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**Lifestyle information and commercial weight management groups to support maternal postnatal weight management and positive lifestyle behaviour: the SWAN feasibility randomised controlled trial**

Shortened running title: Feasibility trial of support for postnatal weight management

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1 **Lifestyle information and access to commercial weight management groups to support maternal**  
2 **postnatal weight management to 12 months: the SWAN feasibility RCT**

3 **Abstract**

4 **Objectives:** To assess feasibility of a future randomised controlled trial (RCT) of clinical and cost-  
5 effectiveness of lifestyle information and commercial weight-management groups to support  
6 postnatal weight management to 12 months post-birth.

7 **Design:** Two-arm feasibility trial, with nested mixed-methods process evaluation.

8 **Setting:** Inner-city unit, South England.

9 **Population:** Women with BMIs  $\geq 25\text{kg/m}^2$  at pregnancy booking or normal BMIs ( $18.5\text{kg/m}^2$ -  
10  $24.9\text{kg/m}^2$ ) identified with excessive gestational weight gain at 36 weeks gestation.

11 **Methods:** Randomised to standard care plus commercial weight-management sessions commencing  
12 8-16 weeks postnatally or standard care only.

13 **Main outcomes:** Feasibility outcomes included assessment of recruitment, retention, acceptability,  
14 and economic data collation. Primary and secondary endpoints included difference between groups  
15 in weight 12 months postnatally compared with booking (proposed primary outcome for a future  
16 trial), diet, physical activity, smoking, alcohol, mental health, infant feeding, NHS resource use.

17 **Results:** 193 women were randomised; 98 intervention and 95 control; only four women had excessive  
18 gestational weight gain. A slightly greater weight change was found among intervention women at 12  
19 months, with greatest benefit among women attending 10+ weight management sessions. There  
20 was >80% follow-up to 12 months, low risk of contamination and no group differences in trial  
21 completion.

22 **Conclusion:** It was feasible to recruit and retain women with  $\text{BMIs} \geq 25\text{kg/m}^2$  to an intervention to  
23 support postnatal weight management; identification of excessive gestational weight gain requires  
24 consideration. Economic modelling could inform out-of-trial costs and benefits in a future trial.

25 A definitive trial is an important next step.

26 **Funding:** NIHR Public Health Research Programme 14/67/14

27 **Key words:** Postnatal, weight management, randomised controlled trial, feasibility

28 **Trial registration:** This trial is registered as ISRCTN 39186148

29 **Protocol:** <https://njl-admin.nihr.ac.uk/document/download/2012000>

30 **Tweetable abstract**

31 **A feasibility RCT of postnatal weight support showed women with BMIs $\geq$ 25kg/m<sup>2</sup> can be recruited**  
32 **and followed to 12 months postnatally**

33

34

35 **Introduction**

36

37 At six to eight weeks postnatally, two thirds of women have a higher weight than before pregnancy<sup>1</sup>,  
38 with postpartum weight retention contributing to poorer long-term health<sup>2,3</sup> and failure to  
39 breastfeed<sup>4,5</sup>. There is limited evidence for pregnancy-specific weight management interventions<sup>6,7,8</sup>.  
40 A meta-analysis of individual participant data of diet and physical activity interventions<sup>9</sup> reported less  
41 gestational weight gain in intervention than control groups, but no significant reductions in other  
42 outcomes of interest.

43

44 The USA Institute of Medicine defines clinically significant weight loss in the general population as  $\geq 5\%$   
45 of initial weight within 6 months of the intervention, a reduction associated with fewer weight  
46 morbidities<sup>10</sup>, although smaller weight loss may result in health gains<sup>11</sup>. A Cochrane review of diet  
47 and/or exercise for postnatal weight reduction<sup>12</sup> found exercise alone was not effective (two trials,  
48  $n=53$ , mean difference  $-0.10\text{kg}$ , 95% CI  $-1.90$  to  $1.71$ ), but diet (one trial,  $n=45$ , mean difference  $-$   
49  $1.70\text{kg}$ , 95% CI  $-2.08$  to  $-0.132$ ) or diet plus exercise (seven trials,  $n=573$ , mean difference  $-1.93\text{kg}$ , 95%  
50 CI  $-2.96$  to  $-0.89$ ) was effective. Data were insufficient to infer other potential risks or benefits for  
51 women or infants<sup>12</sup>.

52

53 Interventions to reduce postpartum weight retention across all BMI categories have included  
54 counselling, individualised physical activity plans, healthy eating groups, and clinic visits. In one  
55 systematic review, seven of 11 trials found a decrease in weight retention, six including diet and  
56 physical activity interventions<sup>2</sup>. No study considered cost-effectiveness, with wide heterogeneity in  
57 approaches to intervention implementation. Dalrymple et al (2018)<sup>13</sup> reviewed lifestyle interventions  
58 in overweight and obese women for postpartum weight management. Seven postpartum-only

59 interventions showed significant improvements in weight compared with controls, suggesting  
60 potential for weight management.

61

62 A general population study of individuals with obese or overweight BMIs (N=740) indicated that  
63 commercial weight loss programmes (where where an individual can choose from a range of options  
64 and providers to suit their lifestyle and budget, including group or online interventions) may be more  
65 beneficial than healthcare-based programmes (which may include a prescribed programme of  
66 contacts with a clinician in a healthcare setting)<sup>14</sup>. Commercial weight programmes achieved better  
67 weight loss at programme end (mean difference 2.3kg (1.3 to 3.4kg) and were approximately £40  
68 cheaper per person than primary care services.

69

70 This single centre, two-arm individually randomized feasibility trial with a nested mixed-methods  
71 process evaluation assessed feasibility of conducting a future definitive RCT to determine  
72 effectiveness and cost effectiveness of lifestyle information and access to a commercial weight  
73 management group (Slimming World® (Alfreton, UK)) to support longer-term postnatal weight  
74 management and positive lifestyle behaviour in women at risk of poor weight management.

75

## 76 **Methods**

### 77 *Participant eligibility*

78 Women 18 years and over, speaking and reading English, with a singleton pregnancy who had not  
79 accessed weight management groups during this pregnancy.

### 80 *Recruitment*

81 Recruitment, from one inner-city maternity unit, reflected two approaches: 1) Women with BMIs  
82  $\geq 25\text{kg/m}^2$  identified from antenatal booking information; at 26 weeks gestation, women were sent a  
83 letter advising a Research Midwife (RM) would contact them, which also explained how the woman  
84 could contact the RM if she did not want to receive further information. Two weeks later, the RM  
85 contacted women who had not asked to be removed from the contact list, to explain the study; 2)  
86 Women with healthy BMIs at antenatal booking who gained more weight than recommended by IOM  
87 guidelines<sup>10</sup> could self-refer, or be referred by clinicians, to RMs to be weighed at 36 weeks' gestation  
88 (routine weighing is not recommended in NHS antenatal care<sup>15</sup>). As this approach did not succeed,  
89 the protocol was revised to send letters to all women with normal booking BMIs who were 32-34  
90 weeks gestation, inviting them to be weighed for excessive gestational weight gain at 36 weeks  
91 gestation.

92

93 All women received a Patient Information Sheet (PIS) prior to seeking written informed consent from  
94 those who agreed to participate at 36 weeks gestation.

95

#### 96 *Intervention*

97 Women received standard care (see below), plus a lifestyle information leaflet with evidence-  
98 informed guidance on breastfeeding, diet, smoking cessation, reducing alcohol and managing  
99 sleep<sup>16,17</sup> and access to a commercial weight management programme (Slimming World®, Alfreton,  
100 UK) for 12 weekly sessions, commencing anytime from 8-16 weeks postnatally. Women could choose  
101 which group they attended and when they started, to accommodate birth recovery, lifestyle and  
102 family demands. They could take their infants with them.

103

104 Slimming World® (Alfreton, UK) groups are homogeneous in content and delivery<sup>18</sup>, promoting key  
105 behaviour change techniques including goal setting, social support and positive reinforcement,  
106 underpinned by social cognitive theory relevant to motivation and self-efficacy for weight  
107 management<sup>19,20</sup>. A food optimising system encourages healthy eating, recommending that 80% of  
108 foods are fruit, vegetables, and satiating foods (carbohydrates and protein); alongside measured  
109 portions of fibre and calcium-rich foods; and an allowance for foods high in fat or sugar. The plan is  
110 designed to be unrestrictive and adaptable to cultural and dietary preferences, and includes guidance  
111 for breastfeeding women to ensure key nutritional requirements are met. A 'Body Magic' programme  
112 promotes importance of physical activity.

113

114 Women were offered (fees waived) attendance for 12 sessions over 14 consecutive weeks, allowing  
115 two 'holiday' weeks. To achieve 5% weight loss from baseline, a difference considered to improve  
116 health outcomes (Donnelly et al 2009)<sup>21</sup>, attending at least 10 sessions is recommended<sup>19</sup>.

117

#### 118 *Control group*

119 Standard NHS maternity care to six-eight weeks postpartum, including routine midwife, health visitor  
120 and GP contacts.

121

#### 122 *Randomisation*

123 Individual participants were randomly allocated in ratio of 1:1 to intervention or control using a web-  
124 based system developed by King's Clinical Trials Unit, with relevant data entered by the RM. Intention  
125 to treat (ITT) analysis limited attrition and analytical bias. It was not possible to 'blind' RMs or women  
126 to allocation, but those responsible for analyses were blinded to allocation.

127

128

129 *Progression criteria*

130 Progression criteria included recruitment uptake, time to complete recruitment; retention of women  
131 to 12 months postnatally, acceptability of study procedures and intervention, contamination between  
132 study groups, and if relevant data could be collated to inform an economic evaluation.

133

134 *Primary and secondary feasibility outcomes*

135 The primary feasibility outcome, to inform the effect size for a definitive trial, was difference between  
136 study groups in weight 12 months postnatally, expressed as % weight change and weight loss from  
137 documented antenatal-booking weight. A core outcome set was not used.

138

139 Secondary outcomes were selected as appropriate to inform progress to a definitive RCT. These  
140 included rates of 5% and 10% weight reduction and changes in relation to healthy lifestyle and health  
141 behaviours. The following were used:

- 142 • Dietary Instrument for Nutritional Education (DINE© University of Oxford)<sup>22</sup> ]
- 143 • International Physical Activity Short-Form<sup>23</sup>
- 144 • Edinburgh Postnatal Depression Scale\*<sup>24</sup>
- 145 • Smoking status/cigarette dependence<sup>25</sup>
- 146 • Alcohol Use Disorders Identification Test<sup>26</sup>
- 147 • Rosenberg Self-Esteem Scale<sup>27</sup>
- 148 • Impact on body image\*<sup>28</sup>
- 149 • EQ-5D-5L<sup>29</sup>

- 150       • Soft drink intake; breastfeeding intent, uptake and duration; sleep patterns\*; infant health\*:  
151           questions developed for the feasibility study
- 152       • Adult Service Receipt Schedule (AD-SUS)<sup>30</sup>

153   *\*included at six & 12 months*

154

155   At six and 12 months, all women were asked about the timing and type of postnatal weight support  
156   they had accessed to assess potential contamination, and inform future decisions about timing of  
157   commencement of the intervention offer. An integral mixed-methods process evaluation examined  
158   the acceptability of the intervention and study procedures. These findings are reported separately.

159

#### 160   *Patient and public involvement*

161   A group of four local women who had experienced previous pregnancies with BMIs of  $\geq 25\text{kg/m}^2$  were  
162   convened at study development to advise the team on approaches to recruitment, intervention and  
163   outcomes most likely to be of importance to postnatal women. This group met regularly throughout  
164   the study period. VB co-ordinated the PPI group on behalf of the SWAN trial team.

165

166

#### 167   **Data collection**

168   Information at trial entry, including eligibility, booking BMI, parity, age, ethnicity, deprivation score,  
169   total household income, birth mode, gestation, birthweight and inpatient stay were obtained from  
170   maternity records. The baseline questionnaire was completed at recruitment (36 weeks gestation).

171   At six and 12 months women met with RMs to be weighed and complete questionnaires. If women  
172   could not meet the RM, they could post questionnaires by post, recording their current weight.

173

174 **Sample size**

175 The proposed sample size was 190, allowing 30% loss to follow up to achieve data from 130 women  
176 at 12 months post-birth and inform estimates of required sample size for any clinically important  
177 differences to within 30% of true value. The mean (SD) percentage weight change following Slimming  
178 World's programme of 12 weekly groups is -5.5%, (3.3)<sup>18</sup>. Assuming numbers were typical, 65 women  
179 in each group were required to detect a difference of 2% between intervention and control arms with  
180 90% power at the 5% significance level (2-tailed).

181

182

183 **Analysis**

184 Recruitment was assessed as number of women randomised per month, with 95% confidence  
185 intervals derived from the Poisson distribution, and retention as proportion of women randomised  
186 providing analysable data for primary assessment at 12 months. Linear regression was used for the  
187 primary endpoint and other continuous measures. Adjustment was made for corresponding  
188 measurements made pre-randomisation<sup>31</sup>. Binary regression with a log-link was used to assess risk  
189 ratios for all binary outcomes, adjusting for maternal age, BMI, ethnicity, and parity. Following  
190 CONSORT and other recommendations<sup>32</sup>, risk differences were also estimated. Significance tests were  
191 only conducted to test for differences in dropout rates between groups, and estimates of treatment  
192 effects.

193

194 For primary analysis, participants were analysed in the groups into which they were randomly  
195 allocated. Estimated differences and 95% Confidence Intervals were calculated for specified primary

196 and secondary analyses (significance at 5%). Sensitivity analyses were used to assess robustness of  
197 conclusions to missing outcome data and departures from randomized treatment

198

199 Reduction of weight by more than 5% and 10% at six and 12 months were analysed as binary variables,  
200 with health ratios and risk differences presented. Sub-group analysis of the primary endpoint among  
201 overweight (BMI 25–29.9 kg/m<sup>2</sup>) and obese (BMI ≥30 kg/m<sup>2</sup>) women was pre-planned, with  
202 interaction tests to determine if treatment effect varied by sub-group.

203

204 To explore if women who attended 10+ sessions had greater 12-month weight loss than women  
205 attending nine or fewer, or control women, or if women who documented their own weight in  
206 questionnaires had different weight change than women who attended appointments, subgroup  
207 analysis using the per-protocol subgroup was conducted.

208

209

210

211

## 212 **Ethical approval**

213 Approval was granted by Health Research Authority London – Camberwell St Giles REC on 2<sup>nd</sup>  
214 September 2016 (reference:16/LO/1422) and HRA approval on 11<sup>th</sup> October 2016.

215

## 216 **Results**

### 217 **Recruitment and retention**

218 Between November 2016 and July 2017, of 1132 women potentially eligible, 835 (73.5%) were not  
219 recruited, 59 (5.2%) were later ineligible (e.g., had a premature birth), and contact data on 43 (3.8%)  
220 women were missing from their records. In most cases, study letters were returned unopened or  
221 phone calls not returned. Women who were contacted and asked why they would not consider  
222 recruitment reported practical barriers, such as moving house, or not having any concerns about their  
223 weight. Of 195 (17.2%) women who agreed to attend the recruitment appointment, two changed  
224 their minds; 193 were recruited and randomised, 97% of whom had BMIs  $>25\text{kg/m}^2$ . Only four of nine  
225 women with a healthy BMI at booking who responded to a study letter and met the RMs at 36 weeks  
226 gestation had EGWG and were eligible to participate.

227

228 The CONSORT diagram (Figure 1), shows trial participant flow. Two women withdrew, one from the  
229 control at six month follow-up, and one from the intervention at 12 months. Neither asked for data  
230 to be withdrawn. Only women who returned a six month questionnaire were sent a 12 month  
231 completed a questionnaire, 20 women returning a copy by post; at 12 months, 69/83 (83.1%)  
232 intervention and 71/75 (94.6%) control women completed questionnaires; 32 returned by post.

233

#### 234 **Baseline characteristics**

235 Antenatal booking BMI data informed study outcome comparisons. Customised birthweight centiles<sup>33</sup>  
236 included correction for expected birthweight for maternal height, weight, ethnicity, parity, neonatal  
237 gender and gestation at delivery (Table 1).

238

239 Mean maternal age was 32 (SD=5.2), and mean maternal booking BMI  $30.51\text{kg/m}^2$  (SD=5.4) (Table 1).  
240 More intervention women had a mean BMI  $\geq 30\text{ kg/m}^2$  at booking and twice as many had planned  
241 caesarean section compared with controls. Mean gestational birth age was 39.4 weeks (SD=2.5), and

242 mean infant birthweight 3.43kgs (SD=503). Most women lived in areas of highest social deprivation<sup>34</sup>,  
243 although a third of women had total household incomes of  $\geq$ £61k. A slightly lower proportion of white  
244 women were recruited compared with the local maternity population, with a slightly higher  
245 proportion of Black women<sup>35</sup>. Differences between groups at baseline were not assessed  
246 statistically<sup>36</sup>.

247

#### 248 **Proposed primary and secondary outcomes**

249 After adjusting the most powerful predictors measured pre-randomization, using linear regression and  
250 removing any biases due to chance imbalance at baseline, weight loss at 12 months postnatally was  
251 greater than at six months (Table 2), supporting 12 months as a future primary endpoint.

252

253 Pre-planned sub-group analysis of various secondary endpoints showed no significant differences  
254 between the intervention and control group (Table 3). ). There was no evidence of differences in  
255 weight outcomes among women with higher BMIs who self-reported or were weighed by RMs.

256

257 Of the 98 intervention women, 46 (47%) attended one or more weight management sessions. Based  
258 on per-protocol analysis, women who attended 10+ sessions (19/46, 41%) had greater weight loss at  
259 12 months than women who attended nine or fewer sessions or none at all, or were control group  
260 (95% CI 1.05 to 8.93, p0.013).

261

262 There was no evidence of differences between groups and dietary intake, physical activity, body  
263 image, sleep patterns, tobacco smoking, self-esteem or EQ-5D scores (Tables S1-S7).

264

265 With respect to other secondary outcomes, differences if present were only detected at six months.  
266 Intervention women were more likely to be drinking diet or sugar-free squash than control women  
267 (OR 2.84, 95% CI 1.11 to 7.29, p=0.029), with no differences at baseline or 12 months (Table S8,  
268 appendices). They were also more likely to have EPDS scores  $\geq 12$  at six months, indicating possible  
269 depression (intervention, 9/83 (10.8%), control 1/75 (1.3%), RR=8.13 (1.06 to 62.69), p=0.01) (Table  
270 S9, appendices) and less likely to drink any alcohol than control women at six months (44/53.0% 'v'  
271 33/44.6; p=0.038, 95% CI -2.719 to -0.083), but not at baseline or 12 months (Table S10, appendices).

272

273 At six months, most women (95%) reported that they had breastfed (Table S11), although more  
274 control women exclusively breastfed. At 12 months, over a third continued to breastfeed. Women  
275 introduced their infants to solid foods at a mean age of 22.2 (SD=3.72) weeks in the intervention and  
276 23.4 (SD=4.78) the control. Intervention women stopped breastfeeding earlier than control (20.0  
277 weeks (SD=14.4) compared with 24.2 (SD=15.9) weeks).

278

279

280

### 281 **Acceptability of trial processes and intervention**

282 There was low risk of contamination; only five control women joined Slimming World and a further  
283 four joined a similar commercial programme. In total, 25/83 (30%) intervention and 28/75 (37%)  
284 control women accessed additional weight management support at six months, with similar rates at  
285 12 months. Most control women accessed support five to six months postnatally. Joining a gym was  
286 most popular in both groups (30% and 50% respectively).

287

288

289 There was little or no difference in trial completion between groups (Difference -2.2%, 95% CI -15.2  
290 to 10.8), and responses to measures showed high overall completion (>80%, Table S12).

291

292

293 Of 46/98 (47%) intervention women who attended at least one Slimming World®(Alfreton, UK)  
294 session, most accessed the support after 10 weeks postnatal and mean number of sessions attended  
295 was 6.74 (SD=3.94). Most women continued with the same group they started with. Of the 52 women  
296 who did not attend, of 39 (75%) providing reasons, most described “opportunity” or “motivation”  
297 issues, including that it was too soon after birth, or did not recognise they had a weight problem.

298

299

### 300 **Health Economics**

301 Selected economic data collection tools to collate information from women’s questionnaires and  
302 maternity records, were suitable as a basis for an evaluation of cost-effectiveness in a definitive trial.

303

### 304 **Discussion**

#### 305 **Main findings**

306 It was possible to recruit and retain women with  $BMI \geq 25 \text{ kg/m}^2$  to this feasibility RCT, although  
307 approaches to recruit women with excessive gestational weight gain were not successful.  
308 Intervention women had greater weight loss at 12 months, with evidence of a ‘dose effect’ in terms  
309 of number of sessions attended, with minimal impacts on other lifestyle behaviours. It was feasible to  
310 combine women’s self-report and maternity record data to evaluate within-trial economic impacts.

311 We aimed to recruit 190 women over six months, and recruited 193 women over eight months, the  
312 additional time reflecting protocol revisions to identify and recruit women with excessive gestational

313 weight gain. A high number of potentially eligible women did not respond to contacts, which could  
314 reflect a number of issues, including that women had too many other commitments during pregnancy,  
315 or did not want to consider postnatal weight management support, but high follow up rates of women  
316 who were recruited were reassuring.

317

318 Our findings provide some support for using measurements at 12 months, rather than six months,  
319 which our PPI group agreed with. . The difference in weight was slightly greater at 12 months than at  
320 six months among intervention women. If real, this may be because some women had not yet received  
321 the full intervention at six months, but could reflect the need for women to have longer access to fully  
322 adapt to the weight management programme. This would support findings of a general population  
323 trial where individuals allocated to a 52 week open group weight management programme had  
324 greater weight loss over a two year period than those randomised to a 12 week programme or  
325 received brief advice and self-help materials.<sup>37</sup>

326

327 Secondary outcomes showed minimal differences. Those which were found (e.g., higher EPDS scores  
328 at six months among intervention women) are important to consider further in future research given  
329 evidence of physical and psychological co-morbidity in this population<sup>38</sup>. Few intervention women  
330 recalled the lifestyle information leaflet offered at recruitment, but for women in late pregnancy/early  
331 postnatal period it was unlikely that healthy lifestyle advice was an immediate priority. For a definitive  
332 trial, providing additional information alongside weight management support, would have to be  
333 considered, including optimal format of dissemination.

334

335 There was an apparent dose-response effect on weight outcomes, with greatest benefit found among  
336 women who attended 10+ Slimming World®(Alfreton, UK) sessions. A higher uptake would have been

337 encouraging, however, as the sample included women from an inner-city area with childcare and  
338 other responsibilities, who may not have encountered a similar weight management intervention  
339 before, that just under half attended at least one session could be viewed positively. Previous trials  
340 have reported similar uptake of weight management interventions among those in high and low-  
341 income areas<sup>39</sup>, with potential for targeted schemes to support weight management among adults  
342 living in areas of higher social deprivation. Process evaluation findings will inform uptake and  
343 retention strategies for a future trial.

344

345 It was feasible to generate economic data using participant self-report information and maternity  
346 records.

347

#### 348 **Strengths and limitations**

349 We could recruit pregnant women with high BMIs from diverse ethnic backgrounds living in an inner  
350 city area, and follow to 12 months postnatally. Women completed a broad range of health outcome  
351 measures, with no apparent problems with data completion. Intervention group women could access  
352 sessions at a venue, day and time to suit needs and lifestyles, an issue our PPI group considered of  
353 high importance to support women who had recently given birth. The programme is standardised  
354 and evidence-based<sup>18</sup> and suitable for new mothers, including those who were breastfeeding.

355

356 For a future trial, we have evidence of how to potentially increase uptake of the intervention, including  
357 extending the duration of 'offer' and providing more information about the programme following  
358 group allocation. Women were willing to meet the RMs at the two scheduled follow up contact points,  
359 indicating that this approach will support high data completion in a future trial. PPI support and advice  
360 as the trial progressed enabled any ongoing issues to be quickly addressed and resolved.

361 Economic modelling to inform longer-term impacts on outcomes of importance may be warranted in  
362 a future trial.

363

364 Limitations included being unable to identify and recruit women with excessive gestational weight  
365 gain, meaning findings are only relevant to women with BMIs >25kg/m<sup>2</sup>. That some measures had  
366 not been validated in a postnatal population means validity and interpretation cannot be confirmed.  
367 As a single centre feasibility study, findings may not be generalised.

368

### 369 **Interpretation in light of other evidence**

370 This is one of the first UK studies to consider a specific postnatal weight management intervention.  
371 The importance of postnatal intervention is becoming clearer, given concerns about longer-term  
372 impacts of maternal obesity, and lack of evidence of effectiveness of pregnancy-only interventions<sup>7,8</sup>.  
373 A recent review of reviews again showed interventions involving physical activity and/or dietary  
374 changes could be effective in managing postnatal weight, although findings should be interpreted with  
375 caution due to statistical heterogeneity<sup>39</sup>.

376

377 As women with higher BMIs experience a range of persistent co-morbidity, such as diabetes and  
378 hypertensive disorders<sup>40,41</sup>, the timing and content of a postnatal weight management intervention  
379 has to reflect birth recovery, demands of parenthood, potential return to employment, social  
380 circumstances and mobility of the population. This study shows that women who were interested in  
381 weight management support were willing to participate and complete the study, but approaches have  
382 to be flexible and reflect each woman's decision about when she feels timing of an intervention is  
383 appropriate.

384

385 Failure to recruit women with excessive gestational weight gain suggests these women will remain  
386 'under the radar', with implications for life-course health. UK guidance<sup>15</sup> is that women should not be  
387 weighed routinely. Even contacting women directly did not identify a large number who met IoM  
388 criteria for EGWG at 36 weeks. The potential to inform lifestyle behaviours was less clear, but could  
389 reflect positive lifestyle behaviours, such as high breastfeeding uptake in our local population<sup>35</sup> (no  
390 data on longer-term rates were available locally). Integration of evidence, and discussion of findings  
391 with our PPI group, highlighted several key findings to optimise intervention uptake in a definitive  
392 study, including offering more information about the intervention in pregnancy, a longer  
393 commencement period, and alternative approaches to presenting information on positive health  
394 behaviours.

395

396 Inclusion of economic modelling of longer-term impacts could prove an essential vehicle for a more  
397 complete and robust examination of programme cost-effectiveness

## 398 **Conclusion**

399 Most feasibility objectives were achieved. Process evaluation findings indicate that if commercial  
400 weight management sessions are to support women with higher BMIs to achieve and sustain postnatal  
401 weight loss and adapt positive lifestyle change, a wider window of commencement should be offered  
402 and the duration of the intervention extended. An online intervention arm could counteract some  
403 'opportunity' issues identified by women for not attending sessions, but evidence of effectiveness of  
404 such formats is needed. As economic impacts over the course of a short-term trial are unlikely to  
405 demonstrate cost-effectiveness of weight management longer-term for women and their infants, a  
406 future definitive trial would need to consider economic modelling

407

408 Women who participated may have been more motivated and interested, but once recruited, follow  
409 up and adherence was good. A further larger trial of effectiveness of lifestyle information and  
410 commercial weight management groups is an important next step to consider how best to support  
411 weight management among women with higher BMIs who have recently given birth.

412

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### 415 **Disclosure of interests**

416 Amanda Avery, alongside her academic position at the University of Nottingham, also holds a  
417 consultancy position at Slimming World (Slimming World® (Alfreton, UK)). Neither Amanda Avery nor  
418 Slimming World, had access to study data, were involved in data collection or data analyses. None of  
419 the other authors have anything to declare.

420

### 421 **Contribution to authorship**

422 DB conceived and designed the SWAN feasibility trial with the support of CT, NK, EON, AA, AH, MU  
423 and PS. AH developed and designed the economic analysis. PS, AH, CT, MZ, VB, MU and DB analysed  
424 the data. VC and SOC enrolled women into the study, arranged follow up of women and completed  
425 all data entry. DB drafted the first version of the manuscript. CT, MZ, AH, SR, PS, LP, VC, SOC, SM, AA,  
426 VB, MU, EON, NK, BO edited the manuscript, read and approved the final version.

### 427 **Details of Ethics Approval**

428 Ethics approval was granted by the Health Research Authority London – Camberwell St Giles REC on  
429 2<sup>nd</sup> September 2016 (reference number 16/LO/1422) and HRA approval was received on 11<sup>th</sup> October  
430 2016.

431

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436

#### 437 **Supporting information**

438 Tables S1 to S12 present data on outcome measures of maternal health, lifestyle behaviours, quality

439 of life and trial completion to 12 months.

440

#### 441 **REFERENCES**

442 1. Walker LO, Timmerman GM, Sterling BS, Kim M, Dickson P (2004). Do low-income women attain  
443 their pre-pregnant weight by the 6th week of postpartum? *Ethn Dis* 14, 119–126.

444

445 2. van der Pligt P, Willcox J, Hesketh KD, Ball K, Wilkinson S, Crawford D, Campbell K. Systematic  
446 review of lifestyle interventions to limit postpartum weight retention: implications for future  
447 opportunities to prevent maternal overweight and obesity following childbirth. *Obesity Reviews*  
448 2013; 14: 792–805 doi: 10.1111/obr.12053

449

450 3. Rooney BL, Schauburger CW, Mathiason MA. Impact of perinatal weight change on long-term  
451 obesity and obesity-related illnesses. *Obstet Gynecol* 2005; 106: 1349–1356.

452

453 4. Babendure JB, Reifsnider E, Mendias E, Moramarco MW, Davila YR. Reduced breastfeeding rates  
454 among obese mothers: a review of contributing factors, clinical considerations and future  
455 directions. *International Breastfeeding Journal*. 2015; 10: 1-11.

456

457

458 5. Turcksin, R., Bel, S., Galjaard, S., & Devlieger, R. (2012). Maternal obesity and breastfeeding  
459 intention, initiation, intensity and duration: a systematic review. *Maternal Child Nutrition*, 10(2),  
460 166–83.

461

462 6. Haugen M, Brantsæter AL, Winkvist A, Lissner L, Alexander J, Oftedal B, Magnus P et al.  
463 Associations of pre-pregnancy body mass index and gestational weight gain with pregnancy  
464 outcome and postpartum weight retention: a prospective observational cohort study. *BMC*  
465 *Pregnancy Childbirth*. 2014 Jun 11;14:201. doi: 10.1186/1471-2393-14-201.

466

467

468 7. Dodd JM, Turnbull DA, McPhee A, Deussen AR, Grivell RM, Yelland LN et al. Antenatal lifestyle  
469 advice for women who are overweight or obese; the LIMIT randomised trial. *BMJ* 2014, 348:g  
470 1285.

471

472 8. Poston L, Bell R, Croker H, Flynn AC, Godfrey KM, Goff L et al on behalf of the UPBEAT Trial  
473 Consortium (2015). Effect of a behavioural intervention in obese pregnant women (the UPBEAT  
474 study): a multicentre, randomised controlled trial. 3 (10); 767–777.

475

476 9. The International Weight Management in Pregnancy (i-WIP) Collaborative Group. Effect of diet  
477 and physical activity based interventions in pregnancy on gestational weight gain and pregnancy  
478 outcomes: meta-analysis of individual participant data from randomised trials. *BMJ* 2017; 358 doi:  
479 <https://doi.org/10.1136/bmj.j3119>

480

- 481 10. Rasmussen KM, Yaktine AL, Institute of Medicine (U.S.) Weight Gain During Pregnancy:  
482 Reexamining the Guidelines. Washington, DC: National Academies Press; 2009. Committee to  
483 Reexamine IOM Pregnancy Weight Guidelines. [[Google Scholar](#)]  
484
- 485 11. Zomer E, Gurusamy K, Leach R, Trimmer C, Lobstein T, Morris S et al . Interventions that cause  
486 weight loss and the impact on cardiovascular risk factors: a systematic review and meta-analysis.  
487 *Obes Rev* 2016; **17**: 1001–11.  
488
- 489 12. Amorim Adegboye AR, Linne YM. Diet or exercise, or both, for weight reduction in women after  
490 childbirth. *Cochrane Database of Systematic Reviews* 2013, Issue 7. Art. No.: CD005627. DOI:  
491 10.1002/14651858.CD005627.pub3.  
492
- 493 13. Dalrymple KV, Flynn AC, Relph SA, O’Keefe M, Poston L. Lifestyle Interventions in Overweight and  
494 Obese Pregnant or Postpartum Women for Postpartum Weight Management: A Systematic  
495 Review of the Literature. *Nutrients*. 2018; 10: 1704; doi:10.3390/nu10111704  
496
- 497 14. Jolly K, Lewis A, Beach J, Denley J, Pemaayne A, Deeks JD et al . Comparison of range of commercial  
498 or primary care led weight reduction programmes with minimal intervention control for weight  
499 loss in obesity: Lighten Up randomised controlled trial. *BMJ*, 2011. 343:d6500 doi:  
500 10.1136/bmj.d6500  
501
- 502 15. National Institute for Health and Care Excellence. Weight gain before, during and after pregnancy.  
503 2010  
504
- 505 16. NICE Public Health Guidance 53, 2014. Managing overweight and obesity in adults – lifestyle  
506 weight management services

507

508 17. NICE Guideline 37, 2014. Routine Postnatal Care of Women and their Babies

509 18. Stubbs RJ, Pallister C, Whybrow S, Avery A, Lavin J (2011). Weight Outcomes Audit for 34,271

510 Adults Referred to a Primary Care/Commercial Weight Management Partnership Scheme. *Obesity*

511 *Facts*; 4: 113-120

512 19. Elfhag K, Rössner S: Who succeeds in maintaining weight loss? A conceptual review of factors

513 associated with weight loss maintenance and weight regain. *Obes Rev* 2005, 6(1):67–85.

514 20. Wing RR, Jeffery RW. Benefits of recruiting participants with friends and increasing social support

515 for weight loss and maintenance. *J Consult Clin Psychol* 1999, 67(1):132–138.

516 21. Donnelly, JE, Blair, SN, Jakicic, JM, Manore, MM, Rankin, JW, Smith, BK. Appropriate physical

517 activity intervention strategies for weight loss and prevention of weight regain for adults. *Med Sci*

518 *Sports Exerc* 2009; 41: 459– 471.

519 22. Roe L, Strong C, Whiteside C, Neil A, Mant D. Dietary Intervention in Primary Care: Validity of the

520 DINE Method for Diet Assessment. *Family Practice*, 1994. 11;4: 375-381.

521 23. Craig CL, Marshall AL, Sjostrom M, Bauman A, Booth ML, Ainsworth BE et al International Physical

522 Activity Questionnaire: 12-country reliability and validity. *Medicine and Science in Sports and*

523 *Exercise* 2003, 35:1381-1395.

524 24. Cox JL, Holden HJ, Sagovsky R: Detection of postnatal depression. Development of the 10-item

525 Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987, 150:782–786

526 25. Ussher M, Aveyard P, Manyonda I, Lewis S, West R, Lewis B et al (2012) Physical activity as an aid

527 to smoking cessation during pregnancy: the LEAP randomised trial protocol. *Trials*, 13:186.

- 528 26. Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG: AUDIT: The Alcohol Use Disorders  
529 Identification Test: Guidelines for Use in Primary Care, Second Edition. World  
530 Health Organization; 2001. [http://whqlibdoc.who.int/hq/2001/WHO\\_MSD\\_MSB\\_01.6a.pdf](http://whqlibdoc.who.int/hq/2001/WHO_MSD_MSB_01.6a.pdf)
- 531 27. Rosenberg, M. (1965). Society and the adolescent self-image. Princeton, NJ: Princeton University  
532 Press
- 533 28. Fairburn CG, Beglin SJ .1994. International Journal of Eating Disorders;16(4):363-70.
- 534 29. Devlin NJ, Shah KK, Feng Y, Mulhern B, van Hout B. Valuing health-related quality of life: An EQ-  
535 5D-5L value set for England. Health economics. 2018;27(1):7-22.
- 536 30. Barrett B, Waheed W, Farrelly S, Birchwood M, Dunn G, Flach C, et al. Randomised controlled trial  
537 of joint crisis plans to reduce compulsory treatment for people with psychosis: economic  
538 outcomes. PLoS ONE 2013;8(11):e74210
- 539 31. Vickers AJ, Altman DG. Analysing controlled trials with baseline and follow up measurements.  
540 British Medical Journal. 2001;323:1123-1124.
- 541 32. UK MRC. Process evaluation of complex interventions. UK Medical Research Council Guidance  
542 2014.
- 543 33. Gardosi J, Francis A. Software for the calculation of customised birth weight percentiles. Version  
544 6.2, 2000-2007. Published on <http://www.gestation.net>
- 545 34. Smith T, Noble M, Wright G, McLennan D, Plunkett E. The English Indices of Multiple Deprivation.  
546 London. Department for Communities and Local Government
- 547 35. Child Health Profile. Lambeth. March 2019. Public Health Lambeth. Annual Report.
- 548 36. Altman D, Dore A. Randomisation and baseline comparisons in clinical trials. Lancet. 1990.  
549 20;335(8682):149-53.

- 550 37. Ahern AL, Wheeler GM, Aveyard P, Boyland EJ, Halford JSG, Mander AP et al. Extended and  
551 standard duration weight-loss programme referrals for adults in primary care (WRAP): a  
552 randomised controlled trial. *Lancet* 2017; 398; 2214-2225
- 553 38. Molyneaux E, Poston L, Ashurst-Williams S, Howard LM. Obesity and mental disorders during  
554 pregnancy and postpartum: a systematic review and meta-analysis. *Obstet Gynecol*. 2014  
555 Apr;123(4):857-67. doi: 10.1097/AOG.000000000000170. Review.
- 556 39. Ferguson JA, Daley AJ, Parretti HM. Behavioural weight management interventions for postnatal  
557 women: A systematic review of systematic reviews of randomized controlled trials. *Obes Rev*.  
558 2019 Jun;20(6):829-841. doi: 10.1111/obr.12834. Epub 2019 Apr 2.
- 559 40. Scott-Pillai R, Spence D, Cardwell CR, Hunter A, Holmes VA. The impact of body mass index on  
560 maternal and neonatal outcomes: a retrospective study in a UK obstetric population, 2004-2011.  
561 *British Journal of Obstetrics and Gynaecology*. 2013;120(8):932-9.
41. Sebire NJ, Jolly M, Harris JP, Wadsworth J, Joffe M, Beard RW, et al. Maternal obesity and  
pregnancy outcome: a study of 287,213 pregnancies in London. *Int J Obes Relat Metab Disord*.  
2001;25:1175-82

**Table 1. Baseline characteristics on all women randomised.**

\* EGWG : Excessive gestational weight gain, loM criteria, \*\* Ethnicity based on UK census categories, \*\*\*IMD: Index of Multiple Deprivation [48], \*\*\*\* Customised birthweight centiles [46], ^numbers are slightly reduced due to some missing values

Women's characteristics	Intervention	Control
	Intervention (n= 98)	Control (n= 95)
Age (years)	32.44 (5.10)	33.06 (5.37)
Height (m)	1.64 (0.07)	1.64 (0.06)
Maternal weight		
Weight (kg)	83.77 (18.77)	80.53 (13.17)
Mean booking BMI (kg/m <sup>2</sup> )	31.18 (6.47)	29.83 (4.11)
<25, no EGWG*	0 (0.0%)	1(1.1%)
25-29.9, no EGWG	2 (2.0%)	1(1.1%)
25-29.9, EGWG	20 (20.4%)	31(32.6%)
30-34.9, no EGWG	37(37.8%)	26(27.4%)
30-34.9, EGWG	9(9.2%)	18(18.9%)
35+, no EGWG	14(14.3%)	11(11.6%)
35+, EGWG	11(11.2%)	6(6.3%)
Ethnicity**		
White	38 (38.8%)	40 (42.1%)
Black	40 (40.8%)	36 (37.9%)
Asian	6 (6.1%)	2 (2.1%)
Other	14 (14.3%)	17 (17.9%)
Total household income		
£0-£5,475	7 (7.1)	5 (5.2)
£5,476-£15,000	11 (11.2)	9 (9.4)
£16,000-£30,000	14 (14.2)	11 (11.5)
£31,000-£45,000	8 (8.1)	10 (10.5)
£46,000-£60,000	7 (7.1)	11 (11.5)
£61,000+	32 (32.2)	31 (32.6)
Would not say	19 (19.3)	18 (19.1)
IMD (centile scale)***^	0.27 (0.15)	0.28 (0.17)
IMD quintiles		
1 (least deprived)	2 (2.0%)	2 (2.2%)
2	2 (2.0%)	3 (3.2%)
3	11 (11.2%)	15 (16.1%)
4	49 (50.0%)	41 (44.1%)
5 (most deprived)	34 (34.7%)	32 (34.4%)
Gestation at birth (wks)	39.38 (1.54)	39.49 (3.36)
Mode of birth^		
Vaginal (normal)	45(46.4%)	53(56.4%)
Vaginal (assisted)	10(10.3%)	12(12.8%)
Planned C.section	30 (30.9%)	14(14.9%)
Emergency C.section	10(10.3%)	14(14.9%)
Birthweight****	3378.14 (497.51)	3500.00 (505.90)
<10 <sup>th</sup> centile	14/90 (15.6%)	7/89 (7.9%)

<3<sup>rd</sup> centile

5/90 (5.6%)

2/89 (2.2%)

**Table 2. Average weights and weight changes at antenatal booking, trial entry, six and 12 months postnatally adjusted for baseline.**

562 \* Differences in weight change are adjusted for weight at end of pregnancy, maternal age, parity,  
563 ethnicity and BMI. \*\* Numbers are reduced slightly due to missing values for age & parity.

564

	Intervention Mean (SD)	Control Mean (SD)	Difference* (95% CI)
<b>Baseline (n)</b>	98	95	
Estimated antenatal weight	82.52 (18.77)	79.28 (13.17)	
Weight at start of pregnancy (kg)	83.77 (18.77)	80.53 (13.17)	
Weight at end of pregnancy (kg)	94.04 (16.93)	89.31 (11.97)	
<b>Six months postnatal (n)</b>	82	72	
<b>Weight (kg)</b>	83.24 (17.68)	81.88 (12.60)	
<b>Adjusted treatment effects</b>			
6 months postnatal (n)**	80	71	
Weight change (kg)	-8.74 (9.73)	-6.57 (6.43)	-1.66 (-4.49 to 1.16)
Weight change (%)	-9.56 (11.01)	-7.52 (7.24)	-1.83 (-5.06 to 1.41)
12 months postnatal (n)	69	71	
Weight (kg)	82.35 (18.41)	81.89 (14.60)	
12 months postnatal (n)**	68	70	
Weight change (kg)	-10.26 (8.24)	-7.50 (7.12)	-3.63 (-6.45 to -0.81)
Weight change (%)	-11.48 (8.96)	-8.65 (7.72)	-4.02 (-6.98 to -1.07)

**Table 3. Weight reduction by more than 5% and 10% at six and 12 months postnatally**

	Intervention	Usual Care	Health Ratio (95% CI)	Risk Difference (95% CI)
Six months				
More than 5% weight reduction	20/82 (24.4%)	10/72 (13.9%)	1.76 (0.88 to 3.50)	10.5% (-1.8 to 22.8)
More than 10% weight reduction	6/82 (7.3%)	2/72 (2.8%)	2.63 (0.55 to 12.64)	4.5% (-2.3 to 11.3)
12 months				
More than 5% weight reduction	16/69 (23.2%)	18/71 (25.4%)	0.91 (0.51 to 1.64)	-2.2% (-16.4 to 12.0)
More than 10% weight reduction	9/69 (13.0%)	3/71 (4.2%)	3.09 (0.87 to 10.93)	8.8% (-0.4 to 18.0)