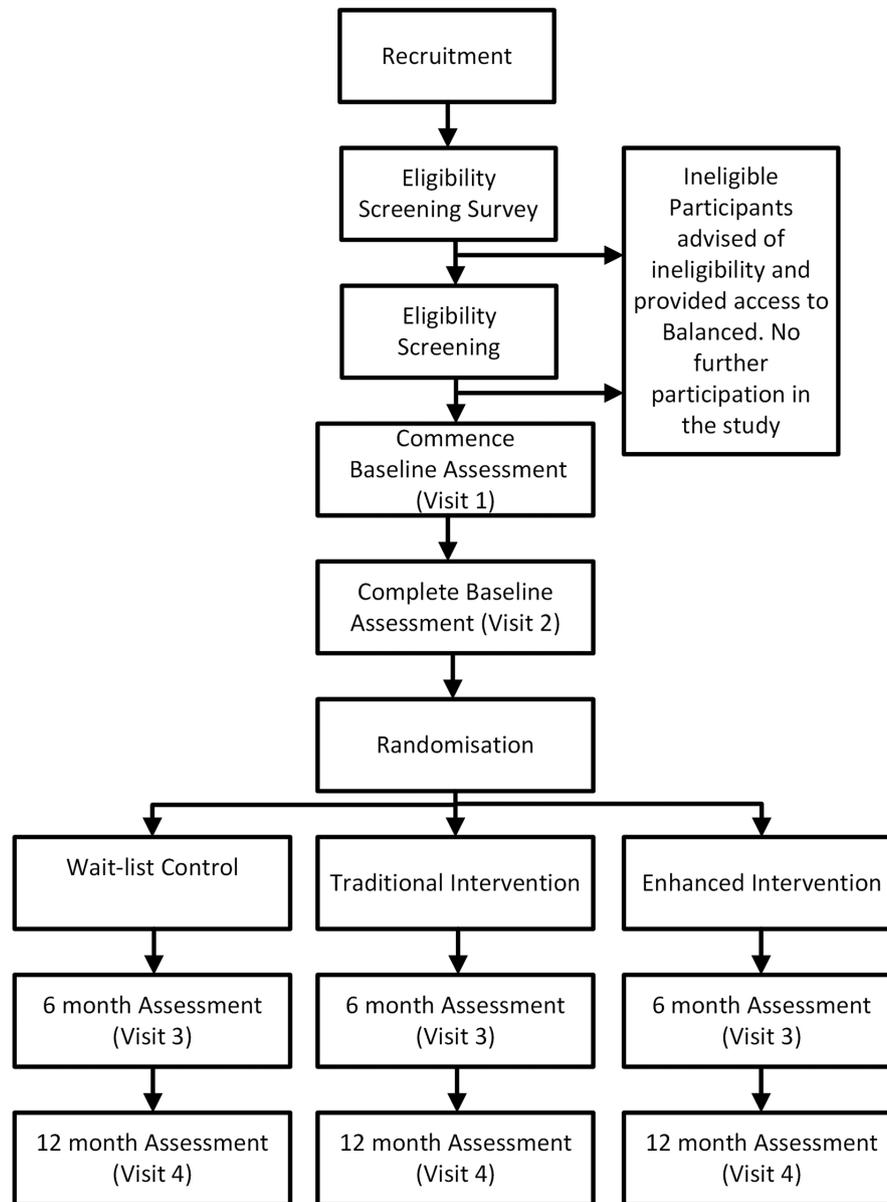


Figure 1 Participant flow through study.

Participants in the waitlist control group will be offered access to the enhanced intervention after the completion of the 12-month assessment. The study was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12617000735358). The Universal Trial Number is U1111-1219-2050. The design, conduct and reporting of this study will adhere to the Consolidated Standards of Reporting Trials guidelines. All participants will provide informed consent to participate and can withdraw at any time for any reason. The funding bodies had no role in the design, conduct or reporting of the trial.

Study setting

The target population for the Move, Eat & Sleep study is overweight or obese adults living in the Newcastle area, New South Wales, Australia, who meet eligibility criteria, assessed through an online screening questionnaire.

Recruitment

Participants from the Newcastle area, New South Wales, Australia, will be recruited using posters distributed at The University of Newcastle Callaghan campus, community notice boards, community events, study advertisements via radio, electronic communication (email lists and social media), local businesses and participant registries. Recruitment materials will direct individuals to the information sheet, consent form and eligibility survey. Recruitment commenced in May 2017 and was completed in September 2017.

Eligibility criteria

To be eligible for inclusion in the study individuals must report:

1. Being aged between 18 years and 65 years.

2. Self-reported weight and height consistent with a body mass index (BMI) between 25.0 kg/m² and 40.0 kg/m².
3. Access to either an iOS or Android smartphone or tablet that can access the internet.
4. Being willing and able to attend the University of Newcastle Callaghan campus on four occasions to complete assessments.

Participants will be excluded from participating in the study if they:

1. Are currently using a tracking device for physical activity and/or sleep (eg, Fitbit and Jawbone).
2. Are pregnant.
3. Report a doctor-diagnosed sleep disorder (eg, insomnia, restless legs, narcolepsy, obstructive sleep apnoea).
4. Are currently taking medication related to assisting sleep or weight management.
5. Have a condition that would contraindicate participation in physical activity, modifying diet and/or sleep.
6. Have had weight loss of 4.5 kg or more in the past 3 months or intending to participate in another weight loss programme during the study period.
7. Have had weight loss surgery at any time.
8. Are currently employed as a shift worker on a rotating roster including night shifts.

Participants satisfying eligibility criteria will be contacted by project staff via telephone or email to arrange an appointment time. Ineligible persons will be contacted via telephone or email to advise them they are ineligible and offered access to other freely available resources related to physical activity, diet and sleep health.^{26 27}

Study procedure

Eligible participants will be asked to attend The University of Newcastle Callaghan campus on four occasions to complete assessments. Assessments will occur at baseline (two visits), 6 months postbaseline (one visit) and 12 months postbaseline (one visit). Electronic consent to participate in the study will be provided when completing the eligibility survey. Table 1 provides an overview of the assessments to be conducted at each visit. The research assistant responsible for conducting anthropometric and cardiovascular risk measures will receive training to perform these measures. At visit 1, participants will have their height and weight measured and BMI confirmed (for eligibility in the study) and their HbA1c measured. In addition, participants will complete the Australian Eating Survey, which is a food frequency questionnaire (FFQ) and will be provided with an accelerometer (Geneactiv) to wear continuously for 8 days. After 8 days, participants will return for visit 2, to return the accelerometer and complete the online surveys. Participants will then be randomly allocated to one of the three study groups. Participants allocated to either of the active intervention groups will be provided with personalised dietary recommendations from an accredited practising dietitian, based on the results generated from their Australian Eating Survey and intervention materials (see Intervention

description). Intervention group participants will be given access to the 'Balanced' app and an additional calorie counting platform (Calorie King), provided with a set of body weight scales (Tanita HD-380), a Fitbit activity tracker and a participant handbook (see Intervention description).^{27 28} Prior to visits 3 and 4, participants will be mailed an accelerometer to wear continuously for 8 days and then return to the university. At visits 3 and 4, participants will complete anthropometric and survey assessment measures. Participants will be reimbursed with a gift voucher to the value of \$10 at the completion of visits 2, 3 and 4, to cover travel and parking costs, corresponding to a maximum of \$30 per participant over the course of the study. The 6-month assessments were conducted between November 2017 and March 2018, the 12-month assessments commenced in June 2018 and are ongoing.

Randomisation and blinding

Following completion of baseline assessments, participants will be randomised to one of the study groups in equal ratios using permuted block randomisation, with block sizes of six. Randomisation will be stratified by BMI (25.0–29.9 and 30.0–40.0) to ensure group balance on this important prognostic variable. The randomisation sequence will be developed by an independent statistician at the Hunter Medical Research Institute and implemented in a secure web-based system. This system can be accessed by the project manager to reveal group allocation after each participant completes baseline assessments. Group allocation is concealed prior to the project manager accessing the portal. Participants who share a living residence will be allocated to the same group to avoid contamination between groups. The research assistant conducting the anthropometric assessments is blinded to group allocation, while dietitians providing the dietary counselling are not be blinded to group allocation, in order to allow appropriate, group-specific counselling advice. Participants will be blinded to group allocation until visit 2 is completed, and they are allocated to an intervention group; participant blinding is not possible after group allocation is completed due to the nature of the intervention. Participants will be asked not to disclose their group allocation during the assessment of anthropometric and cardiovascular risk measures. Analyses of primary outcomes will be conducted blinded to group allocation.

Intervention

The Move, Eat & Sleep study is a technology-based, multi-behavioural intervention to promote weight loss in overweight and obese adults. Participants randomised to an intervention group will receive access to a version of the Balanced app described elsewhere in detail,^{27 28} which was modified to also allow self-monitoring of dietary goals and weight. The Balanced app allows participants to self-monitor and set goals for target behaviours and weight and to receive graphical feedback comparing target behaviours and weight to their goals. Participants were also provided

Table 1 Overview of assessment schedule and measures

	Measure	Instrument	Assessment time point			
			Eligibility	Baseline	6 months	12 months
Eligibility survey	Inclusion and exclusion criteria	Self-report.	✓			
Primary outcome	Weight (kg)	Measured weight.		✓	✓	✓
Secondary outcomes	Waist circumference (cm)	Measured waist circumference.		✓	✓	✓
	Glycated haemoglobin	A1CNow+ (Polymer Technology Systems).		✓	✓	✓
	Physical activity	Active Australia Questionnaire; Modified Godin Leisure Time Questionnaire. ^{27 70}		✓	✓	✓
	Dietary intake/patterns	Australian Eating Survey (food frequency questionnaire). ²⁶		✓	✓	✓
	Sleep quality	The Pittsburgh Sleep Quality Index. ⁵²		✓	✓	✓
	Insomnia symptoms	Insomnia Severity Index. ⁵³		✓	✓	✓
	Sleep timing	The Sleep Timing Questionnaire. ⁵⁴		✓	✓	✓
	Health-related quality of life	RAND-36. ⁶⁰		✓	✓	✓
	Severity of depression, anxiety and stress symptoms	Depression, Anxiety and Stress Scale (DASS-21). ⁵⁹		✓	✓	✓
	Sitting behaviour	The Workforce Sitting Questionnaire. ⁵¹		✓	✓	✓
	Activity and sleep monitoring	Geneactiv Accelerometer.		✓	✓	✓
Mediators/moderators	Addictive eating behaviours	Yale Food Addiction Scale. ⁵⁸		✓	✓	✓
	Dietary restraint, uncontrolled eating, emotional eating	Three-Factor Eating Questionnaire R18. ⁵⁶		✓	✓	✓
	Chronotype	Morningness–Eveningness-Revised.		✓	✓	✓
	Sleep hygiene behaviours	The Sleep Hygiene Index. ⁵⁵		✓	✓	✓
	App usage and engagement	Balanced app database.			Continuous	
Sample characteristics	Demographics	Age, sex and chronic disease status.		✓	✓	✓
	Anthropometry			✓	✓	✓
	Socioeconomic factors	Education, income, marital status, occupation and working hours.		✓		

with body weight scales to self-monitor weight (Tanita HD380), a Fitbit to self-monitor activity (Fitbit Alta) and sleep behaviours (if allocated to the enhanced group), individualised in-person dietary counselling, a participant handbook and additional email and text message based

support (table 2). Participants in the traditional group will not self-monitor sleep health via the Balanced app or Fitbit and will not receive any intervention content related to sleep health. The in-app content and functionality provided by the Balanced app can be configured to

**Table 2** Overview of the timing and frequency of intervention component delivery

Intervention component	Delivery	Frequency	Study month													
			1	2	3	4	5	6	7	8	9	10	11	12		
Individualised weekly summary*	Email	Weekly	✓	✓	✓	✓	✓	✓								
Behaviour change tool sheets	Email	Monthly	✓	✓	✓											
Weekly fact	SMS	Weekly	✓	✓	✓	✓	✓	✓								
Self-monitoring physical activity, diet goals, sleep health	Balanced app	Daily	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Self-monitoring of body weight	Balanced app	Weekly	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Self-monitoring prompt	SMS/email†	Weekly	✓	✓	✓	✓	✓	✓								
Self-monitoring of energy intake	External e-Health and m-Health platform‡§	Unspecified	✓	✓	✓	✓	✓	✓								
Personalised dietary feedback	In person by dietitian	Once¶	✓													
Self-monitoring and feedback on dietary quality	External online assessment**	Monthly	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

*Individualised weekly summary contains information on the behavioural and weight data participants self-monitored in the previous week and achievement of goals.

†Criteria for receiving SMS self-monitoring prompt for physical activity, diet and sleep: if non-usage occurred on at least 4/7 days per week. Separate reminders for weekly self-monitoring of weight will be integrated into the personalised weekly summary. Participants will receive an additional email reminder to self-monitor physical activity, diet and sleep behaviours if they have received non-usage reminders for three consecutive weeks.

‡The external e-Health platform is CalorieKing website or the ControlMyWeight app by CalorieKing.

§Participants suggested to conduct this self-monitoring activity on an as needed basis throughout the study period, for a duration of 4 days at each time.

¶Personalised dietary feedback will be provided by an accredited practising dietitian based on the results generated from their Australian Eating Survey completed at visit 2.

**Dietary quality and feedback on dietary quality will be offered to participants completing the Healthy Eating Quiz www.healthyeatingquiz.com.au on a monthly basis.

provide only intervention content specific to the intervention group a participant is allocated to. [Table 2](#) provides a summary of the intervention components and their delivery frequency throughout the intervention. Participants will be asked to use the Balanced app daily for self-monitoring of target behaviours but are instructed they can use the app as much or as little as they like and will have access to the app continuously throughout the entire study period. The individualised weekly summaries provide an overview of participant's weight loss and engagement in target behaviours in comparison with their goals based on self-monitoring data entered into the Balanced app. The additional email messages and SMS to participants follow a standardised protocol that is designed to maximise the specificity, timeliness and the relevance of messages.^{27 29} These email messages and SMS will be manually sent to participants by the project manager on the same day each week throughout the intervention period. Self-monitoring reminders are intended to re-engage participants in the self-monitoring process as e-Health and m-Health interventions frequently observe a decline in usage over the initial weeks of the

intervention and greater frequency of self-monitoring may be an important part of the behaviour change and weight loss process.^{30–32} Participants will also receive a weekly 'Fact of the Week' text message, which provides educational facts regarding how the target behaviours can contribute to weight loss and promote continued engagement with the intervention to help facilitate behaviour change. The development of the intervention content was guided by using specific behaviour change techniques (eg, education, goal setting, self-monitoring, feedback on behaviour) to operationalise constructs from social cognitive and self-regulatory theories.^{33–35}

Traditional group

The traditional intervention group will receive intervention materials targeting change in physical activity and dietary behaviours and weight status as described below.

Self-monitoring

Participants will be able to self-monitor physical activity, dietary behaviours and weight using the provided apps. Minutes of moderate-to-vigorous intensity physical

activity based on steps per minute will be measured using the Fitbit and data automatically synchronised to the Balanced app similar to previous research.²⁸ Participants will manually enter daily steps from the Fitbit and their participation in resistance training (yes/no response) into the Balanced app. Dietary behaviour will be self-monitored by manually entering into the Balanced app which of the 10 daily food goals are completed each day using a dichotomous (yes/no) response for each goal. The daily food goals are intended to promote a high-quality diet and a reduction in energy intake. The 10 food goals are: eating two serves of fruit, eating five serves of vegetables, choosing wholegrain breads and cereals, choosing low fat dairy products, choosing lean meats (or alternatives), choosing healthy snacks (from the core food groups), drinking plenty of water and limiting intake of fast food, soft drinks/energy drinks and alcohol.³⁶ Energy intake will be self-monitored for 4 days per week through the intervention period using a freely available calorie counting website and/or app (CalorieKing website or the ControlMyWeight app by CalorieKing), which the research team will install for participants on their mobile device. This allows participants to self-monitor their average daily energy intake (kilojoules/day) against their recommended energy intake, which will be provided at visit 2. Previous research has used similar 4-day monitoring periods to balance the need to obtain an indication of usual dietary intake without overburdening participants.³⁷ The education materials will advise participants to repeat the self-monitoring of energy intake at monthly intervals, or more frequently if desired, throughout the intervention. Education materials will also advise participants to complete regular self-assessment of dietary quality using a freely accessible online survey (<http://www.healthyeatingquiz.com.au>), which provides an overall diet quality score known as the Australian Recommended Food Score depicting diet quality as well as personalised feedback and suggestions for ways to improve diet quality. Participants will be encouraged to weigh themselves once per week using the scales provided and manually enter their weight into the Balanced app. Regular self-monitoring of body weight during weight loss attempts is associated with greater weight loss and success of achieving weight loss goals.³⁵

Educational resources

Participants will be provided with educational information via in-app content, email and SMS messages, a printed participant handbook and in person via the counselling session. This information will detail how target behaviours can influence weight loss and strategies to achieve weight loss. In-app educational resources for physical activity provide information on the health benefits of physical activity, current national guidelines for physical activity with a focus on the amount of physical activity necessary for weight loss and the importance of aerobic, resistance training and increased incidental activity (daily steps) to minimise sedentary behaviour.^{28,38} Handbook educational

resources will also provide information on strategies and examples to create activity goals, action plans and overcome barriers to participation in physical activity. The participant handbook also provides instruction on how to perform a series of body weight resistance training activities to promote engagement in these behaviours. In-app educational resources for dietary behaviours will also provide information on the health benefits of good dietary behaviours, the current national dietary guidelines and practical advice on improving dietary intake and reducing energy intake to promote weight loss.⁵ Specific information was provided on promoting intake of five core food groups and limiting intake of alcohol and energy-dense discretionary foods and drinks that contain saturated fat, added sugar and salt. The participant handbook contains the same type of information with additional information on how to plan healthy meals, how to control portions sizes and interpret food labels. In-person dietary counselling will be provide participants with personalised advice regarding the specific changes they can make to target behaviours as described below.

Feedback

Participants will be provided with feedback on behaviours and weight throughout the intervention period via in-app feedback in the Balanced app and individualised weekly email summaries. In-app feedback from the Balanced app consists of a series of four graphs (daily, 1 week, 3 month and all periods) showing self-monitored data in comparison with the goal for that behaviour or for weight (figure 2).²⁸ The Balanced app also uses a Traffic Light feature on the app's home screen (dashboard) to provide participants with dynamic feedback on their performance relative to their goal (figure 3). A green light indicates a participant is meeting, exceeding or close to their goal; an orange light indicates they are progressing towards their goal although are not close; and a red light indicates they are markedly below their goal. Individualised weekly email summaries provide participants with an individually tailored report summarising the behavioural and weight data they self-monitored in the previous week and achievement of goals. Participants could also receive feedback about their energy intake through completion of a 4-day food diary using the external calorie counting service described above. This will provide participants with their average daily energy intake that they can compare with their daily energy intake goal. To receive feedback about their diet quality throughout the intervention period, participants could also complete the online Healthy Eating Quiz (www.healthyeatingquiz.com.au), which is a short (10–15 min) validated survey that provides an overall indication of dietary quality and also provides automated individualised feedback on ways participants can make changes to their diet to improve their dietary quality. Further details on the Healthy Eating Quiz are available elsewhere.²⁶ Face-to-face personalised feedback about participants' current dietary intake and quality will be provided by

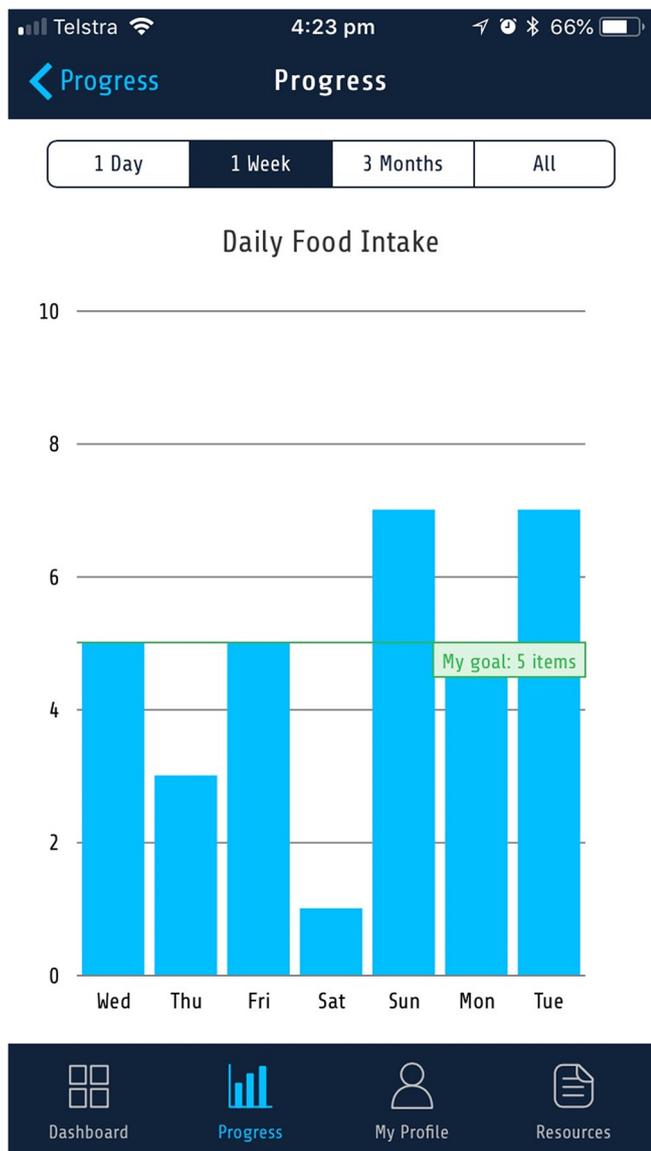


Figure 2 Graphical feedback of the number of daily food goals achieved relative to goal in the Balanced app.

the Accredited Practising Dietitian at baseline using the results of the Australian Eating Survey completed at visit 1.²⁶ This 20 min one-on-one session will follow a standardised study protocol to provide feedback on participants' current energy contribution of core foods and discretionary foods to their total energy intake, and how this compares with dietary recommendations, to promote adherence to National Dietary Guidelines and Australian Guide to Healthy Eating, as well as feedback about their overall diet quality, energy from major food groups and nutrient profiles.⁵ It will provide advice on how they can induce an energy deficit for weight loss, change target behaviours based on intervention materials, the importance of changing target behaviours in relation to weight loss based on intervention materials and a personalised daily energy target to reduce their weight by 0.5–1 kg per week and achieve 5% weight loss in the next 6 months. Participants will receive written feedback via a system

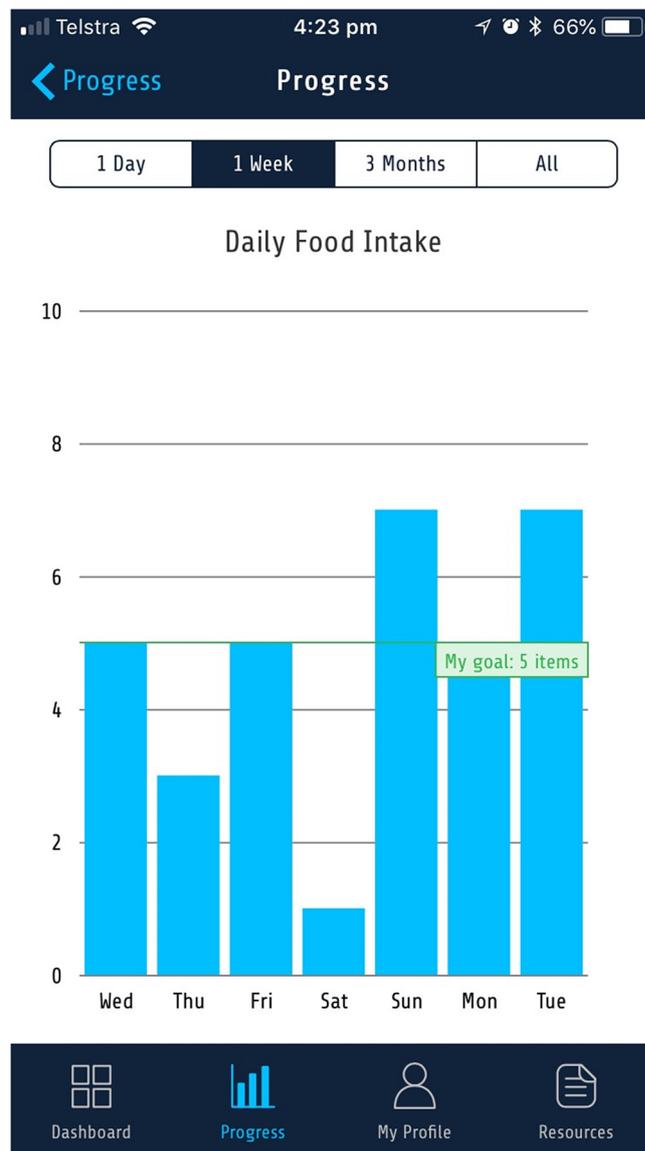


Figure 3 Balanced app Dashboard.

generated report, which promotes adherence to dietary guidelines.⁵

Enhanced group

The enhanced intervention group will receive the same intervention content as the traditional group and include additional intervention materials also targeting improvements in sleep. The specific sleep materials are reported in detail elsewhere.^{27 28} Self-monitoring of sleep in the Balanced app consists of *sleep time* (time of going to sleep), *wake time* (time of waking), *sleep quality* (derived from the ratio of sleep duration/time between time to sleep and time to wake) and sleep hygiene behaviours.²⁸ Participants will self-monitor sleep time, wake time and sleep quality using the Fitbit.²⁸ Completion of 10 specific sleep hygiene behaviours will be manually self-monitored by participants indicating completion of each behaviour on the previous day using a dichotomous (yes/no) response. The 10 behaviours were selected based on their utility to improve sleep health from a public health perspective

and include: avoiding consumption of caffeine, alcohol, use of light-emitting devices and excessive intake of fluids or heavy meals before bedtime and promoting regulation of light, noise and temperature in the bedroom, regular exercise, maintenance of consistent sleep and wake times, having and following a prebedtime routine, securing comfort (eg, proper pyjamas and bedding) and managing stress.³⁹ Educational resources contained in the Balanced app for sleep health will provide information on the health benefits of good sleep health, recommendations for sleep duration and quality, highlight the importance of overall sleep health and not just sleep duration⁴⁰⁻⁴¹ and sleep hygiene behaviours.³⁹ The participant handbook and tool sheets included information on a range of stimulus control, stress management techniques (ie, progressive muscle relaxation, deep breathing and mindfulness) and guidance on cognitive and behavioural self-regulation strategies to promote sleep health.⁴²⁻⁴³ Using the same four time periods as implemented for other behaviours, participants will be provided with graphical feedback on their daily duration of sleep, their sleep quality, the timing of sleep (time to sleep and time to wake) and the number of sleep hygiene behaviours performed in comparison with their goals for each component of sleep. Participants will also set goals for each of these behaviours except for sleep quality as sleep quality can be enhanced by engaging in activities that may improve sleep quality (eg, sleep hygiene behaviours), but sleep quality itself is not directly under the control of the individual.²⁸ The traffic light system will provide participants with feedback based on their sleep duration in comparison with their goal.

Outcome measures

All outcome measures are completed at baseline, 6 months (immediate postactive intervention period) and 12 months (follow-up) at The University of Newcastle, Australia. The same instruments will be used for measurements at each time point. Assessors are trained prior to the assessments to follow a standardised protocol. Participants will receive assessment reminders by telephone, email and text message.

Primary outcome

The primary outcome measure for the study is weight (kg). Weight will be measured in light clothing and without shoes on calibrated digital scales to within 0.01 kg (Biospace BSM370 Portable Automatic BMI Stadiometer, Biospace Co, Ltd, Seoul, Korea). Weight will be measured twice, with two values considered consistent if they differ by less than 0.1 kg. If the two measurements vary by more than 0.1 kg, a third measurement will be taken. The average of the two acceptable measures within 0.1 kg will be reported. Weight loss will also be expressed as percentage weight loss.

Secondary outcomes

Waist circumference

Waist circumference (cm) will be measured at the observable narrowest point between the lower coastal border

and iliac crest (Seca 203, Seca GmH & Co. Hamburg Germany). Two measurements will be taken, with acceptable values within 0.5 cm. If these measures are not within 0.5 cm, a third measurement will be taken. The average of the two acceptable measures will be reported.

Glycated haemoglobin

HbA1c will be measured using a capillary blood sample and analysed using the validated A1C Now+ (Polymer Technology Systems).

Sleep, physical activity and sedentary behaviour

Measures of sleep, physical activity and sedentary behaviour will be measured through data collected by the Geneactiv accelerometer and through self-report. The Geneactiv is a small (36×30×12 mm, 16 g) waterproof accelerometer, which has been shown to provide valid estimates of sleep, physical activity and sedentary behaviour.⁴⁴⁻⁴⁷ Participants will wear the Geneactiv activity monitor 24 hours per day for 8 days on their non-dominant wrist and complete a written monitoring log to record the time of day that they go to bed, wake up and if the monitor was removed for any reason. A minimum of 16 hours wear per day will be considered valid and a minimum of five valid days is required for data to be included in analysis.²⁸⁻⁴⁸ To increase adherence to accelerometer wear protocols, participants will be sent a reminder text message every 3 days during the measurement period. Validated methods will be used to identify and quantify non-wear time, sleep, sedentary and physical activity behaviours.⁴⁴⁻⁴⁷ Sleep outcomes will be duration, time to sleep and time to wake, day-to-day variability in time to sleep and time to wake, and the number of awakenings. Physical activity outcomes will include daily minutes of sedentary, light, moderate and vigorous intensity physical activity during waking hours estimated using established cut points.⁴⁷⁻⁴⁸

Self-report measures of physical activity, sitting and sleep will also be collected. Data on the frequency of moderate and vigorous intensity physical activity and walking for recreation and transport over the past week will be collected using the Active Australia survey, which has acceptable levels of validity and test-retest reliability.⁴⁹⁻⁵⁰ Two items will be used to assess the duration and frequency of resistance training in the last week.²⁷ The Workforce Sitting Questionnaire will be used to assess average time spent sitting per day. This instrument measures time spent sitting at work, using a computer at home, watching television and sitting during leisure activities, on both work and non-work days. The Workforce Sitting Questionnaire has acceptable levels of test-retest reliability and validity.⁵¹

Self-report measures of sleep will be collected using the Pittsburgh Sleep Quality Index (PSQI), the Insomnia Severity Index (ISI) and the Sleep Timing Questionnaire.⁵²⁻⁵⁴ The PSQI will assess the quality and duration of sleep over the previous month using 19 items that measure seven separate components of sleep including duration,

sleep onset latency and sleep problems. An overall score of sleep quality will be calculated, and the subcomponents will be reported.⁵² The ISI is a seven-item questionnaire that will be used to assess the nature, severity and impact of insomnia symptoms on daytime functioning. Items are scaled using a 5-point Likert scale, and the dimensions evaluated are the severity of sleep onset latency, sleep maintenance and early morning waking problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others and distress caused by sleep difficulties.⁵³ The ISI has acceptable levels of internal consistency and test-retest reliability.⁴⁰ Self-reported sleep timing and variation in sleep timing will be assessed using the Sleep Timing Questionnaire. This is an 18-item instrument that assesses habitual bedtimes and wake times on weekdays and weekends.⁵⁴ The Sleep Timing Questionnaire has demonstrated acceptable levels of test-retest reliability, validity with accelerometry and sleep diary measures of sleep timing.⁵⁴

Sleep hygiene

Sleep hygiene practices will be assessed using the 13-item Sleep Hygiene Index, which assesses how frequently individuals engage in behaviours that affect sleep hygiene.⁵⁵ The Sleep Hygiene Index has acceptable levels of internal consistency, test-retest reliability and validity compared with the Pittsburgh Sleep Quality Index and the Epworth Sleepiness Scale.⁵⁵

Dietary intake and quality

Dietary intake and quality will be measured using the Australian Eating Survey (AES). The following dietary outcomes will be measured: (1) average daily energy intake; (2) dietary intake: core foods contribution to total energy intake, individual core food groups contribution to total energy, discretionary foods contribution to total energy, macronutrient contribution to total energy and micronutrient profiles; and (3) overall diet quality. The AES is a validated 120-item semiquantitative FFQ with 24 questions on vegetables, 11 on fruit, 9 on breads/cereals, 9 on dairy foods, 32 on lunch/main meal food items, 9 on beverages, 20 on snack foods/dessert and 6 on sandwich spreads/dressings and sauces.²⁶ Participants indicate the frequency of consumption of the foods items and food types over the previous 6 months with response options ranging from 'never' to '≥7 times per day'. Standard portion sizes for adult men and women are determined for each food item using data derived from the most current National Nutrition Survey. Nutrient intakes are computed using Australian AusNut 1999 database (All Foods) Revision 17 primarily and AusFoods (Brands) Revision 5 (Australian Government Publishing Service, Canberra). The estimated mean individual daily intake for 20 macronutrients and micronutrients was calculated using FoodWorks (version 3.02.581, Xyris Software Australia, Highgate Hill, Queensland). The AES also provides an Australian Recommended Food Score

(ARFS) as a measure of diet quality.²⁶ The ARFS uses a subset of 70 AES FFQ questions and focuses on dietary variety within food groups recommended in the Australian Dietary Guidelines. The ARFS has eight subscales with 20 questions related to vegetables, 12 to fruit, 12 to breads and cereals, 10 to dairy foods, 7 to meat/flesh foods, 6 to non-meat/flesh protein foods, 2 to spreads/sauces and 1 to water. Points are given based on frequency of consumption, related to dietary guidelines. The ARFS score is calculated by summing the points for each item and a total score out of 73 is given for diet quality.

Eating behaviours

Eating behaviours will be measured using the Three-Factor Eating Questionnaire R18 (TFEQ-R18) and the modified Yale Food Addiction Scale (mYFAS). The TFEQ-R18 is an 18-item questionnaire that measures three factors of eating behaviour: (1) cognitive restraint (conscious restriction of food intake aimed to control body weight and/or to promote weight loss), uncontrolled eating (tendency to overeat due to a loss of control over intake accompanied by subjective feelings of hunger) and emotional eating (inability to resist emotional cues).^{56 57} The 18 items are measured on a four-point response scale (definitely true/mostly, true/mostly, false/definitely and false), and item scores are summated into subscale scores (cognitive restraint, uncontrolled eating and emotional eating). Higher scores are indicative of greater cognitive restraint, uncontrolled eating and emotional eating. The TFEQ-R18 has been reported in previous studies as having adequate internal consistency reliability coefficients for the three subscales, as well as for the whole questionnaire (ranging between 0.75 and 0.87). The mYFAS is a nine-item validated questionnaire used to identify individuals who exhibit addictive symptoms towards foods that are high fat/high sugar foods, with reference to the past 12 months.⁵⁸ This tool assesses several symptoms in addition to a categorisation of 'food addiction'. Food addiction diagnosis is met, if an individual endorses at least three of the seven dependence symptoms and meets criterion for clinical impairment and/or distress. The mYFAS has acceptable levels of internal consistency (Cronbach $\alpha=0.75$) and test-retest reliability (kappa=0.79).

Depression, anxiety and stress

Symptoms of depression, anxiety and stress will be assessed using the Depression, Anxiety and Stress Scale (DASS-21).⁵⁹ The DASS-21 asks participants to report how much each emotional experience (eg, feeling sad/depressed and feeling scared for no reason) statement applied to them over the past week, selecting from four response options from 'did not apply to me at all' to 'applied to me very much, or most of the time'.

Health-related quality-of-life

Health-related quality-of-life will be assessed using the validated and widely used RAND 36-item Health Survey 1.0 (SF-36).⁶⁰ This instrument examines a person's perceived

health status and assesses eight health concepts. These include physical functioning, bodily pain, role limitations due to physical health problems and due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, general health perceptions and perception of change in health.

Chronotype

Participant chronotype will be assessed using the reduced Morning/Evening Questionnaire (rMEQ).⁶¹ The rMEQ is strongly correlated with the full Morning/Evening Questionnaire ($r=0.878$) and can be used to classify participants across the 'morningness–eveningness' typology.⁶²

Usability, satisfaction and process evaluation

The 10-item System Usability Scale has acceptable reliability and validity that will be used to assess participant satisfaction with the Balanced app.⁶³ After the 6-month assessment is completed, a random selection of participants of approximately 10 participants per intervention group will complete a semistructured interview. Interviews (approximately 20 min) will aim to provide information on what intervention strategies and components participants valued, aspects that could be improved or modified and their overall satisfaction with the allocated intervention.

Engagement and use of the intervention platform

Overall interaction with the app will be measured continuously throughout the study period by data provided in the app database, which records the time and date a self-monitoring entry was made and the actual value or response entered into the app. This information will be collected for all data entered into the Balanced app. Measures of engagement and usage will include the number, frequency and pattern of self-monitoring entries made and the time to non-usage attrition.^{31 64 65}

Demographic characteristics

Sociodemographic data will be collected by online questionnaire at baseline. Participants will provide information on their age, sex, marital status, ethnicity, medical history, postal code, years of education, occupational level, hours of work (daytime, night time and afternoon), number of days worked in previous week and average hours of work each day. Area-level socioeconomic status will be determined by postal code of residence using the 'Index of Relative Socioeconomic Advantage and Disadvantage' from the Australian Bureau of Statistics census-based Socio-Economic Indexes for Areas.

Sample size

Meta-analyses of traditional physical activity and diet-based weight loss interventions report average weight loss of 1.95–3.79 kg with less weight loss resulting from interventions of longer duration.⁶⁷ Therefore, we conservatively estimate mean weight loss of 2.4 kg at 6 months in the traditional weight loss group. Several studies report that participants with better quality sleep at the beginning

of the intervention achieve greater weight loss in comparison with participants who report poorer quality sleep.^{17 18} An intervention study targeting improved sleep quality in combination with physical activity and diet reported an additional 3% weight loss in the physical activity, diet and sleep group relative to the physical activity and diet interventions.²⁴ However, the influence of improved sleep health for weight loss in physical activity and diet interventions is relatively unclear. Therefore, we conservatively estimated weight loss in the enhanced intervention to be 4.8 kg at 6 months.

The primary analysis will compare the control group to the two combined intervention groups (mean difference=3.6 kg; $\alpha=0.05$; power=0.80). A secondary analysis will be conducted to compare the two intervention groups. To provide 80% power to detect a difference of 3.6 kg difference between control and the combined intervention groups, assuming an allocation ratio of 1:2, a total 31 participants per group is required. This assumes an average weight of 94 kg, significance level of 0.05, pre–post correlation of 0.9 (consistent with observed values in our previous research) and an SD of 13.4 kg for weight.^{66 67} A meta-analysis of e-Health weight loss interventions reported an average dropout rate of 22%,⁶ which varied greatly between studies, and we have achieved <20% dropout in previous weight loss studies with a duration of 6 months.⁶⁶ Therefore, we assumed a dropout rate of 17% in the current study, leading to 38 randomised individual participants required for each group (total $n=114$).

Statistical methods

All analyses will follow an intention-to-treat principle. The primary comparison will be between the combined intervention groups (group 1: traditional and group 2: enhanced) and control. A secondary (exploratory) analysis will assess differences between the two intervention groups (group 1: traditional and group 2: enhanced). Secondary analyses will also examine between-group differences in primary and secondary outcomes at 12 months.

Generalised linear models will be used to examine baseline-adjusted weight at 6 months. Treatment group differences in weight will be estimated in an analysis of covariance framework (ie, adjusting for baseline values of the outcome). The model will include fixed effects for baseline weight, group and the BMI stratification variable. Generalised linear mixed models (GLMMs) will be used to assess group differences in baseline-adjusted weight at 12 months. The GLMM model will include fixed effects for baseline weight, time, group, the time \times group interaction and the BMI stratification variable. A random intercept will be used to account for repeated measures on individuals. Differences between groups in primary and secondary outcomes will be examined using similar GLM and GLMM approaches using a response distribution and link function as appropriate to the outcome, with an alpha level of 0.05. The GLMM provide unbiased estimates of the treatment effect under the assumption that data are missing at random. Sensitivity

analyses using methods such as multiple imputation and pattern mixture modelling will be undertaken to investigate the robustness of conclusions to different assumed missing data mechanisms. Sensitivity analyses will also explore the influence of participants living in the same residence being allocated to the same intervention group by accounting for this clustering. Analysis of mediators will be examined using established frameworks,⁴² and analysis of moderators will be assessed by including an interaction term in the model of interest. Analyses will be conducted using Stata.

Data monitoring

All expected and unexpected adverse events reported by participants will be recorded in an events register, reported to the Human Research Ethics Committee. Possible adverse events may include discomfort associated with increasing physical activity levels, discomfort or embarrassment due to the personal or sensitive nature of the survey items and discomfort associated with collection of anthropometric and cardiovascular risk assessments. Data from surveys, accelerometers and the intervention data base (app) will be stored using a unique trial identifying number on password-protected computers and electronic servers. Data from these sources will be merged into a master study database and approximately 5% of records randomly selected for data quality checks of accuracy and completeness. Given the purpose of the trial, the nature of the intervention and the type of data collected, no Data Safety Monitoring Board will be established for this study.

Study sponsorship and organisation

The sponsor of the trial is the University of Newcastle, and funding was provided by grants provided by Diabetes Australia and the National Heart Foundation of Australia. The trial will be conducted and evaluated independent of the study sponsor and funder. The study is coordinated independently of the study sponsor and funder by researchers in the Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, Australia, with the study overseen by the trial management committee comprising the chief investigators.

Patient and public involvement

Participant input was received on a previous version of the intervention app (Balanced) that guided the design of the app for the current study. Participants were not involved in the design of the current study, the selection of outcome measurements, research questions or the recruitment of additional participants. Burden associated with participation in the study and satisfaction with the intervention and study will be assessed as part of the process measures collected in the study. Participants will receive a plain English summary of the study outcomes on its completion.

Ethics and dissemination

The trial will be undertaken in compliance with the Declaration of Helsinki. All participants will provide electronic consent to participate prior to completing the eligibility

survey. Protocol modifications will be registered with the Ethics Committee and trial register. Results of the study will be disseminated via peer-reviewed publications and presentations at national and international conferences and will also form part of student dissertations.

DISCUSSION

The study will examine the influence of a multicomponent m-Health intervention targeting activity, diet and sleep behaviours on weight loss in overweight or obese adults. There is growing interest in the role of activity, diet and sleep behaviours in weight status and cardiovascular risk.^{68 69} We are unaware of previous studies that have targeted these behaviours using a technology-delivered weight loss intervention. Examining the efficacy of an intervention that is potentially scalable is important given the high population prevalence of overweight or obesity, physical inactivity, poor dietary quality and indicators of poor sleep health.^{2 23 25} Strengths of this study include the unique combination of behaviours targeted by the multiple behaviour intervention, and objective measures of physical activity and sleep. An additional strength is the duration of the intervention period that is longer than several previous interventions, combined with a 12-month follow-up assessment.⁶ Limitations of the study include being conducted in a single geographical area and excluding participants with diagnosed sleep disorder and shift workers. Given the growth in smartphone ownership, the app-based delivering of the intervention has the potential for wide reach, although the potential reach of the intervention and participant engagement with it may be less than that if the intervention was also accessible by website.³¹ Study outcomes will provide information on the potential benefit of improvements in physical activity, diet and sleep on the outcome of weight loss.

Author affiliations

¹Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, Newcastle, New South Wales, Australia

²School of Medicine and Public Health, Faculty of Health and Medicine, University of Newcastle, Callaghan, New South Wales, Australia

³School of Human Movement and Nutrition Sciences, University of Queensland, Brisbane, Queensland, Australia

⁴School of Health Sciences, Faculty of Health and Medicine, University of Newcastle, Callaghan, New South Wales, Australia

⁵Brain and Mind Centre, Central Clinical School, Sydney Medical School, University of Sydney, Sydney, New South Wales, Australia

⁶School of Science and Health, Western Sydney University, Sydney, New South Wales, Australia

⁷School of Education, Faculty of Education and Arts, University of Newcastle, Callaghan, New South Wales, Australia

⁸Department of Respiratory and Sleep Medicine, John Hunter Hospital, Newcastle, New South Wales, Australia

⁹Centre for Clinical Epidemiology and Biostatistics, Faculty of Health and Medicine, University of Newcastle, Callaghan, New South Wales, Australia

¹⁰Charles Perkins Centre, Faculty of Medicine and Health, School of Public Health, University of Sydney, Sydney, New South Wales, Australia

¹¹Physical Activity Research Group, School for Health, Medical and Applied Sciences, Central Queensland University, Rockhampton, Queensland, Australia

Contributors MJD conceptualised the study, and TLB and SF contributed to the development of the dietary intervention and assessment methodology. TLB, SF, ATR, BM, RCP, CV, WJB, EGH and MJD contributed to the intervention development and design. MJD and SF drafted the manuscript, and all authors provided critical review of the manuscript. MJD and EGH developed the data analysis plan. MJD wrote the initial manuscript draft. WJB, TLB, CEC, SF, NG, GSK, PJM, MH, EGH, BM, RCP, ATR, ES and CV contributed to the writing of the final manuscript and provided critical comments during revisions. All authors approved the final version prior to submission. MJD and SF will be responsible for recruitment, data collection and intervention delivery.

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Competing interests None declared.

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