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Weight loss maintenance program for men

Efficacy of a targeted intervention to prevent weight regain in men over three years: A weight loss maintenance RCT.

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What is already known about this subject?

- Weight regain after weight loss is common.
- Behavioral weight loss maintenance programs can reduce the amount of weight regained, but most are too intensive for widespread dissemination.
- Men are under-represented in both weight loss and weight loss maintenance research.

What does this study add?

- A gender-tailored, self-administered weight loss program that encouraged sustainable changes helped men achieve clinically meaningful weight loss.
- Men who also received a gender-tailored, self-administered weight loss maintenance program did not achieve statistically greater maintenance compared to those that did not after three years.
- The strong maintenance effects in both groups highlight the utility of gender-tailored programs that help men achieve initial weight loss with sustainable lifestyle changes.

Abstract

Objective: To examine whether a gender-tailored WLM program could reduce men's weight regain following weight loss. **Methods:** Ninety-two men who lost at least 4 kg during a 3-month weight loss phase were randomized to receive: (i) a 6-month WLM program (WL+WLM; n=47) or (ii) no resources (WL-Only; n=45). The WLM program included written materials and messages (SMS, video email), plus other resources (e.g., pedometer, GymstickTM). The primary outcome was weight change in the first year post-randomization. Participants were assessed at '-3 months' (pre-weight loss), '0 months' (randomization into the WLM Phase), '6 months', '1 year' and '3 years'. **Results:** Prior to randomization, participants lost a mean (SD) of 7.3kg (2.5). Retention was 83% at 1-year and 71% at 3 years. Intention-to-treat analysis detected a significant group-by-time difference in weight regain favoring the intervention group at 6 months (-1.9 kg, 95%CI -3.7,-0.1), but not at 1- or 3-year follow-up. Three years after completing the original program the WL-Only and WL+WLM groups had maintained 59% and 51% of their initial weight loss, respectively. **Conclusions:** Men with overweight/obesity demonstrated clinically meaningful WLM, three years after successfully losing weight. An additional WLM program contributed to enhanced WLM effects in the short-term only. (ACTRN12612000749808).

Introduction

To address escalating obesity rates (1), researchers have extensively tested behavioral weight loss interventions (2). These interventions have shown reasonable short-term efficacy (2), but long term success rates are poor. Indeed, meta-analyses indicate that close to 50% of lost weight is typically regained in the first year after treatment alone (3, 4). To address this problem, researchers are now evaluating additional weight loss maintenance (WLM) interventions (5, 6), which suggest that long term success may require unique skills and behaviors to those used during weight loss. These programs have shown initial promise; a recent meta-analysis determined that additional WLM programs reduce weight regain by approximately 1.6 kg over 12 months (5).

However, many previous WLM programs included substantial face-to-face contact (5), which reduces the likelihood of realistic dissemination. In addition, weight loss and WLM RCTs are commonly limited by a lack of male participants (5, 7). To date, few weight management programs have been designed specifically for men (8, 9). Consequently, men perceive weight management as a ‘feminized realm’ and are less likely than women to attempt weight loss (8). Targeted weight loss programs may be one strategy to reduce this sex-imbalance (10, 11). A recent RCT demonstrated the effectiveness of the gender-tailored *SHED-IT Weight Loss (WL) Program* to assist men with weight loss (10). The program was socio-culturally designed to appeal to specifically to men (12) and was self-administered to increase scalability. Despite including no face-to-face contact, the weight loss results were comparable to those observed in other far more intensive interventions (9).

Although gender-tailoring has shown promise for weight loss programs (10, 11), no studies have examined the utility of gender-tailoring during WLM (5, 6). Given the majority of weight loss is regained in the first year after treatment (3, 4), the primary aim of this study was to investigate whether a gender-tailored, self-administered WLM program for men (i.e.,

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the *SHED-IT WLM Program*) would significantly improve men's maintenance of lost weight and other health outcomes in the first year after completing the *SHED-IT WL Program*. A secondary aim was to investigate whether any initial benefits were maintained at 3-year follow-up.

Methods

Participants

Detailed study methods have been published elsewhere (13). Briefly, men who were overweight or obese (BMI 25-40 kg/m²) and aged 18 to 65 years were recruited from the Hunter Region of New South Wales, Australia. Most men were recruited through radio interviews and newspaper articles that followed a University media release. Men were ineligible to enroll if they could not attend in-person assessments, had no internet or mobile phone, had insulin-dependent diabetes, or had experienced substantial recent weight loss. All men provided informed consent.

Study Design

This study consisted of two phases (see Figure 1). In the 3-month weight loss phase (WL Phase; pre-post design), all men were provided with the *SHED-IT WL Program*, which was successfully tested in both an efficacy RCT (14, 15) and an effectiveness RCT (10, 16). To enter the WLM Phase (RCT), men were required to lose at least 4 kg during the initial program, which confers clinically meaningful benefits for men in all BMI categories (17).

The WLM Phase was a parallel-group, assessor blinded RCT. Men were randomly allocated (1:1 ratio) to receive: i) the 6-month *SHED-IT WLM Program*, which was developed for this study (WL+WLM group), or ii) no additional resources (WL-Only group). Relative to randomization, the assessments were conducted at 'minus 3 months' (beginning of the WL Phase; August 2012), '0 months' (end of WL Phase and randomization into WLM Phase; November 2012), '6 months' (May 2013), and '1-year' (November 2013). After

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receiving additional funding and ethics approval, participants were also invited to a brief assessment at 3 years (November 2015), to assess the long-term impact of the program on anthropometric outcomes. Importantly, participants had no prior knowledge of this assessment and were assessed within 3 weeks of being contacted. The study received institutional ethics approval and was prospectively registered (ACTRN12612000749808).

The SHED-IT Weight Loss Program (WL Phase)

The *SHED-IT WL Program* is described in detail elsewhere (10). The program is self-administered, grounded in Social Cognitive Theory (SCT) and educates men about the importance of losing weight through sustainable and realistic lifestyle changes. The program includes: (i) a DVD presented by a study chief investigator, (ii) a Handbook and Log Book, and (iii) a pedometer and tape measure. Men self-monitored their diet and physical activity using the free CalorieKingTM website (www.calorieking.com.au) or MyFitnessPalTM app to create a 2000 kJ deficit on most days. Although previous versions of the program included personalized e-feedback, this was replaced with weekly motivational text messages to increase scalability. As such, this was the first occasion that the *SHED-IT WL Program* was completely self-administered. The program was provided to participants as a standardized resource pack following the ‘study entry’ assessment (see Figure 1).

The SHED-IT Weight Loss Maintenance Program (WLM Phase)

The SHED-IT WLM Program was designed to complement the original SHED-IT WL Program by providing men with additional knowledge, skills and support in the 6 months immediately post-weight loss, which is a critical period for weight regain (3, 4). Although the SHED-IT WL Program supported general strategies to increase energy expenditure (e.g., increase daily step counts) and decrease energy intake (e.g., reduce portion size), the SHED-IT WLM Program placed specific emphasis on key behaviors that have been empirically associated with successful WLM. These behaviors included increasing moderate-to-vigorous

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physical activity (MVPA) to at least 300 minutes per week (18), limiting intake of energy-dense, nutrient-poor discretionary foods (19, 20), eating breakfast regularly (21, 22), eating more fruits and vegetables (23), and watching less than 2 hours of TV per day (24).

Cognitive-behavioral techniques such as cognitive reframing were also included. The WLM program did not advocate further weight loss, but men were advised to continue weekly weigh-ins and to revert to weight loss strategies if they regained 2.5 kg or more during WLM.

The resources included: (i) a Handbook and Log Book; (16) (ii) weekly video email messages; (iii) bi-weekly motivational text messages; (iv) an elastic tubing, resistance training device (GymstickTM) and (v) a resistance training program. Participants were advised to continue self-monitoring their diet and activity for at least 2 days/week. For a summary of key components in the SHED-IT WL and WLM Programs, see supplementary Table S1.

Theoretical Framework and Gender Tailoring

While there was a clear distinction between the advice provided in the *SHED-IT WL Program* and *SHED-IT WLM Program*, both programs shared a focus on gradual and sustainable lifestyle change. Further, both targeted core SCT constructs including (e.g., self-efficacy, goal setting) (13, 25). Both programs included a *Log Book* where men were completed key SCT tasks including goal setting and self-monitoring.

The programs were gender-tailored including surface-structure components (e.g., male-specific research findings and images) and deep-structure (value-based) components (e.g., focus on scientific legitimacy) (12, 26, 27). Given that men generally do not engage with programs that significantly disrupt their lifestyle (27), the programs taught men to achieve energy balance without completely eliminating ‘luxury’ foods (e.g. the occasional beer). Sensitive humor was also incorporated through all resources (26).

Data Collection and Measures

Assessments were conducted by trained, blinded assessors. The primary outcome was weight

change (kg) in the first year post-randomization. For a summary of all study outcomes and validated measures, see Table 1. (28) (29) (30) (31) (32)

Sample Size

The sample size calculation was based on the primary outcome of weight change in the first year post-randomization (and the conclusion of the *SHED-IT WL Program*). Without additional support, reviews indicate that 50% of lost weight is regained in the first year after treatment (3, 4). In combination with pilot data (10), this information was used to estimate that the WL-Only group would regain approximately 4 kg in the first year after randomization. Thus, to determine the efficacy of the *SHED-IT WLM Program*, the study was powered to detect a 3 kg difference between groups at 1 year. This difference falls outside the range of normal daily weight fluctuation (33), is sufficient to maintain clinically meaningful health benefits (17), and allowed for a small amount of weight regain in the WL+WLM group.

The standard deviation of weight change in the 12 months after randomization was assumed to be 4 kg. This was based on 9-month post-program follow-up data from men who had lost at least 4 kg during a previous SHED-IT Weight Loss trial (14, 15). Thus, 29 men per group were required at 1 year for 80% power to detect a 3 kg between-group difference ($p < 0.05$; two-sided test). Using attrition projections informed by previous studies (10, 14, 15), 195 men were required to begin the *SHED-IT WL Program*. During the WL Phase, 20% of men were expected to drop out ($n=39$) and 40% were expected to complete the program without achieving sufficient weight loss to enter the WLM Phase ($n=78$). Of the remaining 78 men who would progress to the WLM RCT, we expected to retain 75% at 1 year ($n=58$).

Randomization and Allocation

Participants were randomized at an individual level by an external statistician. Allocation was stratified by: (i) randomization BMI ($< 30 \text{ kg/m}^2$; $\geq 30 \text{ kg/m}^2$), and (ii) initial weight loss (4.0-

7.4 kg; ≥ 7.5 kg). Allocation sequences within strata were generated by a computer-based random-number-producing algorithm in randomly varied block lengths. Information for each study arm was pre-packed into identical opaque envelopes and ordered according to the randomization schedule by a research assistant who was not involved in enrolment, assessment or allocation. After completing all assessments, participants met with a blinded member of the research team who allocated the participant to the next available position in their stratification category before opening the corresponding envelope and providing details of the allocation with a standardized protocol.

Statistical Analysis

All analyses were completed with IBM SPSS v22.0 (IMB Corp, New York, USA). Data are presented as means (SD or 95%CI) for continuous variables and counts (%) for categorical variables. Differences in key characteristics between attenders and non-attenders were tested with independent samples *t*-tests and chi-squared tests ($p < 0.05$). Linear mixed models assessed all outcomes for the impact of treatment, time (categorical) and the treatment-by-time interaction ($p < 0.05$). These models are robust to the biases of missing data and model the missing responses using a likelihood-based analysis that included all available data, consistent with an intention-to-treat approach. Age, socio-economic status, BMI and initial change score (from the WL Phase) were specified a-priori as potential covariates. Where significant, a term was added to the model to adjust for these effects and two-way interactions with time and treatment were then examined. If these interactions were significant, they were also adjusted for in the model.

Results

In total, 209 men provided consent and received the *SHED-IT WL Program* after completing the study entry assessments (Figure 2). After three months, 92 men had lost at least 4 kg and were willing to participate in the WLM Phase. The demographic characteristics and

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randomization values for each study outcome are reported in Tables 2 and 3, respectively.

Randomized participants were significantly older than non-randomized participants ($p < 0.01$), but did not differ on any other demographic characteristic or outcome variable. As the intervention effects during weight loss provide an essential context for the effects observed during WLM (34), WL Phase data are also presented in Table 3. In addition, study entry values for each outcome are located in Table S2.

Retention was 83% at 6 months and 1 year and 71% at 3 years, with no significant differences in retention between groups (all $p > 0.05$). Compared to those who attended the one-year assessment, non-attenders had a greater mean randomization weight. Non-attenders at three years had significantly ($p < 0.05$) greater randomization weight, waist circumference, blood pressure and daily energy intake.

Change in weight

During the WL Phase, randomized men lost a mean (SD) of 7.3 kg (2.5) to attain a mean weight of 98.3 kg (14.3) (Figure 3). At the conclusion of the 6-month WLM program, a significant between-group difference in weight regain was detected (-1.9 kg, 95% CI -3.7, -0.1) favoring the WL+WLM group (-0.3 kg, 95% CI -1.5, 1.0) over the WL-only group (+1.6 kg, 95% CI 0.3, 2.9). This equated to a total weight loss of 7.6 kg in the WL+WLM group compared to 5.8 kg in the WL-Only group. However, this group-by-time effect was not observed at 1 year (-1.6 kg, 95% CI -3.8, 0.6) or 3 years (+0.5 kg, 95% CI -1.9, 2.9) (Table 4). At 3 years, the WL-Only and WL+WLM groups had maintained 59% and 51% of their initial weight loss, respectively (Figure 4). Of those who attended the 3-year assessment, 85% of the WL+WLM group and 88% of the WL-Only group remained below their original, 'entry' weight. In addition, 36% of the WL+WLM group and 47% of the WL-Only group had maintained a 5% weight loss or greater at 3 years.

Change in secondary outcomes

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During the WL Phase, significant within group improvements were observed for most secondary outcomes including BMI, body composition, waist, blood pressure, resting heart rate, physical activity, energy intake, risky alcohol consumption, portion size, and breakfast consumption (Table 3). During WLM, significant group-by-time effects favoring the intervention group were only observed for fruit and vegetable intake and breakfast consumption (Table 4). Although the linear mixed models detected significant group-by-time effects for BMI and visceral fat area, the effect sizes were negligible and the mean group-by-time differences in these variables were not significant at 3 years. Thus, these p-values may indicate a difference in trajectories to reach a similar endpoint. For example, although the mean BMI of the WL-Only group increased steadily over the three years, the mean BMI of the WL+WLM group remained relatively stable up to the 1-year assessment before increasing toward the 3-year assessment.

Although no significant between-group differences in daily step count or energy intake were observed during the WLM Phase, both groups demonstrated favorable maintenance of the initial improvements in these outcomes. Overall, RCT participants reported a reduction in mean daily energy intake of approximately 1900 kJ during the WL Phase. By 1-year, the men had maintained an approximate 1200 kJ/day reduction (Table 4). Similarly, while no significant between-group differences were found for physical activity, men reported an increase in their activity of ~1600 steps/day during the WL Phase and maintained an increase of ~1300 steps/day at 1 year.

Process evaluation

Of the 47 WL+WLM participants, 40 completed the program evaluation at post-test (85%). In addition, 32 men submitted their WLM Log Book for analysis (68%). As seen in Supplementary Table S3, participants reported that the SHED-IT WLM Program was a helpful addition to the SHED-IT WL Program, improved their knowledge and skills about

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WLM, and provided them with sufficient support to maintain their weight loss. Notably, 97% of men read the WLM Handbook at least once and 73% of men read the weekly emails most or all of the time. However, engagement with the WLM Log Book was generally poor with few participants completing all tasks (Supplementary Table S4). The median number of documented resistance training workouts was 2 from a possible 48. In the process evaluation, half of the WL+WLM group indicated that they did not self-monitor their diet or physical activity with the website or app during the WLM phase.

Discussion

This study investigated whether a gender-tailored, self-administered WLM intervention could reduce weight regain in a sample of men who had lost weight with a linked gender-tailored weight loss program. At 6 months, a significant difference in weight regain was detected between groups, which favored the WL+WLM group, but this effect did not persist once the WLM program had concluded. Significant WLM intervention effects were observed for daily fruit and vegetable intake and frequency of breakfast consumption at 6 months and 1-year. At 3 years, the WL-Only and WL+WLM groups had maintained 59% and 51% of their initial 7.3 kg weight loss, respectively, which was notable as both groups received only self-help resources without any face-to-face or individualized support.

This study demonstrated that a gender-tailored, self-administered WLM program could provide a short-term, protective effect against weight regain among men who had recently lost weight. However, this initial benefit was not evident at three years post-randomization. This recidivism may be partially explained by the WL+WLM group's suboptimal compliance with some program components, such as the WLM Log Book and online self-monitoring. Although the men may have completed undocumented resistance training, the median number of recorded workouts was small. Given the substantial

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challenges associated with long-term WLM (35, 36), this suggests that future programs may require more support or a greater frequency and/or duration of contact during WLM to encourage men to engage with all program components.

However, it is also important to acknowledge that despite receiving only 3 weeks' notice about the 3-year follow-up, both the WL-only and WL+WLM groups demonstrated strong WLM outcomes compared to other, far more resource intensive programs that include multiple face-to-face, group- and/or phone-based counseling sessions (5). Without additional intervention, reviews suggest that 50% of lost weight is generally regained in the first year after weight loss (3, 4). As such, it is notable that the WL-Only and WL+WLM groups, who received no personalized support during the study, had only regained 41% and 48% of their initial weight loss by 3 years. In contrast, the personal-contact WLM intervention arm from the U.S. WLM Trial, who received 20 face-to-face sessions during weight loss and 12 face-to-face or phone-based consultations during WLM, had regained ~50% of lost weight at 30 months (5, 37).

The *SHED-IT WL Program* was originally developed as a stand-alone intervention that educated men on how to make realistic and sustainable lifestyle changes. Although the *SHED-IT WLM Program* was informed by research suggesting that successful WLM requires unique skills and behaviors (23), other researchers have challenged this contention and proposed that a sustainable approach during weight loss is more critical (34). In contrast to the current study, many previous WLM RCTs have used unsustainable weight loss strategies during the WL Phase, that do not include long-term cognitive or behavioral strategies (5, 6), which may create a difficult transition to WLM (34). Despite strong evidence that unique skills and behaviors are required during WLM (20, 23), this study highlights the importance of enhancing men's understanding of energy balance and improving their knowledge and skills on losing weight through realistic and sustainable changes to lifestyle behaviors.

The 1.6 kg difference in weight regain between groups after one year aligns with the maintenance effect reported in a recent meta-analysis of RCTs testing behavioral WLM programs (5). However, the unexpected success of the WL-Only group resulted in a ceiling on the effects that could be demonstrated in the WL+WLM group. Despite receiving standardized resource packs in both phases of the trial, the WL+WLM group regained only 11% of their initial 7.3 kg weight loss at 1 year, compared to 32% in the WL-Only group.

The behavioral outcomes were mixed. Significant, clinically meaningful effects were detected for daily servings of fruit and vegetables and frequency of breakfast consumption favoring the WL+WLM group. These are important findings given: (i) 96% of Australian men are not meeting fruit and vegetable intake recommendations (38) and (ii) long term WLM is associated with both fruit and vegetable intake (19, 21, 23) and regular breakfast consumption (21, 22). In addition, the men maintained an increase of ~1200 steps per day above study entry levels at the 1-year assessment. However, as reported previously the WL+WLM group did not demonstrate any additional improvements in moderate-to-vigorous physical activity or energy-dense, nutrient-poor discretionary food intake compared to the WL-Only group (39). Moreover, no between-group differences were detected in key cognitions relating to these behaviors, such as self-efficacy, outcome expectations or goal setting (39). As these behaviors appear critical for achieving long-term WLM (20, 40), this lack of effect may have contributed to the non-significant difference in weight regain between groups at 1- and 3- year follow-up.

Strengths and Limitations

This assessor-blinded RCT had several strengths including: use of intention-to-treat analysis, allocation concealment during randomization, objective physical activity assessment, strong retention rates and three year follow-up, which is rarely reported in the literature (5). Further, few WLM trials to date have been conducted outside of the USA or Scandinavia and many

have recruited clinical samples, which limits generalizability (5). This study also had some limitations. As the RCT only included men who lost at least 4 kg during the WL Phase, study generalizability is limited to men that are able to lose weight. However, this is a standard design feature in WLM studies and aligns with the primary aim of the study (5). In addition, due to funding timelines the WL Phase lasted only three months (5), which may have reduced the number of eligible participants for the WLM Phase. Further, although intention-to-treat analyses were used, 29% of randomized participants were unavailable at 3 year follow-up, which may have affected the results.

Conclusion

This study indicates that a gender-tailored, self-administered WLM program can provide a short-term, protective effect against weight regain among men who had recently lost weight. However, this effect did not persist once the WLM program had concluded. Although the primary hypothesis was not supported in the current study, the strong maintenance effects observed over three years in both the WL-Only and WL+WLM groups highlight the utility of gender-tailored, self-administered approaches for assisting men to achieve and maintain modest weight loss relative to higher-intensity programs tested in the WLM literature.

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Figure legends

Figure 1. A schematic diagram of the SHED-IT Weight Loss Maintenance Trial, depicting both the weight loss (WL) and weight loss maintenance (WLM) phases.

Figure 2. CONSORT flowchart for the SHED-IT Weight Loss Maintenance Trial.

Figure 3. Intention-to-treat analysis of weight change by treatment group. Data are means and 95% confidence intervals.

Figure 4. Mean (95% CI) percent maintenance of initial weight loss by treatment group during the weight loss maintenance phase (intention-to-treat analysis).