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

Abstract

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 BMIs ≥25kg/m^2 at pregnancy booking or normal BMIs (18.5kg/m^2-24.9kg/m^2) identified with excessive gestational weight gain at 36 weeks gestation.

M**ethods:** 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 endpoints 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: 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 10+ 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≥25kg/m^2 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.

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

Trial registration: This trial is registered as ISRCTN 39186148

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

Tweetable abstract

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A feasibility RCT of postnatal weight support showed women with BMIs≥25kg/m^2 can be recruited and followed to 12 months postnatally

Introduction

At six to eight weeks postnatally, two thirds of women have a higher weight than before pregnancy[1], with postpartum weight retention contributing to poorer long-term health[2,3] and failure to breastfeed[4,5]. There is limited evidence for pregnancy-specific weight management interventions[6,7,8]. A meta-analysis of individual participant data of diet and physical activity interventions[9] 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 ≥5% of initial weight within 6 months of the intervention, a reduction associated with fewer weight morbidities[10], although smaller weight loss may result in health gains[11]. A Cochrane review of diet and/or exercise for postnatal weight reduction[12] found exercise alone was not effective (two trials, n=53, mean difference -0.10kg, 95% CI -1.90 to 1.71), but diet (one trial, n=45, mean difference -1.70kg, 95% CI -2.08 to -0.132) or diet plus exercise (seven trials, n=573, mean difference -1.93kg, 95% CI -2.96 to -0.89) was effective. Data were insufficient to infer other potential risks or benefits for women or infants[12].

Interventions to reduce postpartum weight retention across all BMI categories have included counselling, individualised physical activity plans, healthy eating groups, and clinic visits. In one systematic review, seven of 11 trials found a decrease in weight retention, six including diet and physical activity interventions[2]. No study considered cost-effectiveness, with wide heterogeneity in approaches to intervention implementation. Dalrymple et al (2018)[13] 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 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) [14]. Commercial weight programmes achieved better weight loss at programme end (mean difference 2.3kg (1.3 to 3.4kg) and were approximately £40 cheaper per person than primary care services.

This single centre, two-arm individually randomized feasibility trial with a nested mixed-methods process evaluation assessed feasibility of conducting a future definitive RCT to determine effectiveness and cost effectiveness of lifestyle information and access to a commercial weight management group (Slimming World® (Alfreton, UK)) 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: 1) Women with BMIs ≥25kg/m^2 identified from antenatal booking information; at 26 weeks 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; 2) Women with healthy BMIs at antenatal booking who gained more weight than recommended by IOM guidelines[10] could self-refer, or be referred by clinicians, to RMs to be weighed at 36 weeks' gestation (routine weighing is not recommended in NHS antenatal care[15]). 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 gestation, inviting them to be weighed for excessive gestational weight gain at 36 weeks gestation.

All women received a Patient Information Sheet (PIS) prior to seeking written informed consent from those who agreed to participate at 36 weeks 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[16,17] and access to a commercial weight management programme (Slimming World®, Alfreton, UK) for 12 weekly sessions, commencing anytime from 8-16 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® (Alfreton, UK) groups are homogeneous in content and delivery[18], 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[19,20]. 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 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 2009)[21], attending at least 10 sessions is recommended[19].

Control group

Standard NHS maternity care to six-eight weeks postpartum, including routine midwife, health visitor and GP 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 (ITT) 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:

- Dietary Instrument for Nutritional Education (DINE© University of Oxford)[22]]
- International Physical Activity Short-Form[23]
- Edinburgh Postnatal Depression Scale*[24]
- Smoking status/cigarette dependence[25]
- Alcohol Use Disorders Identification Test[26]
- Rosenberg Self-Esteem Scale[27]
- Impact on body image*[28]
- EQ-5D-5L[29]

- Soft drink intake; breastfeeding intent, uptake and duration; sleep patterns*; infant health*: questions developed for the feasibility study
- Adult Service Receipt Schedule (AD-SUS)[30]

**included at six & 12 months*

At six 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 ≥25kg/m^2were 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 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, birthweight and inpatient stay were obtained from maternity records. The baseline questionnaire was completed at recruitment (36 weeks gestation). At six and 12 months women met with RMs to be weighed and complete questionnaires. If women 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)[18]. 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[31]. 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[32], 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

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

Reduction of weight by more than 5% and 10% at six and 12 months were analysed as binary variables, with health ratios and risk differences presented. Sub-group analysis of the primary endpoint among overweight (BMI 25–29.9 kg/m²) and obese (BMI ≥30 kg/m²) women was pre-planned, with interaction tests to determine if treatment effect varied by sub-group.

To explore if women who attended 10+ 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 2nd September 2016 (reference:16/LO/1422) and HRA approval on 11th October 2016.

Results

Recruitment and retention

Between November 2016 and July 2017, of 1132 women potentially eligible, 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 >25kg/$m^{2.}$ Only four of nine women with a healthy BMI at booking who responded to a study letter and met the RMs at 36 weeks gestation had EGWG and were eligible to participate.

The CONSORT diagram (Figure 1), shows trial participant flow. Two women withdrew, one from the control at six month follow-up, and one from the intervention at 12 months. Neither asked for data to be withdrawn. Only women who returned a six month questionnaire were sent a 12 month completed a questionnaire, 20 women returning a copy by post; at 12 months, 69/83 (83.1%) intervention 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[33] included correction for expected birthweight for maternal height, weight, ethnicity, parity, neonatal gender and gestation at delivery (Table 1).

Mean maternal age was 32 (SD=5.2), and mean maternal booking BMI 30.51kg/m^2 (SD=5.4) (Table 1). More intervention women had a mean BMI ≥30 kg/m^2 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 3.43kgs (SD=503). Most women lived in areas of highest social deprivation[34], although a third of women had total household incomes of ≥£61k. A slightly lower proportion of white women were recruited compared with the local maternity population, with a slightly higher proportion of Black women[35]. Differences between groups at baseline were not assessed statistically[36].

Proposed primary and secondary outcomes

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

Pre-planned sub-group analysis of various secondary endpoints showed no significant differences between the intervention and control group (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 10+ 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 to 8.93, p0.013).

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 (Tables S1-S7).

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

At six months, most women (95%) reported that they had breastfed (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 (SD=3.72) weeks in the intervention and 23.4 (SD=4.78) the control. Intervention women stopped breastfeeding earlier than control (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 six months, with similar rates at 12 months. Most control women accessed support five to six 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%, Table S12).

Of 46/98 (47%) intervention women who attended at least one Slimming World®(Alfreton, UK) session, most accessed the support after 10 weeks postnatal and mean number of sessions attended was 6.74 (SD=3.94). Most women continued with the same group 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 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.

Discussion

Main findings

It was possible to recruit and retain women with BMIs≥25kg/m^2 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 six months, and recruited 193 women over eight 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 six months, which our PPI group agreed with. . The difference in weight was slightly greater at 12 months than at six months among intervention women. If real, this may be because some women had not yet received the full intervention at six 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 two year period than those randomised to a 12 week programme or received brief advice and self-help materials.[37]

Secondary outcomes showed minimal differences. Those which were found (e.g., higher EPDS scores at six months among intervention women) are important to consider further in future research given evidence of physical and psychological co-morbidity in this population[38]. 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 10+ Slimming World®(Alfreton, UK) 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 and low-income areas[39], 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. Intervention group women could access sessions at a venue, day and time to suit needs and lifestyles, an issue our PPI group considered of high importance to support women who had recently given birth. The programme is standardised and evidence-based[18] and suitable for new mothers, including those who were 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 findings are only relevant to women with BMIs >25kg/m^2. That some measures had not been validated in a postnatal population means 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[7,8]. 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 due to statistical heterogeneity[39].

As women with higher BMIs experience a range of persistent co-morbidity, such as diabetes and hypertensive disorders[40,41], 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 these women will remain 'under the radar', with implications for life-course health. UK guidance[15] is that women should not be weighed routinely. Even contacting women directly did not identify a large number who met IoM criteria for EGWG 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[35] (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 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 was 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.

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Disclosure of interests

Amanda Avery, alongside her academic position at the University of Nottingham, also holds a consultancy position at Slimming World (Slimming World® (Alfreton, UK)). 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.

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, BO edited the manuscript, 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 2nd September 2016 (reference number 16/LO/1422) and HRA approval was received on 11th October 2016.

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Supporting information

Tables S1 to S12 present data on outcome measures of maternal health, lifestyle behaviours,quality of life and trial completion to 12 months.

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Table 1. Baseline characteristics on all women randomised.

* EGWG : Excessive gestational weight gain, IoM 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^2)	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)
$<10^{th}$ centile	14/90 (15.6%)	7/89 (7.9%)

<3rd 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)
Baseline (n)	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 (n)	82	72	
Weight (kg)	83.24 (17.68)	81.88 (12.60)	
Adjusted treatment effects			
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)