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Impact of a Self-Guided, eHealth Program Targeting Weight Loss and Depression in Men: A Randomised Trial

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SHED-IT: Recharge was adapted from the SHED-IT program, which was developed

by members of the current research team. After the conclusion of the SHED-IT: Recharge trial, the original SHED-IT program was commercialized by the University of Newcastle. Under an agreement with the University, a portion of income received via this process is returned to the research team in the form of research support. We have no other known conflicts of interest to disclose.

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Abstract

Objective: Obesity and depression are major, inter-related health concerns for men, yet many do not receive support to manage these conditions. This study investigated whether a self-guided, eHealth program (SHED-IT: Recharge) could reduce weight and depressive symptoms in men with overweight or obesity and low mood.

Method: Overall, 125 men (BMI 25–42 kg/m^2) with depressive symptoms (Patient Health Questionnaire-9 [PHQ-9] score ≥5) were recruited for a 6-month RCT. Men were randomised to i) the SHED-IT: Recharge group (n=62) or ii) a wait-list control group (n=63). The 3-month program included printed, and online resources (e.g., website, interactive modules). It was adapted from an evidence-based weight loss program for men to include an additional focus on 'mental fitness'. The primary outcomes were weight and depressive symptoms (PHQ-9) at 3 months. Men were assessed at baseline, 3 months (post-intervention), and 6 months. Intention-to-treat linear mixed models examined program outcomes.

Results: At 3 months, medium-sized treatment effects were detected for both weight (adjusted mean difference -3.1 kg, 95%CI -4.3, -1.9, d = 0.9) and depressive symptoms (adjusted mean difference -2.4 units, 95%CI -4.0, -0.9, d = 0.6). These effects were maintained at 6 months and supported by sustained improvements in other health outcomes.

Conclusions: A self-guided, eHealth program that combined behavioural weight loss advice with mental health support decreased weight and depressive symptoms in men. Integrated interventions targeting physical and mental health may be an effective strategy to engage and support men with overweight or obesity and low mood.

Keywords: low mood, obesity, males, intervention, online

Public health statement: In this randomised trial, an unguided, eHealth intervention improved the physical and mental health of men with overweight or obesity, and mild-to-severe depressive symptoms. Although the 3-month program was completely self-directed,

men in the intervention group reduced their mean weight and depressive symptoms by 3.3 kg and 46% at post-intervention, respectively. These changes were significantly greater than those observed in a wait-list control group (-0.2 kg, 19% reduction in symptoms) and were maintained at 6-month follow-up. Integrated online interventions targeting men's physical and mental health could play a key role in preventing and treating depression in men.

Impact of a Self-Guided, eHealth Program Targeting Weight Loss and Depression in Men: A Randomised Trial

Depressive disorders are leading contributors to the burden of disease in Australia (Australian Institute of Health and Welfare, 2019a) and internationally (Liu et al., 2019). Despite disproportionally affecting women (Liu et al., 2019), these disorders still affect large numbers of men. Global estimates suggest over 109 million men experienced a depressive disorder in 2019, or 2.96% of men worldwide (Institute for Health Metrics and Evaluation, 2021). Following Australia's most recent national mental health survey, the Australian Bureau of Statistics (2008) estimated that over 420,000 men experienced a depressive episode in the previous 12 months, representing 5.3% of the adult male population.

Although mental health concerns are common in men, they are less likely than women to seek professional help (Call & Shafer, 2018). In Australia, only 40% of men with a mental or substance-use condition accessed professional services for their mental health in 2011-2012, compared to 55% of women (Harris et al., 2015). Similarly, after adjusting for prevalence rates, estimates suggest women are 1.6 times more likely than men to access mental health care in both the United States (Wang et al., 2005) and the United Kingdom (McManus et al., 2016). This difference is often attributed to stigma, given the dominant form of masculinity in many Western countries rewards men for being tough, stoic, and self-reliant (Rice et al., 2013). However, it is also possible that existing mental health treatments are not engaging or accessible for some men (Seidler et al., 2018). To address this, the Australian Men's Health Policy (2020-2030) identified a need for innovative mental health programs that are appropriate and acceptable to men (Australian Government, 2020).

In this context, integrated interventions that support men to improve both physical and mental health have promise for several reasons. First, depression is closely associated with multiple lifestyle behaviours including physical activity (Gianfredi et al., 2020), diet

(Molendijk et al., 2018), and sleep (Fang et al., 2019). Thus, interventions targeting these behaviours may generate indirect improvements in men's mental health. Second, improving diet quality and increasing physical activity are already common strategies men report using to manage their mental health (Proudfoot et al., 2015). Third, programs emphasising physical health may engage men who strongly conform to traditional masculine norms (Berger et al., 2013), are reluctant to admit they have depression (Fields & Cochran, 2011), or who are experiencing subclinical symptoms (Wang et al., 2016).

Of all men with depression, this integrated approach may be most beneficial for those also living with overweight or obesity. In a seminal meta-analysis (N = 58,745), Luppino and colleagues (2010) identified that adults with overweight or obesity were 27% and 55% more likely to develop depression over time compared to those in the healthy weight range. Of interest, adults with depression were also 58% more likely to develop obesity over time compared to those without depression, which suggests a complex reciprocal association may exist between the two conditions.

While these effects were not specific to males, they pose unique problems for men. In Australia, poor health behaviours are highly prevalent in men, and 75% are living with overweight or obesity compared to 60% of women (Australian Bureau of Statistics, 2018a). According to the Australian Institute of Health and Welfare (2019b), 83% of men are not meeting physical activity guidelines, 97% have inadequate fruit and vegetable intake, and 24% are exceeding the lifetime risk guidelines for alcohol consumption. Only 49% of Australian men indicate they are getting adequate sleep (Adams et al., 2017). Of concern, similar patterns of unhealthy lifestyle behaviours have been documented in men internationally (National Center for Health Statistics, 2021; Ng et al., 2014; White et al., 2011). Given these behaviours are critical for maintaining positive physical and mental health, targeted strategies to enhance the health behaviours of men with overweight or obesity

and depression are warranted. Despite this, a recent review of lifestyle behaviour change interventions targeting men did not identify any studies that were specifically designed to detect changes in men's mental health or support men with pre-existing mental health conditions (Drew et al., 2020).

To date, four randomised controlled trials have investigated the benefits of combining behavioural weight loss strategies with cognitive behavioural mental health support in adults with overweight or obesity and depression (Faulconbridge et al., 2018; Linde et al., 2011; Ma et al., 2019; Pagoto et al., 2013). Notably, all studies highlighted the potential for integrated treatments to reduce simultaneously reduce depressive symptoms and improve weight status in this subgroup. However, given 85% of participants in these studies were women, and two of the four targeted women exclusively (Linde et al., 2011; Pagoto et al., 2013), the utility of this approach to improve men's physical and mental health remains unclear. This reflects a broader trend in weight loss research, where 73% of participants have been women and only 5% of studies included male-only samples (Pagoto et al., 2012). Moreover, of the studies that did recruit men only, even fewer studies tested 'gender-tailored' programs that accounted for the biological, psychological, and socio-cultural variables that influence men's health. A similar pattern has been observed in mental health programs, where few studies have targeted men and most 'gender neutral' programs are more effective for women (Seaton et al., 2017).

Another limitation of previous studies is the lack of interventions with potential for widespread translation and scale up. To support the substantial number of men experiencing depression and/or obesity, particularly in disadvantaged, regional, or remote areas, interventions must be both effective and scalable. However, most health promotion programs for men include multiple consultations with highly trained professionals (Robertson et al., 2014; Seaton et al., 2017). Although this often enhances program outcomes, it also increases costs and can make the intervention more challenging to disseminate at scale. In contrast,

eHealth programs that 'deliver health services through the internet and related technologies' (Pagliari et al., 2005) can reduce these barriers (Hutchesson et al., 2015).

In this context, we conducted the current study to determine whether a self-guided, eHealth program integrating behavioural lifestyle advice with targeted mental health support could improve the physical and mental health of men with overweight/obesity and low mood. We hypothesised that men in the intervention group would demonstrate significantly greater improvements in weight and depressive symptoms at post-intervention compared to a wait-list control group. Our secondary aims were: i) to examine the impact of the program on several physical and psychological comorbidities of depression and obesity (e.g., anxiety, blood pressure), ii) to identify if program effects were maintained 3 months post-intervention, and iii) to examine potential moderators of the treatment effect for each primary outcome.

Method

The description and interpretation of this study aligns with reporting guidelines from the *Consolidated Standards of Reporting Trials* (CONSORT) (Moher et al., 2010) and APA *Journal Article Reporting Standards* (JARS) for clinical trials.

Study design

The study was an assessor-blinded, parallel-group randomised controlled trial (RCT) comparing an intervention to a self-assessment, wait-list control group (Figure 1). The University of Newcastle Human Research Ethics Committee approved the study, and the protocol was prospectively registered on the Australia New Zealand Clinical Trials Registry (ACTRN12619001209189). The design, conduct and reporting of the study adhered to the CONSORT guidelines (Schulz et al., 2010).

Participants

Between August and September 2019, 125 men from Newcastle and the Hunter Region of Australia self-selected into the study. Eligible men were 18-70 years old, had a

Body Mass Index (BMI) from 25-42 kg/m^2, and had experienced at least mild depressive symptoms over the past two weeks (Patient Health Questionnaire - 9 item (PHQ-9) score ≥5) (Kroenke & Spitzer, 2002). Although a PHQ-9 score of 10 has greater sensitivity for detecting major depressive disorder, we opted for a lower threshold to acknowledge that men are often less willing to report depressive symptoms using existing diagnostic scales (Fields & Cochran, 2011). We also anticipated that the intervention would have utility for both prevention and treatment of depression (Wang et al., 2016). The primary recruitment strategies were local exposure from a University media release and Facebook advertising. Recruitment materials indicated we were seeking volunteers to evaluate a new program designed to help men lose weight and improve their mood. The materials did not focus specifically on depression given i) men with subclinical symptoms were eligible to enrol, and ii) it may have suppressed enrolments from men with greater adherence to traditional masculine norms (Magovcevic & Addis, 2005).

As seen in Table 1, we included some additional eligibility criteria to minimise the impact of potential confounds and ensure participants could safely engage with the program.

To improve study generalisability, we did not exclude men who were accessing counselling or taking antidepressant medication provided they had not changed their treatment plan in the previous 4 weeks. However, men did require a medical clearance from their general practitioner if they reported any health concerns in a pre-exercise screener (e.g., recent heart attack or stroke). All men provided written informed consent prior to enrolment.

The SHED-IT: Recharge Program

Men in the intervention group received the 3-month *SHED-IT (Self-Help, Exercise and Diet using Information Technology): Recharge Program*, which included a combination of eHealth and printed resources (see Table S1). The program was adapted from the *SHED-IT Weight Loss Program for Men*, which has been tested in both efficacy (Morgan et al., 2009,

2011) and effectiveness RCTs (Morgan et al., 2013). Briefly, *SHED-IT* is a self-guided, eHealth weight loss program that teaches men how to lose weight through sustainable and realistic lifestyle behaviour change. To begin the program, participants are directed to read a study handbook (32 pages, ~60 min time commitment) and watch two introductory videos on the study website (~30 min time commitment). Following this, the men are encouraged to complete a series of weekly tasks set out in the study logbook (e.g., setting and reviewing goals). For a summary of all weekly tasks and the approximate time commitment, see Table S2. As seen in Table S1, the program targets a range of behaviour change techniques aligned with key constructs from Bandura's Social Cognitive Theory (e.g., self-efficacy, goal setting) to increase the likelihood of sustained lifestyle change (Bandura, 2004).

To appeal to men, the program is also 'gender-tailored' at both the surface level (e.g., including pictures of men and information from male-specific studies) and deeper level, where core program components are adapted to align with men's preferences and values (Morgan et al., 2016). For example, program messages were often delivered in a light-hearted manner, given men value health communication that is frank and direct, but also incorporates humour (Smith et al., 2008). This tailoring also extends to the program's mode of delivery. Given men are often expected to be self-reliant, and are often limited by work and family commitments, their engagement with face-to-face programs that include regular appointments is particularly poor (Pagoto et al., 2012). In contrast, the online self-guided nature of the SHED-IT program may appeal to men given it is easily accessible, confidential, non-confrontational, and promotes autonomy and self-sufficiency (Berger et al., 2013; Ellis et al., 2013; Wang et al., 2016).

To further tailor the program for men with low mood, *SHED-IT: Recharge* varied from the original program in several areas. First, the program content provided a greater and more consistent emphasis on the mental health benefits of weight loss and lifestyle behaviour

changes, in addition to the physical benefits. We also provided information and behaviour change advice relating to previously untargeted behaviours that have been linked to managing depression, including sleep (Franzen & Buysse, 2008) and resistance training (Gordon et al., 2018). In addition, participants received four new interactive 'mental fitness' modules we created using the Articulate Rise e-learning authoring program (Articulate, 2021). Each module was built using a range of pre-set 'blocks' (e.g., text, interactive pictures and charts, quizzes) that we populated with information and strategies relating to cognitive behavioural skills for managing depression. An advantage of the Rise software is that it produces modules that are automatically responsive (i.e., the content automatically adjusts to suit each user's screen size). These modules were gradually introduced through the program in Week 4 (cognitive restructuring), Week 7 (mindfulness), Week 10 (behavioural activation), and Week 13 (relapse prevention). Each module included approximately three web pages of information and activities, plus a summary quiz (approximately 15-20 min time commitment). The modules were supported with follow-up tasks that participants completed in the program logbook (e.g., completing a thought monitoring diary). For a summary of the program flow, including which tasks participants were encouraged to complete each week, see Supplementary Table S2.

Wait-list control group

Men allocated to the control group were not prevented from usual care but did not receive any program materials until after the study had concluded.

Safety processes

Given the self-guided, online nature of the study, we implemented a range of safeguards to ensure participant safety. First, contact details for the research team (phone, email) were included in the information statement and all study resources. If participants experienced any concerns with their mood or otherwise during the trial, they were

encouraged to communicate these with the team at any stage. All emails received an automated reply with contact information for 24-hour mental health support services and a confirmation we would get in touch within 72 hours (to allow for weekends when the account would not be monitored). To manage participant expectations, the information statement also reported that: i) the program was not an evidence-based mental health intervention, ii) participation would not guarantee health improvements, iii) the program was designed to be an adjunct to traditional mental health support services, and iv) men would not be prevented from seeking external support during the study, if required.

In addition, we asked participants to complete the PHQ-9 questionnaire on seven occasions during the 6-month study period (recruitment, baseline, mid-intervention, post-intervention, mid-follow-up, follow-up). Following this, a registered psychologist contacted all men who reported symptom exacerbations or any suicidal ideation, including those who were ineligible, to discuss support options.

Outcome measures

Assessments were held in September 2019 (baseline), December 2019 (3 months, post-intervention), and March 2020 (6 months) at the University of Newcastle, Australia. Trained research assistants who were blind to group assignment followed standard protocols to collect all measures. Participants did not receive incentives or financial compensation for attending assessments or completing surveys.

Primary outcomes

The dual primary outcomes were changes in depressive symptoms and weight from baseline to 3 months. Depressive symptoms were measured with the 9-item Patient Health Questionnaire (PHQ-9) depression scale, which has established validity as a diagnostic measure of depressive disorders in both clinical and community samples (Kroenke & Spitzer, 2002). Weight was measured objectively by research assistants on a digital scale to 0.01 kg

(CH-150kp, A&D Mercury Pty Ltd, Australia). Participants were asked to wear light clothing and removed their shoes for the measure. Weight was measured twice, with accepted values within 0.1kg. If measurements were outside the acceptable range, a third measure was taken and the average of the two closest measures was used for analyses.

Secondary outcomes

Secondary Depression Measures. To allow for comparison with other studies, participants also completed the Beck Depression Inventory, which is valid and reliable instrument for assessing depressive symptom severity (Beck & Steer, 1987). However, given the current study's explicit focus on weight loss, the weight change item was not included in the total score. In addition, the validated 22-item Male Depression Risk Scale (MDRS-22) (Rice et al., 2013) was used to assess domains reflecting a potential male-type of depression (e.g., aggression, substance abuse, somatic symptoms, risk-taking behaviours).

Anxiety. Symptoms of anxiety were measured using the valid and reliable 7-item Generalised Anxiety Disorder Questionnaire (GAD-7) (Spitzer et al., 2006).

Waist circumference. Waist circumference was measured level with the umbilicus using a non-extensible steel tape (KDSF10-02, KDS Corporation, Osaka, Japan). Repeated measures were taken until two values fell within a 0.5 cm range. The average of the two acceptable measures was used for analyses.

Body Mass Index. To calculate BMI (kg/m2), height was measured on a calibrated stadiometer (Veeder-Root (VR) High Speed Counter, Harpenden / Holtain, Mentone Education Centre, Morrabin, Victoria) using the stretch stature method. Repeated measures were taken until two values fell within a 0.3 cm range. The average of the two acceptable measures was used for analyses.

Body Fat Percentage. Body fat percentage was assessed using the valid and reliable InBody720 (Biospace Co., Ltd, Seoul, Korea), a multi-frequency bioimpedance device

featuring an eight-point tactile electrode system (Gibson et al., 2008).

Blood pressure, resting heart rate, and arterial stiffness. Systolic and diastolic blood pressure, resting heart rate and arterial stiffness (augmentation index) were measured using an automatic sphygmomanometer (Pulsecor Cardioscope II, Pulsecor Ltd., Auckland, New Zealand) under standardised procedures. Participants were seated for five minutes before the first measurement with an additional two-min rest between measures. Outcomes were assessed three times with the mean of the two closest measures used for analyses.

Blood lipids. Total cholesterol, HDL-Cholesterol, LDL-Cholesterol and Triglycerides (composite measures) were measured (mmol/l) via a fasting finger prick blood sample and analysed using lipid panel strips and the handheld CardioChek® device (Polymer Technology Systems, Inc., Indiana, US; BHR Pharmaceuticals Ltd., Nuneaton, UK).

Process outcomes. At post-intervention, Logbooks were collected to document the intervention groups' adherence to weekly program tasks (e.g., goal setting, weight monitoring). Program perceptions and overall satisfaction were assessed via a brief program evaluation survey collected at post-intervention.

Sociodemographic details. Participants provided information on several sociodemographic indicators at baseline including age, marital status, occupation, employment status, education level, and Aboriginal and Torres Strait Islander identity. Socioeconomic status was determined by linking the participant's residential postcode to the Index of Relative Socioeconomic Advantage and Disadvantage from the census-based Socio-Economic Indexes for Areas (SEIFA) database (Australian Bureau of Statistics, 2018b).

Sample size

Based on pilot data (Young & Morgan, 2018), 118 participants would provide 80% power to detect a 4 kg group-by-time difference in weight (baseline SD: 14 kg, pre-post correlation: 0.9) and a 3.2 point difference in PHQ-9 score (Cohen's d = 0.8, baseline SD: 4

units, pre-post correlation: 0.5) at 3 months (primary endpoint). This power calculation includes an adjusted significance level (a = 0.025) to account for the dual primary outcomes and assumes 80% retention at 3 months.

Importantly, modest weight losses of 3-4 kg are associated with reductions in multiple risk factors for cardiovascular disease and type 2 diabetes (Zomer et al., 2016). With an anticipated baseline mean PHQ-9 score of 9 (Young & Morgan, 2018) , a group-by-time difference of 3.2 PHQ-9 units would also allow us to detect a 50% reduction in depressive symptoms among the intervention group at 3 months (~4.5 units), while accounting for an expected 15% reduction of symptoms in the wait-list group (Posternak & Miller, 2001). This 50% reduction threshold is a preferred indicator of successful treatment response when using PHQ-9 data (Coley et al., 2020).

Randomisation and allocation

Randomisation was stratified based on participants' anti-depressant medication status, depression severity (PHQ-9: <10 / ≥10), and BMI (<33 kg/m^2 / ≥33 kg/m^2). Within each stratum, an independent statistician generated unique allocation sequences (1:1 ratio) using a computer-based random number-producing algorithm. These allocation sequences were stored in a restricted computer folder that was inaccessible to those involved in assessment, allocation, and data entry. Prior to assessments, a research assistant prepacked information for each arm into white, opaque envelopes and ordered these within stratum according to the relevant allocation sequence. This research assistant had no further role in the trial.

After completing baseline assessments, participants were directed to a separate room to meet with a study chief investigator who was not involved in the assessments. This investigator reviewed the participant's baseline data before selecting and opening the next available envelope from the appropriate stratification category. The investigator then provided the participant with details on their group assignment and provided men in the

intervention group with their program materials.

Statistical analysis

Analyses were performed using IBM SPSS Statistics version 25. All variables were checked for plausibility and missing values. Data are presented as mean (SD) for continuous variables and counts (percentages) for categorical variables. Characteristics of completers versus dropouts were tested using independent *t* tests for continuous variables and chi-squared (χ^2) tests for categorical variables.

Primary outcomes

Intention to treat, linear mixed models examined weight and depressive symptoms (PHQ-9) for the impact of group (intervention vs. control), time (categorical) and the group-by-time interaction. Linear mixed models are a recommended analysis technique for behavioural trials (Elobeid et al., 2009) as they ensure outcomes for participants lost to follow-up are modelled in the analyses, consistent with an intention-to-treat approach . Age, socio-economic status, and baseline depression treatment (i.e., use of antidepressant medication and/or psychotherapy) were examined to determine whether they contributed significantly to the models. If a covariate was significant, a term was added to the model to adjust for the effects and two-way interactions with time and treatment were also examined. If these interactions were significant, they were also adjusted for. Cohen's d effect sizes were calculated (mean change score difference divided by standard deviation of change) and interpreted as small (d = 0.2), medium (d = 0.5) and large (d = 0.8).

Potential moderators of intervention effects for the study primary outcomes were explored using interaction tests. Subgroup analyses were conducted for the following variables if $p \leq .10$ for the group-by-moderator interaction: Socio-economic status (SEIFA decile 1-5 / 6-10), baseline weight status (overweight / obesity), baseline depressive symptoms (PHQ-9 <10 / ≥10), and if the participant was receiving mental health treatment at

baseline (e.g., antidepressant medication and/or psychotherapy, Yes / No). The plan for this moderator analysis was added to the clinical trials registry after the study had commenced, but prior to the collection of post-intervention data. Using chi squared tests, a post-hoc analysis examined whether the proportion of participants who achieved clinically meaningful changes each primary outcome varied between the groups. The cut offs to determine clinically meaningful improvements aligned with the effect sizes selected for the sample size calculations (i.e., 50% reduction in baseline PHQ-9 score, 4 kg weight loss).

Secondary outcomes

In line with the primary outcomes, secondary outcome data were also examined with linear mixed models. We did not conduct multiplicity adjustments for these secondary outcomes as they were intended to complement the primary outcome data and provide preliminary insights for definitive hypothesis testing in future studies (Bender & Lange, 2001). In this exploratory context, we have interpreted secondary intervention effects where $p<.05$ as suggestive, rather than statistically significant outcomes.

Results

Participants

Figure 1 shows participant flow through the study. Overall, 155 of the 226 men who completed the online eligibility survey met the inclusion criteria. Of this group, 125 consented and were randomised (intervention, n = 62, control, n = 63). Participant retention was 80% at 3 months (n = 100) and 78% at 6 months (n = 98), with 82% of men attending at least one assessment post-randomisation. Between-group differences in retention were not significant at 3 months ($\chi^2 = 1.15$, df = 1, p = 0.28) or 6 months ($\chi^2 = 0.03$, df = 1, p = 0.87). Men who did not attend follow up assessments were not significantly different to those who did attend on any demographic variables or baseline study outcomes (all $p>0.05$).

As seen in Table 2, the two study arms were comparable on all baseline

characteristics. The mean age of the sample was 48.4 years (SD 11.7), mean weight was 103.8 kg (SD 15.8), and mean PHQ-9 score was 9.2 (SD 4.1). Overall, 58% of men reported PHQ-9 scores in the mild depression range (PHQ-9 score: 5 – 9) compared to 42% in the moderate-to-severe range (PHQ-9 score: 10 – 27). At baseline, 30% of men were taking anti-depressant medication and 14% were participating in psychotherapy. Most participants were married (74%), born in Australia (85%), and living in areas of low-to-middle socio-economic status (78%). Three percent identified as Aboriginal or Torres Strait Islander.

Impact on primary outcomes

Table 3 presents the results of the intention to treat analysis for differences between the study arms for the two primary outcomes.

Depressive symptoms

At 3 months (post-intervention, primary endpoint), a significant difference favouring the intervention group was observed for change in depressive symptoms (-2.4, 95% CI = -3.9, -0.8, p <0.01), representing a medium effect size (d = 0.55, 95% CI 0.19, 0.90). These improvements were maintained at 6 months (-2.4, 95% CI = -4.0, -0.7). A significantly greater proportion of the intervention group achieved a 50% reduction in depressive symptoms than the control group at both 3 months (52% vs 21%, $p < 0.001$) and 6 months (63% v 25%, $p < 0.001$).

The intervention effect on depressive symptoms at post-test was moderated by BMI status and use of mental health treatment at baseline (both $p = 0.02$ for group-by-moderator interaction). Subgroup analyses showed the adjusted difference between groups for depressive symptoms was greater for men with obesity (-2.4, 95%CI -4.6, -0.3) compared to men with overweight (-2.1, 95%CI -4.1, -0.1), and for men who were already accessing mental health treatment (-3.5, 95%CI -6.9, -0.2) compared to those who were not (-2.0, 95%CI -3.8, -0.2). The intervention effect on depressive symptoms did not vary by socio-

economic status or baseline depression severity (both $p > .10$).

Weight

At 3 months (post-intervention, primary endpoint), a significant difference favouring the intervention group was observed for change in weight (-3.1 kg, 95% CI = -4.3, -1.9, $p < 0.001$), representing a large effect size ($d = 0.92$, 95% CI = 0.56, 1.28) (Table 3). This effect had increased at 6 months (-3.6 kg, 95% CI = -5.1, -2.0). A significantly greater proportion of the intervention group achieved a 4 kg weight loss compared to the control group at both 3 months (35% vs 6%, $p < 0.01$) and 6 months (40% v 15%, $p <0.001$).

The intervention effect on weight did not vary by baseline BMI status, depression severity, or use of mental health treatment at post-intervention (all $p > .10$ for group-by-moderator interaction terms). However, the group-by-socio-economic status interaction was significant ($p = .06$), indicating that socio-economic status moderated the intervention's effect on weight loss. Subgroup analysis showed the adjusted difference between groups was larger for men living in areas of greater socio-economic advantage (-4.7 kg, 95% CI -7.0, -2.4) compared to those living in areas of greater disadvantage (-1.9 kg, 95% CI -3.2, -0.6).

Impact on secondary outcomes

Table 3 also presents the results of the intention to treat analysis for differences between the study arms for the secondary outcomes.

Secondary mental health outcomes

As seen in Table 3, the PHQ-9 intervention effect was supported by medium-to-large improvements in depressive symptoms measured using the Becks Depression Inventory II (d = 0.7) and the Masculine Depressive Risk Scale (d = 0.4) at post-test. The intervention effect on anxiety was small (d = 0.3). At follow-up, the changes in masculine depression and anxiety were largely maintained, but the BDI intervention effect had reduced (d = 0.3).

Secondary physical health outcomes

At post-test, medium-to-large intervention effects were observed for all secondary adiposity measures including BMI (d = 1.0), waist circumference (d = 0.8), and body fat percentage (d = 0.5). As seen in Table 3, these effects were largely maintained or improved at follow-up (all d = 0.7-0.8). In contrast, the intervention impact on secondary cardio-metabolic outcomes was limited. Although small-to-medium intervention effects were observed for some outcomes including HDL-cholesterol (d = 0.4) and the total cholesterol/HDL-C ratio (d = 0.4), these were not evident at follow-up (both d < 0.1).

Adverse events

During the 6-month trial, men's depressive symptoms were monitored via the PHQ-9 on five equally spaced occasions (baseline, mid-intervention, post-intervention, mid-follow-up, follow-up). Overall, symptom exacerbations (i.e., increases in PHQ-9 scores of 5 or more units between any two assessments) were reported on 16 occasions by 15 participants (12% of sample; 11 control). Of the 98 men who completed the final assessment (including 14 of 15 who reported the symptom exacerbations at some stage), only three reported PHQ-9 scores that were 5 or more units above baseline levels. When contacted by the study psychologist, all men who reported exacerbations indicated they adequately supported to manage their symptoms.

Process evaluation

Of the 62 men in the intervention group, 51 completed the process evaluation questionnaire at post-test (82%). In addition, 36 men submitted their program Logbook for analysis (58%). As seen in the online supplemental material (Table S3) these participants were largely satisfied with the program and its components. On a scale of 1 (poor) to 5 (excellent), the mean program rating was 4.4 (SD 0.7). On a scale of 1 (strongly disagree) to 5 (strongly agree), most participants indicated that the program was enjoyable, easy to follow,

and worth recommending to a friend (all means > 4.0). According to the respondents, the program was better at teaching men how to lose weight (mean 4.3, SD 0.7) than how to manage their mood (mean 3.8, SD 0.9).

Although men were largely satisfied with the program, engagement with the Logbook was mixed (Table S4). Most men checked off key Week 1 tasks, which included calculating their daily kJ allowance (78%), watching the *SHED-IT* guide to weight loss online video (75%), and setting program goals relating to weight (67%), physical activity (64%) and diet (67%). However, fewer men reported completing the four mental fitness modules (range: 17% - Relapse Prevention to 56% - Cognitive Restructuring). In the ongoing tasks, the men were more likely to complete weight and physical activity monitoring (median weeks completed 11/13) compared to MyFitnessPal food and exercise diary entries (median entries 12/52), online resistance training workouts (median workouts 3/24), and follow-up mental fitness tasks (median tasks 1/6). The interquartile ranges for each task indicate that while the top 25% of men were highly engaged with the tasks, the bottom 25% did not engage at all.

Discussion

The current study examined the impact of a self-guided, eHealth weight loss program with integrated mental health support on men's physical and mental health. In total, 125 men with overweight or obesity, and mild to severe depressive symptoms participated. In line with our hypotheses, we detected significant and clinically meaningful intervention effects on depressive symptoms (PHQ-9) and weight loss at post-intervention, compared to the control group. These improvements were maintained at 6-month follow-up. These primary outcome data were supported by corresponding, medium-to-large sized improvements in secondary depression (i.e., BDI and MDRS-22) and adiposity outcomes (e.g., waist, BMI). However, the program's short-term impact on anxiety and some cardio-metabolic health markers were not maintained. Process data indicated that the men were highly satisfied with the program,

though engagement with some resources and tasks was mixed.

At 6 months (3 months post-intervention), men in the *SHED-IT: Recharge* intervention group maintained a 52% mean reduction in baseline symptoms, compared to a 25% reduction in the control group. This represented a medium sized intervention effect (-2.4 PHQ-9 units, d = 0.6). Recent meta-analyses of Cognitive Behaviour Therapy (vs wait-list control) indicate that the current intervention was as effective as self-guided online CBT for treating depressive symptoms (SMD = 0.6, 9 comparisons) (Karyotaki et al., 2021), but less effective than traditional face to face CBT (g = 0.8, 55 comparisons) (Cuijpers et al., 2013). The current intervention effect was superior to the impact of previous weight loss interventions programs on depression (SMD = 0.2) (Jones et al., 2020).

Of interest, the impact of the SHED-IT: Recharge program on depression was more effective for men with obesity compared to those with overweight. This aligns with other evidence indicating that the risk of depression appears to increase as body weight increases (Luppino et al., 2010). The moderator analyses also indicated that the intervention was more effective for those already receiving mental health treatment, which supports the call for developing online interventions to augment in-person services for men with depression (Gagnon & Oliffe, 2015). Depression status at baseline (i.e., mild vs moderate-to-severe) did not significantly moderate the interventions impact on depressive symptoms. This suggests the intervention has application for men experiencing a range of severity of depressive symptoms and could have utility for prevention, early intervention, and treatment of depression.

The intervention's impact on PHQ-9 scores was supported by concomitant improvements in depressive symptoms measured via the BDI and the MDRS-22. Like the PHQ-9, the BDI is one of the most common self-report measures of traditional, internalised depressive symptoms in adults (Beck & Steer, 1987). In contrast, the MDRS-22 is a measure of

externalised symptoms (e.g., anger), which are hypothesised to reflect 'masculine-type' depression (Rice et al., 2013). Although this concept is not widely accepted, early studies highlight the clinical utility of measuring these externalised symptoms in men. For example, Rice and colleagues (2019) determined that the MDRS-22 was more accurate than the PHQ-9 in identifying men with a recent suicide attempt. Further, while women appear to experience depression at twice the rate of men (GBD 2017 Disease and Injury Incidence and Prevalence Collaborators, 2020), a nationally representative US mental health study (n = 5692) determined that this sex disparity was no longer evident when externalised depressive symptoms were considered alongside traditional symptoms (Martin et al., 2013). In this context, it is notable that the current study identified improvements in both traditional and externalised depressive symptoms. In contrast, the program's impact on anxiety was small, though it was comparable in magnitude to other recent weight loss trials (Jones et al., 2020). Given 25% of the sample did not report meaningful anxiety symptoms at baseline (GAD-7 <5), our capacity to detect larger improvements may have been limited.

In addition to the mental health outcomes, the program generated meaningful improvements in the men's physical health. At post-intervention, men in the intervention group had lost 4 kg, compared to 0.4 kg in the control group, representing a large group-by-time difference at 6 months ($p < 0.001$). To compare, a meta-analysis of eHealth weight loss interventions compared to no-intervention control groups identified an overall effect of -2.7 kg at post-intervention ($p<0.001$, $k = 11$) (Hutchesson et al., 2015). Given most weight loss interventions have directly or indirectly targeted women (Robertson et al., 2014), this may provide support for the role of gender-tailoring to increase engagement and program outcomes for men (Morgan et al., 2016). However, the current effect was 1-2 kg smaller than we have detected previous *SHED-IT* studies (Morgan et al., 2013; Morgan et al., 2009). This may reflect the increased challenges of engaging men with depressive symptoms to complete

a completely self-guided intervention.

At follow up, the overall improvements in weight were supported by sustained, medium-to-large improvements in several other health indicators including waist circumference, BMI, and percent body fat. However, while some improvements were detected in cardio-metabolic outcomes (e.g., HDL-cholesterol), these were not maintained at follow up. While modest weight loss can reduce blood pressure and improve lipid profiles (e.g., Neter et al., 2003), our eligibility criteria may have affected our capacity to observe these changes. As we did not automatically exclude men based on medication use, 33% of participants were already taking blood pressure or cholesterol medication at baseline, and only 21% were hypertensive.

The moderator analysis indicated that the program's impact on weight was more pronounced among men living in more advantaged suburbs compared to less advantaged suburbs. Currently, 77% of Australian men living in the most disadvantaged areas are overweight or obese compared to 73% in the most advantaged areas (Australian Institute of Health and Welfare, 2020). This socio-economic gradient is reflected in many other countries (Devaux & Sassi, 2013). To prevent unintended 'intervention-generated' inequalities, it is essential to understand how we can adapt the program to meet the needs of all men. A positive outcome is that we experienced strong engagement from men living in areas of low-to-middle socio-economic status, who represented 78% of the sample.

The process evaluation results indicated that the participants were satisfied with the program and would recommend it to others. There were high levels of engagement from men during recruitment and strong retention rates at 3 and 6 months. This supports the notion that while men are generally less likely to seek help for their physical or mental health, they are willing to engage in targeted programs specifically designed to meet their unique preferences (Morgan et al., 2016). However, our analysis of participant resources indicated mixed adherence to some program tasks. This is consistent with other eHealth interventions

(Hutchesson et al., 2015), but remains an important issue to address in future program iterations. As men may have completed the tasks without documenting their progress, a more automated process to collect adherence data would provide clearer insights in the future.

Strengths

To the authors' knowledge, this was the first RCT to test the efficacy of a self-guided, eHealth program for men with overweight or obesity and depressive symptoms. The study had several strengths including: use of intention-to-treat analyses, appropriate and transparent randomisation procedures, assessor blinding, and strong retention rates. We also collected a range of validated mental health outcomes and objective physical health data.

Limitations

Alongside the strengths, our study also had limitations. First, we cannot confirm the long-term efficacy of the program as the study duration was only 6 months. While the long-term efficacy of the SHED-IT program has been established in a previous study (Young et al., 2017), a longer-term evaluation of the adapted SHED-IT: Recharge program is warranted. Second, the primary assessment of depression was based on a self-report scale. Although the PHQ-9 is a well-validated tool, it would be of interest to validate the findings among a sample of men with a clinician-rated diagnosis of major depressive disorder to determine its utility in that context. Third, while the information statement indicated that participants were not guaranteed any health benefits, it did disclose the purpose of the study in accordance with ethical requirements (i.e., that we were evaluating a program designed to help men lose weight and improve their mood). This message was also included in our recruitment materials. As is particularly relevant to psychological intervention studies, these factors may have induced expectancy biases in some participants, which may have inflated the intervention effect (Rutherford et al., 2010). Our study design did not permit blinding of participants, and future replications should consider active comparison groups to minimise

this effect. Finally, the study tested a multicomponent intervention against a wait-list control group. While useful for initial evaluations of novel interventions, this design can also lead to increased intervention effects in some cases (Mohr et al., 2009). This design also limits insight into which components were most important. For example, given the men were generally more compliant with completing the weight loss components of the program, rather than the mental fitness components, it is possible that the original *SHED-IT* program could have been sufficient to generate the mental health benefits observed in this study. However, it is also possible that enhancing men's engagement with the mental fitness components could lead to even greater improvements in mood. Identifying the specific mechanisms of change and unique benefits of concurrently targeting physical and mental health are important aims for future studies.

Clinical implications

This study indicated that a gender-tailored, eHealth program could provide clinically meaningful short-term improvements in depressive symptoms and weight among men with overweight or obesity and low mood. While the intervention did not include any built-in contact with the research team outside of study assessments, men in the intervention group maintained a 4.0 kg weight loss from baseline at 6 months and reported a 50% reduction in depressive symptoms. Although many men are reluctant to seek help for their physical or mental health, we experienced strong community interest by men to participate in the current trial, which exceeded both our required sample size and available funding. These results suggest that self-guided, eHealth programs targeting physical and mental health could play a key role in treating both depression and obesity in men in clinical and community settings.

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Table 1

Eligibility criteria for the SHED-IT Recharge trial.

Inclusion criteria	Exclusion criteria
• Male • Aged 18 – 70 years • BMI between 25.0 and 42.0 kg/m^2 • Current depressive symptoms indicated by a PHQ-9 score ≥5 • Own a computer, tablet or smartphone with internet access • Available to attend three assessment sessions over 6 months	• Serious risk of suicide (determined via study psychologist) • Started a new antidepressant medication (or changed dose) in the past 4 weeks • Started psychotherapy (or changed therapy arrangements) in the past 4 weeks • Had bariatric surgery in the past 12 months or planned to have during the study • Unable to speak, read or understand English • Planned to move out of the area during the study period • Participating (or planned to participate) in a concurrent weight loss program • Not willing to be randomised • Lost 5% or more of body weight in the past 6 months • Did not provide a doctor's clearance if risks were identified on pre-exercise screener (e.g., recent heart attack)

Table 2.

Demographic characteristics.

Demographic characteristic	**Study arm (n, %)**		
	SHED-IT: Recharge (n = 62)	**Wait-list control (n = 63)**	**Total sample (n = 125)**
Age (Mean, SD)	47.2 (11.7)	49.7 (11.6)	48.4 (11.7)
PHQ-9 category			
Mild (5-9)	37 (60)	35 (56)	72 (58)
Moderate-to-severe (≥10)	25 (40)	28 (44)	53 (42)
BMI category			
Overweight (BMI 25-29.9 kg/m^2)	17 (27)	19 (30)	36 (29)
Obesity (BMI 30 - <42.0 kg/m^2)	45 (73)	44 (70)	89 (71)
Married / de facto	49 (79)	44 (70)	93 (74)
Aboriginal or Torres Strait Islander	3 (5)	1 (2)	4 (3)
Born in Australia	55 (89)	51 (81)	106 (85)
English primary language	60 (97)	63 (100)	123 (98)
Post-school qualifications	55 (89)	51 (81)	106 (85)
Employed full-time	36 (58)	32 (51)	68 (54)
Socio-economic quintile			
1 (Most disadvantaged)	4 (6)	3 (5)	7 (6)
2	14 (23)	17 (27)	31 (25)
3	30 (48)	29 (46)	59 (47)
4	10 (16)	12 (19)	22 (18)
5 (Most advantaged)	4 (6)	2 (3)	6 (5)

Table 3. *Changes in study outcomes for participants (n = 125, intention-to-treat analyses).*

Outcome	Group	Baseline	3-month change from baseline (Mean, 95% CI)			6-month change from baseline (Mean, 95% CI)		
		Mean (SE)	Within group	Mean difference between groups	p-value [Cohen's d]	Within group	Mean difference between groups	p-value [Cohen's d]
Depressive symptoms (PHQ-9) [a b]	Intervention	9.1 (0.5)	-4.2 (-5.3, -3.1)			-4.7 (-5.9, -3.6)		
	Control	9.3 (0.5)	-1.8 (-2.9, -0.6)	-2.4 (-4.0, -0.9)	<0.01 [0.55]	-2.3 (-3.5, -1.1)	-2.4 (-4.1, -0.8)	<0.01 [0.52]
Weight (kg)	Intervention	104.1 (2.0)	-3.3 (-4.2, -2.5)			-4.0 (-5.0, -2.9)		
	Control	103.5 (2.0)	-0.2 (-1.1, 0.7)	-3.1 (-4.3, -1.9)	<0.001 [0.92]	-0.4 (-1.5, 0.7)	-3.6 (-5.1, -2.0)	<0.001 [0.84]
Depressive symptoms (BDI) [c d e]	Intervention	13.8 (0.8)	-7.4 (-8.9, -5.8)			-7.2 (-9.0, -5.3)		
	Control	15.1 (0.8)	-2.9 (-4.5, -1.3)	-4.5 (-6.7, -2.2)	<0.001 [0.71]	-4.8 (-6.7, -2.9)	-2.4 (-5.0, 0.3)	<0.001 [0.32]
Masculine depressive symptoms (MDRS-22) [c]	Intervention	25.4 (2.1)	-11.3 (-15.5, -7.2)			-12.9 (-17.0, -8.8)		
	Control	25.6 (2.1)	-4.2 (-8.4, 0.0)	-7.1 (-13.0, -1.2)	0.02 [0.43]	-7.3 (-11.5, -3.2)	-5.6 (-11.4, 0.3)	0.062 [0.34]
Anxiety symptoms (GAD-7)	Intervention	7.3 (0.6)	-3.3 (-4.3, -2.4)			-3.8 (-4.9, -2.7)		
	Control	8.1 (0.6)	-2.1 (-3.1, -1.1)	-1.3 (-2.7, 0.1)	0.07 [0.33]	-2.9 (-3.9, -1.8)	-0.9 (-2.4, 0.6)	0.19 [0.22]
BMI (kg/m2)	Intervention	32.5 (0.52)	-1.0 (-1.3, -0.8)			-1.2 (-1.6, -0.9)		
	Control	32.7 (0.51)	-0.1 (-0.4, 0.2)	-1.0 (-1.3, -0.6)	<0.001 [0.95]	-0.1 (-0.5, 0.2)	-1.1 (-1.6, -0.6)	<0.001 [0.82]
Waist circumference (cm) [c d]	Intervention	114.3 (1.4)	-4.4 (-5.3, -3.5)			-4.8 (-5.9, -3.6)		
	Control	114.0 (1.4)	-1.5 (-2.5, -0.6)	-2.9 (-4.2, -1.6)	<0.001 [0.78]	-1.5 (-2.7, -0.4)	-3.2 (-4.9, -1.6)	<0.001 [0.70]
Body fat (%) [c d]	Intervention	33.0 (0.7)	-1.4 (-2.1, -0.6)			-2.8 (-3.8, -1.8)		
	Control	32.7 (0.7)	+0.0 (-0.7, 0.8)	-1.4 (-2.4, -0.3)	0.01 [0.48]	0.1 (-0.9, 1.0)	-2.8 (-4.2, -1.5)	<0.001 [0.75]
Systolic blood pressure [c]	Intervention	127.5 (1.8)	-7.7 (-10.6, -4.8)			-6.8 (-10.0, -3.6)		
	Control	129.3 (1.7)	-7.2 (-10.2, -4.2)	-0.5 (-4.7, 3.7)	0.81 [0.04]	-6.9 (-10.0, -3.8)	+0.1 (-4.4, 4.6)	0.95 [0.01]

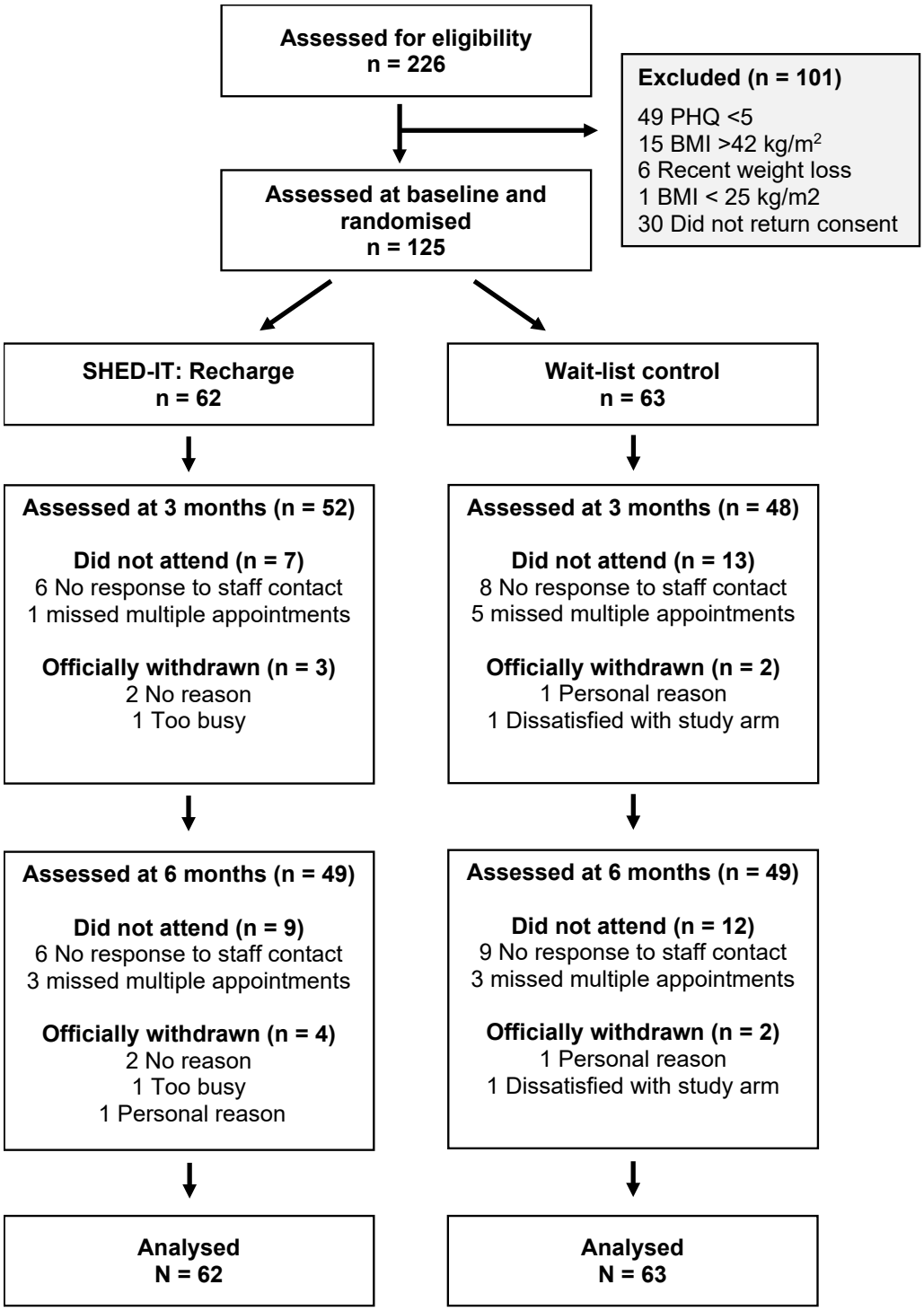
Table 3. *Changes in study outcomes for participants (n = 125, intention-to-treat analyses).*

Outcome	Group	Baseline	3-month change from baseline (Mean, 95% CI)			6-month change from baseline (Mean, 95% CI)		
		Mean (SE)	Within group	Mean difference between groups	p-value [Cohen's d]	Within group	Mean difference between groups	p-value [Cohen's d]
Diastolic blood pressure	Intervention	79.9 (1.0)	-4.0 (-5.6, -2.5)			-4.3 (-6.3, -2.4)		
	Control	80.7 (1.0)	-2.2 (-3.8, -0.6)	-1.8 (-4.0, 0.4)	0.11 [0.29]	-3.5 (-5.5, -1.6)	-0.8 (-3.5, 1.9)	0.27 [0.10]
Arterial stiffness [c]	Intervention	69.9 (4.2)	-7.7 (-12.9, -2.6)			-5.0 (-11.5, 1.4)		
	Control	69.4 (4.2)	-2.8 (-8.1, 2.5)	-5.0 (-12.3, 2.4)	0.18 [0.24]	1.9 (-4.4, 8.3)	-6.9 (-16.0, 2.1)	0.26 [0.27]
Resting pulse [c]	Intervention	66.0 (1.2)	0.2 (-1.8, 2.3)			-0.5 (-2.7, 1.6)		
	Control	67.2 (1.2)	-0.5 (-2.6, 1.7)	0.7 (-2.3, 3.7)	0.64 [0.08]	-2.1 (-4.2, 0.0)	1.6 (-1.5, 4.6)	0.60 [0.18]
Total cholesterol [f]	Intervention	5.2 (0.1)	-0.1 (-0.4, 0.2)			0.0 (-0.4, 0.3)		
	Control	5.0 (0.1)	0.2 (-0.1, 0.5)	-0.3 (-0.7, 0.2)	0.23 [0.21]	-0.1 (-0.4, 0.2)	0.1 (-0.4, 0.6)	0.40 [0.06]
HDL-cholesterol [c d]	Intervention	1.3 (0.0)	0.0 (0.0, 0.1)			0.0 (-0.1, 0.1)		
	Control	1.2 (0.0)	-0.1 (-0.1, 0.0)	0.1 (0.0, 0.1)	0.02 [0.36]	0.0 (-0.1, 0.1)	0.0 (-0.1, 0.1)	0.05 [0.09]
LDL-cholesterol [c f g h]	Intervention	3.2 (0.1)	0.0 (-0.3, 0.3)			0.1 (-0.2, 0.5)		
	Control	3.0 (0.1)	0.3 (0.0, 0.6)	-0.3 (-0.7, 0.1)	0.17 [0.26]	0.0 (-0.3, 0.3)	0.1 (-0.3, 0.5)	0.32 [0.08]
Triglycerides	Intervention	1.7 (0.1)	-0.1 (-0.4, 0.1)			-0.4 (-0.7, -0.2)		
	Control	1.8 (0.1)	-0.0 (-0.2, 0.3)	-0.2 (-0.5, 0.2)	0.30 [0.18]	-0.1 (-0.4, 0.1)	-0.3 (-0.7, 0.1)	0.24 [0.31]
Total cholesterol/HDL-C ratio [c]	Intervention	4.3 (0.2)	-0.2 (-0.5, 0.1)			-0.1 (-0.4, 0.3)		
	Control	4.3 (0.1)	0.3 (0.0, 0.6)	-0.5 (-0.9, -0.1)	0.02 [0.43]	0.0 (-0.3, 0.3)	-0.1 (-0.5, 0.4)	0.05 [0.07]

[a] Adjusted for existing support (i.e., psychotherapy and/or anti-depressant medication), b Adjusted for existing support by group, [c] Adjusted for age, [d] Adjusted for age by time, [e] Weight change item not included in total score, [f] Adjusted for support, [g] Adjusted for age by group, [h] Adjusted for socio-economic status by time.

Figure headings

Figure 1. Study recruitment and retention flow chart.



Appendix Table 1. Data transparency

- The data reported in this manuscript were collected as part of a larger data collection. Findings from the data collection will be reported in separate manuscripts.
- The current manuscript is the primary outcomes paper and reports data relating to weight and depressive symptoms (study primary outcomes), secondary mental health outcomes (e.g., anxiety) and secondary physical health outcomes (e.g., waist circumference, blood biomarkers).
- A secondary manuscript is in preparation which focuses on the cognitive and behavioral outcomes of the trial (e.g., physical activity, diet, sleep quality, cognitive flexibility).