Sheffield Hallam University

SHARPENS YOUR THINKING

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

PAXMAN, Jenny, HALL, Anna, HARDEN, Charlotte, O'KEEFFE, Jean and SIMPER, Trevor

Available from Sheffield Hallam University Research Archive (SHURA) at:

http://shura.shu.ac.uk/5724/

Published version

Repository use policy

Sheffield Hallam University Research Archive
http://shura.shu.ac.uk

1 **Weight loss is coupled with improvements in affective state for obese**

2 **participants engaged in behavior change therapy based on incremental, self-**

3 **selected 'Small Changes'**

4

5 **Jenny R. Paxman[a]*, Anna C. Hall[a], Charlotte J. Harden[a], Jean O'Keeffe[a,b], and**

6 **Trevor N. Simper[a]**

7

8 [a] Centre for Food Innovation, Stoddart Building, Sheffield Hallam University, Howard

9 Street, Sheffield, UK, S1 1WB.

10 [b] Versa Organization Ltd, 182 Skipton Road, Keighley, UK, BD21 2SA.

11

12 *Corresponding Author

13 Jenny R. Paxman, Centre for Food Innovation, Stoddart Building, Sheffield Hallam

14 University, Howard Street, Sheffield, UK, S1 1WB.

15 Tel: +44 (0)114 2253319

16 Fax: +44 (0)114 2255036

17 Email: j.r.paxman@shu.ac.uk

18

19 **Abbreviations**

20

21 **BMI;** body mass index

22 **BMR;** basal metabolic rate

23 **EI;** energy intake

24 **GWB;** General Well-being Scale

25 **HDL;** high density lipoprotein

26 **NMES;** non-milk extrinsic sugars

27 **POMS;** Profile of Mood States Questionnaire

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

29

30   **Abstract**

31

32   The aim of this study was to investigate the effects of a group behavior change

33   intervention, involving self-selected, contextualized and mediated goal setting on

34   anthropometric, affective and dietary markers of health. It was hypothesized that the

35   intervention would elicit changes consistent with accepted health recommendations for

36   obese individuals. A rolling program of 12-week 'Small Changes' interventions over 24

37   months recruited 71 participants; each program accommodated 10-13 adults (BMI ≥

38   30kg/m^2). 58 participants completed 'Small Changes'. Repeated measures were made

39   at baseline, 6 and 12 weeks. Anthropometric measures included height and weight (to

40   calculate BMI), body composition, waist circumference and blood pressure. Affective

41   state was monitored using relevant validated questionnaires. Dietary assessment

42   employed 3-day household measures food diaries with Schofield Equations to monitor

43   under-reporting. Relevant blood measures were recorded throughout. Across the

44   measurement period, 'Small Changes' elicited a significant reduction in body weight

45   (baseline 102.95±15.47 Vs 12 weeks 100.09±16.01kg, $p<0.0005$), coupled with

46   associated significant improvements in BMI, body fat percentage and waist

47   circumference measures. There were additional, significant positive changes in

48   measures of affective state including General Wellbeing (baseline 58.92±21.22 Vs 12

49   weeks 78.04±14.60, $p<0.0005$) and Total Mood Disturbance (baseline 31.19±34.03 Vs

50   12 weeks 2.67±24.96, $p<0.0005$).   Dietary changes that occurred were largely

51   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.

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.

84   Following a scientifically unsound diet may therefore result in quantitative and

85   qualitative nutritional imbalance [7].

86

87   Weight-loss pharmacotherapy requires long-term application to be effective, can be

88   financially costly and may be accompanied by unpleasant side effects [8]. Prospective

89   randomized controlled trials have established the efficacy of anti-obesity drugs, but not

90   for longer than two years [9] and it is generally accepted that pharmacotherapy

91   interventions must be combined with lifestyle modification in order to maximize their

92   efficacy [10]. Bariatric surgery can be associated with major nutritional and medical

93   complications [11] yet is arguably the most effective and durable way to reduce weight

94   in the morbidly obese [12].

95

96   Behavior change techniques (e.g. awareness raising activities and self-selected goal

97   setting), have been shown to be effective in tackling overweight and obesity when they

98   are coupled with positive dietary and physical activity modifications; more so than any of

99   these strategies used in isolation [13]. A recent systematic review concluded that

100   approaches combining diet, behavior modification and exercise training elicited the most

101   successful outcome when treating the overweight (BMI≥25.0kg/m^2) or obese

102   (BMI≥30.0kg/m^2) [14]. In practice, behavior change philosophies differ dramatically

103   from one to the next making comparison difficult. One consistent feature however, is a

104   multidisciplinary ethos [14].

105

106　The effect of a behavior change intervention on collective wide-ranging anthropometric,

107　affective and dietary markers in the obese has not been widely reported and the effects

108　of our 'Small Changes' approach are previously unpublished. We hypothesize that

109　behavior change therapy based on incremental, self-selected 'Small Changes' will elicit

110　beneficial changes for obese participants across all of these markers of health and

111　wellbeing.

112

113　'Small Changes' is a psycho-social behavior change intervention program for weight

114　management.   It draws on a neuro-linguistic programming approach initiated by

115　Bandler and Grinder in 1975 [15] and uses solution based therapy [16] and motivational

116　interviewing [17] techniques in facilitating participants' self-selection of small lifestyle

117　changes. These changes may be weight management orientated and consistent with

118　those championed by Hill [18]; however, they may focus more broadly on issues around

119　self-control, family life, stresses or personal organization. These changes are

120　contextualized within the lives of the participants (i.e. it is the barriers faced by the

121　individual that are tackled). 'Small Changes' uses a 12-week protocol. The

122　multidisciplinary outcomes reported here have been pooled from 12-week 'Small

123　Changes' programs run over a 24 month period from Sept 2007-Sept 2009 in Sheffield,

124　UK.

125

126

2. Methods and Materials

128

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.

132

2.1 Recruitment, Attrition and Completion Rates

134

'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$\geq$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.

142

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

146 to include or exclude participants dependent on their responses but was informative for

147 the facilitators. Participants tended to be highly motivated to change, hence their

148 attendance at the outset. Exclusion criteria included a BMI <30kg/m^2, known,

149 unmanaged serious health issues (except obesity), diagnosed type one diabetes (due to

150 fasting prescribed in our method) or fitted for a pace maker/ other implantable electronic

151 device (contraindicated in bioelectrical impedance analysis). These data were collected

152 using a basic medical screening questionnaire. This research was approved via the

153 appropriate University ethics procedures (reference: OMREC/FIRC/2006/02). All

154 participants gave written informed consent to take part.

155

156 ***2.2 Program Structure***

157

158 'Small Changes' is facilitated by experts in nutrition (Registered Public Health

159 Nutritionists), physical activity and behavior change. Learning and awareness-raising

160 opportunities are presented via twelve 2 hr weekly sessions that address issues that are

161 accepted to contribute to obesity such as understanding relationships between food,

162 mood and hunger, tackling barriers to weight management and developing sustainable

163 support mechanisms. In session 1, participants were provided with personal

164 pedometers. They were encouraged to monitor their step count and were asked to

165 report back in sessions periodically throughout the program with intent to increase their

166 personal step count, rather than reach an advised target.

167

168   Each session began with individual reports from participants about progress since the

169   last session. Each person's successes were acknowledged and congratulated. The

170   session mediators then encouraged discussion of a themed element (e.g. reading food

171   labels, portion size analysis or alcohol intake) that sometimes involved completion of

172   simple activities (see figure 1). In the second hour of the sessions participants pledged

173   to make a small lifestyle change. Each participant proposed a pledge which, where

174   necessary, was mediated via the program facilitators.   For example, a participant may

175   pledge to cut out chocolate. The mediator would usually praise such commitment but

176   enquire as to how much chocolate the participant normally ate. If they habitually

177   consumed a chocolate bar daily, mediation may have taken place to contextualize the

178   pledge to that participant's circumstances, for example, the participant may have been

179   asked whether complete exclusion was realistic. In most instances, reconsideration

180   would occur and a more achievable target (such as consuming chocolate only twice a

181   week) would be set instead. Pledges are designed to be incremental and each different

182   weekly pledge is carried throughout the program and hopefully beyond, normally

183   resulting in at least twelve changes (one per week) being made by each participant

184   throughout 'Small Changes'.

185

186   Various measures were made at baseline, 6 and 12 weeks in order to monitor progress.

187   These are outlined below.

188

2.3 Physical Measures

190

191   Participants were asked to void their bladders prior to physical measurement. Height

192   (without shoes) and weight (indoor clothing) were recorded to the nearest 0.1cm and

193   0.1kg respectively (SECA 709 mechanical column scales with SECA 220 telescopic

194   measuring rod; SECA Birmingham, United Kingdom). For consistency, participants

195   were asked to wear the same clothes at each visit. Height measurements were made

196   at the point of normal breath inspiration with the head orientated in the Frankfort

197   horizontal plane. From these measures, BMI was calculated and rounded to the

198   nearest 0.1.

199

200   Bioelectrical impedance analysis was undertaken on non-conducting foam matting

201   using BodyStat 1500 (BodyStat Ltd., Isle of Man, British Isles). Measurements were

202   made as per the manufacturer's instructions following 5 minutes of supine rest.

203   Participants were asked to fast overnight and limit physical activity prior to

204   measurement. Percentage body fat and lean weight (kg) were recorded to the nearest

205   0.1% or 0.1kg respectively.

206

207   Systolic and diastolic blood pressures were determined using an A & D Medical UA-787

208   *Plus* Digital Blood Pressure Monitor (A & D Instruments Ltd., Oxfordshire, UK). The

209   correct cuff size (22-32cm or 32-45cm) was selected on a case by case basis.

210   Measurements were made in triplicate as per the manufacturer's instructions and mean

211   values were then calculated.

212

213   Waist circumference (to the nearest 0.1cm) was measured using an inelastic, flexible

214   tape measure of adequate length. Clothing around the abdomen was removed or

215   loosened, except in the case of underwear, and pockets were emptied. Participants

216   stood erect with their feet approximately 10-15cm apart and their weight equally

217   distributed, arms by their sides, palms facing inwards. Measurements were made in a

218   horizontal plane midway between the iliac crest and lowest rib, at the end of gentle

219   expiration.

220

221   *2.4 Questionnaires*

222

223   The General Well-being Scale (GWB) proposed by Dupuy in 1971 [19] assesses

224   positive feelings about the inner state across a variety of core affective states including

225   anxiety, depression, general health, positive well-being, self-control and vitality. The

226   GWB has an 18-item scale where the first 14 items are scored 0-5, anchored with

227   appropriate terms (e.g. "Have you felt downhearted or blue?" anchored with "All of the

228   time" through to "None of the time"). The final 4 items (e.g. "How relaxed or tense have

229   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-

252 dejection, anger-hostility, fatigue-inertia, and confusion-bewilderment all representing

253 negative mood, and vigor-activity representing positive mood. The scores across all of

254 the six states were summed to determine overall total mood disturbance (weighting

255 vigor-activity negatively) to provide a single overall estimate of affective state.

256

257 *2.5 Dietary Assessment*

258

259 Dietary information was collected using 3-day estimated household measures diet

260 diaries. Participants were fully briefed (by Associate Registered Public Health

261 Nutritionists) on how to complete the diaries and a written example of a diary was given

262 to participants to take away. Timing of meals, foods consumed, brand (where

263 appropriate), portion size and leftovers were recorded over 3 consecutive days

264 (including 1 weekend day). They were then analyzed using dietary analysis software

265 (NetWisp version 4.0 for Windows, Tinuviel Software, Warrington, UK). Mean daily

266 energy and fiber intake, and percentage contribution of macronutrients to total energy

267 were analyzed.

268

269 Schofield equations [25] (revised) were used to estimate basal metabolic rate (BMR)

270 and mean daily EI was taken from the NetWISP dietary analysis. BMR:EI < 1.1 was

271 used as a proxy for under-reporting [26].

272

2.6 Blood Measures

274

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.

291

292   A single droplet whole blood sample was collected via OneTouch® Ultra® Test Strips

293   with FastDrawTM design. The OneTouch® Ultra® Blood Glucose Monitoring System

294   was used to determine total glucose (reference range 1.1 to 33.3 mmol/l; Lifescan Inc.,

295   Bucks, UK).

296

297   ***2.7 Statistical Analyses***

298

299   SPSS (version 17.0 for Windows, SPSS Inc., Chicago, Illinois) was used to conduct a

300   one-way analysis of variance to determine if significant differences existed across a

301   range of baseline characteristics between participants who completed the 'Small

302   Changes' program (n=40), those who completed the program but with an incomplete

303   dataset (completers, missing data, n=18) and non-completers (n=13). One-way

304   repeated measures analyses of variance were used to compare physical, blood,

305   questionnaire and dietary analysis measures at baseline, 6 and 12 weeks. Data are

306   presented as means and standard deviations in tables 2 to 4 and table 6, and as

307   frequencies in table 5. Where appropriate, these analyses were corrected using the

308   Huynh-Feldt correction. Pearson Product Moment Correlations were conducted to

309   determine the relationship between relevant physical measures. A Pearson Chi-square

310   was undertaken to compare the level of under-reporting (according the Schofield

311   equation) in each of the three measurement periods. A probability value of <0.05 was

312   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

334   lean weight (see table 2). Interestingly for waist circumference, most of the change

335   seen over 12 weeks appears to have occurred in the initial 6 week period. Percentage

336   change in weight was significantly positively correlated with percentage change in %

337   body fat ($p < .001$, see figure 2A) and % change in waist circumference ($p < .0005$, see

338   figure 2B). Mean systolic and diastolic blood pressure were classed as non-

339   hypertensive [27] and did not alter significantly over the intervention.

340

341   **3.2 Questionnaires**

342

343   'Small Changes' elicited a significant improvement in psychological well-being ($p <$

344     $.0005$, see table 3). Mean ($\pm$ SD) GWB at baseline was 58.92 (21.22) which would be

345   classed as 'stress problems'. By the end of the intervention, it was 78.04 (14.60)

346   categorized as low-positive well-being.

347

348   Assessment via the TFEQ-R 18 showed significant changes in all three eating

349   behaviors (increased cognitive restraint and reduced uncontrolled and emotional eating;

350     $p < .0005$ and $p < .0005$ respectively) during the intervention (see table 3). The change

351   in uncontrolled eating was significantly negatively correlated with percentage weight

352   change (data not shown; r = -.357, n = 50, $p = .011$). A negative correlation between

353   emotional eating and percentage weight change was approaching significance (data not

354   shown).

355

356   The POMS questionnaire demonstrated significantly and dramatically reduced overall

357   mood disturbance during 'Small Changes' ($p < .0005$, see table 3). Of the six affective

358   states (raw scores) measured, each was significantly improved, with the exception of

359   fatigue-inertia (see table 3 for details).

360

361   When examining the changes in affective state more closely it seems most of the

362   improvement occured in the first 6 weeks of the intervention. This is certainly the case

363   for GWB but appears also in some TFEQ-R 18 measures and for Total Mood

364   Disturbance and certain POMS raw scores.

365

366   **3.3 Dietary Assessment**

367

368   Diaries were completed and returned by 46 participants. The significant reduction in

369   reported mean EI ($p < .0005$) was accompanied by significant mean weight loss. EI

370   was restricted most noticeably in the first 6 weeks of the intervention though continued

371   restriction is evident from 6 to 12 weeks. The contribution to total EI from the various

372   macronutrient categories and subcategories was not equal across the three

373   measurement periods. Across the intervention EI from protein, total carbohydrate and

374   sugars significantly increased ($p = .007$, $p = .028$ and $p = .044$, respectively) and EI from

375   total fat and saturated fat significantly decreased ($p < .0005$ and $p = .040$, see table 4).

376   However, the significantly increased levels of Schofield assessed under-reporting at

377   week 12 compared to the high baseline and 6-week levels ($p = .012$) raises cause for

378   concern (see table 5).

379

380   *3.4 Blood Measures*

381

382   Any blood measures reported to be outside of the measurement range were repeated

383   using fresh samples. Where these subsequent measures were out with the

384   measurement range (1 participant's total cholesterol, 15 participants' total triglycerides

385   and 3 participants' plasma HDL cholesterol) they were excluded from analysis. All total

386   glucose measures were within the accepted measurement range. There was no

387   significant change in fasted total cholesterol, triglycerides or glucose during 'Small

388   Changes', though there was a significant decrease in HDL cholesterol (see table 6).

389

390   **4. Discussion**

391

392   *4.1 Benefits of behavior change*

393

394 We accept the hypothesis posed for this research that a 'Small Changes' intervention

395 would elicit changes consistent with accepted health recommendations for obese

396 individuals. Previous behavior change research suggests participants benefit from the

397 collective experience of a group and the supportive skills of the facilitator enable

398 participants to set goals, manage relapse and self-monitor their progress [28]. Our

399 findings demonstrate such benefits may be more wide-ranging than previously thought.

400 Across a large number of physical, psychological and dietary measures we have

401 demonstrated the significant benefits of even a short-term behavior change intervention

402 involving self-selected, mediated goal setting.

403

404 **_4.2 Weight is lost with encouraging body compositional changes_**

405

406 Mean weight loss was 2.8%. For obese individuals, it is generally agreed that a 5 to

407 10% weight reduction over 3 to 6 months is achievable and associated with health

408 benefits, particularly if maintained for a year or more [29]. Weight lost in this 12-week

409 intervention was in keeping with this suggested goal even though 'Small Changes' does

410 not actively prescribe lifestyle changes and pledges are largely self-defined by

411 participants. Encouragingly, weight loss appears to be associated with positive body

412 compositional changes including reduced body fat %, preservation of lean tissue and

413 reduced waist circumference. Critically, where individuals have a history of weight gain,

414 a feature which collectively characterizes 'Small Changes' participants, weight

415 maintenance is considered a success [29].

416

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.

423

4.3 'Small Changes' significantly improves affective state

425

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.

432

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

437   weight loss program with type II diabetic patients, via either a 6-week very low calorie

438   diet (VLCD) or intensive conventional diet and exercise (ICD), with led weekly group

439   therapy for 6 months, then participant arranged monthly group sessions thereafter over

440   5 years. Both groups were lighter overall at 5 years (losing weight rapidly in the case of

441   the VLCD group, more slowly in the ICD group). By 3 years the VLCD group had

442   regained at least half of the weight lost, and by 5 years they had regained even more.

443   Weight loss was steady in the ICD group. They assessed GWB at baseline, 3 and 5

444   years in each group. GWB didn't alter significantly in either group. Similarly to our

445   study, GWB did not seem to be linked to weight change.

446

447   GWB has been shown to be linked with activity levels, however. Galper et al. [32]

448   demonstrated a positive dose-response between physical activity level/ cardio-

449   respiratory fitness and emotional well-being measure using the GWB in a large cross-

450   sectional study of adults. It may be that the positive changes in GWB seen in 'Small

451   Changes' are, at least in part, due to increased physical activity levels. Physical activity

452   is promoted throughout the program and participants are encouraged to monitor their

453   activity using the pedometers provided. There are opportunities to report daily step

454   count, which may act as a motivator to increase activity. As activity level was not a

455   measured outcome of this intervention, further study is warranted.

456

457   Eating behaviors are both psychologically and physiologically determined [33].

458   Interestingly, it is emerging that these behaviors are labile in response to changes in

23

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

481   reporting raw scores over total mood disturbance [30], so both have been included here.

482   It is of particular interest that the only mood state that did not show significant

483   improvement was fatigue-inertia, while the seemingly opposed rating of vigor-activity

484   did. It appears there may be added psychological benefit of contextualized group

485   behavior change therapy such as that used in 'Small Changes' over individualized diet

486   and exercise therapy commensurate with that used by Melanson and colleagues [36].

487

488   POMS was used with overweight, habitually sedentary participants [37] to rate positive

489   (vigor-activity) and negative mood (other mood states) before, after and, retrospectively,

490   during an exercise intervention (active) versus a control (sedentary) condition.

491   Interestingly, only where participants reported increased negative mood was EI in the

492   active condition significantly greater than in the sedentary condition.   These findings

493   lend support for tailoring weight management interventions in order to pay due attention

494   to participants' individual mood states and explore possible cognitive underpinnings for

495   pervading moods (such as social physique anxiety and self-efficacy) [37].

496

497   The extent to which improved mood in response to behavior change therapy can be

498   maintained post intervention is questionable. Melanson and colleagues [36] measured

499   participants in their 12-week diet and exercise therapy intervention for a further 12

500   weeks, at the end of which improved mood scores for depression-dejection, fatigue-

501   inertia and vigor-activity remained significant and there was an additional significant

502   improvement in confusion-bewilderment from baseline. Such follow-up data are not

503   available yet for 'Small Changes'..

504

505   ***4.4 Dietary changes are consistent with evidence-based health promotion***

506

507   The reported dietary changes from 'Small Changes' included a significant reduction in

508   mean daily EI, which might be expected of those attempting to manage their weight.

509   Additional significant changes were seen across the macronutrient profile. Mean daily

510   intake of energy from protein and carbohydrate increased and mean daily intake of

511   energy from total fat and saturated fat decreased. This rejection of fat and saturated fat

512   is in keeping with currently accepted health messages for weight management

513   promoted both via 'Small Changes' and nationally in the UK (as seen in The Food

514   Standards Agency's EatWell initiative and the Change4Life program described

515   elsewhere [38, 39]). Movement away from high energy density, fat-rich foods towards

516   carbohydrate and protein-rich foods, might in part explain the reduced mean daily EI.

517   Seemingly contrary to evidence-based health promotion messages however, mean

518   daily sugar intake as a proportion of energy increased significantly. Whether this is

519   attributable to an increased intake of non-milk extrinsic sugars (NMES) or of naturally

520   occurring sugars in fruits, for example, is open to debate. Fruit and vegetable

521   consumption is promoted during 'Small Changes' in line with the UK 5 A DAY message

522   and, anecdotally, participants report eating more fruit and vegetables. The 2008-9

523   National Diet and Nutrition Survey does not report data on sugar but recognizes the

524 proportion of carbohydrate consumed by 19-64y UK adults attributable to fruit at only

525 6% [40]. The main food sources of NMES in this age group are sugar preserves and

526 confectionery, non-alcoholic beverages and cereals and cereal products [40]. Future

527 work in this area might benefit from the consideration of total sugars alongside NMES in

528 order to provide clarification.

529

530 The dietary data reported here were collected using 3-day estimate household

531 measures diet diaries and though every effort was made to ensure participants were

532 well-trained and followed accepted protocols for dietary assessment, it is important to

533 acknowledge that under-reporting may have influenced these findings. Dietary

534 assessment in those with BMIs ≥30kg/m^2 can be confounded by under-reporting [41],

535 especially where these individuals are women [42]. The prevalence of under-reporting

536 within this obese cohort was expectedly high, in part due to the fact participants were

537 trying to lose weight [42]. Previous research has demonstrated that under-reporting

538 should not alter the macronutrient from energy ratio [41] though it is not necessarily

539 nutrient neutral in terms of absolute nutrient intake [41].

540

541 Of greatest concern in relation to the dietary assessment findings was the increase in

542 the prevalence of under-reporting from baseline to the end of the intervention. It is

543 difficult to ascertain whether under-reporting indeed became more prevalent or whether

544 borderline under-reporters merely reduced their EI in line with 'Small Changes'

545 principles and thus became classified as under-reporters according to the Schofield

546 equations used [25].

547

548 Individuals following weight-loss diets are acknowledged to be more likely to under-

549 report [42] than those not attempting to lose weight. The BMR:EI cutoff of 1:1 was used

550 here [26] as implausibly low and therefore incompatible with long-term energy balance,

551 however, there is considerable contention within the literature as to what constitutes

552 under-reporting. Had a higher cut-off been used, under-reporting might have been an

553 even greater concern in this obese but dieting cohort.

554

555 Because the reliability of data gathered via dietary assessment is always questionable

556 we have not reported the changes in micronutrient intake that occurred during the

557 'Small Changes' intervention and recommend that the dietary assessment data

558 presented here are interpreted with caution.

559

560 **4.5 No concerning changes in blood measures**

561

562 Blood lipids and glucose were monitored across the intervention. It is noteworthy that at

563 all three measurement periods mean total cholesterol did not exceed guidelines [43] for

564 desirable total cholesterol (<5.17mmol/L). Of all the blood measures, only HDL

28

565 cholesterol levels altered significantly during the intervention period. The significantly

566 reduced HDL cholesterol levels seen at week 12 compared to baseline are mildly

567 concerning, though mean levels remained above the high risk cut-off (<1.03mmol/L)

568 [43]. Mean triglycerides exceeded guidelines for desirable triglycerides (<1.69mmol/L)

569 at all three measurement periods [43], however sample exclusion for triglycerides was

570 high and was exclusively due to undetectable low, rather than high, readings. The

571 accuracy of dry chemistry in clinical practice is questionable, particularly if it is used for

572 diagnostic purposes and where capillary samples are employed [43]. The reduced

573 sample size and directional bias (particularly evident for triglycerides) suggest the need

574 for more robust, but more invasive, wet analytical techniques to be employed in future

575 research. Blood glucose remained relatively constant and within normal fasting levels

576 across all three measurement periods. However, the repeated measures design used

577 in the present study looked to compare change over time and was not designed for

578 comparison with published guidelines.

579

580 ***4.6 Goal setting within the context of people's lives***

581

582 The 'Small Changes' success is likely to lie in the contextualization of goal setting to

583 individual participants' lives and circumstances, and in the frequency of contact and

584 group support it provides [29].   Nothwehr and Yang [13] demonstrated that frequent

585 goal setting is significantly and positively correlated with the implementation of positive

586 diet and lifestyle changes. They also suggest that goals focused on diet and lifestyle

587 change tended to be more successful than goals focused on weight loss. 'Small

588 Changes' seeks to anchor participant-led goal setting ensuring goals are SMART

589 (specific, measurable, attainable, realistic and time-bound). By taking this approach the

590 group mediators can help participants implement their lifestyle intentions.

591

592 These findings from 'Small Changes' should be interpreted with caution. This relatively

593 small-scale study reports promising improvements in weight-related measures coupled

594 with positive changes in affective state. Though the sample size used here is small it is

595 not out of keeping with other published behaviour change interventions [34-36]. As is

596 common in weight management interventions, the rate of attrition was of concern,

597 though reportedly not out of keeping with other group behaviour change interventions in

598 research settings (on average ~13.5%, according to Grave and colleagues [44]). Out of

599 the initial 71 participants enrolled, 82% completed the programme, though 31% of

600 completers failed to engage fully with all of the measurement periods. Naturally, the

601 lack of a control group makes it impossible to attribute any potentially beneficial effects

602 seen here directly to the 'Small Changes' intervention. However randomization to a

603 non-treatment group has ethical implications regarding intention to treat and

604 additionally, the mere inclusion of measurement periods in a non-treatment protocol can

605 elicit a placebo effect hindering interpretation of the findings. Results from the 'Small

606 Changes' intervention reported here are in keeping with the literature base [14] and

607 there seems no reasonable alternative explanation as why participants showed such

608 significant improvements across the range of variables measured. Future 'Small

609 Changes' work would ideally be more gender balanced in order to extrapolate the

610 findings more widely.

611

612 We have demonstrated, for the first time, that the 'Small Changes' approach elicits

613 improvements across a wide range of health-orientated measures. Not only is weight

614 lost in line with guidelines for health, but a more positive affective state is achieved,

615 coupled with other key positive physical and dietary changes over a relatively short

616 intervention period. Further work is clearly required to ascertain the sustained effects of

617 'Small Changes' however, these positive findings may assist in framing the future

618 approach for health professionals tackling the obesity epidemic.

619

620 **5. Acknowledgment**

621

628 property for the 'Small Changes' initiative rests with J. O'Keeffe and Versa Organization

629 Ltd., an incorporated company and registered charity.

630

631 **6. References**

632

633 [1] HCHC (House of Commons Health Committee). Obesity: Third report of Session

634 2003-04 Volume 1. London, The Stationery Office Ltd; 2004.

635 [2] Rosenberger PH, Henderson KE, Grilo CM. Correlates of body image

636 dissatisfaction in extremely obese female bariatric surgery candidates. *Obesity*

637 *Surgery* 2006;16:1331-1336.

638 [3] Jéquier E. Pathways to obesity. *International Journal of Obesity* 2002;26:Suppl.

639 2:S12-S17.

640 [4] Wing RR, Jeffery RW. Effect of modest weight loss on changes in cardiovascular

641 risk factors: are there differences between men and women or between weight loss

642 and maintenance? *International Journal of Obesity* 1995;19:67–73.

643 [5] Mark AL. Dietary therapy for obesity is a failure and pharmacotherapy is the

644 future: a point of view. C*linical and Experimental Pharmacology and Physiology*

645 2006;33:857-862.

646 [6] Serdula MK, Mokdad AH, Williamson DF, Galuska DA, Mendlein JM, Heath GW.

647 Prevalence of attempting weight loss and strategies for controlling weight. *Journal*

648 *of the American Medical Association* 1999;282:1353-1358.

649 [7] Boschi V, Siervo M, D'Orsi P, Margiotta N, Trapanese E, Basile F et al. Body

650 composition, eating behavior, food-body concerns and eating disorders in

651 adolescent girls. *Annals of Nutrition & Metabolism* 2003;47:284-293.

652 [8] Halford JCG. Pharmacotherapy for obesity. *Appetite* 2006;46:6-10

653 [9] Padwal R, Li SK, Lau DC. Long-term pharmacotherapy for overweight and

654 obesity: a systematic review and meta-analysis of randomized controlled trials.

655 *International Journal of Obesity* 2003;27:1437-1446.

656 [10] Schnee DM, Zaiken K, McCloskey WW. An update on the pharmacological

657 treatment of obesity. *Current Medical Research and Opinion* 2006;22:1463-1474.

658 [11] Mitka M. Surgery useful for morbid obesity, but safety and efficacy questions

659 linger. *Journal of the American Medical Association* 2006;296:1575 -1577.

660 [12] Johnson W, DeMaria E. Surgical Treatment of Obesity. *Current Treatment*

661 *Options in Gastroenterology* 2006;9:167-174.

662 [13] Nothwehr F, Yang J. Goal setting frequency and the use of behavioral

663 strategies related to diet and physical activity. *Health Education Research*

664 2007;22:532-538.

665   [14] Söderlund A, Fischer A, Johansson T. Physical activity, diet and behavior

666   modification in the treatment of overweight and obese adults: a systematic review.

667   *Perspectives in Public Health* 2009;129:132-142.

668   [15] Bandler R, Grinder J. The Structure of Magic I: A Book About Language and

669   Therapy. Science & Behavior Books. California, Palo Alto; 1975.

670   [16] Berg IK. Family based services: A solution-focused approach. New York, W.

671   W. Norton; 1994.

672   [17] Miller WR, Rollnick S. Motivational Interviewing: Preparing People to Change

673   (2nd Ed.). NY, Guilford Press; 2002.

674   [18] Hill JO. Can a small-changes approach help address the obesity epidemic? A

675   report of the Joint Task Force of the American Society for Nutrition, Institute of Food

676   Technologists, and International Food Information Council. *American Journal of*

677   *Clinical Nutrition* 2009;89:477-484.

678   [19] Dupuy H. The General Well-being Scale. The National Health and Nutritional

679   Survey National Center for Health Statistics. U.S. P.H.S.; 1971.

680   [20] Karlsson J, Persson L-O, Sjöström L, Sullivan M. Psychometric properties and

681   factor structure of the Three-Factor Eating Questionnaire (TFEQ) in obese men and

682   women. Results from the Swedish Obese Subjects (SOS) study. *International*

683   *Journal of Obesity* 2000;24:1715-1725.

684   [21] Stunkard AJ, Messick S. The Three-Factor Eating Questionnaire to measure

685   dietary restraint, disinhibition and hunger. *Journal of Psychosomatic Research*

686   1985;29:71-83.

687   [22] Keränen AM, Savolainen MJ, Reponen AH, Kujari ML, Lindeman SM, Bloigu RS

688   et al. The effect of eating behavior on weight loss and maintenance during a lifestyle

689   intervention. *Preventive Medicine* 2009;49:32-38.

690   [23] Konttinen H, Haukkala A, Sarilo-Lähteenkorva S, Silventoinen K, Jousilahti P.

691   Eating styles, self-control and obesity indicators. The moderating role of obesity

692   status and dieting history on restrained eating. *Appetite* 2009;53:131-134.

693   [24] McNair DM, Lorr M, Droppleman LF. Profile of mood states. Educational and

694   Industrial Testing Service, San Diego; 1971.

695   [25] DH (Department of Health). Dietary reference values for food energy and

696   nutrients for the UK: report of the Panel on DRVs of the Committee on the Medical

697   Aspects of Food Policy (COMA). The Stationery Office, UK; 1991.

698   [26] Becker W, Welten D. Under-reporting in dietary surveys: implications for

699   development of food-based dietary guidelines. *Public Health Nutrition* 2001;4:683-

700   687.

701   [27] Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF et al.

702   British hypertension society guidelines. Guidelines for management of hypertension:

703   report of the Fourth Working Party of the British Hypertension Society, 2004 – BHS

704   IV. *Journal of Human Hypertension* 2004;18:139-185.

705   [28] McLean N, Griffin S, Toney K, Hardeman W. Family involvement in weight

706   control, weight maintenance and weight-loss interventions: a systematic review of

707   randomized trials. *International Journal of Obesity* 2003;27:987-1005.

708   [29] Avenell A, Sattar N, Lean M. ABC of Obesity: Management: Part I—Behavior

709   change, diet, and activity. *British Medical Journal* 2006;333:740-743.

710   [30] Paisey RB, Frost J, Harvey P, Paisey A, Bower L, Paisey RM et al. Five year

711   results of a prospective very low calorie diet or conventional weight loss program in

712   type 2 diabetes. *Journal of Human Nutrition and Dietetics* 2002;15:121-127.

713   [31] Galper DI, Trivedi MH, Barlow CE, Dunn AL, Kampert JB. Inverse association

714   between physical inactivity and mental health in men and women. *Medicine &*

715   *Science in Sports & Exercise* 2006;38:173-178.

716   [32] Harden CJ, Corfe BM, Richardson JC, Dettmar PW, Paxman JR. Body mass

717   index and age affect Three-Factor Eating Questionnaire scores in male subjects.

718   *Nutrition Research* 2009;29:379-382.

719   [33] Bryant EJ, King NA, Blundell JE. Disinhibition: its effects on appetite and weight

720   regulation. *Obesity Reviews* 2008;9:409-419.

721   [34] Lejeune MPG, van Aggelen-Leijssen DPC, van Baak MA, Westerterp-Plantenga

722   WS. Effects of dietary restraint vs. exercise during weight maintenance in obese

723   men. *European Journal of Clinical Nutrition* 2003;57:1338–1344.

724   [35] Melanson KJ, Dell'Olio J, Carpenter MR, Angelopoulos TJ. Changes in multiple

725   health outcomes at 12 and 24 weeks resulting from 12 weeks of exercise counseling

726   with or without dietary counseling in obese adults. *Nutrition* 2004;20:849-856.

727   [36] Cramer SR, Nieman DC, Lee JW. The effects of moderate exercise training on

728   psychological well-being and mood state in women. *Journal of Psychosomatic*

729   *Research* 1991;35:437-449.

730   [37] Schneider KL, Spring B, Pagoto SL Exercise and energy intake in overweight,

731   sedentary individuals. *Eating Behaviors* 2009;10:29-35.

732   [38] Food Standard Agency; Eat well, be well. Available at;

733   http://www.eatwell.gov.uk/. Last accessed March 2011.

734   [39] NHS Change4Life. Available at; http://www.nhs.uk/change4life/Pages/change-

735   for-life.aspx. Last accessed March 2011.

736   [40] Food Standards Agency; National Diet and Nutrition Survey; Headline Results

737   from Year 1 (2008-9). Available at;

738   http://www.food.gov.uk/science/dietarysurveys/ndnsdocuments/ndns0809year1.

739   Last accessed; March 2011.

740   [41] Hirvonen T, Männistö S, Roos E, Pietinen P. Increasing prevalence of

741   underreporting does not necessarily distort dietary surveys. *European Journal of*

742   *Clinical Nutrition* 1997;51:297-301.

743   [42] Pryer JA, Vrijheid M, Nichols R, Kiggins M, Elliott P. Who are the 'low energy

744   reported' in the Dietary and Nutritional Survey of British Adults? *International*

745   *Journal of Epidemiology* 1997;26:146-154.

746   [43] Rubin DA, McMurray RG, Harrell JS, Carlson BW, Bangdiwala S. Accuracy of

747   Three Dry-Chemistry Methods for Lipid Profiling and Risk Factor Classification.

748   *International Journal of Sport Nutrition and Exercise Metabolism* 2003;13:358-368.

749   [44] Grave RD, Suppini A, Calugi S, Marchesini G. Factors Associated with Attrition

750   in Weight Loss Programs. *International Journal of Behavioral Consultation and*

751   *Therapy* 2006; 2:341-353.

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)