



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

D Bick,<sup>a</sup> C Taylor,<sup>b</sup> V Bhavnani,<sup>c</sup> A Healey,<sup>d</sup> P Seed,<sup>e</sup> S Roberts,<sup>d</sup> M Zasada,<sup>b</sup> A Avery,<sup>f</sup> V Craig,<sup>g</sup> N Khazaezadah,<sup>h</sup> S McMullen,<sup>c</sup> S O'Connor,<sup>g</sup> B Oki,<sup>h</sup> EO Ntim,<sup>g</sup> L Poston,<sup>e</sup> M Ussher<sup>i</sup>

<sup>a</sup> Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK <sup>b</sup> School of Health Sciences, University of Surrey, Guildford, UK <sup>c</sup> NCT, London, UK <sup>d</sup> Kings Health Economics, Health Services and Population Research Department, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK <sup>e</sup> Department of Women and Children's Health, King's College London, London, UK <sup>f</sup> Faculty of Science, University of Nottingham, Nottingham, UK <sup>g</sup> Guy's and St Thomas' NHS Foundation Trust, London, UK <sup>h</sup> Public Health, London Borough of Lambeth, Lambeth, London, UK <sup>i</sup> Population Health Research Institute, St George's, University of London, London, UK

Correspondence: D Bick, Warwick Clinical Trials Unit, Warwick Medical School, Gibbet Hill, Coventry CV4 7AL, UK.  
Email: debra.bick@warwick.ac.uk

Accepted 25 November 2019.

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

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

**Setting** Inner-city unit, south England.

**Population** Women with body mass indices (BMIs)  $\geq 25$  kg/m<sup>2</sup> at pregnancy booking or normal BMIs (18.5–24.9 kg/m<sup>2</sup>) identified with excessive gestational weight gain at 36 weeks of gestation.

**Methods** Randomised to standard care plus commercial weight management sessions commencing 8–16 weeks postnatally or standard care only.

**Main outcomes** Feasibility outcomes included assessment of recruitment, retention, acceptability and economic data collation. Primary and secondary end points included difference between groups in weight 12 months postnatally compared with booking (proposed primary outcome for a future trial), diet, physical

activity, smoking, alcohol, mental health, infant feeding, NHS resource use.

**Results** In all, 193 women were randomised: 98 intervention and 95 control; only four women had excessive gestational weight gain. A slightly greater weight change was found among intervention women at 12 months, with greatest benefit. Among women attending ten or more weight management sessions. There was >80% follow up to 12 months, low risk of contamination and no group differences in trial completion.

**Conclusion** It was feasible to recruit and retain women with BMIs  $\geq 25$  kg/m<sup>2</sup> to an intervention to support postnatal weight management; identification of excessive gestational weight gain requires consideration. Economic modelling could inform out-of-trial costs and benefits in a future trial. A definitive trial is an important next step.

**Keywords** Feasibility, postnatal, randomised controlled trial, weight management.

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

Please cite this paper as: Bick D, Taylor C, Bhavnani V, Healey A, Seed P, Roberts S, Zasada M, Avery A, Craig V, Khazaezadah N, McMullen S, O'Connor S, Oki B, Ntim EO, Poston L, Ussher M. Lifestyle information and commercial weight management groups to support maternal postnatal weight management and positive lifestyle behaviour: the SWAN feasibility randomised controlled trial. *BJOG* 2019; <https://doi.org/10.1111/1471-0528.16043>.

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

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

## Introduction

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

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

Interventions to reduce postpartum weight retention across all body mass index (BMI) categories have included counselling, individualised physical activity plans, healthy eating groups and clinic visits. In one systematic review, seven of eleven trials found a decrease in weight retention, six including diet and physical activity interventions.<sup>2</sup> No study considered cost-effectiveness, with wide heterogeneity in approaches to intervention implementation. Dalrymple et al.<sup>13</sup> reviewed lifestyle interventions in overweight and obese women for postpartum weight management. Seven postpartum-only interventions showed significant improvements in weight compared with controls, suggesting potential for weight management.

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

This single centre, two-arm individually randomised feasibility trial with a nested mixed-methods process evaluation assessed the feasibility of conducting a future definitive randomised controlled trial (RCT) to determine effectiveness and cost-effectiveness of lifestyle information

and access to a commercial weight management group (Slimming World<sup>®</sup>) to support longer-term postnatal weight management and positive lifestyle behaviour in women at risk of poor weight management.

## Methods

### Participant eligibility

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

### Recruitment

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

All women received a Patient Information Sheet before seeking written informed consent from those who agreed to participate at 36 weeks of gestation.

### Intervention

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

Slimming World<sup>®</sup> groups are homogeneous in content and delivery,<sup>18</sup> promoting key behaviour change techniques including goal setting, social support and positive reinforcement, underpinned by social cognitive theory relevant to motivation and self-efficacy for weight management.<sup>19,20</sup> A food optimising system encourages healthy eating,

recommending that 80% of foods are fruit, vegetables and satiating foods (carbohydrates and protein); alongside measured portions of fibre and calcium-rich foods; and an allowance for foods high in fat or sugar. The plan is designed to be unrestrictive and adaptable to cultural and dietary preferences, and includes guidance for breastfeeding women to ensure key nutritional requirements are met. A 'Body Magic' programme promotes the importance of physical activity.

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

### Control group

Standard NHS maternity care to 6–8 weeks postpartum, including routine midwife, health visitor and general practitioner contacts.

### Randomisation

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

### Progression criteria

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

### Primary and secondary feasibility outcomes

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

Secondary outcomes were selected as appropriate to inform progress to a definitive RCT. These included rates of 5% and 10% weight reduction and changes in relation to healthy lifestyle and health behaviours. The following were used (asterisks indicate that they were included at 6 and 12 months):

- Dietary Instrument for Nutritional Education (DINE<sup>®</sup>, University of Oxford)<sup>22</sup>
- International Physical Activity Short-Form<sup>23</sup>
- Edinburgh Postnatal Depression Scale<sup>\*24</sup>
- Smoking status/cigarette dependence<sup>25</sup>

- Alcohol Use Disorders Identification Test<sup>26</sup>
- Rosenberg Self-Esteem Scale<sup>27</sup>
- Impact on body image<sup>\*28</sup>
- EQ-5D-5L<sup>29</sup>
- Soft drink intake; breastfeeding intent, uptake and duration; sleep patterns<sup>\*</sup>; infant health<sup>\*</sup>: questions developed for the feasibility study
- Adult Service Receipt Schedule (AD-SUS)<sup>30</sup>

At 6 and 12 months, all women were asked about the timing and type of postnatal weight support they had accessed to assess potential contamination and inform future decisions about timing of commencement of the intervention offer. An integral mixed-methods process evaluation examined the acceptability of the intervention and study procedures. These findings are reported separately.

### Patient and public involvement

A group of four local women who had experienced previous pregnancies with BMIs of  $\geq 25$  kg/m<sup>2</sup> were convened at study development to advise the team on approaches to recruitment, intervention and outcomes most likely to be of importance to postnatal women. This group met regularly throughout the study period. VB co-ordinated the patient and public involvement (PPI) group on behalf of the SWAN trial team.

### Data collection

Information at trial entry, including eligibility, booking BMI, parity, age, ethnicity, deprivation score, total household income, birth mode, gestation and birthweight were obtained from maternity records. The baseline questionnaire was completed at recruitment (36 weeks of gestation). At 6 and 12 months women met with RMs to be weighed and complete questionnaires. If women could not meet the RM, they could return questionnaires by post, recording their current weight.

### Sample size

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

### Analysis

Recruitment was assessed as number of women randomised per month, with 95% CIs derived from the Poisson distribution, and retention as proportion of women randomised

providing analysable data for primary assessment at 12 months. Linear regression was used for the primary end point and other continuous measures. Adjustment was made for corresponding measurements made pre-randomisation.<sup>31</sup> Binary regression with a log-link was used to assess risk ratios for all binary outcomes, adjusting for maternal age, BMI, ethnicity and parity. Following CONSORT and other recommendations,<sup>32</sup> risk differences were also estimated. Significance tests were only conducted to test for differences in dropout rates between groups, and estimates of treatment effects.

For primary analysis, participants were analysed in the groups into which they were randomly allocated. Estimated differences and 95% CIs were calculated for specified primary and secondary analyses (significance at 5%). Sensitivity analyses were used to assess robustness of conclusions to missing outcome data and departures from randomised treatment

Reduction of weight by more than 5 and 10% at 6 and 12 months were analysed as binary variables, with health ratios and risk differences presented. Subgroup analysis of the primary end point among overweight (BMI 25–29.9 kg/m<sup>2</sup>) and obese (BMI ≥30 kg/m<sup>2</sup>) women was pre-planned, with interaction tests to determine if treatment effect varied by subgroup.

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

### Ethical approval

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

### Funding

This study was funded by the NIHR Public Health Research Programme; reference no: 14/67/14.

## Results

### Recruitment and retention

Between November 2016 and July 2017, of 1132 potentially eligible women, 835 (73.5%) were not recruited, 59 (5.2%) were later ineligible (e.g. had a premature birth), and contact data on 43 (3.8%) women were missing from their records. In most cases, study letters were returned unopened or phone calls not returned. Women who were contacted and asked why they would not consider recruitment reported practical barriers, such as moving house, or not having any

concerns about their weight. Of 195 (17.2%) women who agreed to attend the recruitment appointment, two changed their minds; 193 were recruited and randomised, 97% of whom had BMIs >25 kg/m<sup>2</sup>. Only four of nine women with a healthy BMI at booking who responded to a study letter and met the RMs at 36 weeks of gestation had excessive gestational weight gain and were eligible to participate.

The CONSORT diagram (Figure 1) shows trial participant flow. Two women withdrew, one from the control at 6-month follow up, and one from the intervention at 12 months. Neither asked for data to be withdrawn. Only women who returned a 6-month questionnaire were sent a 12-month questionnaire, 20 women returning a copy by post; at 12 months, 69/83 (83.1%) intervention group women and 71/75 (94.6%) control women completed questionnaires; 32 returned by post.

### Baseline characteristics

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

Mean maternal age was 32 years (SD 5.2), and mean maternal booking BMI was 30.51 kg/m<sup>2</sup> (SD 5.4) (Table 1). More intervention women had a mean BMI ≥30 kg/m<sup>2</sup> at booking and twice as many had planned caesarean section compared with controls. Mean gestational birth age was 39.4 weeks (SD 2.5), and mean infant birthweight of 3.43 kg (SD 503). Most women lived in areas of highest social deprivation,<sup>34</sup> although a third of women had total household incomes of ≥£ 61,000. A slightly lower proportion of white women were recruited compared with the local maternity population, with a slightly higher proportion of Black women.<sup>35</sup> Differences between groups at baseline were not assessed statistically.<sup>36</sup>

### Proposed primary and secondary outcomes

After adjusting the most powerful predictors measured pre-randomisation, using linear regression and removing any biases due to chance imbalance at baseline, weight loss at 12 months postnatally was greater than at 6 months (Table 2), supporting 12 months as a future primary end point.

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

Of the 98 intervention women, 46 (47%) attended one or more weight management sessions. Based on per-protocol analysis, women who attended ten or more sessions (19/46, 41%) had greater weight loss at 12 months than women who attended nine or fewer sessions or none at all, or were control group (95% CI 1.05–8.93,  $P = 0.013$ ).

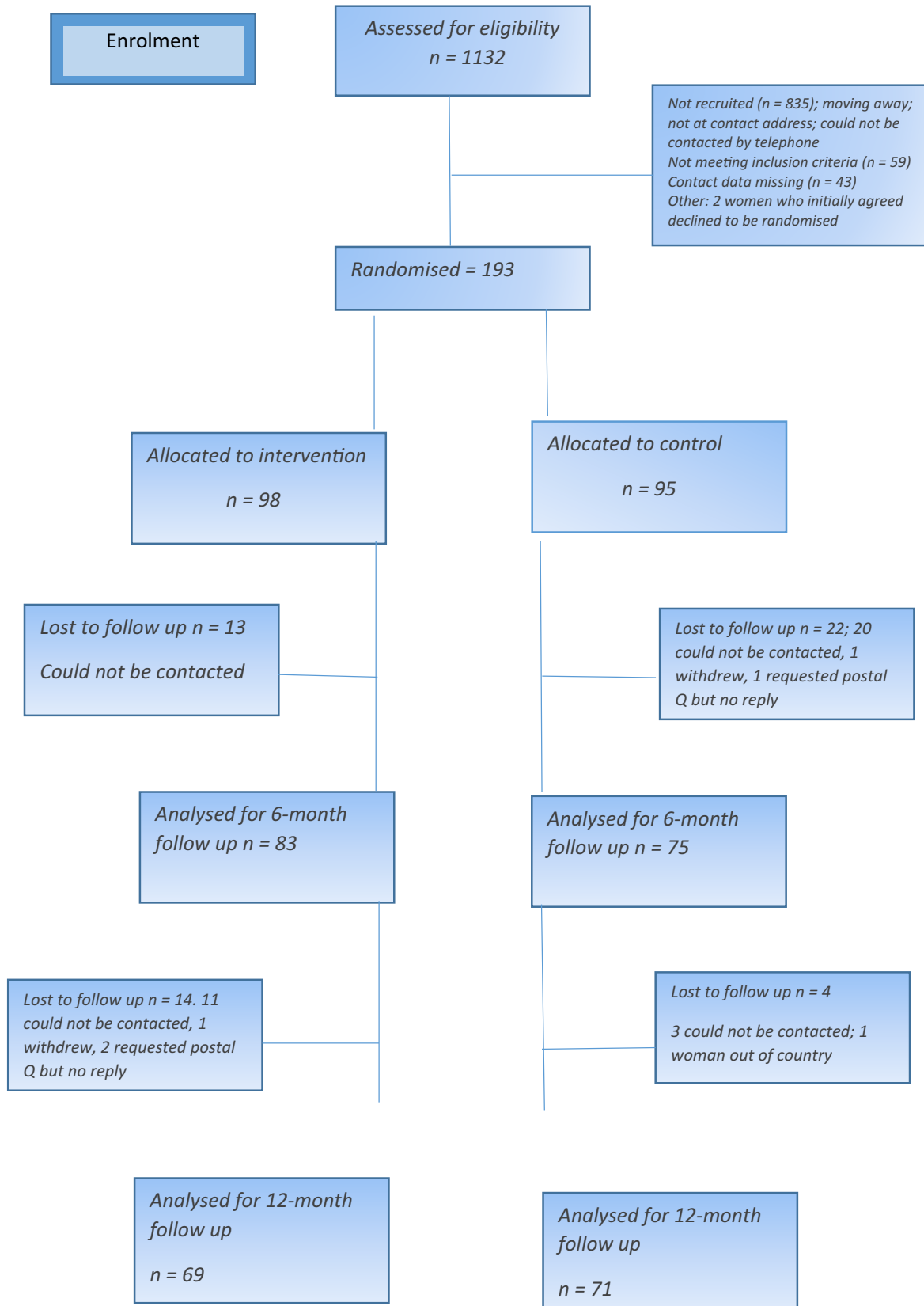


Figure 1. Participant flow diagram.

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

Women's characteristics	Intervention Intervention (n = 98)	Control Control (n = 95)
Age (years)	32.44 (5.10)	33.06 (5.37)
Height (m)	1.64 (0.07)	1.64 (0.06)
<b>Maternal weight</b>		
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 <sup>a</sup>	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%)
<b>Ethnicity<sup>b</sup></b>		
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%)
<b>Total household income</b>		
£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) <sup>c, d</sup>	0.27 (0.15)	0.28 (0.17)
<b>IMD quintiles</b>		
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 (weeks)	39.38 (1.54)	39.49 (3.36)
<b>Mode of birth<sup>d</sup></b>		
Vaginal (normal)	45 (46.4%)	53 (56.4%)
Vaginal (assisted)	10 (10.3%)	12 (12.8%)
Planned caesarean section	30 (30.9%)	14 (14.9%)
Emergency caesarean section	10 (10.3%)	14 (14.9%)
Birthweight <sup>e</sup>	3378.14 (497.51)	3500.00 (505.90)
<10th centile	14/90 (15.6%)	7/89 (7.9%)
<3rd centile	5/90 (5.6%)	2/89 (2.2%)

<sup>a</sup>EGWG = Excessive gestational weight gain, IoM criteria.

<sup>b</sup>Ethnicity based on UK census categories.

<sup>c</sup>IMD = Index of Multiple Deprivation [48].

<sup>d</sup>Numbers are slightly reduced because of some missing values.

<sup>e</sup>Customised birthweight centiles [46].

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

With respect to other secondary outcomes, differences if present were only detected at 6 months. Intervention women were more likely to be drinking diet or sugar-free squash than control women (OR 2.84, 95% CI 1.11–7.29,  $P = 0.029$ ), with no differences at baseline or 12 months (see Supplementary material, Table S8). They were also more likely to have Edinburgh Postnatal Depression Scale scores  $\geq 12$  at 6 months, indicating possible depression [intervention, 9/83 (10.8%), control 1/75 (1.3%), relative risk = 8.13 (1.06–62.69),  $P = 0.01$ ] (see Supplementary material, Table S9) and less likely to drink any alcohol than control women at 6 months (44/53.0% versus 33/44.6;  $P = 0.038$ , 95% CI  $-2.719$  to  $-0.083$ ), but not at baseline or 12 months (see Supplementary material, Table S10).

At 6 months, most women (95%) reported that they had breastfed (see Supplementary material, Table S11), although more control women exclusively breastfed. At 12 months, over a third continued to breastfeed. Women introduced their infants to solid foods at a mean age of 22.2 weeks (SD 3.72) in the intervention and 23.4 weeks (SD 4.78) in the control. Intervention women stopped breastfeeding earlier than control women [20.0 weeks (SD 14.4) compared with 24.2 (SD 15.9) weeks].

### Acceptability of trial processes and intervention

There was low risk of contamination; only five control women joined Slimming World and a further four joined a similar commercial programme. In total, 25/83 (30%) intervention and 28/75 (37%) control women accessed additional weight management support at 6 months, with similar rates at 12 months. Most control women accessed support 5–6 months postnatally. Joining a gym was most popular in both groups (30 and 50%, respectively).

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

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

### Health economics

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

**Table 2.** Average weights and weight changes at antenatal booking, trial entry, 6 and 12 months postnatally adjusted for baseline

Intervention	Mean (SD)	Control mean (SD)	Difference* (95% CI)
Baseline ( <i>n</i> )	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)	
Six months postnatal ( <i>n</i> )	82	72	
Weight (kg)	83.24 (17.68)	81.88 (12.60)	
Adjusted treatment effects			
6 months postnatal ( <i>n</i> **)	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 ( <i>n</i> )	69	71	
Weight (kg)	82.35 (18.41)	81.89 (14.60)	
12 months postnatal ( <i>n</i> **)	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)

\*Differences in weight change are adjusted for weight at end of pregnancy, maternal age, parity, ethnicity and BMI.

\*\*Numbers are reduced slightly because of missing values for age and parity.

**Table 3.** Weight reduction by more than 5 and 10% at 6 and 12 months postnatally

	Intervention	Usual care	Health ratio (95% CI)	Risk difference (95% CI)
<b>6 months</b>				
>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)
>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)
<b>12 months</b>				
>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)
>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)

## Discussion

### Main findings

It was possible to recruit and retain women with BMIs  $\geq 25$  kg/m<sup>2</sup> to this feasibility RCT, although approaches to recruit women with excessive gestational weight gain were not successful. Intervention women had greater weight loss at 12 months, with evidence of a 'dose effect' in terms of number of sessions attended, with minimal impacts on other lifestyle behaviours. It was feasible to combine women's self-report and maternity record data to evaluate within-trial economic impacts.

We aimed to recruit 190 women over 6 months, and recruited 193 women over 8 months, the additional time reflecting protocol revisions to identify and recruit women with excessive gestational weight gain. A high number of potentially eligible women did not respond to contacts, which could reflect a number of issues, including that women had too many other commitments during pregnancy, or did not want to consider postnatal weight

management support, but high follow-up rates of women who were recruited were reassuring.

Our findings provide some support for using measurements at 12 months, rather than 6 months, which our PPI group agreed with. The difference in weight was slightly greater at 12 months than at 6 months among intervention women. If real, this may be because some women had not yet received the full intervention at 6 months, but could reflect the need for women to have longer access to fully adapt to the weight management programme. This would support findings of a general population trial where individuals allocated to a 52-week open group weight management programme had greater weight loss over a 2-year period than those randomised to a 12-week programme or to receive brief advice and self-help materials.<sup>37</sup>

Secondary outcomes showed minimal differences. Those which were found (e.g. higher Edinburgh Postnatal Depression Scale scores at 6 months among intervention women) are important to consider further in future research given evidence of physical and psychological co-morbidity in this

population.<sup>38</sup> Few intervention women recalled the lifestyle information leaflet offered at recruitment, but for women in late pregnancy/early postnatal period it was unlikely that healthy lifestyle advice was an immediate priority. For a definitive trial, providing additional information alongside weight management support would have to be considered, including optimal format of dissemination.

There was an apparent dose–response effect on weight outcomes, with greatest benefit found among women who attended ten or more Slimming World® sessions. A higher uptake would have been encouraging, however, as the sample included women from an inner-city area with childcare and other responsibilities, who may not have encountered a similar weight management intervention before, that just under half attended at least one session could be viewed positively. Previous trials have reported similar uptake of weight management interventions among those in high-income and low-income areas,<sup>39</sup> with potential for targeted schemes to support weight management among adults living in areas of higher social deprivation. Process evaluation findings will inform uptake and retention strategies for a future trial.

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

### Strengths and limitations

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

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

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

Limitations included being unable to identify and recruit women with excessive gestational weight gain, meaning that findings are only relevant to women with BMIs >25 kg/m<sup>2</sup>. That some measures had not been validated in a postnatal population meant that validity and interpretation cannot

be confirmed. As a single-centre feasibility study, findings may not be generalised.

### Interpretation in light of other evidence

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

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

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

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

### Conclusion

Most feasibility objectives were achieved. Process evaluation findings indicate that if commercial weight management sessions are to support women with higher BMIs to achieve and sustain postnatal weight loss and adapt positive lifestyle change, a wider window of commencement should be



offered and the duration of the intervention should be extended. An online intervention arm could counteract some 'opportunity' issues identified by women for not attending sessions, but evidence of effectiveness of such formats is needed. As economic impacts over the course of a short-term trial are unlikely to demonstrate cost-effectiveness of weight management longer-term for women and their infants, a future definitive trial would need to consider economic modelling.

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

### Disclosure of interests

Amanda Avery, alongside her academic position at the University of Nottingham, also holds a consultancy position at Slimming World®. Neither Amanda Avery nor Slimming World®, had access to study data, were involved in data collection or data analyses. None of the other authors have anything to declare. Completed disclosure of interest forms are available to view online as supporting information.

### Contribution to authorship

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

### Details of ethics approval

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

### Funding

This study was funded by the NIHR Public Health Research Programme. Reference No: 14/67/14. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, MRC, CCF, NETSCC, the Public Health Research Programme or the Department of Health.

### Acknowledgements

We would like to thank all of the women who participated in our trial.

### Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Table S1.** Dietary intake at baseline, 6 and 12 months by SWAN trial arms.

**Table S2.** Physical activity at baseline, 6 and 12 months by SWAN trial arm.

**Table S3.** Body image at 6 and 12 months by SWAN trial arm.

**Table S4.** Maternal mean sleep duration and infant sleep patterns at 6 and 12 months by SWAN trial arm.

**Table S5.** Tobacco smoking at baseline, 6 and 12 months by SWAN trial arm.

**Table S6.** Self-esteem at baseline, 6 and 12 months by SWAN trial arm.

**Table S7.** EQ-5D at baseline, 6 and 12 months by SWAN trial arm

**Table S8.** Soft drink intake at baseline, 6 and 12 months by SWAN trial arm.

**Table S9.** Edinburgh Postnatal Depression Scale at 6 and 12 months by SWAN trial arm.

**Table S10.** Alcohol score at baseline, 6 and 12 months by SWAN trial arm.

**Table S11.** Breastfeeding at 6 and 12 months by SWAN trial arm.

**Table S12.** Differences in trial completion to 12 months by SWAN trial arm. ■

### References

- Walker LO, Timmerman GM, Sterling BS, Kim M, Dickson P. Do low-income women attain their pre-pregnant weight by the 6th week of postpartum? *Ethn Dis* 2004;14:119–26.
- van der Pligt P, Willcox J, Hesketh KD, Ball K, Wilkinson S, Crawford D, et al. Systematic review of lifestyle interventions to limit postpartum weight retention: implications for future opportunities to prevent maternal overweight and obesity following childbirth. *Obes Rev* 2013;14:792–805.
- Rooney BL, Schauburger CW, Mathiason MA. Impact of perinatal weight change on long-term obesity and obesity-related illnesses. *Obstet Gynecol* 2005;106:1349–56.
- Babundure JB, Reifsnider E, Mendias E, Moramarco MW, Davila YR. Reduced breastfeeding rates among obese mothers: a review of contributing factors, clinical considerations and future directions. *Int Breastfeed J* 2015;10:1–11.
- Turcksin R, Bel S, Galjaard S, Devlieger R. Maternal obesity and breastfeeding intention, initiation, intensity and duration: a systematic review. *Matern Child Nutri* 2012;10:166–83.

- 6 Haugen M, Brantsæter AL, Winkvist A, Lissner L, Alexander J, Oftedal B, et al. Associations of pre-pregnancy body mass index and gestational weight gain with pregnancy outcome and postpartum weight retention: a prospective observational cohort study. *BMC Pregnancy Childbirth* 2014;11:201.
- 7 Dodd JM, Turnbull DA, McPhee A, Deussen AR, Grivell RM, Yelland LN, et al. Antenatal lifestyle advice for women who are overweight or obese; the LIMIT randomised trial. *BMJ* 2014;348:g1285.
- 8 Poston L, Bell R, Croker H, Flynn AC, Godfrey KM, Goff L, et al. Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial. *Lancet Diab Endocrinol* 2015;3:767–7.
- 9 The International Weight Management in Pregnancy (i-WIP) Collaborative Group. Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials. *BMJ* 2017;358:j3119.
- 10 Rasmussen KM, Yaktine AL. *Institute of Medicine (U.S.) Weight Gain During Pregnancy: Reexamining the Guidelines*. Washington, DC: National Academies Press; 2009. Committee to Reexamine IOM Pregnancy Weight Guidelines. [Google Scholar].
- 11 Zomer E, Gurusamy K, Leach R, Trimmer C, Lobstein T, Morris S, et al. Interventions that cause weight loss and the impact on cardiovascular risk factors: a systematic review and meta-analysis. *Obes Rev* 2016;17:1001–11.
- 12 Amorim Adegboye AR, Linne YM. Diet or exercise, or both, for weight reduction in women after childbirth. *Cochrane Database of Systematic Reviews* 2013;7:Art. No.: CD005627. <https://doi.org/10.1002/14651858.CD005627.pub3>
- 13 Dalrymple KV, Flynn AC, Relph SA, O'Keefe M, Poston L. Lifestyle interventions in overweight and obese pregnant or postpartum women for postpartum weight management: a systematic review of the literature. *Nutrients* 2018;10:1704.
- 14 Jolly K, Lewis A, Beach J, Denley J, Pemaayne A, Deeks JD, et al. Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: lighten up randomised controlled trial. *BMJ* 2011;343:d6500.
- 15 National Institute for Health and Care Excellence. *Weight Gain Before, During and After Pregnancy*. London: National Institute for Health and Care Excellence; 2010.
- 16 NICE Public Health Guidance 53. *Managing overweight and obesity in adults – lifestyle weight management services*. London: National Institute for Health and Care Excellence; 2014.
- 17 NICE Guideline 37. *Routine Postnatal Care of Women and their Babies*. London: National Institute for Health and Care Excellence; 2014.
- 18 Stubbs RJ, Pallister C, Whybrow S, Avery A, Lavin J. Weight outcomes audit for 34,271 adults referred to a primary care/commercial weight management partnership scheme. *Obesity Facts* 2011;4:113–20.
- 19 Elfhag K, Rössner S. Who succeeds in maintaining weight loss? A conceptual review of factors associated with weight loss maintenance and weight regain. *Obes Rev* 2005;6:67–85.
- 20 Wing RR, Jeffery RW. Benefits of recruiting participants with friends and increasing social support for weight loss and maintenance. *J Consult Clin Psychol* 1999;67:132–138.
- 21 Donnelly JE, Blair SN, Jakicic JM, Manore MM, Rankin JW, Smith BK. Appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. *Med Sci Sports Exerc* 2009;41:459–71.
- 22 Roe L, Strong C, Whiteside C, Neil A, Mant D. Dietary intervention in primary care: validity of the DINE method for diet assessment. *Fam Pract* 1994;11:375–381.
- 23 Craig CL, Marshall AL, Sjoström M, Bauman A, Booth ML, Ainsworth BE, et al. International Physical Activity Questionnaire: 12-country reliability and validity. *Med Sci Sport Exerc* 2003;35:1381–95.
- 24 Cox JL, Holden HJ, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;150:782–6.
- 25 Ussher M, Aveyard P, Manyonda I, Lewis S, West R, Lewis B, et al. Physical activity as an aid to smoking cessation during pregnancy: the LEAP randomised trial protocol. *Trials* 2012;13:186.
- 26 Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG. *AUDIT: The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care*, 2nd edn. Geneva, Switzerland: World Health Organization; 2001.
- 27 Rosenberg M. *Society and the Adolescent Self-image*. Princeton, NJ: Princeton University Press; 1965.
- 28 Fairburn CG, Beglin SJ. Assessment of eating disorders: interview or self-report questionnaire? *Int J Eat Disord* 1994;16:363–70.
- 29 Devlin NJ, Shah KK, Feng Y, Mulhern B, van Hout B. Valuing health-related quality of life: An EQ-5D-5L value set for England. *Health Econ* 2018;27:7–22.
- 30 Barrett B, Waheed W, Farrelly S, Birchwood M, Dunn G, Flach C, et al. Randomised controlled trial of joint crisis plans to reduce compulsory treatment for people with psychosis: economic outcomes. *PLoS ONE* 2013;8:e74210.
- 31 Vickers AJ, Altman DG. Analysing controlled trials with baseline and follow up measurements. *Br Med J* 2001;323:1123–4.
- 32 UK MRC. *Process Evaluation of Complex Interventions*. London: UK Medical Research Council Guidance; 2014.
- 33 Gardosi J, Francis A. *Software for the calculation of customised birth weight percentiles*. Version 6.2, 2000–2007. Published on <http://www.gestation.net>
- 34 Smith T, Noble M, Wright G, McLennan D, Plunkett E. *The English Indices of Multiple Deprivation*. London: Department for Communities and Local Government; 2019.
- 35 Child Health Profile. *Lambeth. March 2019. Public Health Lambeth. Annual Report*.
- 36 Altman D, Dore A. Randomisation and baseline comparisons in clinical trials. *Lancet* 1990;335:149–53.
- 37 Ahern AL, Wheeler GM, Aveyard P, Boyland EJ, Halford JSG, Mander AP, et al. Extended and standard duration weight-loss programme referrals for adults in primary care (WRAP): a randomised controlled trial. *Lancet* 2017;398:2214–25.
- 38 Molyneaux E, Poston L, Ashurst-Williams S, Howard LM. Obesity and mental disorders during pregnancy and postpartum: a systematic review and meta-analysis. *Obstet Gynecol* 2014;123:857–67.
- 39 Ferguson JA, Daley AJ, Parretti HM. Behavioural weight management interventions for postnatal women: a systematic review of systematic reviews of randomized controlled trials. *Obes Rev* 2019;20:829–41.
- 40 Scott-Pillai R, Spence D, Cardwell CR, Hunter A, Holmes VA. The impact of body mass index on maternal and neonatal outcomes: a retrospective study in a UK obstetric population, 2004–2011. *Br J Obstet Gynaecol* 2013;120:932–9.
- 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.