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The SHED-IT weight loss maintenance trial protocol: a randomised controlled trial of a weight loss maintenance program for overweight and obese men

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Abbreviations: AES, Australian Eating Survey; BMI, body mass index; DQES, Dietary Questionnaire for Epidemiological Studies; FFQ, Food frequency questionnaire; ICC, intra-class correlation coefficient; RCT, randomised controlled trial; SCT, Social Cognitive Theory; SHED-IT, Self-help, Exercise and Diet using Information Technology.

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ABSTRACT

Despite short-term efficacy, many weight loss studies demonstrate poor long-term results and have difficulty recruiting men. Cost-effective treatments that help men achieve long-term weight loss are required. Using a two-phase, assessor-blinded, parallel-group randomised controlled trial design this study will test the effectiveness and cost-effectiveness of a male-only weight loss maintenance intervention. In Phase I (3 months) 209 men received the *SHED-IT Weight Loss program*. In Phase II (12 months) 92 men who lost 4kg or more were randomised to either (i) a maintenance group who received the gender-tailored *SHED-IT Weight Loss Maintenance program*, that includes no face-to-face contact (n=47), or (ii) self-help control (n=45). Randomisation was stratified by weight loss (4kg-7.4kg, ≥ 7.5 kg) and BMI ($<30\text{kg/m}^2$, $\geq 30\text{kg/m}^2$). Assessments occurred at study entry (start of Phase I), baseline (start of Phase II), 6-month (post-test) and will occur at 12-month (follow-up; primary endpoint). The primary outcome is weight change in Phase II (i.e. from baseline at 12 months after randomization). Secondary outcomes include waist circumference (umbilicus and narrowest), blood pressure, body composition, objectively measured physical activity, sedentary time, portion size, dietary intake, quality of life, depressive symptoms, and behavioural cognitions. Costing data will be collected for cost-effectiveness analysis. Generalised linear mixed models (intention-to-treat) will assess outcomes for treatment (maintenance vs. control), time (baseline, 6-month and 12-month) and the treatment-by-time interaction. This will be the first study to evaluate a male-only, gender-targeted weight loss maintenance program. Results will provide evidence regarding feasible and theoretically-driven obesity treatments for men with potential for long-term impact and widespread dissemination.

Trial Registration: Australian New Zealand Clinical Trials Registry
(ACTRN12612000749808)

Keywords: male, weight loss maintenance, randomised controlled trial, obesity, cost-effectiveness, SHED-IT

1. Introduction

Since 1980, the international prevalence of obesity in men has almost doubled [1]. This has had a dramatic effect in Australia, where 70% of men are now overweight or obese [2] and the average male body mass index (BMI) is increasing faster than in most high-income countries [1]. This is concerning as increases in BMI are associated with increased risks of cardiovascular disease, type 2 diabetes and several cancers [3]. Furthermore, obesity is linked to a rapidly expanding list of co-morbidities such as osteoarthritis, hypertension, asthma, sleep apnoea, chronic back pain, sexual dysfunction and depression [4, 5]. Developing engaging and effective weight loss strategies for men that could be practically implemented within strained healthcare budgets is an issue of global importance.

Behavioural weight loss interventions have well-documented short-term efficacy to help people achieve modest weight loss and clinically important health benefits [4, 6, 7]. However, these benefits are often confounded by poor long-term success rates [8], with participants regaining approximately 30-35% of lost weight in the first year after treatment alone [9]. Without additional intervention, most will return to their pre-treatment weight within 5 years [9]. This seemingly intractable problem is likely due to a combination of biological, psychological, social and environmental factors [4] and it is evident that current weight loss approaches are not sufficient for long term success [10]. This provides a strong rationale for the development and evaluation of weight loss maintenance interventions, where participants develop additional knowledge and skills to halt the weight regain trajectory and achieve lasting weight loss.

In addition to the problem of weight regain, a second major shortfall of weight management research is the considerable under-representation of men [11, 12]. A recent systematic review [11] reported that the average proportion of men in 244 behavioural weight loss randomised controlled trials (RCTs) was only 27%. This is supported by other systematic reviews of weight loss studies, where the proportion of men has ranged from 23% [7] to 27% [6]. Although research shows that men prefer a male-only approach [13] and may respond well to gender-tailored or male-focused interventions [14-19], very few weight loss studies have exclusively recruited men (~5%) [11]. In addition, another review [12] recently highlighted that the evidence-base for male-only studies was limited in quality as well as quantity and

recommended that high quality weight loss studies with long-term maintenance were urgently required.

Previously, we have conducted an extensive program of research to establish the efficacy and effectiveness of the *SHED-IT (Self-Help, Exercise and Diet using Information Technology) Weight Loss Program* for men [13-16, 20-23]. This paper describes the design, measurement protocols and analysis plan for the *SHED-IT Weight Loss Maintenance trial*, which will investigate the effectiveness of an additional weight loss maintenance program designed to follow the weight loss program. This study will also investigate a cost-effectiveness analysis, which will provide urgently required evidence [24] regarding the value of this additional maintenance program.

The primary aim of this study is to investigate whether a weight loss maintenance program tailored specifically for men significantly improves maintenance of lost weight and other health outcomes 12 months after an initial weight loss program, in a community sample of overweight and obese men. It is hypothesised that the SHED-IT weight loss maintenance group will achieve significantly greater maintenance of (i) weight loss and (ii) other secondary health outcome improvements at 6- and 12-months after a weight loss program, compared to a SHED-IT weight loss-only (self-help) control group. A secondary hypothesis is that the *SHED-IT weight loss maintenance program* will be more cost-effective than the SHED-IT weight loss-only (self-help) control option. To the authors' knowledge, this will be the first study internationally to test the effectiveness and cost-effectiveness of a weight loss maintenance intervention designed specifically for men.

2. Methods

2.1. Study design

The study design is a two-phase, assessor-blinded, parallel-group RCT (Figure 1). The study has been approved by the University of Newcastle Human Research Ethics Committee and is prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12612000749808). The design, conduct, and reporting of this study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [25].

Figure 1. CONSORT flowchart for primary outcome and study design for the SHED-IT Weight Loss Maintenance trial.

2.2. Participants

Overweight or obese (BMI 25-40kg/m²) men aged 18 to 65 years were recruited in July/August 2012 from the local community of the Hunter Region, New South Wales, Australia. Participants were recruited through current waiting lists, workplace-based emails and notices, and a University media release (radio, newspapers, University website).

2.3. Eligibility

To determine eligibility, interested men were directed to an online questionnaire containing two sections: (i) Eligibility criteria questions (Table 1) and (ii) Stage 1 of the *Adult Pre-exercise Screening Tool* [26]. The eligibility criteria were designed to ensure that participants could safely complete and engage with all aspects of the SHED-IT programs and to rule out potential confounds of treatment effects. To improve the generalisability of the findings, the study did not exclude men for taking medications that may have interacted with weight loss, provided that it was safe for them to do so. This was determined by one of the study chief investigators (RC), who is an exercise physiologist and registered pharmacist. In some circumstances, men taking medications were required to provide a medical clearance from their general practitioner to participate. Men also needed a medical clearance if health concerns were identified in the pre-exercise screener (e.g. previous heart attack or stroke). All men were required to provide written informed consent prior to enrolment.

Table 1. Eligibility criteria for the SHED-IT Weight Loss Maintenance trial.

Inclusion criteria

- Male
- Aged 18 – 65 years
- BMI between 25.0 and 40.0 kg/m²

Exclusion criteria

- Not available for assessment sessions
 - No readily available internet access
 - Does not own a mobile/cell phone
 - Currently participating in an alternative weight loss program
 - Intention to participate in other weight loss program during study period
 - Currently taking medication to lose or gain weight
 - Diabetes requiring insulin treatment
 - Experienced weight loss of 5% or more in the previous 6 months
-

2.4 Background to SHED-IT interventions

This research project builds on the extensive development and refinement of *the SHED-IT Weight Loss program* for men. In brief, in a pilot RCT [15, 16, 20, 21], 65 overweight or obese male university staff and students were randomly assigned to either an Internet-based group (SHED-IT Online) or an Information-only control group (SHED-IT Resources). At 6 months, significant weight loss was observed in both groups, with no significant difference detected between groups. This demonstrated that two versions of a gender-targeted weight loss program could facilitate weight loss in a sample of male university staff and students. However, the scalability of the interventions was limited by the inclusion of a face-to-face information session and the generalisability was reduced by use of a convenience sample.

To address this, the SHED-IT community RCT was conducted in 2010 [14, 22, 23]. To move the interventions towards dissemination, all face-to-face contact within the interventions was removed and replaced with a DVD. Two versions of the SHED-IT program (online and paper-based) were tested in a representative community sample against a true, no-intervention control group. Importantly, after 6 months, significant intervention effects were observed for weight and a range of secondary health indicators in both groups compared to the control group. These RCTs established the efficacy and effectiveness of the SHED-IT program and achieved results that were comparable to those in other, more intensive, male-only weight loss programs [12]. This may have been due to factoring in gender differences in the program design, which may have increased male engagement with the program and strengthened the results [27].

2.5. Phase I: Initial Weight Loss

In total, 209 eligible men provided consent to participate and completed the ‘study entry’ assessment in August 2012 (Figure 1). After this assessment, they received the latest version of the *SHED-IT Weight Loss program*. As detailed above, this program has been developed and successfully tested in previous research and many of the intervention components have been described extensively elsewhere [14, 22]. Briefly, the program included: (i) The ‘*SHED-IT Weight Loss DVD for Blokes*’, (ii) The ‘*SHED-IT Weight Loss Handbook for Blokes*’, (iii) The ‘*SHED-IT Weight Loss Log Book for Blokes*’, and (iv) weight loss tools including a pedometer, a tape measure and kJ counter book. All resources were specifically designed to appeal to men and informed by qualitative [13] and quantitative [16] process evaluations, and

the men's health literature (e.g. [28, 29]). Men were also encouraged to self-monitor their food intake and physical activity, using either the CalorieKing™ website (www.calorieking.com.au) or MyFitnessPal™ mobile phone app (www.myfitnesspal.com), to create a 2000 kJ deficit on most days.

For the purposes of this study, the SHED-IT program was revised and improved in a few key ways, based on the pilot and community RCT. To improve the scalability of the intervention, participants did not receive any personalised e-feedback from the research team, as was provided in the previous versions. However, the men still had access to the feedback services automatically generated by the website or app, including graphs of daily energy targets and macro- and micro-nutrient intakes. In addition, an automated weekly text message component was introduced during the weight loss phase. These texts reinforced the nine SHED-IT weight loss messages and targeted the hypothesised cognitive and behavioural mediators of behaviour change outlined in Bandura's *Social Cognitive Theory* [30] (e.g. self-efficacy, social support), while remaining light-hearted in nature with sensitive use of humour. This component also served as a low-cost way to maintain the frequency of contact with participants during the weight loss phase. This was an important consideration given that a recent systematic review showed that increased frequency of contact was a key factor associated with success in male-only weight loss studies [12].

2.6. Phase II: Weight Loss Maintenance Randomised Controlled Trial

The 'baseline' assessments for this weight loss maintenance study were conducted in November 2012 (Figure 1). This was the first assessment of Phase II and represented the start of the weight loss maintenance RCT. In total, 176 men attended these assessments, representing an 84% retention of Phase I participants. At these assessments, all men who lost at least 4 kg during Phase I (n = 92) were randomised to either (i) a weight loss maintenance group who received the newly developed *SHED-IT Weight Loss Maintenance program* (n = 47), or (ii) a self-help control group who did not receive any additional resources (n = 45). Men who had not lost at least 4 kg were not eligible for Phase II of this study (n = 77) and their involvement in the trial ceased at this point. Seven men lost 4 kg but declined participation in Phase II. See section 2.10 for additional detail on the randomisation process.

2.6.1. The SHED-IT Weight Loss Maintenance program

The *SHED-IT Weight Loss Maintenance* program was designed to provide men with the knowledge and skills required to maintain their weight loss over time. As in the weight loss program, the weight loss maintenance resources were developed to appeal to men and to present standard information in ways that make the messages more meaningful for men [14, 15, 22]. This tailoring included both surface- and deep-structure components, as described in Reniscover et al.'s cultural tailoring framework [31]. The surface structure components included the use of male-specific research findings, images and anecdotes in the intervention materials. The deep structure components, which address men's preferences and values, included the use of a frank and realistic approach [32], a focus on the scientific-basis of the recommendations, and encouragement of an autonomous approach to eating and exercise [13]. Given that men generally do not engage with weight management programs that significantly disrupt their lifestyle [13, 33], the resources focused on teaching men how to balance their energy intake in a sustainable way while still being able to enjoy occasional luxuries, such as a beer or glass of wine. Sensitive humour was also used throughout the resources to deliver key messages, which is valued by men [32] and perceived as a central facet of masculinity [34]. In addition, the intervention materials have been informed by a series of important resources including: (i) the developing evidence-base for successful weight loss maintenance strategies (e.g. [35]), (ii) Bandura's *Social Cognitive Theory* of health behaviour [30], (iii) recent systematic reviews of male-only weight management programs [12], web-based weight control programs [7], and weight loss maintenance interventions [36], (iv) the National Health and Medical Research Council Clinical Practice Guidelines for the Management of Obesity in Adults, Adolescents and Children in Australia [4], and (v) the men's health literature (e.g. [13, 28, 29, 37]).

The *SHED-IT Weight Loss Maintenance* program includes: (i) the '*SHED-IT Weight Loss Maintenance Handbook for Blokes*', (ii) the '*SHED-IT Weight Loss Maintenance Log Book for Blokes*' (to complete key social cognitive and behavioural tasks), (iii) weekly '*SHED-IT Weight Loss Maintenance emails*' (including video messages delivered by PJM and MDY), (iv) bi-weekly text messages, (v) the '*SHED-IT Resistance Training Handbook for Blokes*', and (vi) a digiwalker SW200 pedometer and a gymstickTM, which is a portable exercise tool that uses elastic resistance bands. Participants were advised to continue self-monitoring their diet using CalorieKingTM or MyFitnessPalTM for at least 2 days per week or as needed. For

additional detail on the program components see Table 2.

2.7. Theoretical Framework of the *SHED-IT* programs

Both the *SHED-IT Weight Loss program* and the *SHED-IT Weight Loss Maintenance program* were informed by the behaviour change principles outlined in Bandura's *Social Cognitive Theory* (SCT) [30]. The central theme of SCT is that behaviour is influenced by the dynamic interplay between the environment, the person, and the behaviour itself. This interaction is referred to as 'reciprocal determinism'. SCT also contains a causal framework of determinants that are hypothesised to influence the adoption and maintenance of behaviour [38]. Within SCT, the most important of these determinants is perceived *self-efficacy*, which is purported to have a direct influence on behaviour. Self-efficacy is also hypothesised to indirectly affect behaviour through its influence on the other constructs in the model. These constructs are *outcome expectations* (the perceived consequences of performing the behaviour), *self-regulation* (e.g. goal setting and planning) and perceived *socio-structural factors*, such as social support and the perceived environment.

Importantly, in addition to specifying these constructs, SCT also provides guidance on how best to target these constructs to bring about positive and sustained behaviour changes. For example, Bandura outlines several key sources of information that can help to build self-efficacy, including (i) building a sense of mastery, (ii) verbal persuasion, and (iii) modelling from a relatable role model. For additional detail on how SCT was operationalised within the *SHED-IT Weight Loss Maintenance program* components, see Table 2.

Table 2. *SHED-IT Weight Loss Maintenance* intervention components, behaviour change techniques and social cognitive theory mapping.

Intervention Component	Additional detail	Behaviour Change Techniques [39]	Social Cognitive Constructs Targeted
SHED-IT WLM Handbook for Blokes	<ul style="list-style-type: none"> • What is weight loss maintenance? • Embracing the plateau • Setting achievable goals • Finding energy balance • The 9 Best WLM Tips for Men • Dealing with setbacks 	<ul style="list-style-type: none"> • Provide information about the consequences of behaviour (in general) • Provide information about the consequences of behaviour (to the individual) • Barrier identification • Prompt self-talk • Relapse prevention/coping planning • Time management • Prompting focus on past successes • Action planning 	<ul style="list-style-type: none"> • Building <i>self-efficacy</i> (verbal persuasion, mastery) • Overcoming <i>barriers/impediments</i> • Encouraging <i>self-regulation</i> (goal setting and planning) • Providing information to generating positive <i>outcome expectations</i>
SHED-IT WLM Log Book for Blokes	<ul style="list-style-type: none"> • Recalculating energy requirements • Weight maintenance chart • Goal setting • Physical activity monitoring <ul style="list-style-type: none"> • <i>Steps</i> • <i>Weekly minutes</i> • Strategies to engage family and friends • SHED-IT resistance training program 	<ul style="list-style-type: none"> • Set graded tasks • Goal setting (behaviour & outcome) • Plan social support • Prompt self-monitoring (behaviour and outcome) • Provide rewards contingent on successful behaviour 	<ul style="list-style-type: none"> • Building <i>self-efficacy</i> (mastery) • Encouraging <i>self-regulation</i> (goal setting) • Engaging <i>social support</i> networks
SHED-IT WLM Emails + Video messages (weekly)	<ul style="list-style-type: none"> • Weekly HTML emails will be sent to reinforce key messages from the WLM Handbook, to prompt participants to complete key sections of Log Book and to keep participants engaged with the program. • Each email will also include a video message from two of the researchers (PJM & MDY). Each video will support 	<ul style="list-style-type: none"> • Model/demonstrate the behaviour • Provide information about the consequences of behaviour in general • Provide information on consequences of behaviour to the 	<ul style="list-style-type: none"> • Building <i>self-efficacy</i> (modelling & verbal persuasion) • Providing <i>social support</i> to participants • Engaging <i>social support</i>

	the written content in the email and the presenters will cover practical tips and strategies using light-hearted examples to promote weight loss maintenance (e.g. changing the home environment to reduce junk food consumption).	individual <ul style="list-style-type: none"> • Provide instruction on how to perform the behaviour • Barrier identification/problem solving • Action planning • Environmental restructuring • Prompt self-talk 	networks <ul style="list-style-type: none"> • <i>Self-regulation</i> (planning)
SHED-IT Resistance Training Handbook	<ul style="list-style-type: none"> • Introduction to resistance training • Benefits of resistance training • Exercising safely • Instructions on how to perform body weight and gymstick exercises (with beginner and advanced levels) 	<ul style="list-style-type: none"> • Model/demonstrate the behaviour • Set graded tasks • Prompt self-monitoring of behaviour 	<ul style="list-style-type: none"> • Building <i>self-efficacy</i> (modelling) • Overcoming <i>barriers/impediments</i>
Text messages (bi-weekly)	<ul style="list-style-type: none"> • Light-hearted prompts for the nine SHED-IT weight loss messages • Will also target the hypothesised mediators of behaviour change in Bandura's <i>Social Cognitive Theory</i> [30] 	<ul style="list-style-type: none"> • Barrier identification • Environmental restructuring • Plan social support • Use of follow-up prompts • Prompt review of behavioural goals • Prompt review of outcome goals 	<ul style="list-style-type: none"> • Providing <i>social support</i> to participants • Building <i>self-efficacy</i> (verbal persuasion) • Encouraging <i>self-regulation</i> (goal setting and planning) • Engaging <i>social support</i> networks
Study website / app	<ul style="list-style-type: none"> • Participants will be advised to continue self-monitoring their diet and exercise at least 2 days a week or as needed. • Participants advised to switch their kJ allowance from weight loss mode to weight loss maintenance mode. 	<ul style="list-style-type: none"> • Prompt self-monitoring (behaviour and outcome) • Goal setting (behaviour & outcome) 	<ul style="list-style-type: none"> • Encouraging <i>self-regulation</i> (self-monitoring, goal setting)
WLM Tools	<ul style="list-style-type: none"> • Yamax SW200 pedometer to self-monitor step counts • GymstickTM (gold) to complete above SHED-IT Resistance Training Program 	<ul style="list-style-type: none"> • Prompt self-monitoring of behaviour • Environmental restructuring 	<ul style="list-style-type: none"> • Encouraging <i>self-regulation</i> of behaviour (self-monitoring)
WLM, Weight Loss Maintenance			

2.8. Outcome measures

All assessments for this study are being taken in the Human Performance Laboratory at the University of Newcastle, Australia with the same instruments at each time point. Assessors are trained to follow standardized measurement protocols and will be blinded to group allocation at all assessments. To date, measures have been obtained from participants at study entry (August 2012), baseline (November 2012) and 6-months (May 2013) and will be taken at 12 months (November 2013, primary endpoint).

2.8.1. Physiological measures

Weight is measured in light clothing, without shoes on a digital scale to 0.01 kg (CH-150kp, A&D Mercury Pty Ltd, Australia). Weight is measured twice, with accepted values within 0.1kg. If measurements are outside the acceptable range, a third measure is taken. The average of the two acceptable measures will be reported. The primary outcome for this study is weight change (kg) in Phase II (i.e. weight change from randomisation to the 12-month assessment).

Body Mass Index is calculated using the standard equation ($\text{weight [kg]} / \text{height[m]}^2$). Height was measured, at study entry only (i.e. beginning of Phase I), to 0.1 cm using the stretch stature method on a stadiometer (Veeder-Root (VR) High Speed Counter, Harpenden/Holtain, Mentone Education Centre, Morrabain, Victoria). Height was measured twice, with accepted values within 0.3 cm. A third measure was taken if measurements were outside the acceptable range. The average of the two acceptable measures will be reported.

Waist circumference is measured at two points: (i) level with the umbilicus, and (ii) at the narrowest circumference between the lower costal border and the umbilicus. Two measures are taken at each site, with accepted values within 0.5 cm. Further measures are taken if measurements are outside the acceptable range. The average of the two acceptable measures will be reported. To improve reliability, each measurement is recorded with a non-extensible steel tape (KDSF10-02, KDS Corporation, Osaka, Japan) by an assessor with Level 1 Anthropometry qualifications from the *International Society for the Advancement of Kinanthropometry*.

Blood pressure and resting heart rate are measured three times using NISSEI/DS-105E digital electronic blood pressure monitors (Nihon Seimitsu Sokki Co. Ltd., Gunma, Japan) under standardised procedures. Participants are seated for five minutes before the first blood pressure measurement with a two-minute rest between subsequent measures. Further measurements are taken if the blood pressure or resting heart rate values fall outside of the acceptable ranges (i.e. systolic within 10 mmHg, diastolic within 5 mmHg and resting heart rate within 5 beats per minute). The mean of the two closest systolic pressures and the corresponding diastolic pressure be reported. The mean of the two lowest resting pulse pressures will be used.

Body composition is assessed using the InBody720 (Biospace Co., Ltd, Seoul, Korea), a multi-frequency bioimpedance device featuring an eight-point tactile electrode system. This device has been shown to be a valid and reliable device for body composition assessment [40]. Measures of body composition reported will include body fat percentage, visceral fat area (cm²) and skeletal muscle mass.

Sexual function is assessed using the International Index of Erectile Function-5 (IIEF-5) questionnaire, which is a validated measure of erectile function [41]. Improved erectile function was a key outcome observed in the SHED-IT weight loss community trial [14, 42] and the current study will investigate the sustainability of these effects during weight loss maintenance.

2.8.2. Physical activity and sedentary behaviour measures

Step counts are objectively measured using Yamax SW200 pedometers (Yamax Corporation, Kumamoto City, Japan), which are both reliable [43] and valid [44] physical activity measures for adults. The pedometers are provided at each assessment session and participants are instructed on how to attach the pedometers (at the waist on the right hand side) and asked to remove the pedometers only when sleeping, when the pedometer might get wet (e.g. swimming, showering) or during contact sports. Participants are asked to wear the pedometers for seven consecutive days and keep to their normal routine. At the end of each day participants are instructed to record their steps on a pedometer record sheet and reset their pedometers to zero. Participants are instructed to note down if they did an activity like cycling, swimming, contact sports or another activity that does not involve stepping and

include details (type of activity and duration), or if they forget to wear their pedometer. Step counts will be averaged to create a mean steps per day measure and participants will be included in the analyses if they complete at least four days of pedometer monitoring. The average of existing days will be imputed for participants who have three or less days of missing data.

Light, moderate and vigorous physical activity are measured with a modified version [45] of the validated Godin Leisure-Time Exercise Questionnaire [46]. This questionnaire contains three sections where participants indicate how many times in the past month they engaged in light-, moderate-, and vigorous-intensity physical activity in bouts of at least 10 minutes. Participants also estimate the average session duration for each category. These ‘frequency’ and ‘duration’ responses are then multiplied within each category to provide a measure of minutes of light, moderate and vigorous physical activity in the previous month.

Sedentary behaviour is assessed using the Sitting Questionnaire, which has been shown to be both a valid and reliable measure of sitting time in various domains [47].

2.8.3. Dietary measures:

Dietary intake is assessed using the Australian Eating Survey (AES). The AES is a 120-item semi-quantitative Food Frequency Questionnaire (FFQ), which has been validated in both adult males and females [48]. Portion sizes for individual food items will be generated by the Australian Bureau of Statistics (ABS) [49] and unpublished data from the 1995 Australian National Nutrition Survey; or the “natural” serving size for common items such as a slice of bread. Participants are asked about frequency of their consumption over the previous six months with frequency options ranging from ‘Never’ up to ‘4 or more times per day’ but varying depending on the food item. Twenty-one questions directly relate to the intake of vegetables and 11 questions relate to fruit, with seasonality of some fruits addressed in the nutrient analysis.

Nutrient intakes from the AES will be computed using the Australian AusNut 1999 database (All Foods) Revision 17 and AusFoods (Brands) Revision 5 (Australian Government Publishing Service, Canberra) to generate individual mean daily macro-and micro-nutrient intakes. The AES also includes questions to assess the total number of daily serves of fruit,

vegetables, bread, dairy products, eggs, fat spreads, sweetened beverages and snack foods, as well as the type of bread, dairy products and fat spreads used. In addition, 12 questions investigate food-related behaviours, including items on frequency of take-away food consumption and eating while watching television.

Portion size is assessed using portion size photographs from the Dietary Questionnaire for Epidemiological Studies Version 2 (DQES v2), FFQ from the Cancer Council Victoria [50]. These photos are used to calculate a single portion size factor (PSF) to indicate whether on average a person eats median size serves (PSF=1), more than the median (PSF > 1), or less than the median (PSF < 1) serve sizes for main meals. The DQES was developed specifically for use in Australian adults by the Cancer Council of Victoria as an update of a FFQ used in a cohort of Australian volunteers aged 40–69 years. Both the development of the questionnaire and its validation have been reported previously [51].

Risky alcohol consumption is measured using an adaptation of the Australian Government Department of Veteran Affairs, Alcohol Use Disorders Identification Test (AUDIT) 2009, which is a valid and reliable measurement tool in determining alcohol use, alcohol disorders and alcohol misuse [52].

Weekly breakfast consumption is measured with a single item developed for this study where participants indicate the number of days per week that they usually eat breakfast, with response options ranging from 0 days per week to 7 days per week.

2.8.4. Psychological measures

Quality of life and general health are assessed using the validated UK short form 12 (SF-12) questionnaire [53].

Depressive symptoms are measured with the Patient Health Questionnaire eight item depression scale (PHQ-8), which has established validity as a diagnostic measure of depressive disorders in both clinical and community samples [54].

Cognitive restraint is measured with the Cognitive Restraint Subscale from the 3-Factor Eating Questionnaire [55] as identified by Karlsson et al [56].

Weight loss expectations are measured with Part II of the validated Goals and Relative Weights Questionnaire (GRWQ) [57].

2.8.5. Social cognitive measures

The hypothesised behavioural mediators outlined in Bandura's *Social Cognitive Theory* [30] are measured with validated scales relating to (i) physical activity and (i) energy-dense, nutrient-poor discretionary choices, referred to 'junk food'. Physical activity intention, from the *Theory of Planned Behaviour* [58], and autonomous motivation, from *Self-determination Theory* [59], are also measured to allow investigation of integrated theories, which has been recommended in the literature [60]. The construct validity, content validity and two week test-retest reliability of these scales was assessed in a separate, representative sample (n = 22) of overweight and obese Australian men (mean (SD) age 39.7 (14.8) years; BMI 29.1 (5.1) kg/m²). The internal consistency [cronbach's α] and reliability (intra-class correlation coefficient [ICC]) of each scale from this pilot-testing phase are detailed in Tables 3 and 4.

Physical activity cognitions: Prior to completing the physical activity cognitions, participants are asked to read a definition of 'regular physical activity'. For the purposes of this study, 'regular physical activity' is defined as 'at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week'. This behavioural referent was chosen as it reflects an overlap in the best available international physical activity recommendations for the minutes of physical activity required for weight loss and weight loss maintenance [61]. The description of moderate intensity activity used matches the following definition from the *Australian Physical Activity Guidelines for Adults* [62]:

"Moderate-intensity activity will cause a slight, but noticeable, increase in your breathing and heart rate. A good example of moderate-intensity activity is brisk walking, that is at a pace where you are able to comfortably talk, but not sing. Other examples include mowing the lawn, digging in the garden, or medium-paced swimming or cycling".

To standardise the measures to this referent and reduce potential confusion, the term 'regular physical activity' was used to replace 'regular exercise' or 'exercise' throughout the

measures, where possible. See Table 3 for addition details on the physical activity scales used.

Energy-dense, nutrient-poor food or ‘junk food’ cognitions: Most of the ‘junk food’ social cognitive measures were adapted from measures originally designed to capture low-fat dietary behaviour. The behavioural referent was changed from ‘following a low-fat diet’ to ‘reducing junk food intake’ for this study as research shows this is a key problem area for men [20, 23]. Further, although following a low-fat diet has been previously linked to weight loss maintenance [10, 35], recent evidence suggests that dietary composition is not as important as overall energy intake [63, 64]. While completing this section of the questionnaire, all men are provided with a laminated reference card containing definitions of healthy food and ‘junk food’ adapted from the *Australian Guide to Healthy Eating* [65]. In addition, this card also contains pictures of the most commonly consumed ‘junk foods’ reported by men in the SHED-IT community RCT (e.g. bacon, chocolate, potato chips, ice cream and pizza) [14]. See Table 4 for additional details on the ‘junk food’ scales used.

Table 3. Social cognitive theory measures for physical activity with validity and reliability statistics.

Construct	Source	Example	Items (Range)	Anchors	α	ICC (95% CI)
Self-efficacy	[66]	<i>e.g. I am confident that I can get 'regular physical activity' when I am a little tired</i>	8 (1-5)	Not at all confident – Completely confident	0.96	0.88 (0.68 to 0.95)
Goal setting ^a	[67]	<i>e.g. I often set physical activity goals</i>	10 (1-5)	Strongly disagree – Strongly agree	0.81	0.80 (0.50 to 0.92)
Planning	[68]	<i>e.g. I make plans concerning when I am going to engage in 'regular physical activity'</i>	4 (1-7)	Strongly disagree – Strongly agree	0.93	0.70 (0.30 to 0.87)
Positive outcome expectations	[66]	<i>e.g. 'Regular physical activity' would help me control my weight</i>	5 (1-5)	Strongly disagree – Strongly agree	0.78	0.74 (0.36 to 0.89)
Perceived barriers ^b	[66]	<i>e.g. 'Regular physical activity' would take up too much of my time</i>	3 (1-5)	Strongly disagree – Strongly agree	0.72	0.82 (0.58 to 0.93)
Social support (prospective)	[69]	<i>e.g. People in my social network are likely to help me get 'regular physical activity'</i>	2 (1-5)	Strongly disagree – Strongly agree	0.81	0.80 (0.53 to 0.92)
Social support (past month) ^c	[70]	<i>e.g. During the past month, my family/friends were active with me</i>	10 (1-5)	Never/does not apply – Very often	Family 0.95	0.96 (0.91 to 0.98)
					Friends 0.96	0.92 (0.80 to 0.97)
Intention ^d	[71]	<i>e.g. I am motivated/determined to engage in 'regular physical activity'</i>	2 (1-7)	Extremely unmotivated / undetermined – Extremely motivated / determined	0.92	0.92 (0.80 to 0.97)
Autonomous motivation ^e	[72]	<i>e.g. The reason I would get 'regular physical activity' is because I want to take responsibility for my own health</i>	6 (1-7)	Not at all true – Very true	0.93	0.92 (0.70 to 0.97)

α , Cronbach's alpha (internal consistency); ICC, intra-class correlation coefficient; CI, confidence interval

^a Original anchors ("does not describe me" to "describes me completely") were replaced as the pilot sample found them difficult to interpret

^b Scale adapted from a 5 item measure that demonstrated unacceptable internal consistency in the pilot sample ($\alpha = 0.46$)

^c Scale measured separately for family and friends

^d Construct from 'theory of planned behaviour'

^e Construct from 'self-determination theory'

Table 4. Social cognitive measures for intake of energy-dense, nutrient-poor foods with validity and reliability statistics.

Construct	Adapted from	Example	Items (Range)	Anchors	α	ICC (95% CI)
Self-efficacy	[73]	<i>e.g. How tempted would you be to eat your favourite junk food while having a good time with friends at a party</i>	12 (1-5)	Not at all tempted – Extremely tempted	0.86	0.76 (0.42 to 0.90)
Positive outcome expectations	[74]	<i>e.g. if I eat less junk food I expect I will lose weight</i>	8 (1-5)	Strongly disagree – Strongly agree	0.84	0.77 (0.45 to 0.91)
Barriers	[74]	<i>e.g. if I eat less junk food I expect I will be bored with what I have to eat</i>	12 (1-5)	Strongly disagree – Strongly agree	0.87	0.89 (0.74 to 0.96)
Planning	[75]	<i>e.g. when it comes to eating less junk food, I make detailed plans regarding when I have to pay attention to prevent lapses</i>	5 (1-4)	Strongly disagree – Strongly agree	0.94	0.89 (0.74 to 0.96)
Behavioural strategies	[76]	<i>e.g. in the past month I set goals to eat less junk food</i>	15 (1-5)	Never – Many times	0.86	0.77 (0.47 to 0.91)
Social support (prospective)	[69]	<i>e.g. People in my social network are likely to help me eat less junk food</i>	2 (1-5)	Strongly disagree – Strongly agree	0.92	0.80 (0.52 to 0.92)
Social support (past month) ^a	[70]	<i>e.g. In the past month, my family/friends encouraged me not to eat junk food when I'm tempted to do so</i>	5 (1-5)	Never – Very often	Family 0.88	0.87 (0.69 to 0.95)
					Friends 0.86	0.91 (0.79 to 0.96)
Social sabotage (past month) ^a	[70]	<i>e.g. In the past month, my family/friends offered me junk food I'm trying not to eat</i>	5 (1-5)	Never – Very often	Family 0.86	0.83 (0.58 to 0.93)
					Friends 0.69	0.76 (0.41 to 0.90)
Perceived environment ^b	[77]	<i>Participants indicate how frequently various junk foods (e.g. chocolate, potato chips) are available in their day-to-day life</i>	13 (1-4)	Never/rarely - Always	0.75	0.75 (0.39 to 0.90)

α , cronbach's alpha (internal consistency); ICC, intra-class correlation coefficient; CI, confidence interval

^a Scale measured separately for family and friends

^b Items chosen to reflect the most commonly consumed energy-dense, nutrient-poor discretionary choices reported by men in the SHED-IT Community RCT [14].

2.8.6. Process measures

Log books: Adherence to self-monitoring (total number of daily diet entries, daily exercise entries and weekly weigh-ins) will be calculated from the online food and exercise diaries in Phase I and Phase II. In addition, all men were asked to hand in their '*SHED-IT Weight Loss Log Book for Blokes*' at the end of Phase I. Similarly, men in the weight loss maintenance intervention group will be asked to hand in their '*SHED-IT Weight Loss Maintenance Log Book for Blokes*' at the end of Phase II. These will be photocopied and posted back.

Adherence to the following log book tasks will be documented: (i) calculating kJ output (Phase I only), (ii) completing waist charts (Phase I only) (iii) completing weight charts (iv) goal setting, (v) step count monitoring, (vi) creating social support strategies, (vii) physical activity monitoring (minutes of MVPA; Phase II only), and (viii) completing the resistance training program (Phase II only).

Program evaluations: Detailed process questionnaires will be administered to examine men's perceptions of the *SHED-IT Weight Loss program* (n = 28 items) and the *SHED-IT Weight Loss Maintenance program* (n = 28 items). These questionnaires will include scales, individual items and open-ended questions that require men to describe the strengths and weaknesses of the program along with their suggestions for improvement. The process evaluations will cover issues such as the study feasibility, use and appraisal of intervention components and overall levels of satisfaction. We will also ask how much participants would be willing to pay for the offered interventions. The *SHED-IT Weight Loss program* evaluation was administered to all participants at the end of Phase I. The *SHED-IT Weight Loss Maintenance program* evaluation will be administered to participants from this group at the end of Phase II.

2.8.7. Costing measures

A variety of measures are used to gauge the various costs and savings participants will incur throughout the study. At each assessment participants self-report their level of access to various health professionals such as general practitioners, dietitians and physiotherapists in the previous 6 months. Medication usage is also be monitored throughout the study. At follow-up time points, participants indicate how much time they spent on the CalorieKingTM website or MyFitnessPalTM app in the previous 6 months. Participants are asked to identify whether they experienced any of a series of potential costs (e.g., joining a gym) and savings

(e.g., reduced alcohol expenses) as a result of changes they made after starting the SHED-IT program. To assess travel costs, participants report which mode of transport they used to attend each assessment. In addition to participant costs, implementation costs associated with the program delivery, such as the cost of resources and staff costs, will also be monitored throughout the study. Participants will not receive any incentives or reimbursements for completing assessments or otherwise during the study.

2.9. Sample size

The sample size calculation is based on the primary outcome of weight change in Phase II (i.e. weight change from randomisation to the 12-month assessment). Using 12-month follow up data from the SHED-IT pilot study [16], we have assumed this will have a standard deviation of 4kg. Thus, 29 men in each treatment group at the primary endpoint (12-month) will give the study 80% power to detect a difference in weight change between groups of 3kg at the 5% significance level using a two sided test. A between-group difference of 3kg was chosen as this is outside the range of normal weight fluctuation and is sufficient to sustain clinically meaningful health benefits [78].

To ensure adequate power for the RCT in Phase II, 195 men were required to enter Phase I. Following this, 80% of this original sample ($n = 156/195$) were expected to complete the assessments at the end of Phase I. Of those assessed, 50% ($n = 78/156$) were expected to have lost the 4 kg necessary to enter the RCT in Phase II. Finally, of those who entered Phase II, we expected to retain 75% at the 12-month follow-up assessments ($n = 58/78$). These projections were grounded in extensive previous research with men in the SHED-IT studies [14-16, 22] and have been reliable to date (See Figure 1). Given the accuracy of these predictions, we expect that the study will be powered with the necessary 29 men in each treatment group at the Phase II 12-month assessment.

2.10. Randomisation

Participants were randomised at an individual level by an independent statistician who will not have any contact with participants during the trial. Allocation was stratified by BMI category calculated at the 'baseline' assessment ($<30 \text{ kg/m}^2$ and $\geq 30 \text{ kg/m}^2$) and phase I weight loss (4 kg - 7.4 kg and $\geq 7.5 \text{ kg}$). These categories were based on the distributions of

BMI and initial weight loss in the SHED-IT community RCT [14] and were expected to create four strata of approximately equal size.

The allocation sequence within strata was generated by a computer-based random number-producing algorithm in randomly varied block lengths. Randomisation codes were stored in a restricted computer folder, which was not be accessible by those assessing participants, those involved in allocating participants to groups or those participating in data entry for the study. Complete separation will be achieved between the statistician who generated the randomisation sequence and those who conceal allocation from those involved in implementation of assignments.

2.11. Allocation

Information for the two study groups was pre-packed into identical white, opaque envelopes. These envelopes were consecutively numbered within the four stratification categories and ordered according to the randomisation schedule. The packing and sequencing of these envelopes was completed by a research assistant who was not involved in the enrolment, assessment or allocation of participants. Study participants completed all baseline assessments before proceeding to a separate room to meet with a study chief investigator who was not involved with the baseline assessments. The allocation sequence was concealed during this process. Participants' BMI category and Phase I weight loss was calculated using an excel spreadsheet from the baseline measurements and the participant were allocated the next available number in the relevant stratification category. At this point the envelope was opened by the investigator and details of the particular study group were briefly provided to the participant using a standardised protocol. If the participant was randomised into the weight loss maintenance intervention they were then provided with their program resources.

2.12. Data management, quality assurance and exclusion of bias

Randomisation was undertaken by study chief investigators and the use of randomly varied block sizes ensured that upcoming assignments could not be known in advance. Measures were taken by trained staff at all times points. In order to ensure accurate and consistent measurements, the study weight scale will be professionally calibrated and the height scale will be checked and recalibrated daily before each assessment session. Assessors will be blinded to treatment allocation at all assessments. When men are contacted (via phone and

email) to book in for follow-up assessments they will be asked not to inform the assessors of their group allocation. Data will be entered by research assistants blind to group allocation and a program of plausibility checks will be used to identify unrealistic values. The primary outcome measure (weight) will be double entered to ensure accuracy and a random 20% sample of all other measures will also be double entered.

2.13. Statistical methods

Analyses will be performed using IBM SPSS Statistics version 20 or later. All variables will be checked for plausibility and missing values. Data will be presented as mean (SD) for continuous variables and counts (percentages) for categorical variables. Differences between groups at randomisation and characteristics of completers versus dropouts will be tested using independent *t* tests for continuous variables and chi-squared (χ^2) tests for categorical variables.

2.13.1. Primary analyses plan

Linear mixed models will be used to assess weight and other secondary outcomes for the impact of treatment (weight loss maintenance intervention vs. control), time (treated as categorical with levels at baseline, 6 and 12 months) and the treatment-by-time interaction, with these three terms forming the base model. This will ensure that the outcomes for participants who drop out of the program at 6 or 12-months are retained in the analyses, consistent with an intention-to-treat approach. Age, socio-economic status, phase 1 weight loss and BMI will be examined to determine whether they contribute significantly to the models [79]. If a covariate is significant, a term will be added to the model to adjust for the effects and two-way interactions with time and treatment will also be examined. If these interactions are also significant they will be similarly adjusted for in the model.

2.13.2. Secondary analyses plan - Mediation analysis:

Hypothesised psychological and behavioural mediators of the weight loss maintenance intervention effect will be examined in SPSS using the INDIRECT macro, developed by Preacher and Hayes [80]. This macro generates regression coefficients to reflect (i) the effect of the intervention on the hypothesised mediator, (ii) the association between the hypothesised mediator and the outcome, controlling for treatment condition, and (iii) the total, direct and indirect intervention effects. The macro also generates bias-corrected 95%

confidence intervals around the indirect effect and mediation will be established if these confidence intervals do not include zero. The sample size required for the RCT will provide adequate power for this analysis to detect medium sized mediation effects [81].

2.13.3. Cost effectiveness analysis plan:

The *SHED-IT Weight Loss Maintenance intervention* will be evaluated using the ACE Obesity approach, consistent with the ACE-Prevention methodology. These methods are international best-practice for cost-effective analyses and include (i) the adoption of a health care perspective, (ii) transparent and scientific methods to identify, measure and value both costs and outcomes from the trial, (iii) modelling and uncertainty testing of epidemiological and costing input parameters, and (iv) interpretation of results within a broader decision-making framework [82, 83]. Costing information will be collected from participants throughout the trial and a multi-state life table Markov model will be used to calculate health outcomes resulting from a reduction in weight due to the interventions. Effectiveness will be measured by changes in BMI over time that lowers the risk of weight-related diseases. The model explicitly simulates nine obesity-related diseases including stroke, ischemic heart disease and type 2 diabetes mellitus. Estimates of disease incidence, prevalence and mortality are based on the Australian Burden of Disease 2003 study, updated where appropriate. The model summarises the disease-specific changes in the number of years lived adjusted for disability from the explicitly modelled diseases and average age- and sex-specific disability levels from all other causes.

The analysis will model all costs and population health outcomes over the lifetime of the Australian population, discounting future costs and health outcomes at a rate of 3% per year. The costs and health outcomes are summed over the lifetime to determine the incremental cost-effectiveness ratio, in dollars per disability adjusted life year averted, for each intervention. Monte Carlo analysis is used to derive 95% uncertainty intervals for all outcomes and to determine the probability of intervention cost-effectiveness against a cost-effectiveness threshold of \$50,000 per disability adjusted life year. The incremental cost-effectiveness ratio results are displayed on a cost-effectiveness plane with affordability issues addressed in an acceptability curve. The results of the cost-effective analysis will be considered in the context of other decision making criteria including: strength of evidence;

capacity of the intervention to reduce inequity; acceptability to stakeholders; feasibility; sustainability; and, potential for other consequences.

3. DISCUSSION

Internationally, Australia has one of the highest rates of obesity in men [1] and developing strategies to decrease obesity in this target population is a national and international health priority. There is limited evidence to guide the design of effective and sustainable male-targeted obesity programs that engage men [11, 12], particularly for programs that focus on weight loss maintenance [12]. The current study will contribute key information to the evidence-base by testing the usefulness of a long-term, gender-targeted weight loss maintenance program that aims to educate men on how to maintain their weight loss through the difficult post-intervention period, where treatment effects are known to regress [10].

Currently, research regarding male-only weight loss maintenance interventions is limited. Borg et al. [84] conducted an RCT with 90 men to test the effectiveness of two exercise programs (walking vs. resistance training) for weight loss maintenance compared to a control. Although both programs included weekly meetings, dietary advice and exercise training sessions three times per week, neither intervention group demonstrated significantly different weight regain to the control group at post-test (6 months) or long-term follow-up (29 months). However, the intervention components in this study were not specifically tailored to men and the initial weight loss was achieved by following a very-low energy diet, which may not be a sustainable approach for long term weight loss [4, 85]. Only one other male-only weight loss maintenance RCT has been conducted to date [86], however it published over 15 years ago, did not use intention-to-treat analysis or report a power calculation, and tested the effectiveness of continuing a standardised exercise regime from the weight loss phase against a group who did not continue the exercise regime. There was no significant difference between the groups at 12-month follow up.

To date, the effects of other weight loss maintenance programs have also been modest [36]. In the STOP Regain trial [87], participants in a face-to-face maintenance intervention regained 2.4 kg less than a control group after 18 months. Similarly, in the U.S. Weight Loss Maintenance trial [88], participants who received a monthly personal contact maintenance intervention regained approximately 1.5 kg less than a minimal intervention control group

after two and half years. Both trials also tested an online maintenance intervention, which performed poorer than the face-to-face arm over the course of the study. Although these modest weight losses could bring about clinically important health benefits [4], the face-to-face interventions would be difficult to implement on a large scale. Although the online maintenance intervention in the Weight Loss Maintenance trial would be a more scalable approach, the weight loss phase still involved 20 group-sessions over 6 months with a trained interventionist. These factors could reduce the scalability of the interventions and decrease cost-effectiveness.

The low-intensity nature of the SHED-IT interventions is a considerable strength of this research, as this would likely increase cost-effectiveness and scalability. Sustainability and affordability are major challenges for weight loss treatments, even those with proven effectiveness [89], and many current approaches are not good ‘value for money’ [4, 90]. Current pharmacological treatments are limited and only moderately effective relative to cost [90]. Bariatric surgery is expensive, applicable to only those most obese, and not widely available [4]. Other options, including intensive behavioural treatments requiring multiple in-person contacts are not viable as they require substantial resources, making them too expensive for widespread use relative to effectiveness [10]. To date, cost-effectiveness research into weight loss maintenance programs is lacking [24]. This research is essential, as even modestly effective weight loss interventions would likely be cost-effective for healthcare systems at the population level, provided the losses are maintained [24]. This study will investigate the cost-effectiveness of the SHED-IT weight loss and weight loss maintenance interventions, which may be more viable and cost-effective alternatives to currently available options, as they involve no face-to-face contact or individually-tailored intervention components.

To date, the strength of evidence from weight loss maintenance trials has been limited by multiple methodological concerns [36], which will be addressed in the current study. Strengths of this study protocol include an RCT design with a no-maintenance intervention control group, extensive detail of rigorous and transparent randomisation procedures, a detailed statistical analysis plan that will follow intention-to-treat principles, and an extended assessment timeline that includes a 6-month passive follow-up to assess the maintenance of treatment outcomes after the intervention has ceased. In addition to measuring weight and

other physiological outcomes, we will assess a comprehensive range of secondary outcomes to capture the physiological, behavioural, psychological, social and economic impacts of the program.

This study will build upon a considerable body of research into the *SHED-IT Weight Loss program* to specifically address the problem of weight regain after weight loss. To the authors' knowledge, this will be the first study internationally to test the effectiveness and cost-effectiveness of a weight loss maintenance intervention designed specifically for men.

Competing Interests

The authors declare that they have no competing interests.

Authors' contributions

The study chief investigators PJM, CEC, RCP, CMD, RC, & MDY were responsible for identifying the research question, design of the study, obtaining ethics approval, the acquisition of funding and overseeing study implementation. All authors were responsible for the drafting of this manuscript and have read and approved the final version.

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