Lifestyle information and access to a commercial weight management group to promote maternal postnatal weight management and positive lifestyle behaviour: the SWAN feasibility RCT

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Scientific summary

SWAN feasibility RCT

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Scientific summary

Background

In the UK around half of all pregnant women have a body mass index score in the overweight or obese category ($\geq$ 25 kg/m^2) at their antenatal 'booking' appointment, and concerns are increasing about women with a normal body mass index score (18.0–24.9 kg/m^2) at antenatal booking who develop excessive gestational weight. At 6–8 weeks postnatally, two-thirds of women weigh more than their pre-pregnancy weight. Failure to manage postnatal weight is linked to poor health behaviours including smoking, non-healthy dietary choices, lack of regular exercise and not breastfeeding. Women who start their next pregnancy with a higher body mass index score increase their own and their infant's risk of adverse outcomes. Failure to lose weight within 6 months postnatally is an important predictor of longer-term health, increasing risk of hypertension, diabetes and degenerative joint disease. More women living in areas of higher social deprivation have postnatal weight management problems.

The complexity of supporting individuals with higher body mass index scores is challenging. There is a need for postnatal weight management interventions in UK settings but a lack of evidence about what these should include and when it is best to commence them. There is evidence from general population studies that commercial weight management groups may be of more benefit than NHS providers.

In this feasibility trial we investigated if attendance at a commercial weight management group could potentially support women with a body mass index score of $\geq$ 25kg/m^2 at antenatal booking, and women with normal body mass index scores at antenatal booking who gained excessive pregnancy weight, with postnatal weight management and positive lifestyle behaviour.

Objectives

The primary objective was to assess the feasibility of conducting a definitive randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of lifestyle information and access to a commercial weight management group (Slimming World®, Alfreton, UK) for 12 weeks to support women in an ethnically diverse inner-city population to achieve and maintain postnatal weight management and positive lifestyle behaviour. Specific objectives included:

1. assess recruitment/time to recruitment and retention
2. estimate the impact of lifestyle information and postnatal access to a commercial weight management group on maternal weight change from antenatal booking to 12 months postnatally
3. explore the influence of lifestyle information and postnatal access to weight management sessions on secondary outcomes at 6 and 12 months postnatally, including weight management, diet, physical activity, breastfeeding, smoking cessation, alcohol consumption, physical and mental health, infant health, sleep patterns, body image, self-esteem and health-related quality of life
4. assess the acceptability of intervention and trial procedures
5. assess resource impacts across different agencies likely to be of relevance and identify data appropriate for economic evaluation in a definitive randomised controlled trial based on assessment of the quality and completeness of economic data generated, preliminary within-trial data, cost–utility analysis and review of evidence
6. decide if criteria to inform progression to a definitive randomised controlled trial were met.

Design

The design was a randomised two-arm feasibility trial with a nested mixed-methods process evaluation in line with Medical Research Council guidance for complex interventions.

Setting

The setting was an inner-city NHS trust in the south of England.

Participants

- Women with an overweight (25.0–29.9 kg/m^2) or obese ($\geq$ 30 kg/m^2) body mass index score at antenatal booking.
- Women with a normal body mass index score (18.0–24.9 kg/m^2) at antenatal booking who had excessive gestational weight gain at 36 weeks.

Exclusion criteria

- Women aged < 18 years.
- Insufficient understanding of spoken and written English.
- Current diagnosis of major psychiatric disorder.
- Fetus had a known abnormality.
- Involvement in another postnatal study (to reduce 'burden' of research participation).
- Identified medical complications (e.g. type 1 diabetes).
- Identified eating disorders.
- Previous surgery for weight management.

Intervention

Women were allocated to standard care only (comprising NHS maternity care prior to discharge at 6–8 weeks postnatally) or standard care plus information on positive lifestyle behaviour from late pregnancy and access to commercial weight management sessions for 12 weeks, commencing from 8–16 weeks postnatally, which focused on individualised motivation and support to achieve dietary change.

Randomisation

Participants were randomised to an arm (allocation ratio 1 : 1) using a secure web-based central randomisation service.

Proposed future primary outcome

The trial was not powered to detect statistically significant differences in outcomes as the aim was to assess feasibility. The primary feasibility outcome was difference between trial arms in weight 12 months postnatally, expressed as percentage weight change and weight loss from antenatal booking weight.

Other outcomes included those most appropriate to inform progress to a definitive randomised controlled trial. At baseline (36 weeks' gestation) and 6 and 12 months postnatally, data were collected on:

- dietary and soft-drink intake – using the Dietary Instrument for Nutritional Education (University of Oxford, Oxford, UK) – questions developed for the trial
- physical activity – using the International Physical Activity Short-Form
- mental health – using the Edinburgh Postnatal Depression Scale (not included in baseline questionnaire)
- breastfeeding intent, uptake and duration – using questions developed for the trial
- sleep patterns – using questions developed for the trial (not included in baseline questionnaire)
- smoking – smoking status/cigarette dependence
- alcohol consumption – using the Alcohol Use Disorders Identification Test
- self-esteem – using the Rosenberg Self-Esteem Scale
- infant health – using questions developed for the trial (not included in baseline questionnaire)
- impact on body image
- resource utilisation and costs outcome measures – using the EuroQol-5 Dimensions, five-level version, and the Adult Service Use Schedule.

Trial process evaluation objectives

- Acceptability of the intervention and how it was experienced by women.
- Probable variation in groups attended by women.
- Timing and sources of additional weight management support.
- Acceptability of trial processes and procedures, including risk of contamination.

Data collection schedule

Data on women's antenatal booking body mass index score and relevant sociodemographic and obstetric data were obtained from maternity records. The baseline questionnaire was completed at women's 36 week recruitment appointment and they were weighed by research midwives. Following the birth, data were obtained from maternity records on birth, neonatal outcomes and inpatient duration. At 6 and 12 months, women completed questionnaires that included the same measures as the baseline questionnaire with the addition of questions on infant health, body image and weight management support interventions. Women were weighed at a face-to-face appointment with a research midwife or, if returning their questionnaire by post, documented their weight. On completion of weight management sessions offered, interviews were held with a purposive sample of women allocated to the intervention arm. At 12 months, interviews were held with women purposively selected from both trial arms. For women allocated to the intervention arm, data on the number and timing of weight management sessions attended were obtained from Slimming World.

Sample size and analysis

The proposed sample size was 190 women, allowing a 30% loss to follow-up to ensure that the required sample size of 130 women was achieved. This trial was designed to establish rates at which women could be recruited and retained in a future definitive randomised controlled trial and estimate critical parameters to inform sample size requirements, including estimates of the standard deviation and design effect for the primary end point, allowing for clustering by intervention arm. A total of 130 women would allow estimates of the required sample size for any given clinically important difference to within 30% of the true value. A detailed statistical analysis plan was developed and approved by the Trial Steering Committee prior to trial data analysis. For primary analysis, participants were analysed in the arms into which they were randomly 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 randomised treatment. Qualitative data from women's interviews were analysed using the framework method for thematic analysis and underpinned by the capability, opportunity, motivation and behaviour framework for understanding behavioural change. Quantitative data on acceptability of the intervention and other aspects of feasibility were analysed descriptively and integrated with qualitative data, following 'threads' backwards and forwards from quantitative findings to the qualitative/mixed-methods process findings (and vice versa) to identify aspects that were corroborated or in conflict or where one source was 'silent'.

Analysis of economic data was undertaken to assess if the data collection tools employed were appropriate to evaluate intervention clinical effectiveness and cost-effectiveness in a definitive trial. A preliminary within-trial incremental cost–utility analysis was conducted of the intervention from an NHS/Personal Social Services perspective, inclusive of intervention costs, service contacts and quality-adjusted life-years measured over 12 months postnatally. As longer-term benefits and resource impacts would not be directly measurable over the period of a definitive trial, a rapid evidence review assessed if the wider evidence base would support economic modelling of impacts in a future trial.

Results

Most objectives were achieved. With respect to objective 1, 193 women were recruited, with 98 women allocated to the intervention and 95 women allocated to the control. There was good representation of women from different ethnic groups. Most women lived in areas of high social deprivation, although one-third of women reported household incomes of $\geq$ £60,000. Despite revising recruitment approaches, only four women with a normal body mass index score at antenatal booking who developed excessive gestational weight gain were recruited.

A total of 140 women completed follow-up at 12 months (69 allocated to intervention and 71 allocated to control), with high follow-up rates (> 80%) at 6 and 12 months in both arms. Interviews were held with 13 women on completion of the intervention offer and with 17 women (8 allocated to control and 9 allocated to intervention) at 12 months postnatally.

With respect to objective 2, there was a modest benefit in weight change at 12 months postnatally among women in the intervention arm compared with women in the control arm ($p = 0.062$). Assessment of secondary outcomes to meet objective 3 showed minimal differences between trial arms other than that women in the intervention arm were more likely to have an Edinburgh Postnatal Depression Scale score of $\geq$ 12 at 6 months, indicating a higher risk of depression, and less likely to report consumption of alcohol.

Lack of findings regarding dietary intake and physical activity may be explained in the context of the process evaluation (objective 4), which highlighted the complex relationship between the intervention and outcomes of interest. Few women allocated to the intervention arm could recall the content of the lifestyle information leaflet. Forty-six women (47%) attended at least one weight management session, most commencing when their infant was aged $\geq$ 10 weeks. Key barriers to not attending any sessions included 'opportunity' factors including difficulty organising child care, timing of sessions and family illness. Based on per-protocol analysis, women who attended $\geq$ 10 sessions (19/46; 41%) had greater weight loss at 12 months postnatally than women who attended nine or fewer sessions, did not attend any sessions or were allocated to the control arm (95% CI 1.05 to 8.93; $p = 0.013$).

Qualitative analyses highlighted important issues that influenced how women experienced the intervention. Those who attended $\geq$ 10 sessions found the Slimming World programme easy to follow and compatible with their postnatal lifestyle. Women who attended fewer sessions were more likely to report that weight management was not a priority or insufficient emphasis on exercise. Some did not

like the commercial nature of Slimming World. There was evidence of a dose–response relationship whereby the more weight management sessions women attended, the more women could adapt the programme to their daily lives.

Around one-third of women in both trial arms accessed additional support for weight management, most joining a gym. Among women allocated to the control arm, most accessed support 5–6 months postnatally. There was low risk of contamination, with only four women from the control arm joining Slimming World independently. From 12-month interviews it was apparent that most women understood the trial aims and what being randomised meant and considered recruitment approaches straightforward. Some women would have liked more information about trial processes; for example, women allocated to the intervention arm would have liked more information on Slimming World. Women generally found questionnaires easy to complete and enjoyed longer-term contact with research midwives. Most included measures of lifestyle behaviour had high completion rates at each follow-up point.

Analysis of data to meet objective 5 broadly supported use of the data collection tools used in the trial as a basis for evaluating intervention clinical effectiveness and cost-effectiveness in a definitive trial. Self-reported data pertinent to costing community contacts, accident and emergency contacts and outpatient contacts were broadly complete, as were maternity data for costing labour and birth and EuroQol-5 Dimensions, five-level version, questionnaire data for estimating quality-adjusted life-year outcomes. Missing information for costing inpatient admissions, although not extensive, was more prevalent. Unit cost data suitable for costing service utilisation were universally available across all relevant items included.

Despite high levels of complete data for most individual cost items, aggregation of costs for service contacts meant total costs, paired data on total costs and EuroQol-5 Dimensions, five-level version, utility scores were missing for 33% of cases followed over 12 months and therefore ineligible for inclusion in cost-effectiveness analysis ($N = 140$). Loss of economic data was successfully mitigated through multiple imputation methods.

Analysis highlighted the wide range of services used during the 12 months after birth. Women allocated to the intervention arm had higher mean total costs over 12 months and marginally better quality-adjusted life-year outcomes. Differences in total cost were largely explained by higher admission costs for infants in the intervention arm during the first 6 months post birth. Slightly more women allocated to the intervention arm attended accident and emergency departments 6 and 12 months postnatally and more women allocated to the control arm attended outpatient services at both follow-up points.

A rapid evidence review suggested that modelling of out-of-trial clinical benefits and resource impacts linked to clinically significant short-term weight loss observed in the context of a future definitive trial is feasible but that estimation of impacts where evidence is currently strongest should be prioritised.

Criteria to proceed to a definitive trial were met (objective 6). It was feasible to recruit and retain women with higher body mass index scores at antenatal booking to a trial of a commercial weight management group plus standard care compared with standard care only after birth. Approaches to recruit women with a normal body mass index score who develop excessive gestational weight gain and to optimise the benefit of the intervention need to be considered further.

Conclusion

Attendance at a commercial weight management group could support women's weight management as assessed at 12 months postnatally compared with standard care only, with potentially greater benefit from attending ≥ 10 sessions. Findings support a primary outcome based on comparison of antenatal booking weight and weight at 12 months postnatally. The potential to inform positive lifestyle behaviour

was less clear, probably owing to lack of power and small sample size, but could reflect positive lifestyle behaviour in the local population. Offering women a lifestyle information leaflet was not appropriate to convey and/or embed important public health messages. Integration of quantitative and qualitative findings highlighted several key findings to optimise the potency of the Slimming World offer in a future trial, including more information about the intervention, a wider commencement and a longer intervention period. To consider longer-term impacts on NHS costs in a future trial, economic modelling could be of benefit.

A larger trial of clinical effectiveness and cost-effectiveness is an important next step, given the implications for women's future health, including outcomes of any subsequent pregnancies and impacts on NHS resources.

Trial registration

This trial is registered as ISRCTN39186148.

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