

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 <<http://orcid.org/0000-0003-3596-489X>>, HALL, Anna <<http://orcid.org/0000-0002-1491-7309>>, HARDEN, Charlotte, O'KEEFFE, Jean and SIMPER, Trevor <<http://orcid.org/0000-0002-4359-705X>>

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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 \geq
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 $100.09\pm 16.01\text{kg}$, $p<0.0005$), 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

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

58

59 **Keywords**

60

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

62

63 **1. Introduction**

64

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

74

75 Long term weight reduction in obesity can be of considerable benefit for reducing the
76 risk of nutrition-related chronic disease [4]. Dieting interventions are rarely successful;
77 some even suggest this type of restrained eating induces counter-regulatory responses
78 that could be deemed iatrogenic [5]. Dieting is a common behavioral phenomenon, yet
79 the number of 'dieters' and the rate of obesity appear to have increased in parallel [6].
80 Many dieters succeed in losing weight; though only between 5-10% achieve long-term
81 weight loss [7-13]. This may be because many popular diets are not evidence-based
82 and do not consider the effects on micronutrient status, metabolic parameters, appetite,
83 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 ($BMI \geq 25.0 \text{ kg/m}^2$) or obese
102 ($BMI \geq 30.0 \text{ kg/m}^2$) [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

127 **2. Methods and Materials**

128

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

132

133 ***2.1 Recruitment, Attrition and Completion Rates***

134

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

142

143 At the pre-screening event, a brief history of weight change and dieting attempts was
144 recorded for each participant. Motivation to change and confidence in tackling the
145 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 $<30\text{kg/m}^2$, 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

189 **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

273 **2.6 Blood Measures**

274

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

291

292 A single droplet whole blood sample was collected via OneTouch® Ultra® Test Strips
293 with FastDraw™ 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.

313

314 **3. Results**

315

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

328

329 **3.1 Physical Measures**

330

331 Across the intervention, significant mean weight loss and consequent reductions in BMI
332 ($p < .0005$ and $p < .0005$ respectively) were accompanied by a significant reduction in
333 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 occurred 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

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

423

424 ***4.3 'Small Changes' significantly improves affective state***

425

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

432

433 Participants' GWB improved significantly. It is of interest to note that percentage
434 change in well-being was not significantly correlated with percentage change in body
435 weight (data not shown), suggesting that the program enhances feelings of well-being
436 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

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 $\geq 30\text{kg/m}^2$ 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

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

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621

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624

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629 Ltd., an incorporated company and registered charity.

630

631 **6. References**

632

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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.** $r=.548$, $N=56$, $P<.0005$)