Weight loss is coupled with improvements to affective state in obese participants engaged in behavior change therapy based on incremental, self-selected “Small Changes”

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Weight loss is coupled with improvements in affective state for obese participants engaged in behavior change therapy based on incremental, self-selected 'Small Changes'

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Abbreviations

BMI; body mass index

BMR; basal metabolic rate

EI; energy intake

GWB; General Well-being Scale

HDL; high density lipoprotein

NMES; non-milk extrinsic sugars

POMS; Profile of Mood States Questionnaire

TFEQ-R 18; Three-Factor Eating Questionnaire-R 18

Abstract

The aim of this study was to investigate the effects of a group behavior change intervention, involving self-selected, contextualized and mediated goal setting on anthropometric, affective and dietary markers of health. It was hypothesized that the intervention would elicit changes consistent with accepted health recommendations for obese individuals. A rolling program of 12-week 'Small Changes' interventions over 24 months recruited 71 participants; each program accommodated 10-13 adults (BMI ≥ 30kg/m^2). 58 participants completed 'Small Changes'. Repeated measures were made at baseline, 6 and 12 weeks. Anthropometric measures included height and weight (to calculate BMI), body composition, waist circumference and blood pressure. Affective state was monitored using relevant validated questionnaires. Dietary assessment employed 3-day household measures food diaries with Schofield Equations to monitor under-reporting. Relevant blood measures were recorded throughout. Across the measurement period, 'Small Changes' elicited a significant reduction in body weight (baseline 102.95±15.47 Vs 12 weeks 100.09±16.01kg, p<0.0005), coupled with associated significant improvements in BMI, body fat percentage and waist circumference measures. There were additional, significant positive changes in measures of affective state including General Wellbeing (baseline 58.92±21.22 Vs 12 weeks 78.04±14.60, p<0.0005) and Total Mood Disturbance (baseline 31.19±34.03 Vs 12 weeks 2.67±24.96, p<0.0005). Dietary changes that occurred were largely consistent with evidenced-based recommendations for weight management and

included significant reductions in total energy intake (EI), and in fat and saturated fat as a proportion of energy. The 'Small Changes' approach can elicit a range of health-orientated benefits for obese participants, and while further work is needed to ascertain the longevity of such effects, the outcomes from 'Small Changes' are likely to help inform health professionals when framing the future of weight management. Long term follow-up of 'Small Changes' is warranted.

Keywords

Behavior therapy, obesity, body weight, waist circumference, affect, adults

1. Introduction

Around two-thirds of the population in England is obese or overweight and over 300 million adults are obese worldwide [1]. Obesity has a number of deleterious effects on health. It is a known risk factor for coronary heart disease partly because of its association with hypertension, type 2 diabetes and hypercholesterolemia, and there is increasing evidence that it is a risk factor for stroke, osteoarthritis and some cancers [1]. The negative psychosocial effects of obesity are well documented and include body dissatisfaction, depression and low self esteem [2]. The recent rapid rise in obese and overweight can be attributed to overarching changes in behavior and inability to respond to a rapidly changing environment [3].

Long term weight reduction in obesity can be of considerable benefit for reducing the risk of nutrition-related chronic disease [4]. Dieting interventions are rarely successful; some even suggest this type of restrained eating induces counter-regulatory responses that could be deemed iatrogenic [5]. Dieting is a common behavioral phenomenon, yet the number of 'dieters' and the rate of obesity appear to have increased in parallel [6]. Many dieters succeed in losing weight; though only between 5-10% achieve long-term weight loss [7-13]. This may be because many popular diets are not evidence-based and do not consider the effects on micronutrient status, metabolic parameters, appetite, psychological well-being and long-term hormonal regulators of EI and expenditure.

Following a scientifically unsound diet may therefore result in quantitative and qualitative nutritional imbalance [7].

Weight-loss pharmacotherapy requires long-term application to be effective, can be financially costly and may be accompanied by unpleasant side effects [8]. Prospective randomized controlled trials have established the efficacy of anti-obesity drugs, but not for longer than two years [9] and it is generally accepted that pharmacotherapy interventions must be combined with lifestyle modification in order to maximize their efficacy [10]. Bariatric surgery can be associated with major nutritional and medical complications [11] yet is arguably the most effective and durable way to reduce weight in the morbidly obese [12].

Behavior change techniques (e.g. awareness raising activities and self-selected goal setting), have been shown to be effective in tackling overweight and obesity when they are coupled with positive dietary and physical activity modifications; more so than any of these strategies used in isolation [13]. A recent systematic review concluded that approaches combining diet, behavior modification and exercise training elicited the most successful outcome when treating the overweight (BMI≥25.0kg/m^2) or obese (BMI≥30.0kg/m^2) [14]. In practice, behavior change philosophies differ dramatically from one to the next making comparison difficult. One consistent feature however, is a multidisciplinary ethos [14].

The effect of a behavior change intervention on collective wide-ranging anthropometric, affective and dietary markers in the obese has not been widely reported and the effects of our ‘Small Changes’ approach are previously unpublished. We hypothesize that behavior change therapy based on incremental, self-selected 'Small Changes' will elicit beneficial changes for obese participants across all of these markers of health and wellbeing.

'Small Changes' is a psycho-social behavior change intervention program for weight management. It draws on a neuro-linguistic programming approach initiated by Bandler and Grinder in 1975 [15] and uses solution based therapy [16] and motivational interviewing [17] techniques in facilitating participants’ self-selection of small lifestyle changes. These changes may be weight management orientated and consistent with those championed by Hill [18]; however, they may focus more broadly on issues around self-control, family life, stresses or personal organization. These changes are contextualized within the lives of the participants (i.e. it is the barriers faced by the individual that are tackled). 'Small Changes' uses a 12-week protocol. The multidisciplinary outcomes reported here have been pooled from 12-week ‘Small Changes’ programs run over a 24 month period from Sept 2007-Sept 2009 in Sheffield, UK.

2. Methods and Materials

We conducted an intervention study to investigate the effects of the 12-week 'Small Changes' intervention using a repeated measures design on a range of physical, affective, dietary and blood measures.

2.1 Recruitment, Attrition and Completion Rates

'Small Changes' participants were recruited via advertisements positioned around the University, in local newspapers, on local radio stations and in various department stores throughout Sheffield city centre, via local blogs and word of mouth. Each 'Small Changes' cohort recruited 10-13 obese (BMI≥30kg/m^2) adults. Suitable participants were invited to an informal gathering. Each cohort's pre-screening event was scheduled so to be held on the same weekday, at the same time and in the same location as the 'Small Changes' weekly sessions would subsequently be delivered.

At the pre-screening event, a brief history of weight change and dieting attempts was recorded for each participant. Motivation to change and confidence in tackling the problem were assessed by trained facilitators. This qualitative information was not used

to include or exclude participants dependent on their responses but was informative for the facilitators. Participants tended to be highly motivated to change, hence their attendance at the outset. Exclusion criteria included a BMI <30kg/m^2, known, unmanaged serious health issues (except obesity), diagnosed type one diabetes (due to fasting prescribed in our method) or fitted for a pace maker/ other implantable electronic device (contraindicated in bioelectrical impedance analysis). These data were collected using a basic medical screening questionnaire. This research was approved via the appropriate University ethics procedures (reference: OMREC/FIRC/2006/02). All participants gave written informed consent to take part.

2.2 Program Structure

'Small Changes' is facilitated by experts in nutrition (Registered Public Health Nutritionists), physical activity and behavior change. Learning and awareness-raising opportunities are presented via twelve 2 hr weekly sessions that address issues that are accepted to contribute to obesity such as understanding relationships between food, mood and hunger, tackling barriers to weight management and developing sustainable support mechanisms. In session 1, participants were provided with personal pedometers. They were encouraged to monitor their step count and were asked to report back in sessions periodically throughout the program with intent to increase their personal step count, rather than reach an advised target.

Each session began with individual reports from participants about progress since the last session. Each person's successes were acknowledged and congratulated. The session mediators then encouraged discussion of a themed element (e.g. reading food labels, portion size analysis or alcohol intake) that sometimes involved completion of simple activities (see figure 1). In the second hour of the sessions participants pledged to make a small lifestyle change. Each participant proposed a pledge which, where necessary, was mediated via the program facilitators. For example, a participant may pledge to cut out chocolate. The mediator would usually praise such commitment but enquire as to how much chocolate the participant normally ate. If they habitually consumed a chocolate bar daily, mediation may have taken place to contextualize the pledge to that participant's circumstances, for example, the participant may have been asked whether complete exclusion was realistic. In most instances, reconsideration would occur and a more achievable target (such as consuming chocolate only twice a week) would be set instead. Pledges are designed to be incremental and each different weekly pledge is carried throughout the program and hopefully beyond, normally resulting in at least twelve changes (one per week) being made by each participant throughout 'Small Changes'.

Various measures were made at baseline, 6 and 12 weeks in order to monitor progress. These are outlined below.

2.3 Physical Measures

Participants were asked to void their bladders prior to physical measurement. Height (without shoes) and weight (indoor clothing) were recorded to the nearest 0.1cm and 0.1kg respectively (SECA 709 mechanical column scales with SECA 220 telescopic measuring rod; SECA Birmingham, United Kingdom). For consistency, participants were asked to wear the same clothes at each visit. Height measurements were made at the point of normal breath inspiration with the head orientated in the Frankfort horizontal plane. From these measures, BMI was calculated and rounded to the nearest 0.1.

Bioelectrical impedance analysis was undertaken on non-conducting foam matting using BodyStat 1500 (BodyStat Ltd., Isle of Man, British Isles). Measurements were made as per the manufacturer's instructions following 5 minutes of supine rest. Participants were asked to fast overnight and limit physical activity prior to measurement. Percentage body fat and lean weight (kg) were recorded to the nearest 0.1% or 0.1kg respectively.

Systolic and diastolic blood pressures were determined using an A & D Medical UA-787 *Plus* Digital Blood Pressure Monitor (A & D Instruments Ltd., Oxfordshire, UK). The

correct cuff size (22-32cm or 32-45cm) was selected on a case by case basis. Measurements were made in triplicate as per the manufacturer's instructions and mean values were then calculated.

Waist circumference (to the nearest 0.1cm) was measured using an inelastic, flexible tape measure of adequate length. Clothing around the abdomen was removed or loosened, except in the case of underwear, and pockets were emptied. Participants stood erect with their feet approximately 10-15cm apart and their weight equally distributed, arms by their sides, palms facing inwards. Measurements were made in a horizontal plane midway between the iliac crest and lowest rib, at the end of gentle expiration.

2.4 Questionnaires

The General Well-being Scale (GWB) proposed by Dupuy in 1971 [19] assesses positive feelings about the inner state across a variety of core affective states including anxiety, depression, general health, positive well-being, self-control and vitality. The GWB has an 18-item scale where the first 14 items are scored 0-5, anchored with appropriate terms (e.g. "Have you felt downhearted or blue?" anchored with "All of the time" through to "None of the time"). The final 4 items (e.g. "How relaxed or tense have you been?") are scored on a Likert scale of 10 to 0 anchored by appropriate terms (e.g.

230 “Very relaxed” to “Very tense”). ‘Small Changes’ participants were instructed to use the
231 last month as their reference period for completing the GWB, in accordance with
232 guidelines for its use [19]. Higher GWB scores indicate higher levels of psychological
233 well-being. The following cut-offs can be used for guidance; 81-110 = positive well-
234 being, 76-80 = low positive, 71-75 = marginal, 56-70 = stress problem, 41-55 = distress,
235 26-40 = serious, 0-25 = severe.

236

237 The Three-factor Eating Questionnaire-R 18 (TFEQ-R 18) was administered and
238 psychometric measures of cognitive restraint, uncontrolled eating and emotional eating
239 were recorded. The TFEQ-R 18 [20] was developed using factor analyses from
240 Stunkard and Messick’s [21] original 51 item TFEQ. It is a psychometrically valid
241 instrument devised for use in an obese population [20]. Of the total items presented in
242 the questionnaire, six are assigned to cognitive restraint (control of food intake to
243 influence body weight), nine to uncontrolled eating (difficulties in regulating eating in
244 response to extreme appetite or external environment) and three to emotional eating
245 (overeating during dysphoric mood states) [22-23]. Raw scores for each factor in the
246 TFEQ-R 18 are expressed as a percentage of the maximum score [22-23].

247

248 The Profile of Mood States questionnaire (POMS) was developed by McNair and
249 colleagues in 1971 [24] and is designed to determine affective mood state fluctuation.
250 Participants completed the 65 five-point adjective rating scales designed to identify six
251 transient, fluctuating affective states (raw scores); tension-anxiety, depression-

dejection, anger-hostility, fatigue-inertia, and confusion-bewilderment all representing negative mood, and vigor-activity representing positive mood. The scores across all of the six states were summed to determine overall total mood disturbance (weighting vigor-activity negatively) to provide a single overall estimate of affective state.

2.5 Dietary Assessment

Dietary information was collected using 3-day estimated household measures diet diaries. Participants were fully briefed (by Associate Registered Public Health Nutritionists) on how to complete the diaries and a written example of a diary was given to participants to take away. Timing of meals, foods consumed, brand (where appropriate), portion size and leftovers were recorded over 3 consecutive days (including 1 weekend day). They were then analyzed using dietary analysis software (NetWisp version 4.0 for Windows, Tinuviel Software, Warrington, UK). Mean daily energy and fiber intake, and percentage contribution of macronutrients to total energy were analyzed.

Schofield equations [25] (revised) were used to estimate basal metabolic rate (BMR) and mean daily EI was taken from the NetWISP dietary analysis. BMR:EI < 1.1 was used as a proxy for under-reporting [26].

2.6 Blood Measures

Following a 12 hour fast, a single use Accu-chek® Softclix® Pro lancing device (Roche Diagnostics Ltd., West Sussex, UK) was used to obtain capillary blood samples; one to determine total cholesterol and the other for the measurement of whole blood triglycerides. Two 30µl samples were collected in Microsafe Collection and Dispensing Tubes (Inverness Medical, Cheshire, UK) and applied immediately to Reflotron® Cholesterol Test Strips (measurement range 2.59 - 12.9mmol/L) and Reflotron® Triglyceride Test Strips (measurement range 0.80 - 6.86mmol/L; both Inverness Medical, Cheshire, UK). Whole blood was collected in 300µL EDTA dipotassium salt coated centrifuge tubes (Microvette CB 300, Hematology/ Potassium EDTA; SARSTEDT Ltd., Leicestershire, UK), spun at room temperature for 2 min (Centrifuge MC6; SARSTEDT Ltd., Leicestershire, UK) and analyzed within 3 min. 30µl plasma was separated from the sample in order to measure plasma (high density lipoprotein) HDL. The sample was then applied to the Reflotron® HDL Cholesterol Test Strip (measurement range 0.26 - 2.59mmol/L; Inverness Medical, Cheshire, UK). The Reflotron® Plus (Inverness Medical, Cheshire, UK), a reflectance photometer, was then used to analyze each sample.

A single droplet whole blood sample was collected via OneTouch® Ultra® Test Strips with FastDrawTM design. The OneTouch® Ultra® Blood Glucose Monitoring System was used to determine total glucose (reference range 1.1 to 33.3 mmol/l; Lifescan Inc., Bucks, UK).

2.7 Statistical Analyses

SPSS (version 17.0 for Windows, SPSS Inc., Chicago, Illinois) was used to conduct a one-way analysis of variance to determine if significant differences existed across a range of baseline characteristics between participants who completed the 'Small Changes' program (n=40), those who completed the program but with an incomplete dataset (completers, missing data, n=18) and non-completers (n=13). One-way repeated measures analyses of variance were used to compare physical, blood, questionnaire and dietary analysis measures at baseline, 6 and 12 weeks. Data are presented as means and standard deviations in tables 2 to 4 and table 6, and as frequencies in table 5. Where appropriate, these analyses were corrected using the Huynh-Feldt correction. Pearson Product Moment Correlations were conducted to determine the relationship between relevant physical measures. A Pearson Chi-square was undertaken to compare the level of under-reporting (according the Schofield equation) in each of the three measurement periods. A probability value of <0.05 was considered significant.

3. Results

Seventy-one participants enrolled in 'Small Changes' over 24 months. Thirteen participants failed to complete the course due to ill-health and personal circumstances. Of the 58 who completed the 12-week intervention, 18 did so without fully engaging with all measurement periods. Questionnaires and diet diaries were, in some instances, never returned, despite repeated follow-up. Forty participants finished the program with complete datasets. Participant characteristics are shown Table 1. One-way analyses of variance show that baseline characteristics (age, weight and BMI) were not significantly different between participants who completed 'Small Changes' compared to those who did not engage with all measurements (completers, missing data) and non-completers of the program (data not shown). However, it is noteworthy that male non-completers were heavier than male completers, though the opposite trend existed for female participants.

3.1 Physical Measures

Across the intervention, significant mean weight loss and consequent reductions in BMI ($p < .0005$ and $p < .0005$ respectively) were accompanied by a significant reduction in mean % body fat and waist circumference ($p = .019$ and $p = .008$) with no change in

lean weight (see table 2). Interestingly for waist circumference, most of the change seen over 12 weeks appears to have occurred in the initial 6 week period. Percentage change in weight was significantly positively correlated with percentage change in % body fat ($p < .001$, see figure 2A) and % change in waist circumference ($p < .0005$, see figure 2B). Mean systolic and diastolic blood pressure were classed as non-hypertensive [27] and did not alter significantly over the intervention.

3.2 Questionnaires

'Small Changes' elicited a significant improvement in psychological well-being ($p < .0005$, see table 3). Mean (± SD) GWB at baseline was 58.92 (21.22) which would be classed as 'stress problems'. By the end of the intervention, it was 78.04 (14.60) categorized as low-positive well-being.

Assessment via the TFEQ-R 18 showed significant changes in all three eating behaviors (increased cognitive restraint and reduced uncontrolled and emotional eating; $p < .0005$ and $p < .0005$ respectively) during the intervention (see table 3). The change in uncontrolled eating was significantly negatively correlated with percentage weight change (data not shown; r = -.357, n = 50, $p = .011$). A negative correlation between emotional eating and percentage weight change was approaching significance (data not shown).

The POMS questionnaire demonstrated significantly and dramatically reduced overall mood disturbance during 'Small Changes' ($p < .0005$, see table 3). Of the six affective states (raw scores) measured, each was significantly improved, with the exception of fatigue-inertia (see table 3 for details).

When examining the changes in affective state more closely it seems most of the improvement occured in the first 6 weeks of the intervention. This is certainly the case for GWB but appears also in some TFEQ-R 18 measures and for Total Mood Disturbance and certain POMS raw scores.

3.3 Dietary Assessment

Diaries were completed and returned by 46 participants. The significant reduction in reported mean EI ($p < .0005$) was accompanied by significant mean weight loss. EI was restricted most noticeably in the first 6 weeks of the intervention though continued restriction is evident from 6 to 12 weeks. The contribution to total EI from the various macronutrient categories and subcategories was not equal across the three measurement periods. Across the intervention EI from protein, total carbohydrate and sugars significantly increased ($p = .007$, $p = .028$ and $p = .044$, respectively) and EI from total fat and saturated fat significantly decreased ($p < .0005$ and $p = .040$, see table 4).

However, the significantly increased levels of Schofield assessed under-reporting at week 12 compared to the high baseline and 6-week levels (p = .012) raises cause for concern (see table 5).

3.4 Blood Measures

Any blood measures reported to be outside of the measurement range were repeated using fresh samples. Where these subsequent measures were out with the measurement range (1 participant's total cholesterol, 15 participants' total triglycerides and 3 participants' plasma HDL cholesterol) they were excluded from analysis. All total glucose measures were within the accepted measurement range. There was no significant change in fasted total cholesterol, triglycerides or glucose during 'Small Changes', though there was a significant decrease in HDL cholesterol (see table 6).

4. Discussion

4.1 Benefits of behavior change

We accept the hypothesis posed for this research that a 'Small Changes' intervention would elicit changes consistent with accepted health recommendations for obese individuals. Previous behavior change research suggests participants benefit from the collective experience of a group and the supportive skills of the facilitator enable participants to set goals, manage relapse and self-monitor their progress [28]. Our findings demonstrate such benefits may be more wide-ranging than previously thought. Across a large number of physical, psychological and dietary measures we have demonstrated the significant benefits of even a short-term behavior change intervention involving self-selected, mediated goal setting.

4.2 Weight is lost with encouraging body compositional changes

Mean weight loss was 2.8%. For obese individuals, it is generally agreed that a 5 to 10% weight reduction over 3 to 6 months is achievable and associated with health benefits, particularly if maintained for a year or more [29]. Weight lost in this 12-week intervention was in keeping with this suggested goal even though 'Small Changes' does not actively prescribe lifestyle changes and pledges are largely self-defined by participants. Encouragingly, weight loss appears to be associated with positive body compositional changes including reduced body fat %, preservation of lean tissue and reduced waist circumference. Critically, where individuals have a history of weight gain, a feature which collectively characterizes 'Small Changes' participants, weight maintenance is considered a success [29].

The interrelationship between BMI and 'Small Changes' completion status is of interest and though no significant difference existed between completers and non-completers in this study sample as a whole, there is an emerging interesting trend to suggest heavier males were less likely to complete where heavier females were more likely to complete. This warrants further investigation with a larger and more gender-balanced sample in order to better understand attrition in behavior change interventions.

4.3 'Small Changes' significantly improves affective state

Improvements in affective state were demonstrated across a range of measures. These validated tools are well-used in a range of health-orientated settings. Though repeated measures use of questionnaires may be affected by learning effects, where participants remember previous responses and try to artificially 'improve' them from one measurement period to the next, the 6-week period between measurements used here has been employed previously [30] and is sufficient to counteract such an effect.

Participants' GWB improved significantly. It is of interest to note that percentage change in well-being was not significantly correlated with percentage change in body weight (data not shown), suggesting that the program enhances feelings of well-being irrespective of weight lost. Paisey and colleagues [31] investigated the effects of a

weight loss program with type II diabetic patients, via either a 6-week very low calorie diet (VLCD) or intensive conventional diet and exercise (ICD), with led weekly group therapy for 6 months, then participant arranged monthly group sessions thereafter over 5 years. Both groups were lighter overall at 5 years (losing weight rapidly in the case of the VLCD group, more slowly in the ICD group). By 3 years the VLCD group had regained at least half of the weight lost, and by 5 years they had regained even more. Weight loss was steady in the ICD group. They assessed GWB at baseline, 3 and 5 years in each group. GWB didn't alter significantly in either group. Similarly to our study, GWB did not seem to be linked to weight change.

GWB has been shown to be linked with activity levels, however. Galper et al. [32] demonstrated a positive dose-response between physical activity level/ cardio-respiratory fitness and emotional well-being measure using the GWB in a large cross-sectional study of adults. It may be that the positive changes in GWB seen in 'Small Changes' are, at least in part, due to increased physical activity levels. Physical activity is promoted throughout the program and participants are encouraged to monitor their activity using the pedometers provided. There are opportunities to report daily step count, which may act as a motivator to increase activity. As activity level was not a measured outcome of this intervention, further study is warranted.

Eating behaviors are both psychologically and physiologically determined [33]. Interestingly, it is emerging that these behaviors are labile in response to changes in

459 body size [34-35] and age [33]. Over the course of 'Small Changes' there were
460 significant improvements in all three TFEQ-R 18 measures of eating behavior (cognitive
461 restraint, uncontrolled eating and emotional eating). It is impossible to elucidate
462 whether these changes are a consequence of, or precursor to the weight loss seen over
463 12 weeks, or both. Konttinen and colleagues [23] found higher levels of cognitive
464 restraint to be associated with lower BMIs and smaller waist circumferences in obese
465 males and females from the Finnish population. They also demonstrated that
466 uncontrolled and emotional eating were both positively correlated with obesity
467 indicators. Similarly, Keränen et al. [22] found that increased levels of cognitive
468 restraint and decreased levels of uncontrolled and emotional eating (as determined by
469 the TFEQ-R 18) were associated with weight loss (in response to intensive lifestyle
470 counseling over 10 visits) and maintenance (up to 18 months). It seems likely,
471 therefore, that these eating behavior changes might improve the weight maintenance
472 outlook for the 'Small Changes' cohort.

473

474 In keeping with previous work, 'Small Changes' elicited significant improvements in
475 participant mood. Melanson and colleagues [36] reported significant improvements in
476 four (tension-anxiety, depression-dejection, fatigue-inertia and vigor-activity) out of the
477 six affective states (raw scores) measured by the POMS questionnaire at 12 weeks in a
478 24-week diet and exercise intervention with overweight and obese adults. 'Small
479 Changes' elicited benefits across all but one of the six affective states (raw scores) as
480 well as total mood disturbance. Previous authors have suggested greater benefit in

reporting raw scores over total mood disturbance [30], so both have been included here. It is of particular interest that the only mood state that did not show significant improvement was fatigue-inertia, while the seemingly opposed rating of vigor-activity did. It appears there may be added psychological benefit of contextualized group behavior change therapy such as that used in 'Small Changes' over individualized diet and exercise therapy commensurate with that used by Melanson and colleagues [36].

POMS was used with overweight, habitually sedentary participants [37] to rate positive (vigor-activity) and negative mood (other mood states) before, after and, retrospectively, during an exercise intervention (active) versus a control (sedentary) condition. Interestingly, only where participants reported increased negative mood was EI in the active condition significantly greater than in the sedentary condition. These findings lend support for tailoring weight management interventions in order to pay due attention to participants' individual mood states and explore possible cognitive underpinnings for pervading moods (such as social physique anxiety and self-efficacy) [37].

The extent to which improved mood in response to behavior change therapy can be maintained post intervention is questionable. Melanson and colleagues [36] measured participants in their 12-week diet and exercise therapy intervention for a further 12 weeks, at the end of which improved mood scores for depression-dejection, fatigue-inertia and vigor-activity remained significant and there was an additional significant

improvement in confusion-bewilderment from baseline. Such follow-up data are not available yet for 'Small Changes'..

4.4 Dietary changes are consistent with evidence-based health promotion

The reported dietary changes from 'Small Changes' included a significant reduction in mean daily EI, which might be expected of those attempting to manage their weight. Additional significant changes were seen across the macronutrient profile. Mean daily intake of energy from protein and carbohydrate increased and mean daily intake of energy from total fat and saturated fat decreased. This rejection of fat and saturated fat is in keeping with currently accepted health messages for weight management promoted both via 'Small Changes' and nationally in the UK (as seen in The Food Standards Agency's EatWell initiative and the Change4Life program described elsewhere [38, 39]). Movement away from high energy density, fat-rich foods towards carbohydrate and protein-rich foods, might in part explain the reduced mean daily EI. Seemingly contrary to evidence-based health promotion messages however, mean daily sugar intake as a proportion of energy increased significantly. Whether this is attributable to an increased intake of non-milk extrinsic sugars (NMES) or of naturally occurring sugars in fruits, for example, is open to debate. Fruit and vegetable consumption is promoted during 'Small Changes' in line with the UK 5 A DAY message and, anecdotally, participants report eating more fruit and vegetables. The 2008-9 National Diet and Nutrition Survey does not report data on sugar but recognizes the

proportion of carbohydrate consumed by 19-64y UK adults attributable to fruit at only 6% [40]. The main food sources of NMES in this age group are sugar preserves and confectionery, non-alcoholic beverages and cereals and cereal products [40]. Future work in this area might benefit from the consideration of total sugars alongside NMES in order to provide clarification.

The dietary data reported here were collected using 3-day estimate household measures diet diaries and though every effort was made to ensure participants were well-trained and followed accepted protocols for dietary assessment, it is important to acknowledge that under-reporting may have influenced these findings. Dietary assessment in those with BMIs ≥30kg/m^2 can be confounded by under-reporting [41], especially where these individuals are women [42]. The prevalence of under-reporting within this obese cohort was expectedly high, in part due to the fact participants were trying to lose weight [42]. Previous research has demonstrated that under-reporting should not alter the macronutrient from energy ratio [41] though it is not necessarily nutrient neutral in terms of absolute nutrient intake [41].

Of greatest concern in relation to the dietary assessment findings was the increase in the prevalence of under-reporting from baseline to the end of the intervention. It is difficult to ascertain whether under-reporting indeed became more prevalent or whether borderline under-reporters merely reduced their EI in line with 'Small Changes'

principles and thus became classified as under-reporters according to the Schofield equations used [25].

Individuals following weight-loss diets are acknowledged to be more likely to under-report [42] than those not attempting to lose weight. The BMR:EI cutoff of 1:1 was used here [26] as implausibly low and therefore incompatible with long-term energy balance, however, there is considerable contention within the literature as to what constitutes under-reporting. Had a higher cut-off been used, under-reporting might have been an even greater concern in this obese but dieting cohort.

Because the reliability of data gathered via dietary assessment is always questionable we have not reported the changes in micronutrient intake that occurred during the 'Small Changes' intervention and recommend that the dietary assessment data presented here are interpreted with caution.

4.5 No concerning changes in blood measures

Blood lipids and glucose were monitored across the intervention. It is noteworthy that at all three measurement periods mean total cholesterol did not exceed guidelines [43] for desirable total cholesterol (<5.17mmol/L). Of all the blood measures, only HDL

cholesterol levels altered significantly during the intervention period. The significantly reduced HDL cholesterol levels seen at week 12 compared to baseline are mildly concerning, though mean levels remained above the high risk cut-off (<1.03mmol/L) [43]. Mean triglycerides exceeded guidelines for desirable triglycerides (<1.69mmol/L) at all three measurement periods [43], however sample exclusion for triglycerides was high and was exclusively due to undetectable low, rather than high, readings. The accuracy of dry chemistry in clinical practice is questionable, particularly if it is used for diagnostic purposes and where capillary samples are employed [43]. The reduced sample size and directional bias (particularly evident for triglycerides) suggest the need for more robust, but more invasive, wet analytical techniques to be employed in future research. Blood glucose remained relatively constant and within normal fasting levels across all three measurement periods. However, the repeated measures design used in the present study looked to compare change over time and was not designed for comparison with published guidelines.

4.6 Goal setting within the context of people's lives

The 'Small Changes' success is likely to lie in the contextualization of goal setting to individual participants' lives and circumstances, and in the frequency of contact and group support it provides [29]. Nothwehr and Yang [13] demonstrated that frequent goal setting is significantly and positively correlated with the implementation of positive diet and lifestyle changes. They also suggest that goals focused on diet and lifestyle

change tended to be more successful than goals focused on weight loss. 'Small Changes' seeks to anchor participant-led goal setting ensuring goals are SMART (specific, measurable, attainable, realistic and time-bound). By taking this approach the group mediators can help participants implement their lifestyle intentions.

These findings from 'Small Changes' should be interpreted with caution. This relatively small-scale study reports promising improvements in weight-related measures coupled with positive changes in affective state. Though the sample size used here is small it is not out of keeping with other published behaviour change interventions [34-36]. As is common in weight management interventions, the rate of attrition was of concern, though reportedly not out of keeping with other group behaviour change interventions in research settings (on average ~13.5%, according to Grave and colleagues [44]). Out of the initial 71 participants enrolled, 82% completed the programme, though 31% of completers failed to engage fully with all of the measurement periods. Naturally, the lack of a control group makes it impossible to attribute any potentially beneficial effects seen here directly to the 'Small Changes' intervention. However randomization to a non-treatment group has ethical implications regarding intention to treat and additionally, the mere inclusion of measurement periods in a non-treatment protocol can elicit a placebo effect hindering interpretation of the findings. Results from the 'Small Changes' intervention reported here are in keeping with the literature base [14] and there seems no reasonable alternative explanation as why participants showed such significant improvements across the range of variables measured. Future 'Small

Changes' work would ideally be more gender balanced in order to extrapolate the findings more widely.

We have demonstrated, for the first time, that the 'Small Changes' approach elicits improvements across a wide range of health-orientated measures. Not only is weight lost in line with guidelines for health, but a more positive affective state is achieved, coupled with other key positive physical and dietary changes over a relatively short intervention period. Further work is clearly required to ascertain the sustained effects of 'Small Changes' however, these positive findings may assist in framing the future approach for health professionals tackling the obesity epidemic.

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The authors report no conflict of interest. 'Small Changes' is now being delivered by Small Changes (Healthcare) Ltd, 273 Abbeydale Road South, Sheffield, S17 3LB, a not for profit social enterprise (Directors; T.N. Simper and J. O'Keeffe). The intellectual

property for the ‘Small Changes’ initiative rests with J. O’Keeffe and Versa Organization Ltd., an incorporated company and registered charity.

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752

Figures

Figure 1

A brief guide to the themed elements of the ‘Small Changes’ sessions over 12 weeks. These are merely themes. The cohort will ultimately establish the focus of the discussion which will be mediated via the facilitators.

Figure 2

Percent change in body weight over the 12-week ‘Small Changes’ intervention was plotted against; **A.** percent change in body fat percentage over 12 weeks, and **B.** percent change in waist circumference over 12 weeks. Pearson Product Moment Correlations demonstrate significant positive correlations in both instances (**A.** r=.421, N=56, *P*<.001; **B.** r=.548, N=56, *P*<.0005)