Title

The Effect of an Augmented Commercial Weight Loss Program on Increasing Physical Activity and Reducing Psychological Distress in Women with Overweight or Obesity: a Clustered Randomised Controlled Trial.

Abstract

Objective: The present study tested the effects of integrating an evidence-based physical activity intervention within an existing commercial weight loss program to assess effects on increasing physical activity and reducing psychological distress. Method and results: The CONSORT guidelines were adopted for the study. Forty nine women with overweight or obesity (M age = 39.5, SD:12.4; M Body Mass Index = 31.02, SD: 2.10) enrolled in a six week commercial weight loss program were randomized to an intervention or a control group. Participants in the control group received care as usual; participants in the intervention group additionally received an evidence-based intervention to increase physical activity that included behaviour change techniques including implementation intentions, goal-setting and self-monitoring. Weekly steps increased in the intervention group (M=31516.25; SD=9310.17 to M=62851.36; SD=13840.4) significantly more ($p < .001$, $\eta_p^2 = .32$) than in the control group (M=30207.67; SD=7833.29) to M=46969.33 (SD=9470.96), along with experiencing significantly lower anxiety ($p < .001$, $\eta_p^2 = .15$), social dysfunction ($p < .001$, $\eta_p^2 = .16$) and depression symptoms ($p < .05$, $\eta_p^2 = .08$) at follow-up. Implications: this intervention warrants extension to those seeking to improve mental health through physical activity.

Keywords: Physical activity, health, behavior change, goal intentions, anxiety, wellbeing.

1a. Background

Globally, more than 1.9 billion adults are overweight (World Health Organization, 2014) which increases the risk of psychosocial, physiological, cardiovascular, metabolic and musculoskeletal health problems (Shultz, Byrne & Hills, 2014). Commercial weight loss programs represent culturally popular means of achieving weight loss (Bye, Avery, & Lavin, 2005; Lowe, Miller-Kovach, Fry, et al., 1999; Tsai & Wadden, 2005). Most commercial programs focus on reducing caloric intake through food restriction, which when done moderately may offer a way to achieve a negative energy balance and subsequent improvements in cardiovascular and glucoregulatory biomarkers (Trepanowski, Canale, Marshall, Kabir & Bloomer, 2011), at least in the short term (Yanovski, 2000). However, the early stages of dietary restraint is associated with deficits in central executive functioning and increases in stress (Green, Elliman, & Kretsch, 2005; Kemps, Tiggemann, Marshall, 2005), which may contribute to poorer self-regulation of eating behaviours (Dohle, Diel, & Hofmann, 2017). These psychological outcomes may explain the poor retention rates in commercial programs (Finley, Barlow, Greenway, Rock, Rolls, & Blair, 2007), in addition to the increased likelihood of weigh regain following programs (Sainsbury et al., 2018), ultimately undermining any short-term positive effects. Programs that focus on a healthy lifestyle by concurrently offering dietary advice with behavioural strategies such as increasing physical activity are more effective than programs that focus on dietary restriction alone, suggesting a holistic lifestyle approach is warranted (Baetge et.al, 2017).

Physical activity levels are usually low in adults, with 59% of male respondents aged 16 and over meeting the recommended levels while 49% of women reached the recommended levels (British Heart Foundation, 2015). Research has established that regular physical activity can improve a plethora of physiological outcomes (e.g. blood pressure, body composition), including improved body composition (Chastin et al., 2018), and reduced

incidence of all-cause mortality (Stamatakis, Kelly, Strain, Murtagh, Ding & Murphy, 2018). Furthermore, it is well established that physical activity has positive associations with mental wellbeing, and may protect against ill-being including psychological distress (Malcom et al., 2013; Biddle, Mutrie & Gorely, 2015; Mansfeild et al., 2018), defined as emotional suffering characterised by somatic, social and psychological symptoms of depression and anxiety (Keyes, 2002). Physical activity levels are markedly lower in populations that are overweight or have obesity, and psychological distress is higher (Petroni et al., 2007). Many of such populations enrolled in commercial weight loss programs struggle with emotional regulation during and after weight loss (Sainsbury et al., 2018), with those displaying more extreme weight loss often showing an increase in psychological distress (Balliot et al., 2017). However, physical activity exerts a moderate effect on the reduction of depressive moods across various clinical and non-clinical populations, and can improve emotional regulation (Rimmer, et al 2012; Cooney et al, 2013; Dunn et al, 2013). Given the above evidence, the addition of physical activity may help populations with overweight or obesity regulate emotional symptoms and thus reduce the likelihood of distress. However, a recent systematic review (Baker et al., 2016) urged caution on the link between exercise and distress in such populations, warranting additional interventions that assess the effects of physical activity on both physical and psychosocial outcomes.

The Medical Research Council (MRC) outline that theory-based interventions demonstrate larger effects on physical activity behaviours than interventions not underpinned by a theory (Craig et al., 2013). Theory-based physical activity interventions can explain psychological mechanisms assumed to regulate the behaviour change process by identifying active techniques that can be implemented in the design and implementation of programs (Hagger & Chatzarantis, 2014). One active intervention ingredient related to physical activity is implementation intentions, which refer to ‘if-then’ plans. Interventions applying

implementation intentions techniques assumed to improve behaviour change by helping the individual making critical environmental cues salient (e.g. 'if I don't enjoy exercising alone'), and associated responses automatic (e.g. 'then I will call a friend to go for a walk'). A meta-analysis by Carraro and Gaudreau (2013) found a large unique effect of implementation intentions, d = 1.03, on physical activity. Moreover, Bélanger-Gravel, Godin, and Amireault (2013) showed that implementation intentions still exert a unique effect on behaviour when integrated within existing physical activity programs.

1b Objectives and hypotheses

Hence, the aim of this study was to test the effects of augmenting a commercial weight loss program with a theory-based module designed to boost physical activity and help emotional regulation during dietary restriction. The theoretical component utilised in the present study was a physical activity consultation based on the work of Kirk et al (2007; see also Tanham et al., 2014). The intervention consisted of four sessions lasting approximately 20 minutes during which participants are encouraged to set goals and to self-monitor their activity that was augmented in the present research by adding the behavior change technique of implementation intentions (Gollwitzer, 1993).

Three hypotheses were tested: i) women randomized to receive the physical activity intervention will be significantly more active at follow up than those receiving the standard version of a commercial weight loss program; ii) women randomized to receive the physical activity intervention will report better emotional regulation, with reductions in anxiety, depression, social dysfunction, somatic symptoms and general-ill health compared to those who received a standard version of the program at follow-up; (iii) both groups would lose weight, with the intervention group displaying greater weight loss because of the addition of physical activity.

2. Method

2a Trial design

The present study was conducted using a clustered randomised controlled trial, and all reporting adhered to the CONSORT guidelines. Individuals enrolled in a commercial weight loss program were randomised into one of two clustered groups: an intervention group who received a multicomponent physical activity consultation in addition to the standard weight loss program (n = 25, M_{age} = 40.70, SD = 12.10), and, a second control group who received the standard commercial weight loss program only (n = 24, M_{age} = 38.30, SD = 12.80).

2b Participants and sample size

One hundred women attending a commercial weight loss program in a town in the Republic of Ireland were invited to take part in the study, based on the inclusion criteria of having a Body Mass Index score of $\geq$ 25, designating them as individuals who are overweight, or have obesity (see Figure 1). Participants were invited via five separate oral recruitment presentations delivered by the second author to the attendees on their first night of attendance. An a priori sample size was calculated using G*POWER (Faul, Erdfelder, Lang, & Buchner., 2007) for a 2x2 ANOVA with a between-within groups interaction and with the pre-defined criteria of medium effect size (f = 0.25), α= 0.05 and power of 90%. A medium effect size was decided based on the meta-analysis conducted by Bélanger-Gravel et al (2013) showing positive effects of implementation intentions on increasing physical activity. An a priori total sample size of 46 was calculated.

Fifty participants agreed to take part providing written consent, and completed data collection on two occasions (week 1 and week 6) in a quiet room on the location the weight loss programme took place in. One control participant dropped out before baseline assessment due to personal reasons. Forty-nine women with a mean age of 39.5 (SD = 12.4)

and mean Body Mass Index of 31 (*SD* = 2.1) took part in the study. Ethical approval was granted by the leading Institution's Research Ethics Filter Committee.

2c Randomisation

Sequence generation

In order to have an evenly split number of participants across control and intervention groups individuals were paired in a 1:1 ratio for randomisation, before baseline data collection and intervention starting date.

Implementation

The second author generated the randomisation sequence by selecting shuffled names from a list, and placing the name into an envelope encoded as intervention or control group.

Allocation concealment and blinding

Intervention participants were not blinded to treatment condition pre-baseline data collection, as it was necessary to confirm that they would take part in the augmented programme including the physical activity consultations. However, both intervention and control participants were blinded to the knowledge that they would have their data matched against the other group. The research team were not blinded to group allocations because of the need to participate in the data collection and analyses on site of the weight loss program.

Insert Figure 1 here

2d Interventions

Standard Weight Loss Program

Participants in both the intervention and control conditions received a weekly multicomponent weight loss program, delivered in a group setting by a trained professional

weight loss practitioner. The sessions mainly focused on healthy eating and weight status. The programme lead provided information on calorie intake, and other alternative low caloric food choices. Participants received an eating plan to promote a healthier life and were encouraged to be more active, however no physical activity plan was provided.

Multi-Component Physical Activity Intervention

In addition to receiving the standardised commercial weight loss programme, participants in the intervention condition attended a 30-minute long group educational physical activity session during week one that was co-delivered by the weight loss practitioner and the second author, who at the time of delivery was a Masters of Science student in Physical Activity and Population Health, and individual physical activity 30-minute long consultations took place in weeks two, three and four, delivered by the second author. The content of the physical activity consultation session was based on a review by Kirk, Barnett, and Mutrie, (2007), and included in-depth discussions about the benefits of physical activity and possible discrepancies between the individual's activity levels (accessed through the data provided from the pedometer device which was visible for the participants, see below for more details) and recommended guidelines; goal setting; and problem solving for overcoming barriers to being active were then formed on the basis of this reflective discussion. Participants in the intervention group completed a physical activity log each day, to enhance self-monitoring, as previous research has shown monitoring to be an effective behavior change technique (Michie, Abraham, Whittington, McAteer, & Gupta, 2009). The log included a section in which participants formed weekly physical activity implementation intentions regarding when, how and where physical activity would take place in the week ahead. These logs were reviewed by the researcher in consultation with the participant one week later, so that the researcher checked the log details matched with what was said to be performed.

2e Outcome measures and procedure

Physical activity was assessed by measuring the mean number of steps taken across 7 days using a Digiwalker DW-200 Yamax pedometer (Yamax, Nottingham, UK). The number of steps was recorded at the end of each day. The number of steps was visible to participants. Approximately 10,000 steps per day are considered to be in line with the physical activity guidelines for health for adults (Tudor-Locke et al 2008). Anthropometric measures of height (centimeters) and weight (kilograms) were recorded to the nearest 0.1cm and 0.1 kg using a freestanding stadiometer (Holtain Limited, Crymych, Dyfed, UK) and standard scales (Sec, Hamburg, Germany) with the participant wearing indoor clothes but having emptied pockets and removed shoes, jewellery and bulky clothing. Body Mass Index (BMI) was calculated by taking body weight in kilograms and dividing by height in meters squared. Distress was assessed using the General Health Questionnaire-28 (GHQ-28). The GHQ-28 assesses three psychological health factors: anxiety/insomnia, social dysfunction, severe depression, and one physical health factor, namely, somatic symptoms. The GHQ-28 also provides a total score for general health.

All participants were recruited for the intervention program meetings over a two week period. Once recruited participants were informed that the study would investigate the effect of a physical activity intervention on physical activity step counts, weight and psychological well-being and that questionnaires would be completed at two time points, in week one and six weeks later. After completion of consent forms, two researchers supervised the data collection and questionnaire completion, that included providing personalised codes to allow researchers to match participants' baseline and follow up data. Height and weight measurements were taken by the researchers and all participants were given a pedometer to wear for seven days. During weeks one, two, three and four, the control group continued with the conventional commercial program while the intervention group received the enhanced

intervention. During week six, the same assessment procedure as conducted at baseline was replicated. Following data collection, two researchers manually inputted raw data from the pedometers and questionnaires into SPSS (version 21) software. To ensure consistency and accuracy, the SPSS file was cleaned through randomly selecting and cross-checking 10% of the inputted data with the raw data. A third researcher then conducted data analyses (described below).

2f Statistical Methods

Separate between group (intervention and control) t-tests were calculated as a randomisation check to establish if there were differences between groups in physical activity or weight at baseline. A 2 (Group) x 2 (Time) mixed factors Analysis of Variance (ANOVA) for the physical activity and weight variables was calculated to determine main and interaction effects. To ensure any significant effects were not a result of scores at baseline, separate analysis of covariance (ANCOVA) tests were calculated. The four subscales of the GHQ-28 were analysed using a 2 x 2 mixed factors Multivariate Analysis of Variance (MANOVA). Statistically significant effects ($p<.05$) were followed-up using separate 2 x 2 mixed factors ANOVA's. To ensure any significant effects for the GHQ-28 were not a result of scores at baseline, separate ANCOVA tests were calculated for each sub domain. Partial eta squared (η_p^2) as a measure of effect size was calculated, providing an indication of what proportion of the variance in the dependent variable is attributable to the intervention. All calculations were performed using the Statistical Package for the Social Sciences (SPSS) version 21.

3. Results

3a Participant flow and group randomisation check at baseline

The CONSORT flow diagram for the study design can be found in Figure 1. The characteristics of the sample at baseline are reported in Table 1. There was no significant

difference between the groups for age and no difference between the control (*M*= 75.43 kg, *SD*= 7.54) and intervention groups (*M*= 75.32 kg, *SD*= 6.67) for weight *t*=.055, df=47, p=.956 at baseline. There was no significant difference between the control (*M*=30207.67, *SD*= 7833.29) and the intervention group (*M*= 31516.25, *SD*= 9310.17) on baseline mean weekly pedometer scores *t*=-.532, df=47, p=.597), and no significant difference between the control and the intervention group on any of the four GHQ-28 sub-scales at baseline $F(5,43)=.464$, p=.802, $\eta_p^2 = .051$.

Insert table 1 here

3b Outcomes, estimation and harms

No negative effects or harms were reported for the standard weight loss programme, and the augmented intervention including physical activity consultations. Effects of the intervention on each of the outcomes are detailed below.

Physical activity

Pre and post intervention data are presented for all variables in Table 2. To investigate if the number of steps per day changed as a result of the intervention, a 2 x 2 mixed factors ANOVA with the independent variables of testing session (time) and for group (intervention versus control) was conducted. There was a significant interaction effect between group and time, $F(1, 47) = 22.41$, $p < .001$, $\eta_p^2 = .32$, with the intervention group exhibiting a greater increase in pedometer scores. While both groups demonstrated an increase in mean steps over time, $F(1, 47) = 244.12$, $p < .001$, $\eta_p^2 = .84$, the intervention group exhibited a larger increase. An ANCOVA was calculated controlling for baseline pedometer scores, the difference between groups at follow up remained statistically significant where in the intervention group performed more steps, $F(1, 46) = 24.10$, $p < .001$, $\eta_p^2 = .35$.

Insert Table 2 here

Weight

There was a slightly greater increase in weight loss for the intervention group. However, there was no significant main effect of group and no significant interaction between time and group. There were significant main effects of time for weight, $F(1, 47) = 144$, $p < .001$, $\eta_p^2 = .75$, with weight significantly decreasing by 3.74 kg for the intervention and 3.39 kg for the control groups from the first to second testing session. An ANCOVA was calculated controlling for baseline weight levels. No statistically significant differences between groups were shown.

GHQ-28

A 2 x 2 mixed MANOVA was conducted with the four subscales of the GHQ-28 as the dependent variables. There was a significant multivariate main effect for group, Wilks' $\Lambda = 3.67$, $F(4, 44) = 5.42$, $p < .001$, η_p^2 .33; time, Wilks' $\Lambda = .303$, $F(4, 44) = 25.29$, $p < .001$, $\eta_p^2 = .33$, and a significant group x time interaction, Wilks' $\Lambda = .712$, $F(4, 44) = 4.44$, $p = .004$, $\eta_p^2 = .28$. Separate analysis for each domain of the GHQ-28 is presented below.

Anxiety

A 2x2 mixed design ANOVA revealed a significant interaction between group and time for anxiety, $F(1, 47) = 8.16$, $p < .001$, $\eta_p^2 = .15$, the intervention group exhibited a greater decrease in scores compared to the control. When an ANCOVA was calculated controlling for baseline anxiety scores, the statistically significant difference between groups remained where in the intervention group scored lower $F(1,46) = 51.95$, $p<.001$, $\eta_p^2 = .53$.

Social Dysfunction

A 2x2 mixed design ANOVA revealed a significant interaction effect between group and time for social dysfunction $F(1,47) = 8.91$; $p<.001$, $\eta_p^2 = .16$. The intervention group exhibited a greater decrease in scores compared to the control. To control for baseline social dysfunction scores an ANCOVA was calculated, the significant main effect remained $F(1,46) = 33.62$, $p<.001$, $\eta_p^2 = .42$.

Depression

A 2x2 mixed design ANOVA revealed a significant interaction effect between group and time for depression $F(1,47) = 4.22$; $p <.001$; $\eta_p^2 = .08$. The intervention group exhibited a greater decrease in depression scores compared to the control. An ANCOVA was calculated. After controlling for baseline depression scores a significant main effect remained $F(1,46) = 10.58$, $p<.01$, $\eta_p^2 = .19$.

Somatic

A 2x2 mixed design ANOVA revealed no significant interaction effect between group and time $F(1, 47)=.03$, $p=.87$, $\eta_p^2 = .001$.

4. Discussion

4a Interpretation

Commercial weight loss programs represent culturally significant resources for individuals aiming to achieve weight loss, yet most programs do not include physical activity and research is inconclusive regarding program's effects on mental health. As such, the aims of the present study were to test whether: (a) the physical activity levels of women with overweight or obesity enrolled in a commercial weight loss program could be boosted with a theory-based physical activity consultation, and (b) whether participants randomized to receive the physical activity intervention reported better emotional health during dieting compared to those who received a standard version of a weight loss program. The findings

show that for women who participated in a weight loss program receiving an enhanced multi-component tailored one-to-one physical activity consultation, number of steps per-day increased and distress was decreased compared with people who received the standard commercial weight loss program. Participants who received the intervention demonstrated lower anxiety, social–dysfunction and depression at follow-up compared to the control group. In addition, a larger reduction in weight was found for the intervention group. Collectively, the findings support evidence showing the effects of physical activity interventions for increasing physical activity behaviour and reducing body weight (WHO, 2010; Biddle, Mutrie, & Gorely, 2015), and extends the evidence that in populations with obesity, enhancing physical activity levels can improve emotional health (Baker et al., 2016). We now discuss the findings offering recommendations to advance research and practice.

The intervention was shown to increase the number of steps performed by the participants in the intervention group compared to the control group at follow up. The change in step count behavior can be interpreted to be a result of the physical activity consultation. According to Wolf (1986), when Cohen's d = .5, (or the equivalent η_p^2 =.06 as included above) this magnitude reflects a practical/clinical change. The behaviour change techniques were operationalised through one-to-one consultations which entailed goal-setting and problem solving based on IIP's for overcoming barriers to being active each day, and the keeping of physical activity logs for self-monitoring reflection and boosting the educational content of the consultations. The positive effects on physical activity behaviour supports the efficacy of self-monitoring and IIP's for improving daily physical activity (Michie, Abraham, Whittington, McAteer, & Gupta, 2009; Bélanger-Gravel, Godin, and Amireault (2013) and may be considered when integrating physical activity into current commercial weight loss programs (Balliot et al., 2017).

A more thorough research design would have allowed us to determine the direct and indirect effects of the intervention's effects on physical activity behaviour as it is not clear how much of the behaviour change can be accounted for by implementation intentions alone. For example, integrated behaviour change frameworks (Hagger & Chatzarantis, 2014) along with extant evidence (Bélanger-Gravel, Godin, and Amireault (2013) suggest that physical activity enhancements may be realised to a combination of conscious and non-conscious processes, in which IIP's exert unique effects. Further research entailing the measurement of IIP's is required to determine the actual mediated or unmediated effect that the addition of IIP's may have added.

For the intervention group on all psychosocial outcome variables (anxiety, social dysfunction and depression) except somatic, the effect size (η_p^2) was above .06. This finding contradicts the majority of studies that indicate that physical activity is not as effective at reducing distress in populations with obesity (Baker et al., 2016). Therefore, due consideration should be given to how physical activity consultations could be included to enhance the health benefits of weight loss programmes (Balliot et al., 2017). It would also be useful to identify how the physical activity consultation could be incorporated within current healthy lifestyle programmes that do not only focus on weight loss, but the wellbeing of the person in general (Breslin et al, 2013; Biddle, Mutrie & Gorely, 2014; Balliot et al., 2017).

There were no negative effects or harms reported for either the intervention or control group. Furthermore, the cost of augmenting the weight loss intervention with physical activity consultations was low, given a volunteer from the research team conducted the meetings. Feedback from the commercial weight loss practitioner revealed a willingness to be trained in the application of physical activity consultation techniques for bolstering the weight loss intervention within their program. The design of such training could be client centred, and cost-efficient through delivery over one day, and bolstered by further top-up

sessions (Ntoumanis, Quested, Reeve & Cheon, 2017). A thorough process evaluation would have helped gain understanding of the overall cost, precise number of sessions, and consultations the participants engaged in, and acceptability of the intervention from the perspective of the participants (Jean-Naylor et al., 2002), and should be considered for further work.

4b Limitations and generalisability

Some potential limitations of this study should be considered. First, the favorable response to the intervention came from women who were already motivated to lose weight and able to afford a commercial weight loss program and so caution should be adopted before generalizing the findings. Second, the length of follow-up was relatively short and it would be valuable to see whether the effects can be sustained in the longer term. Third, because of human resource constraints, some of the research team were required to conduct randomisation, whilst also participating in intervention delivery and data collection, meaning it was not possible to blind outcome assessors to group allocations. Fourth, the physical activity logs were used to enhance the educational messages of the consultations, however, the qualitative content of the logs were not analysed by the researchers. On reflection a log or diary may have provided important additional information on the context of the types of physical activity engaged in. Future research may consider screening physical activity logs or using a self-report physical activity instrument alongside validated wearable devices (e.g. pedometers, accelerometers) for better contextualising the physical activity. Nevertheless, it is encouraging that physical activity habits have been shown to develop in as few as five weeks (Armitage, 2005) and so there are grounds for cautious optimism in conducting further research with longer term follow-ups.

4c Conclusion and implications

This study demonstrated that the inclusion of a multi-component physical activity consultation for women enrolled in a commercial weight loss program were more likely to increase their physical activity, and improve their emotional health than those who attended a standard version of the commercial weight loss program. These findings provide evidence to support the inclusion of face-to-face physical activity consultations that comprises self-monitoring, goal-setting and implementation intentions. Future developments of such commercial weight loss programs may consider a more holistic programme aim beyond weight loss, such as improving multiple aspects of wellbeing through a healthy lifestyle.

Conflict of interest

All authors declare that we have no conflict of interest to declare.

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