RUNNING HEAD: Online weight loss program for men

The SHED-IT Randomized Controlled Trial: Evaluation of an Internet-based Weight Loss Program for Men

PJ Morgan, DR Lubans, CE Collins, JM Warren, R Callister

- A/Prof Philip Morgan, School of Education, University of Newcastle;
- Dr David Lubans, School of Education, University of Newcastle;
- A/Prof Clare Collins, School of Health Sciences, Faculty of Health, University of Newcastle;
- Dr Janet Warren, Danone Baby, Wiltshire UK;
- A/Prof Robin Callister, School of Biomedical Sciences, University of Newcastle.

Corresponding Author:
Associate Professor Philip Morgan
School of Education
Faculty of Education and Arts
University of Newcastle
Callaghan NSW Australia 2308
+ 61 2 4921 7265 (PH)
+ 61 2 4921 7407 (Fax)
Philip.Morgan@newcastle.edu.au

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There are no conflicts of interest, financial or otherwise, of any of the authors.

* The manuscript includes 4 tables.
* The manuscript includes 2 figures.
* Word Count = 4545

This study was funded by a University of Newcastle Strategic Pilot Grant.

ABSTRACT

The aim of this study was to evaluate the efficacy of an Internet-based weight loss program for men in an assessor-blinded randomized controlled trial. Sixty-five overweight/obese male staff and students at the University of Newcastle (mean [sd] age = 35.9 [11.1] years; BMI = 30.6 [2.8]) were randomly assigned to either (i) Internet Group (n = 34) or (ii) control group (information only) (n = 31). Both groups received one face-to-face information session and a program booklet. Internet group participants used the study website to self-monitor diet and activity with feedback provided based on participants' online entries on seven occasions over 3 months. Participants were assessed at baseline, 3- and 6-month follow-up for weight, waist circumference, BMI, blood pressure, resting heart rate, objectively measured physical activity and self-reported total daily kilojoules. Intention-to-treat analysis revealed significant weight loss of 5.3kg (95% CI: -7.3,-3.3) at 6 months for the Internet group and 3.5kg (95% CI: -5.5,-1.4) for the control group. A significant time effect was found for all outcomes but no between group differences. Per-protocol analysis revealed a significant group-by-time interaction ($P <$ .001), with compliers losing more weight at 6 months (-9.1kg; 95% CI -11.8,-6.5) than non-compliers (-2.7kg; 95% CI -5.3,-.01) and the control group (-4.2kg; 95% CI -6.2,-2.2). Simple weight loss interventions can be effective in achieving statistically and clinically significant weight loss in men. The Internet is a feasible and effective medium for weight loss in men but strategies need to be explored to improve engagement in online programs.

Keywords: weight loss, men, obesity, online, treatment

Trial Registration: Australian New Zealand Clinical Trials Registry No: ANZCTRN12607000481471

INTRODUCTION

Obesity is a major cause of preventable death and the direct and indirect health care costs associated with obesity are substantial[1]. Obesity is associated with a range of negative physiological and psychological consequences[2]. In Australia, 67% of men are considered to be overweight or obese[2]. Studies have demonstrated that men are less motivated to lose weight than women, despite being more susceptible to the secondary medical consequences, particularly cardiovascular disease[3, 4]. It has been reported that men are not enthusiastic about attending structured face-to-face weight loss programs which require considerable time, travel and financial demands[4, 5].

The Internet has considerable potential to deliver weight management programs and provide an alternative treatment that minimises the participant burden associated with group sessions and clinic visits[6]. The Internet is accessible 24 hours a day and offers anonymity for overweight men who may be embarrassed or who encounter other barriers in seeking weight loss treatment[7]. Furthermore, in Australia in 2007-08, 67% of households had home Internet access. From 1998 to 2007-08, home access to the Internet more than quadrupled from 16% to 67% [8].

Recent systematic reviews of online weight loss randomized controlled trials (RCTs) [9-11] have concluded that weight loss programs can be effectively delivered over the Internet. Successful online obesity treatment programs have targeted reduced energy intake, increased physical activity and cognitive-behavioral strategies including personalized feedback, self-monitoring and social support. However, limitations of previous studies include no intention-to-treat analysis, no assessor blinding, follow-up measures based only on participants' self-report, moderate retention rates and insufficient follow-up beyond immediate post intervention assessments.

In addition, these reviews have recommended high quality studies need to be carried out in specific sub-groups of the population [9, 10]. For example, the generalizablity of the

findings of most online studies have been questioned as they have recruited predominantly women[9]. No controlled studies have been conducted to evaluate the Internet as a resource to treat obesity in men only. The primary aim of our assessor-blinded RCT was to evaluate the feasibility and efficacy of an Internet-based weight loss program for overweight men. The design, conduct and reporting of this study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [12].

METHODS

Participants

Overweight or obese (BMI between 25 and 37kg/m^2) male staff (academic and non-academic) and students aged 18 to 60 years were recruited from the University of Newcastle from advertisements placed on University noticeboards and website in late August 2007. Participants were screened for eligibility via telephone. Ineligibility criteria included a history of major medical problems such as heart disease in the last five years, diabetes, orthopaedic or joint problems that would be a barrier to physical activity, recent weight loss of ≥4.5kg, or taking medications that might affect body weight. All participants were required to not participate in other weight loss programs during the study and needed to have access to a computer with e-mail and Internet facilities. All participants completed a pre-exercise risk assessment screening questionnaire[13] and provided written informed consent. Ethics approval was obtained from the University of Newcastle Human Research Ethics Committee.

Study design

Participants were randomly allocated to one of two groups: the SHED-IT (Self-Help, Exercise and Diet using Information Technology) Internet Group or a control group. Based on 80% power to detect a significant difference (P = 0.05, two-sided), a sample size of 18 participants for each group was needed to detect a 3kg difference among groups. Assuming a 20% attrition rate, a total sample of 44 subjects was required. The random allocation sequence

was generated by a computer-based random number-producing algorithm in block lengths of six to ensure an equal chance of allocation to each group. To ensure concealment, the sequence was generated by a statistician and given to the project manager. Randomization was completed by a research assistant who was not involved in the assessment of participants and the allocation sequence was concealed when enrolling participants.

Outcome measures were obtained from all participants at baseline (September, 2007) and then 3-months (December, 2007) and 6-months (March, 2008) after the start of treatment. Measurements were taken in the Human Performance laboratory at the University of Newcastle (Australia) using the same instruments at each time point. An experienced anthropometrist and a trained assistant measured all participants at all time points. Inter-rater and intra-rater reliability trails were completed before measures were collected. Participants were blind to group allocation at baseline assessment. Once assessments had been completed, participants received a sealed envelope with a note advising their group allocation. Assessors were blinded to treatment allocation at all time points.

The SHED-IT (Internet) group

The SHED-IT program involved one face-to-face information session (75 minutes) led by one of the male researchers (PM) in September 2007 plus three months of online support. The first 60 minutes of the information session covered instruction relating to the modification of diet and physical activity habits and behavior change strategies including self-monitoring, goal setting and social support, based on Bandura's Social Cognitive Theory [14]. All participants were also provided with a program booklet, which outlined nine key messages for weight loss tailored for men.

The second part of the information session was a 15 minute technical orientation session to familiarize and teach participants how to use a publicly accessible, free website (www.calorieking.com.au) utilized in the study. *Calorie King*^{TM} is a health website that provides tools and information to help individuals improve their diet and physical activity

behaviors. Participants were shown how to log on, enter dietary, exercise and weight data and access the online bulletin board. Participants selected their own unique username and password to track web use throughout the study. Participants received online support over three months (from September-December 2007) to facilitate self-monitoring, goal setting and social support. Participants were able to record and self-monitor their weight change, energy intake and exercise daily, which are recognized as cornerstones of behavioral treatment[15]. Participants were asked to submit daily diaries for the first four weeks, for two weeks in the second month and for one week in the third and last month, which were reviewed on seven occasions by members of the research team. Participants were also asked to enter their weight (in kg) each week. Over the course of the three months, each participant was emailed seven individualized feedback sheets corresponding to a week of diary entries by the research team on strategies to address weight loss, reduce energy intake and increase energy expenditure. The feedback sheets followed a standardized format and provided general encouragement and reinforcement. Participants were also able to submit questions on a website noticeboard which were answered weekly by the research group and accessible to all Internet participants, however, participants were not able to email the research team individually.

The SHED-IT program was designed to appeal specifically to men. Previous research has shown that men desire weight loss programs that provide individualized feedback, are work-place based for convenience, and include participants with whom men identify [4]. We also hypothesized that men would be more likely to enroll if the program included only men. Furthermore, in Australia, men are more likely to use the Internet than women [16]. The program booklet and individualized feedback included anecdotes and weight loss strategies that men could relate to such as examples of physical activities that men commonly participate in.

Control Group

The control group attended one information session, which was identical to the Internet group but without the 15 minute online component description. The same male researcher (PM) delivered the information session for the Internet and control groups. Separate sessions were conducted for Internet and control participants to avoid contamination. Control group participants were also provided with the program booklet.

Outcome measures

Baseline assessments were taken 1-2 weeks before the information session. The primary outcome measure was change in body weight (kg and percent change from baseline). Weight was measured in light clothing, without shoes on a digital scale to 0.1kg (model CH-150kp, A&D Mercury Pty Ltd, Australia). A range of secondary outcome measures were assessed including:

BMI: Height was measured to 0.1 cm using the stretch stature method and a wall mounted stadiometer (model KaWe 44440, Medizin Technik, Mentone Education Centre, Morrabin, Victoria). BMI was calculated using the standard equation (weight [kg]/height[m]^2). Both height and weight was recorded twice and the average of the two measures reported.

Waist circumference: Waist circumference was measured level with the umbilicus to standardise the procedure and due to difficulties locating the midpoint between the iliac crest and bottom rib. Each measurement was recorded with a non-extensible steel tape (KDSF10-02, KDS Corporation, Osaka, Japan). Two measures were taken and if the measures differed by more than two centimetres, a third was recorded. The average of the measures was reported.

Blood Pressure: Systolic and diastolic blood pressure were measured using a NISSEI/DS-105E digital electronic blood pressure monitor (Nihon Seimitsu Sokki Co. Ltd., Gunma, Japan) under standardized procedures. Subjects were seated for at least five minutes before blood pressure was recorded. Blood pressure was measured three times and the average of the three measures is reported.

Physical activity: Yamax SW700 pedometers (Yamax Corporation, Kumamoto City, Japan) were used to objectively measure physical activity. Participants were asked to wear pedometers for seven consecutive days and keep to their normal routine. At baseline assessments, participants were 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. At the end of the day participants were instructed to record their steps and reset their pedometers to zero. Once they had completed seven days of monitoring, participants were instructed to place the pedometer and record sheet in the prepaid envelope provided and return to the research team. Participants were included in all analyses if they had completed at least four weekdays of pedometer monitoring. The average of existing days was imputed for participants who had included at least four days of data. To determine the reliability of the physical activity data, intraclass correlation coefficients (ICCs) were calculated for seven days.

Dietary intake: Dietary behavior was measured using the Dietary Questionnaire for Epidemiological Studies (DQES) Version 2, Food Frequency Questionnaire (FFQ) from the Cancer Council Victoria [17]. The dietary questionnaire was developed specifically for use in Australian adults by the Cancer Council of Victoria as an update of an FFQ used in a cohort of Australian volunteers aged 40-69 years. Both the development of the questionnaire [18] and its validation have been reported previously [19]. The FFQ provides a detailed summary of food intake [20]. At 3- and 6-month assessments, participants were instructed to report on the previous three month dietary intake.

Background details: Age, occupation and socioeconomic status (SES) were collected. SES was based on postal code of residence using the Index of Relative Socioeconomic Advantage and Disadvantage from the Australian Bureau of Statistics census-based Socio-Economic Indexes for Areas (SEIFA)[21].

Process measures: Adherence to self-monitoring (total number of daily diet entries, total number of daily exercise entries and total number of weekly weigh-ins) were calculated from website usage data.

Analysis

Analyses were performed using Statistical Package for the Social Sciences (SPSS version 16.0 software, Chicago, IL). All variables were checked for accuracy, missing values and whether they satisfied normality criteria. Data are presented as mean±sd for continuous variables and counts (percentages) for categorical variables. Differences between groups at randomization and characteristics of completers versus dropouts were tested using independent *t* tests for continuous variables and chi-squared (χ^2) tests for categorical variables. The significance level was set at 0.05. Three analyses were performed on the data using linear mixed models which were fitted with an unstructured covariance structure for all primary and secondary outcomes. Differences of means and 95% confidence intervals (CIs) were determined using the mixed models.

(i) *Intention-to-treat* (ITT) analysis included all randomized participants. To assess the robustness of the primary analysis for the effect of losses to follow up, linear mixed models were used to assess all outcomes for the impact of group (Internet and control), time (treated as categorical with levels baseline, 3-months and 6-months) and the group-by-time interaction, these three terms forming the base model. This approach was preferred to using baseline scores as covariates, as the baseline scores for subjects who dropped out at 3-months and/or 6-months were retained consistent with an ITT analysis. Mixed models are more robust to the biases of missing data, and provide better control of Type 1 and Type 2 errors than last observation carried forward (LOCF) ANOVA [22]. Similarly, imputation methods such as LOCF or baseline carried forward may bias results in obesity trials where untreated overweight men are likely to increase their weight. Baseline weight, age and SES were examined as covariates to see if they contributed significantly to the models. This was analysed by correlating the

difference score (between baseline and 6 months) with the average score (between baseline and 6 months) for these variables.

(ii) *Completers* mixed model analysis included only participants who attended all assessments from both the Internet and control groups (n = 55).

(iii) *Per-protocol* analysis: We also performed a planned per-protocol analysis using mixed models for weight (kg) and waist circumference using Internet participants who complied well with the assigned treatment, defined as submission of requested daily eating and exercise diaries (n>50) over the 3 month period and weekly check-ins (n>12). Results of the per-protocol group were compared with non-compliers in the Internet group and the control group.

RESULTS

Participant flow

Figure 1 illustrates the flow of participants through the trial. A total of 136 men responded to the SHED-IT recruitment materials with most participants responding to notices placed on University noticeboards. Seventy-two men were eligible for the study but seven men were not randomized as no consent was received. In total, 65 overweight or obese adult men were randomized and attended baseline assessments and the target sample was recruited in less than ten days.

Measurements were obtained for 85% of the sample at 3 months (n = 55) and for 83% at 6 months (n = 54), equating to attrition rates of 15% and 17% respectively. There was no difference in follow-up rates between the Internet and control groups at 3 (χ^2 = .28, df = 1, *P* = .60) or 6 months (χ^2 = .03, df = 1, *P* = .87). All randomized participants with baseline data (n = 65) were analysed for the primary outcome at 3 and 6 months. There were no significant differences in baseline characteristics between those lost to follow-up and those retained at 6 months for age, weight or any of the secondary outcomes (*P* >.05).

Baseline data

Table 1 presents baseline characteristics of the sample highlighting no difference by group. The mean (sd) age was 35.9 (11.1) years and comprised 43% students, 41.5% non-academic staff and 15.4% academic staff. The mean weight and waist circumference were 99.1kg (12.8) and 103.1cm (7.5) respectively with 52.3% of the sample considered obese (BMI>30). The ICC (95% confidence intervals) for mean steps/day was .82 (.74 to .88) for seven days.

Change in body weight

Figure 2 highlights the mean change in absolute body weight by treatment group from the ITT analysis. Unadjusted results are reported as bivariate analysis of difference and average scores for baseline weight, age and SES revealed no significant correlations. ITT analysis revealed that both groups lost a significant amount of weight at 6-month follow-up ($P < .001$) (Table 2). Weight decreased significantly in the Internet group from baseline to 3 months ($P < .001$) and baseline to 6 months ($P < .001$) and also decreased significantly in the control group from baseline to 3 months ($P < .001$) and baseline to 6 months ($P < .001$). The difference between the Internet and control groups for changes in weight from baseline to 6 months ($P = 0.228$) was not statistically significant.

Completers analysis showed a significant time effect at 6 months ($P < .001$) but no group-by-time interaction ($P = 0.334$). In the Internet group, participants' weight change ranged from -13.8kg to +2.1kg at 3 months ($P < .001$) and -17.3kg to +1.4kg at 6 months ($P < .001$). In the control group, participants' weight change ranged from -12.2kg to +4.3kg to at 3 months ($P < .001$) and -17.1kg to +3.1kg at 6 months ($P < .001$). Analysis of variance revealed there was no significant difference in change in weight between students, academic staff and non-academic staff at 3 or 6 months ($P > .05$).

Percent weight loss

Weight loss as a percentage of baseline weight was calculated at 3-month and 6-months. Mean percent weight loss in the Internet group was 5.0% at 3 months and 5.7% at 6 months. Mean percent weight loss in the control group was 3.2% at 3 months and 3.9% at 6 months. There was no significant difference in percent weight loss between groups ($P > .05$). At 3 months, significantly more participants (55.6%) in the Internet group had lost more than 5% of their baseline weight compared to the control group (28.0%) ($\chi^2 = 4.03$, df = 1, $P = .04$). At 6 months, 50% and 34.6% of Internet and control group participants respectively had lost more than 5% of their initial weight but this difference was not statistically significant ($\chi^2 = 1.30$, df = 1, $P = .25$).

Change in secondary outcomes

There were no significant between group differences for any of the secondary outcomes from baseline to 3 or baseline to 6 months (Table 2). Values for all secondary outcomes improved significantly from baseline to 3 and 6 months in both groups. At 6 months, participants reduced their: waist circumference ($P < .001$); BMI ($P < .001$) systolic ($P < .001$) and diastolic ($P < .001$) blood pressure; resting heart rate ($P < .001$); daily kJ intake ($P < .001$) and increased physical activity ($P < .05$).

Website use and relationship to weight loss

The mean (sd) number of diet and exercise entries by Internet group participants was 38(33) and 23(26) respectively. Participants recorded an average of 10(6) weekly weight check-ins over the 3-month period. Significant correlations were found between weight loss at 3 months and number of days of diet entries ($P < .001$), number of daily exercise entries ($P =.002$) and number of weekly check-ins ($P = .01$). Similar results were found for weight loss at 6 months: number of daily diet entries ($P < .001$), number of daily exercise entries ($P = .002$) and number of weekly check-ins ($P = .01$).

Per-protocol analysis

A planned per-protocol analysis was performed for weight and waist circumference using Internet group participants who complied with the assigned treatment. Of the 34 participants assigned to the Internet group, 14 (41.2%) complied well with treatment, defined as seven weeks of submission of daily eating and exercise diaries (i.e. > 50 days of entries) and weekly check-ins (n > 12) over the 3-month period. Compliers were more likely to be general staff members than academic staff members or students ($\chi^2(3) = 14.41$, $P = .002$). There was also a significant difference between compliers and non-compliers for age with older participants more likely to comply with the online program than younger participants ($t(32) = -2.8$, $P = .008$).

Linear mixed models compared weight and waist circumference loss between control group participants with compliers and non-compliers (Table 4). A significant group-by-time interaction ($P < .001$) was found with compliers losing significantly more weight at 3 months ($P < .001$) and 6 months ($P < .001$) than non-compliers at 3 months ($P = .011$) and 6 months ($P = .043$) and control group participants at 3 months ($P < .001$) and 6 months ($P < .001$). For waist circumference, a significant group-by-time interaction ($P = .005$) was found with compliers reducing their waist circumference significantly more at 3 months ($P < .001$) and 6 months ($P < .001$) than non-compliers at 3 months ($P = .039$) and 6 months ($P = .004$) and control group participants at 3 months ($P < .001$) and 6 months ($P < .001$).

DISCUSSION

Our study compared the efficacy of two weight loss programs for men. The intervention program combined a single information session and booklet with ongoing Internet-based support whereas the control condition consisted of the information session and booklet only. Importantly, the style of the information session and booklet were designed to deliver clear simple weight loss messages and to appeal specifically to men. Both programs were effective at achieving weight loss with no significant difference between them. Not all

participants provided with the Internet facilities used the features available, but those participants who used the Internet features lost significantly more weight than those who did not. Our findings indicate that many men can achieve substantial weight loss with a low-dose intervention program but that utilizing ongoing Internet support results in greater weight loss.

Our study had several strengths: a randomized design, rigorous randomization procedures, high retention rate, intention-to-treat analysis, comprehensive primary and secondary outcomes assessed including objective measures of adiposity and physical activity, outcomes assessed by blinded researchers, and follow-up assessments three months after the immediate post-intervention assessment.

Regardless of group allocation, men enrolled in our study experienced significant and clinically important improvements in all outcomes (weight, waist circumference, blood pressure, resting heart rate, physical activity, daily kilojoule intake). Patterns of weight loss were similar for both groups and demonstrated that weight loss occurred mostly during the first three months, which in this study was the intervention period. An encouraging finding was that both groups maintained improvements for weight and all secondary outcomes from 3 to 6 months, despite no contact between researchers and participants, although the Internet group still had access to the diet and physical activity monitoring features of the online service but no individualized feedback was provided. However, a longer follow-up period would determine whether their weight loss has been maintained.

Several explanations can be offered regarding why we found no between group differences. Firstly, our control group was not a ‘true’ control, but a minimal intervention. It is likely that both the Internet and control groups may have been successful compared to a no-treatment control group, as previous studies have shown that weight continues to increase in adult males who do not receive treatment [23]. Secondly, the single information session and booklet were designed to provide simplified messages on energy balance tailored for men and presented in a program booklet, which may have attenuated differences between groups.

Finally, the lack of intervention effect may be explained by the fact that less than 50% complied with the recommended online component of the treatment measured by engagement with the website through self-monitoring by the Internet participants.

A key feature of both the programs used in this study was the low level of interaction between the program providers (research team) and participants. Many previous weight loss programs are far more intensive. For example, Tate et al.'s [24] online program included weekly behavioral lessons via email (n = 24), weekly submission of diaries (n = 24), individualized feedback to participants (n = 24), online bulletin board, face-to-face sessions with psychologists, unlimited email opportunities to a therapist and follow-up if they did not log in and resulted in 2.9kg weight loss (35% losing > 5%) after a 6-month intervention. Hunter [25] reported an average weight loss of 1.3kg for an Internet behavioral group which involved exercise and food diaries five times a week for 6 months, weekly personalized feedback, weekly check-ins, completion of interactive weekly lessons on behavioral modification, stimulus control and stress management, interactive quizzes (30 minute lesson time), weekly readings and motivational interviewing telephone calls at 1 and 2 months that were tailored to individual needs. Our findings suggest that many men who self identify as wanting to lose weight can achieve weight loss with much less intensive programs, and this represents a much more cost-effective strategy for initiating weight loss for large numbers of our population.

Despite finding no between group differences in percentage weight loss, the Internet program was effective in almost doubling the number of participants who achieved a weight loss of 5% of body weight compared to the control group (56% compared to 28%) at three months. Internet participants reduced their body weight by an average of 5.7% after six months. Evidence suggests an approximate 5% reduction in body weight in individuals at high risk of Type 2 diabetes, who already have impaired glucose tolerance, has been shown to reduce incidence by 58% over 2.8 years [26].

Our per-protocol findings for weight loss (-9kg) and waist circumference (-10cm) reduction at 3 months after the end of the intervention highlight the effectiveness of the Internet program for compliers who did significantly better than both non-compliers from the Internet group and the control group. As concluded in a recent systematic review [10], successful online programs modify energy balance utilising cognitive-behavioral strategies such as self-monitoring and individualized feedback. Our findings that self-monitoring of diet, exercise and weight were strongly related to weight loss, supports previous studies that have identified the importance of the documentation of behaviour relating to weight loss in predicting weight loss [27].

Our online program provided personalized feedback to participants, which has previously been established as a critical component of maximising compliance and success in online programs [24, 28]. However, only half of the Internet participants engaged in the recommended intervention dose, which supports conclusions from systematic reviews that most online studies suffer from low dose, poor usage levels and poor engagement in the expected activities [11]. Therefore, regardless of personalisation of feedback, strategies to improve adherence to online programs and research to examine what attributes of individuals and website features may predict compliance need to be explored. Alternative or additional delivery models such as supplementing the online component with telephone prompts or face-to-face components may need to be developed for those who don't utilize online features and don't lose weight.

Our study had some limitations that should be noted. First, our study did not include a true control. Although this may limit the findings, the provision of a modified program may have helped recruitment and prevented attrition. It is important to note that a wait list control group may have also led to improved weight profile as the detection of obesity through recruitment and assessment may act as a form of motivation to lose weight. Second, the physical activity assessment strategy may contribute to some reactivity, as both groups of

participants were required to monitor and record their physical activity in a log book over a period of one week. However, the majority of weight loss interventions use self-report measures of physical activity, which are more susceptible to social desirability bias. Thirdly, despite the sample being a convenience sample, SES status was representative of the general NSW population. Finally, although we used an objective measure for weight, the assessments at 3 and 6 months could have acted as a form of motivation for participants and enhanced compliance.

Conclusion

Simple weight loss interventions can be effective in achieving statistically and clinically significant weight loss in men. The Internet is a feasible and effective medium for enhancing weight loss in men but strategies need to be explored to improve engagement in online programs.

Acknowledgments

This research was supported by a University of Newcastle strategic pilot grant. The authors wish to acknowledge our project manager, Mr David Went. We are also grateful for the help of research assistants Emma Turnbull, Michelle Romei, Tsz Lai and Diane Murgatroyd. We thank all study participants.

Competing Interests

The author(s) declare that they have no competing interests.

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LIST OF TABLES

Table 1: Baseline characteristics of men randomized to the control and Internet groups

Characteristics	Control (n = 31)		Internet (n = 34)		Total (N= 65)	
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age (years)	34.0	11.6	37.5	10.4	35.9	11.1
Occupation, n (%)						
Student	14	45.1	14	41.2	28	43.0
Non-academic staff	13	41.9	14	41.2	27	41.5
Academic staff	4	12.9	6	17.6	10	15.4
SES[a] *, n (%)*[b]						
1-2 (lowest)	0	0.0	1	4.2	1	1.9
3-4	5	17.9	7	29.2	12	23.1
5-6	9	32.1	3	12.5	12	23.1
7-8	11	39.3	11	45.8	22	42.3
9-10 (highest)	3	10.7	2	8.3	5	9.6
Weight (kg)	99.2	13.7	99.1	12.2	99.1	12.8
Height (m)	1.8	0.1	1.8	0.1	1.8	0.1
BMI ($kg/m^{2)}$	30.5	3.0	30.6	2.7	30.6	2.8
BMI Category						
Overweight, n (%)	15	48.4	16	47.1	31	47.7
Obese, n (%)	16	51.6	18	52.9	34	52.3
Waist circumference UM (cm)	103.4	8.3	102.8	6.8	103.1	7.5
Systolic blood pressure (mmHg)	135	14	134	14	134	14
Diastolic blood pressure (mmHg)	85	7	84	10	84	9
Resting heart rate (BPM)	79	12	74	12	76	12
Physical activity (steps/day)[c]	8102	2615	8869	2573	8505	2600
Energy intake (kJ/day)[d]	10221	2952	11779	3399	11075	3274

Abbreviations: BMI = Body Mass Index; SES = socioeconomic status; UM = umbilicus measurement; BPM = beats per minute; kJ = kilojoules; g = grams.

[a] Socioeconomic status by population decile for SEIFA Index of Relative Socio-economic Advantage and Disadvantage

[b] n = 28 (Control); n = 31 (Internet);N = 51 (Total)

[c] n = 28 (Control); n = 31 (Internet); N = 59 (Total)

[d] n = 28 (Control); n = 34 (Internet); N = 62 (Total)

Table 2: Changes in outcome variables by treatment group from baseline to 3- and 6-months and differences in outcomes among the treatment groups at 3- and 6-months (ITT analysis)*

		Treatment group			Time		Group * Time
		Mean change from Baseline (95% CI) †					
Outcome	Month	Control	Internet	All	P	Mean difference between groups (95% CI)§	P
Weight (kg)	3	-3.0 (-4.5,-1.4)	-4.8 (-6.4,-3.3)	-3.9 (-5.0,-2.8)			
	6	-3.5 (-5.5,-1.4)	-5.3 (-7.3,-3.3)	-4.4 (-5.8,-3.0)	<.001	-1.9 (-4.8,1.0)	0.228
Waist circumference (cm)	3	-4.4 (-6.3,-2.5)	-5.2 (-7.1, -3.4)	-4.8 (-6.2,-3.5)			
	6	-5.6 (-7.7, -3.5)	-7.0 (-9.1,-4.9)	-6.3 (-7.8,-4.8)	<.001	-1.4 (-4.4,1.6)	0.648
BMI (kg/m^2)	3	-0.9 (-1.4,-0.5)	-1.5 (-2.0,-1.0)	-1.2 (-1.6,-0.9)			
	6	-1.1 (1.7,-0.5)	-1.6 (-2.2,-1.0)	-1.4 (-1.8,-0.9)	<.001	-0.5 (-1.4,0.4)	0.212
Systolic blood pressure (mmHg)	3	-8 (-12,-3)	-6 (-10,-1)	-7 (-10,-3)			
	6	-10 (-14,-6)	-10 (-14,-7)	-10 (-13,-7)	<.001	-0.6 (-6.0,4.9)	0.750
Diastolic blood pressure (mmHg)	3	-6 (-10,-2)	-4 (-8,-1)	-5 (-8,-2)			
	6	-5 (-10,-2)	-6 (-11,-1)	-6 (-9,-2)	<.001	-0.6 (-7.3,6.2)	0.760
Resting heart rate (BPM)	3	-7 (-11,-3)	-9 (-12,-5)	-8 (-11,-5)			
	6	-7 (-12,-3)	-6 (-11,-2)	-7 (-10,-4)	<.001	0.9 (-5.7,7.5)	0.660
Physical activity (mean steps/day)	3	976 (-12, 1965)	1184 (234, 2133)	1080 (395, 1765)			
	6	1302 (241, 2363)	938 (-90, 1966)	1120 (382, 1859)	.005	-364 (-1842,1113)	0.660
Energy intake (kJ/day)	3	-2068 (-3089, -1047)	-3195 (-4159, -2230)	-2631 (-3333, -1929)			
	6	-1881 (-3087,-676)	-3642 (-4764,-2521)	-2761 (-3585,-1939)	<.001	-1761 (-3408,-115)	0.110

Abbreviations: BMI = body mass index; BPM = beats per minute;

* Control group (n = 31) and Internet group (n = 34) at 3 and 6 months

† Time differences were calculated as (3 month – baseline) and (6 month – baseline)

§ Between group differences at 6 months

Table 3: Correlation of website usage to weight and waist circumference change

	Weight change				Waist circumference change			
Website feature	**3 months *r***	**P**	**6 months *r***	**P**	**3 months *r***	**P**	**6 months *r***	**P**
Daily diet entries	.71	< .001	.72	< .001	.74	< .001	.67	< .001
Daily exercise entries	.56	< .001	.53	.002	.68	< .001	.53	.004
Weekly weight entries	.48	.01	.55	.01	.52	.005	.43	.024

Abbreviations:

r = Pearson product moment correlation coefficient

Table 4: Changes in weight and waist circumference from baseline to 3- and 6-months and differences in outcomes among compliers, non-compliers, and control participants.

5

		Treatment Group			Time				Group * Time
		Mean change from Baseline (95% CI) †				Mean difference between groups (95% CI)§			
Outcome	Mth	Compliers n = (14)	Non-compliers n = (20)	Control n = (31)	P value				P value
Weight (kg)	3	-8.1 (-10.0,-6.2)	-2.4 (-4.3,-0.6)	-3.5 (-5.0,-2.1)					
	6	-9.1 (-11.8, 6.5)	-2.7 (-5.3,-0.0)	-4.2 (-6.2, -2.2)	<.001	6.4 (-11.6,1.8)	4.9 (-5.3,11.7)	1.5 (-11.7,5.3)	<.001
Waist C (cm)	3	-8.8 (-11.3,-6.3)	-2.5 (-4.9,-0.13)	-4.6 (-6.4,-2.8)					
	6	-10.7 (-13.4,-7.9)	-4.1 (-6.7,-1.4)	-5.9 (-7.9,-3.8)	.05	6.6 (-9.4,3.6)	4.8 (-7.5,3.2)	1.8 (-5.5,4.9)	.005

Abbreviations: Waist C = Waist circumference; - = minus

† Time differences were calculated as (3 month – baseline) and (6 month – baseline)

§ Between group differences at 6 months

LIST OF FIGURES

Figure 1

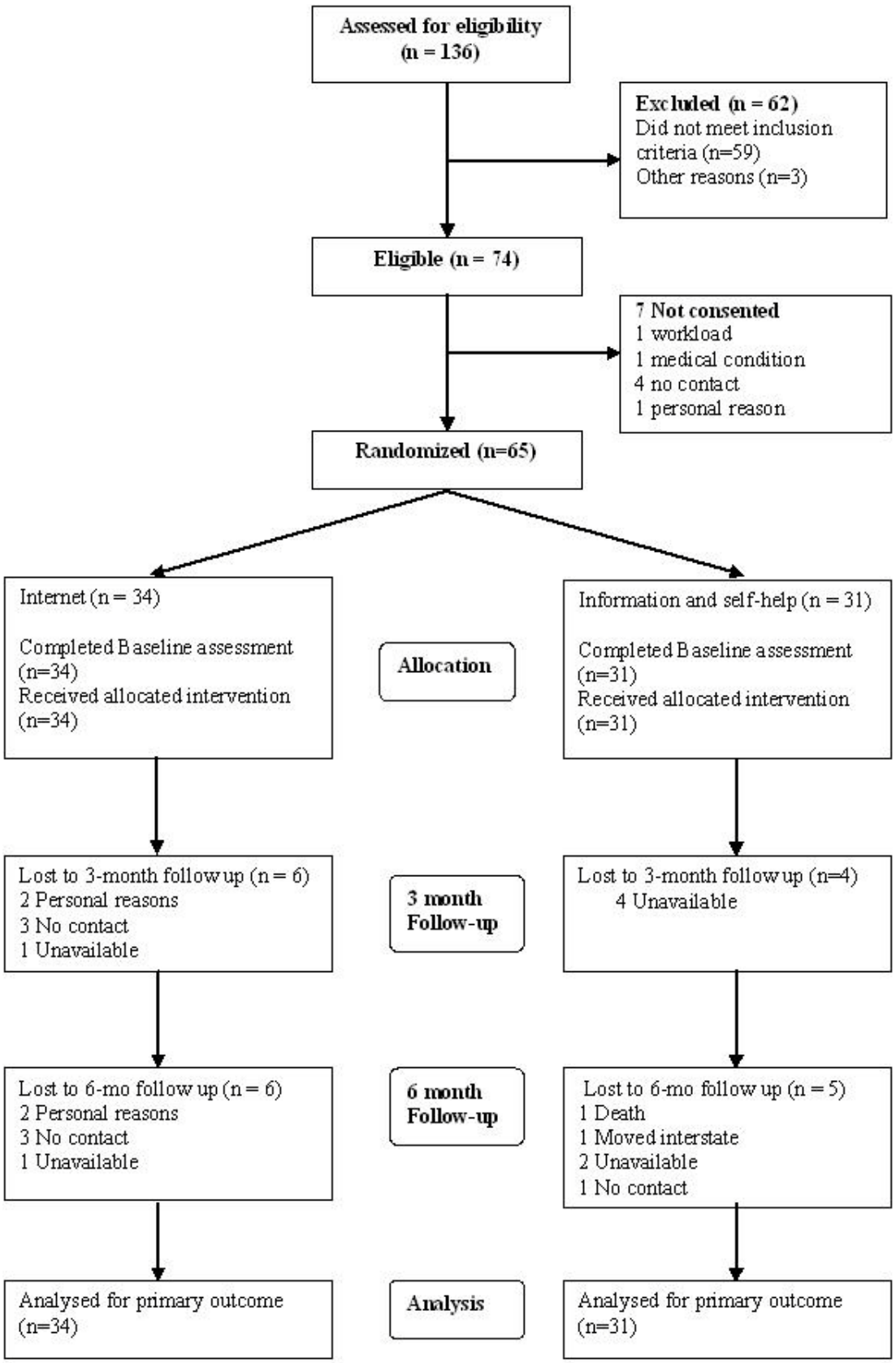
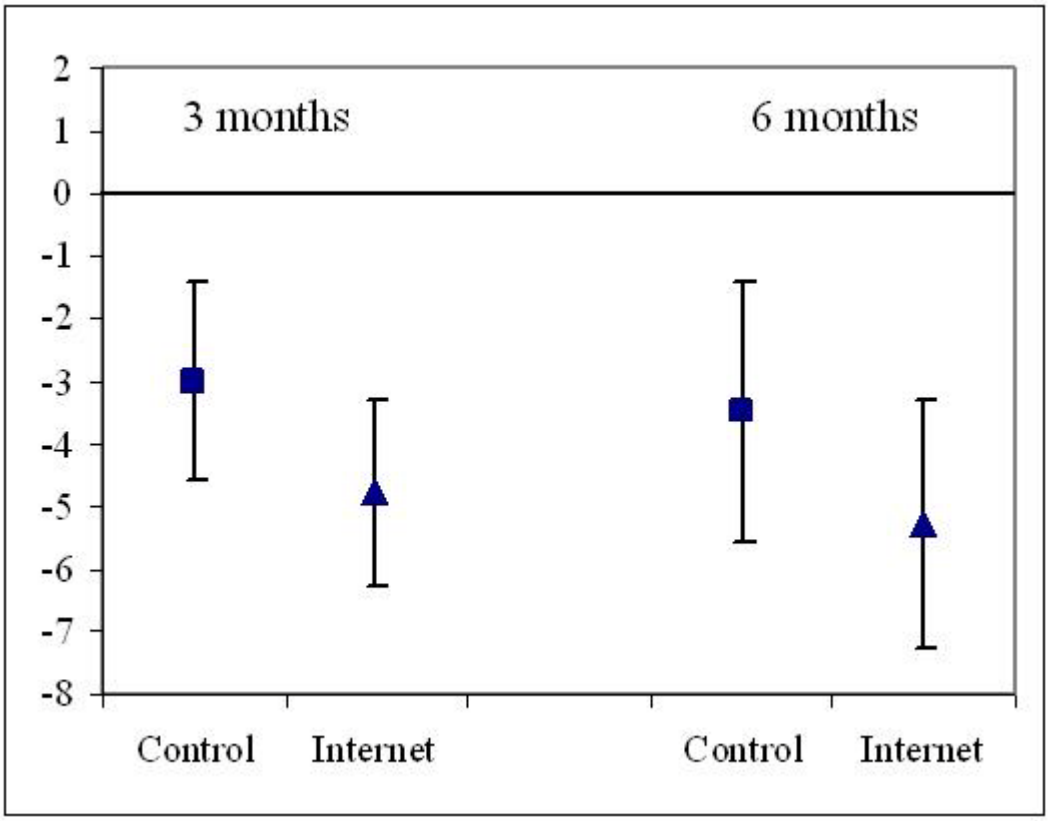

Assessed for eligibility (n = 136)
Excluded (n = 62)
Did not meet inclusion criteria (n=59)
Other reasons (n=3)
Eligible (n = 74)
7 Not consented
1 workload
1 medical condition
4 no contact
1 personal reason
Randomized (n=65)
Internet (n = 34)
Completed Baseline assessment (n=34)
Received allocated intervention (n=34)
Allocation
Information and self-help (n = 31)
Completed Baseline assessment (n=31)
Received allocated intervention (n=31)
Lost to 3-month follow up (n = 6)
2 Personal reasons
3 No contact
1 Unavailable
3 month Follow-up
Lost to 3-month follow up (n=4)
4 Unavailable
Lost to 6-mo follow up (n = 6)
2 Personal reasons
3 No contact
1 Unavailable
6 month Follow-up
Lost to 6-mo follow up (n = 5)
1 Death
1 Moved interstate
2 Unavailable
1 No contact
Analysed for primary outcome (n=34)
Analysis
Analysed for primary outcome (n=31)

Figure 2


2
1
0
-1
-2
-3
-4
-5
-6
-7
-8
3 months
6 months
Control
Internet
Control
Internet