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Feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme in primary care

Daley, Amanda; Jolly, Kate; Ives, Natalie; Jebb, Susan A; Tearne, Sarah; Greenfield, Sheila; Yardley, L; Little, P; Tyldesley-Marshall, Natalie; Bensoussane, Hannah; Pritchett, Ruth; Frew, Emma; Parretti, Helen

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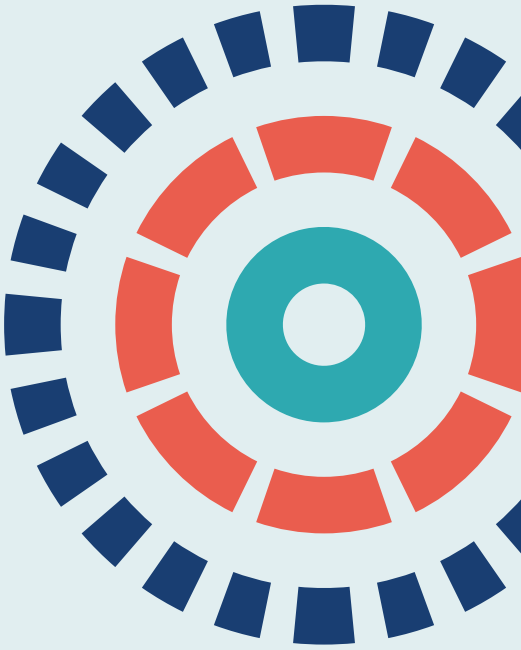

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Practice nurse-supported weight self-management delivered within the national child immunisation programme for postnatal women: a feasibility cluster RCT

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This report

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Abstract

Practice nurse-supported weight self-management delivered within the national child immunisation programme for postnatal women: a feasibility cluster RCT

Amanda J Daley[1*] Kate Jolly[2] Natalie Ives[3] Susan A Jebb[4] Sarah Tearne[3] Sheila M Greenfield[2] Lucy Yardley[5,6] Paul Little[7] Natalie Tyldesley-Marshall[2] Hannah Bensoussane[3] Ruth V Pritchett[2] Emma Frew[2] and Helen M Parretti[2,8]

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Background: Pregnancy is a high-risk time for excessive weight gain. The rising prevalence of obesity in women, combined with excess weight gain during pregnancy, means that there are more women with obesity in the postnatal period. This can have adverse health consequences for women in later life and increases the health risks during subsequent pregnancies.

Objective: The primary aim was to produce evidence of whether or not a Phase III trial of a brief weight management intervention, in which postnatal women are encouraged by practice nurses as part of the national child immunisation programme to self-monitor their weight and use an online weight management programme, is feasible and acceptable.

Design: The research involved a cluster randomised controlled feasibility trial and two semistructured interview studies with intervention participants and practice nurses who delivered the intervention. Trial data were collected at baseline and 3 months later. The interview studies took place after trial follow-up.

Setting: The trial took place in Birmingham, UK.

Participants: Twenty-eight postnatal women who were overweight/obese were recruited via Birmingham Women's Hospital or general practices. Nine intervention participants and seven nurses were interviewed.

Interventions: The intervention was delivered in the context of the national child immunisation programme. The intervention group were offered brief support that encouraged self-management of weight when they attended their practice to have their child immunised at 2, 3 and 4 months of age. The intervention involved the provision of motivation and support by nurses to encourage participants to make healthier lifestyle choices through self-monitoring of weight and signposting to an online

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weight management programme. The role of the nurse was to provide regular external accountability for weight loss. Women were asked to weigh themselves weekly and record this on a record card in their child's health record ('red book') or using the online programme. The behavioural goal was for women to lose 0.5–1 kg per week. The usual-care group received a healthy lifestyle leaflet.

Main outcome measures: The primary outcome was the feasibility of a Phase III trial to test the effectiveness of the intervention, as assessed against three traffic-light stop–go criteria (recruitment, adherence to regular self-weighing and registration with an online weight management programme).

Results: The traffic-light criteria results were red for recruitment (28/80, 35% of target), amber for registration with the online weight loss programme (9/16, 56%) and green for adherence to weekly self-weighing (10/16, 63%). Nurses delivered the intervention with high fidelity. In the qualitative studies, participants indicated that the intervention was acceptable to them and they welcomed receiving support to lose weight at their child immunisation appointments. Although nurses raised some caveats to implementation, they felt that the intervention was easy to deliver and that it would motivate postnatal women to lose weight.

Limitations: Fewer participants were recruited than planned.

Conclusions: Although women and practice nurses responded well to the intervention and adherence to self-weighing was high, recruitment was challenging and there is scope to improve engagement with the intervention.

Future work: Future research should focus on investigating other methods of recruitment and, thereafter, testing the effectiveness of the intervention.

Trial registration: Current Controlled Trials ISRCTN12209332.

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List of supplementary material

Report Supplementary Material 1 Nurses training manual

Report Supplementary Material 2 Participants coding book

Report Supplementary Material 3 Nurses coding book

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/hta25490).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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List of abbreviations

AE	adverse event
BCTU	Birmingham Clinical Trials Unit
BISS	Body Image States Scale
BMI	body mass index
BWH	Birmingham Women's Hospital
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
COREQ	Consolidated Criteria for Reporting Qualitative Research
CRF	clinical report form
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
HRA	Health Research Authority
ICECAP-A	ICEpop CAPability measure for adults
IMD	Index of Multiple Deprivation
IQR	interquartile range
MET	metabolic equivalent of task
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
POWeR	Positive Online Weight Reduction
PPAQ	Pregnancy Physical Activity Questionnaire
PPI	patient and public involvement
PRIME	Public and Researchers Involvement in Maternity and Early Pregnancy
RCT	randomised controlled trial
SAE	serious adverse event
SD	standard deviation
TFEQ	Three-Factor Eating Questionnaire
TSC	Trial Steering Committee
UoB	University of Birmingham
USB	Universal Serial Bus
WCSS	Weight Control Strategies Scale

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Plain English summary

After giving birth, many women find it hard to lose the weight that they gained during pregnancy. Research so far has focused on testing intensive weight loss programmes that cannot be given to all women who give birth because it would be too expensive. Instead, we tested a brief intervention delivered by practice nurses to mothers when they attended their practice to have their child immunised. We completed a study to test how well our recruitment methods worked, how well the intervention could be delivered by nurses during immunisation appointments and whether or not women followed the intervention. Women who were overweight/obese and had given birth at least 4 weeks previously were invited to participate. Women interested in participating were visited at home at the start and end of the study to measure their weight and to collect information about them. Participants were allocated to the intervention group or to a comparison group based on which practice they attended. For the intervention group, nurses encouraged women to monitor their weight weekly and record this on a record card in their child's health record (the 'red book') when they attended the practice to have their child immunised when their child was 2, 3 and 4 months old. Women were encouraged to use an online weight loss programme to help them lose weight and were advised to aim to lose 0.5–1 kg per week. Those in the comparison group were given a healthy living leaflet. Women and nurses were interviewed about their experiences of the study. Recruiting women to the study was difficult; however, women who did participate mostly followed the intervention well and weighed themselves weekly. Nurses liked the intervention; they felt that it could be incorporated into immunisation appointments and suggested some ideas for improvement. The study appeared feasible and acceptable, but better ways of recruiting women are needed.

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Scientific summary

Background

After childbirth, most women do not lose the extra weight that they gained during pregnancy. This is important because postnatal weight retention contributes to the development of obesity in later life and increases the risk of complications in any future pregnancy. Research shows that, regardless of age or ethnic background, postnatal women who are overweight would prefer to weigh less, are interested in implementing weight loss strategies and would like support to help them achieve this outcome because little support is offered by the NHS. Weight management interventions may not only help women to lose any weight gained during pregnancy but also have the potential to stimulate changes that create a healthier environment for the whole family. In the absence of evidence to support the benefit of weight management interventions during pregnancy, postnatal interventions are increasingly important.

A systematic review of systematic reviews by the study authors evaluated the effectiveness of weight management interventions in postnatal women. This reported that women who were randomised to a lifestyle intervention had significantly lower body weight than comparators at last follow-up (mean difference −1.7 kg, 95% confidence interval −2.3 to −1.1 kg). However, many of the interventions that were tested were very intensive and tailored lifestyle-based programmes that were often delivered by skilled health professionals, such as psychologists and dieticians. Despite evidence suggesting that some of these interventions are effective, these intensive interventions require substantial resources to be scaled up. More specifically, resource-intensive interventions cannot be delivered to all 820,000 women who give birth annually in the UK, 520,500 of whom will be overweight at the start of pregnancy. The acceptability of some of the interventions evaluated in the review was low, with high drop-out rates and/or poor levels of engagement. Most trials had small sample sizes with short follow-up. Therefore, high-quality trials are required that test more acceptable, low-cost yet effective weight management interventions that are designed to be suitable for all postnatal women who wish to lose weight after having a baby.

One solution that avoids the need for intensive resources to deliver postnatal behavioural weight management interventions is the provision of brief interventions embedded in existing health-care consultations, consistent with the ambition of the NHS to 'Make Every Contact Count'. Current evidence suggests that brief interventions and/or interventions that encourage self-regulation for the treatment of overweight and obesity can be effective. However, our review did not find any randomised controlled trials that had tested a weight management intervention embedded in routine health-care appointments for postnatal women, and only one trial included in the meta-analysis was conducted in the UK.

Overall objectives

The primary objective of this study was to produce evidence of whether or not a large-scale Phase III cluster randomised controlled trial of a brief weight management intervention, in which postnatal women are encouraged by practice nurses as part of the national child immunisation programme to self-monitor their weight and use an online weight management programme, is feasible and acceptable.

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Main research questions and aims

This research had several aims and objectives:

- in postnatal women, assess the feasibility of delivering an intervention to promote self-management of weight loss, through self-monitoring of weight and signposting to an online weight management programme by practice nurses as part of the child immunisation programme
- assess recruitment to ensure that a Phase III cluster trial is feasible
- determine levels of intervention adherence
- collect data on immunisation uptake rates to ensure that there are no adverse consequences for attendance as a consequence of the intervention
- provide estimates of the variability in the primary outcome (weight) to inform the sample size for a Phase III trial
- determine the potential for intervention contamination (whether or not the usual-care group spontaneously accessed the online weight management programme).

Through semistructured interviews, additional aims were to explore the views of women and practice nurses about the intervention. For participants, the aim was to capture their views about how useful the intervention was at helping them manage their weight, determine which elements of the intervention facilitated and/or impeded its acceptability and explore which intervention components may need to be amended or improved. For nurses, the aim was to explore their views about women's perceptions of the intervention in practice, investigate their feelings about raising the topic of weight with postnatal women at child immunisation appointments and gather suggestions about how to improve the delivery and content of the intervention, including the training provided.

Design

The study involved a cluster randomised controlled feasibility trial with two nested semistructured interview studies involving intervention participants and practice nurses. The unit of randomisation was the practice, stratified by list size (small or large) and practice Index of Multiple Deprivation (low, medium or high). Women who had recently given birth and were registered at participating practices were invited to take part. Group allocation was concealed from participants until baseline data were collected. The aim was to recruit 80 women from 10–12 practices over 8 months. Ethics approval for this study was obtained from the Black Country Ethics Committee (reference number 236462). The University of Birmingham was the sponsor for this trial and management was co-ordinated by the Birmingham Clinical Trials Unit.

The primary method of recruitment was via computerised medical records at the Birmingham Women's Hospital. This approach allowed for systematic identification of all postnatal women who had recently given birth, which reduced the potential for recruitment and selection bias. Every 2 weeks during the recruitment period, Birmingham Women's Hospital conducted searches of potentially eligible women and sent the trial invitation letter and participant information sheet to these women, asking them to contact the study researchers if they were interested in the trial. Women did not receive their letter of invitation until at least 4 weeks post delivery. The hospital completed initial screening of potentially eligible women before sending study letters, and women were further screened by the research team prior to the collection of baseline data. Baseline home visits for the collection of trial data took place between 6 and 7 weeks postnatally and before the first child immunisation appointment. Follow-up home visits took place 3 months after trial entry. Home visits for the collection of trial data were conducted by a researcher.

Intervention participants were invited to take part in a semistructured interview about their views and experiences after they had completed the intervention. After all of their patients had completed

the intervention, practice nurses (or general practitioners if they delivered immunisations) were also interviewed to understand more about their experiences of delivering and implementing the intervention during child immunisation appointments in primary care. All interviews were transcribed by a commercial transcription company and thematically analysed using the framework method. Data management was facilitated using NVivo 12 Plus (QSR International, Warrington, UK).

Setting

This study took place in Birmingham, UK.

Participants

Participants were eligible for the trial if they were aged $\geq$ 18 years; had given birth at least 4 weeks previously; were registered as a patient at one of the participating practices; were planning to have their child immunised and had not yet attended the first child immunisation appointment; had a body mass index of $\geq$ 25kg/m^2 at the baseline home visit; and were able and willing to provide written informed consent. Participants were not eligible if their baby had died or had been removed from their care at birth; they were already actively involved in a weight loss programme or a weight management trial to lose weight; they were unwilling to give consent for the researchers to notify their general practitioner regarding their participation in the trial; or they had been diagnosed with a serious mental health difficulty requiring hospitalisation in the past 2 years or with anorexia and/or bulimia in the past 2 years.

Intervention

The intervention group were offered brief support that encouraged active self-management of their weight when they attended their general practice to have their child immunised. In the UK, in the child immunisation programme, children are routinely immunised at 2, 3, 4 and 12 months of age. The intervention was embedded in the first three of these routine immunisation appointments, so no additional visits by participants were required. The intervention involved the provision of motivation and support by nurses for weight management. Nurses encouraged participants to make healthier lifestyle choices through self-monitoring of their own weight and by signposting them to a previously validated weight management programme (Positive Online Weight Reduction, POWeR) to support them in making healthier lifestyle choices. Nurses were asked not to provide any lifestyle counselling; their role was only to provide encouragement and regular external accountability through weighing at each visit (i.e. so that participants were conscious that their weight was being monitored), and to signpost participants to the POWeR programme for advice and support to lose weight. Participants were asked to weigh themselves weekly and record this on a weight record card that was attached to their child's health record (the 'red book'), or to record their weight using the online POWeR programme. The intervention took place until the third immunisation appointment when the child was approximately 4 months old. Participants were advised to aim for a weight loss goal of 0.5–1 kg per week until they had achieved a body mass index of $<$ 25 kg/m^2 and were no heavier than their pre-pregnancy weight. All nurses who administered child immunisations at intervention practices were trained to deliver the intervention. Training took about 20–25 minutes to complete.

Usual care

The usual-care group received brief written information about following a healthy lifestyle and no other intervention.

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Main outcome measures

The primary aim of the study was to assess the feasibility of undertaking a full-scale Phase III cluster randomised controlled trial according to prespecified traffic-light stop–go criteria; the recruitment to target; and the adherence to weekly self-weighing and registration with the online weight loss programme (POWeR). The potential for the intervention to have an adverse impact on child immunisation rates (recorded attendance by practices) was also assessed. Outcome data that were collected included weight, percentage body fat, depression and anxiety (assessed using the Hospital Anxiety and Depression Scale), body image (assessed using the Body Image State Scale) and self-reported physical activity (assessed using the postnatal version of the Pregnancy Physical Activity Questionnaire). Demographic information was also collected at baseline. As an objective measure of adherence to regular self-weighing, the intervention group received a set of real-time weight tracking scales (BodyTrace scales: BT003; BodyTrace, Inc., Palo Alto, CA, USA) that recorded every time participants weighed themselves; these data were sent to the research team via wireless cellular data transfer. Practices provided data on the immunisation appointments attended by both groups and any missed appointments were investigated and a reason allocated. Intervention fidelity was assessed using an intervention checklist applied to audio-recordings of immunisation appointments. Nine women agreed to participate in a semistructured interview about their experiences of the trial. Six practice nurses and one general practitioner agreed to provide feedback on their experiences of delivering the intervention through participation in a semistructured interview.

Results

Fourteen practices (clusters) were recruited to participate in this study (seven randomised to the intervention and seven to usual care). A total of 368 study invitations were sent by Birmingham Women's Hospital to women registered at these practices. A total of 28 (intervention, $n = 16$; usual care, $n = 12$) participants (from a planned recruitment of 80 participants; 35% of target) consented to the trial; therefore, the recruitment target was not met (red) (95% confidence interval 25% to 45%). Registration with the POWeR website was categorised as amber, as 56% (9/16) of participants registered with the programme (95% confidence interval 32% to 81%). The stop–go criterion for adherence to weekly self-weighing was met (green), with 63% (10/16) of participants achieving this target (95% confidence interval 39% to 86%). There was one withdrawal from the study and on women were lost to follow-up. The intervention did not have an adverse effect on attendance at immunisation appointments. Nurses delivered the components of the intervention at immunisation appointments with high fidelity. Although most participants indicated that they would recommend the study to their friends and felt that regular self-weighing was useful in managing their weight, there was some evidence that this may be associated with anxiety about weight in some women.

The usual-care group participants were, on average, 7.5 kg (adjusted mean difference) heavier in weight than the intervention group participants (95% CI −13.8 to −1.3 kg) at follow-up. The within-group profile of weight over time showed that the intervention group lost weight (unadjusted mean −3.3 kg) while the usual-care group gained weight (unadjusted mean 1.9 kg).

The interview study with the intervention participants highlighted that most of the participants were keen to lose weight after childbirth and were motivated to join the trial because they wanted to lose weight. Participants felt that child immunisation consultations were an acceptable context in which to deliver weight management interventions. Regular self-weighing and recording of weight was viewed as an acceptable and sustainable strategy for weight loss. Women also liked the use of technology to support weight loss. Nurses expressed a range of views about postnatal weight loss and delivering the trial intervention. Nurses felt that mothers did not view being overweight as a concern soon after pregnancy and that mothers were focused on their baby, not their own health. Some nurses felt that the postnatal period was a vulnerable time, in which mothers should not be 'burdened' with any 'pressure' to lose weight. Some nurses were concerned about raising the topic of weight because they considered it a

sensitive topic and they did not have time to address concerns that women might have about their weight. However, nurses also commented that the trial provided a basis on which they could have these conversations and it was useful to be able to refer participants to the online programme for specialist advice/support. Overall, nurses felt that the intervention was easy to deliver, that the intervention was a good idea, that women engaged well with the components and that the intervention was likely to increase motivation for weight loss. Some nurses felt that extra time at immunisation appointments would be needed if the intervention were to be rolled out. Nurses believed that mothers appeared comfortable with being weighed by them.

Conclusions

The findings of this study demonstrated that it is possible for nurses to deliver a brief weight loss intervention to postnatal women, focused on promoting self-management of weight, during child immunisations appointments. Although women and practice nurses responded well to the intervention and adherence to self-weighing was high, the recruitment of participants was challenging. The recruited sample was small and the findings may represent motivated women. The recruitment methods used were not successful and alternative approaches need to be tested prior to a Phase III trial. There is also scope to improve participants' engagement with the intervention.

Trial registration

This trial is registered as ISRCTN12209332.

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Chapter 1 Background to the research

Prevalence of obesity and its consequences for health

In 2015, the Global Burden for Disease Obesity Collaboration estimated that almost 603.7 million people globally were living with obesity; this equates to a global prevalence of around 12%.[1] Approximately two-thirds of the adult population in England are classified as overweight or obese.[2] Sex differences in the prevalence of overweight and obesity have been reported, with more women than men affected.[3] Obesity is known to have negative effects on the physical, mental and social health of the population and their economic productivity.[4] Public Health England have reported that, between 2014 and 2015, obesity cost the NHS approximately £6.1B in treating associated health conditions. During 2017 and 2018, NHS hospitals in England admitted 711,000 patients with a health condition associated directly or indirectly with obesity; this is a 15% increase from 2016 and 2017.[5,6] Some people who are obese may also experience stigmatisation, which can have a detrimental effect on their mental health, quality of life and well-being.[7,8]

Prevalence of obesity and overweight in women of reproductive age

The main child-bearing years of women (aged 25–34 years) hold a higher risk of weight gain than any other age for women and all ages for men.[9] A pooled analysis of global body mass index (BMI) trends estimated that the average BMI for women increased by 0.59 kg/m^2 (95% credible interval 0.49 to 0.70 kg/m^2) each decade between 1975 and 2014, which equates to the global population becoming, on average, 1.5 kg heavier every 10 years.[10] It has been estimated that about 20% of women in the UK aged 25–44 years are living with obesity, and approximately 50–60% of women in this age category are overweight.[11] Evidence also suggests that women living in more deprived areas of the UK are more likely to be overweight or obese.[12,13] This prevalence of overweight and obesity among women in this age category may be explained by that fact that it coincides with women's reproductive years.

Excessive gestational weight gain

Regardless of pre-pregnancy weight status, most women gain above the recommend weight during pregnancy.[14,15] A UK-based longitudinal study found that the number of women experiencing maternal obesity at an early stage of pregnancy had increased over a 15-year period, and that this was more common among women who experienced higher levels of socioeconomic deprivation.[16] It is estimated that, on average, women gain about 14–15 kg during pregnancy and at 1 year after birth 5–9 kg is retained, with an average BMI of 29.4 kg/m^2.[2,17–20] One explanation for excess weight gain during pregnancy is the traditional ideology of 'eating for two',[21,22] which is a common explanation given by women who feel that pregnancy is a time during which they can eat what they choose without restraint. The perceived social pressures placed on women to remain slim are also relaxed during pregnancy.[23] Physical activity levels also typically decrease during pregnancy, so energy expenditure is reduced.[24]

Health effects of excessive gestational weight gain

The negative health outcomes of maternal overweight and obesity for the mother and the baby have been well documented.[25–28] Many of the health risks are inter-related and include the development of gestational diabetes, pre-eclampsia and gestational hypertension in the mother. There may also be perinatal complications for the baby, such as macrosomia, newborn hypoglycaemia, jaundice,

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shoulder dystocia, asphyxiation and stillbirth.[29–31] A systematic review of 11 cohort studies that included data from almost 1 million women reported that an increase in BMI (by one unit or more) was associated with a 56% increased risk [95% confidence interval (CI) 1.48 to 1.96 adjusted odds ratio] of gestational diabetes in the next pregnancy. The risk of gestational diabetes was further exacerbated when maternal BMI increased by more than three BMI units between pregnancies. The review also reported that a moderate increase in BMI of two units or more increased the likelihood of a caesarean section by approximately 16%.[32] Between 2011 and 2013, approximately 50% of the women who died during pregnancy in the UK had complications associated with being overweight or obese.[33] Another systematic review and meta-analysis[34] identified a 264% increase in the odds of child obesity when mothers have obesity before conception.

Postnatal weight retention

Many women report pregnancy as the critical period for the onset of excess weight, which can significantly increase the risk of later obesity and serious chronic diseases including type 2 diabetes, heart disease and cancer.[35–39] Most women will not lose all of their pregnancy-related weight gain.[17,36,40] A UK-based prospective cohort study ($n = 2559$) of postnatal women noted that, by 6 months postnatally, about 73% of women retained at least some of the weight gained during pregnancy.[41] Prospective observational studies have reported that, among women who have a healthy BMI prior to pregnancy, 30% are overweight 1 year after giving birth. Of women who are overweight prior to conception, 44% are obese by 1 year after giving birth, and 97% of women who are obese prior to pregnancy remain so 1 year postnatally. Studies have also suggested that women who gain excessive weight during pregnancy are more likely to retain or gain additional weight during the first 1–2 years following childbirth.[42] Of note, evidence has also indicated that women who lost all pregnancy weight within 6 months of giving birth, irrespective of breastfeeding status, were only 2.4 kg heavier 10 years after childbirth, whereas women who retained postnatal weight were 8.3 kg heavier at the 10-year follow-up.[43] Findings from a systematic review involving 17 studies[44] reported that postnatal weight retention was more attributable to excessive gestational weight gain than pre-pregnancy BMI. This is important because many women will have successive pregnancies and their weight retention will pose risks to their long-term health, as well as increasing the risk of adverse outcomes for the infant during each pregnancy.[20,45,46] The National Institute for Health and Care Excellence (NICE) public health guidance[47] has highlighted gaps in the evidence about acceptable and effective weight management interventions for postnatal women. Of interest here, in 2018 the Royal College of Obstetricians and Gynaecologists acknowledged that more women were conceiving when they were overweight or obese, and that women of childbearing age with a BMI of ≥ 30 kg/m^2 should receive information and advice about the risks of obesity during pregnancy and childbirth, and be supported in losing weight before conception and between pregnancies, in line with NICE guidance.[47,48] More specifically, women should be supported in losing weight in the postnatal period, and women who are overweight should be offered referral to weight management services if available.

Postnatal weight retention and mental health

There is good evidence of an association between mood/postnatal depression and postnatal weight retention.[49,50] Low mood or elevated depressive symptomatology can negatively affect the bonding relationship between the mother and her child.[51] This relationship is more pronounced in women who were obese prior to pregnancy.[52] These findings are relevant because poor bonding can have long-term consequences for the child, including delays in social, cognitive and emotional development.[53]

Parenthood often requires a shift in priorities. Qualitative evidence exploring the views of women has indicated that women may prioritise the care of their child over their own personal needs, and typically tend to be responsible for most child-care duties.[54–56] During the early postnatal period, there can be multiple demands and challenges associated with looking after a baby that have to be managed alongside

adjustments to daily routines, changes in relationships with family and friends, recovery from childbirth, and the physical and emotional effects of recent pregnancy and childbirth.[57,58] The postnatal period can also be an emotionally delicate and demanding time for new mothers, and weight retention and/or poor self-image may be factors in the development of reduced mental health.[59,60]

The postnatal period, particularly the first 6 months, is often characterised by sleep deprivation for the mother, which can consequently affect decisions about health behaviours. Evidence from systematic reviews has identified an inverse association between the amount of sleep and postnatal weight retention.[61] In addition, if women initiate poor health behaviours during the early postnatal period, there is a risk that these behaviours may become established in the mothers' new routine with their baby and the wider family.[62,63] Moreover, studies[64–66] involving a range of populations have shown that sleep deprivation is related to poor eating behaviours and weight gain. Sleep deprivation and fatigue are also likely to reduce women's ability and motivation to engage in regular physical activity.

Weight management interventions

General populations and weight management interventions

A range of lifestyle interventions have been tested to support weight loss or prevent weight gain. The testing of interventions to facilitate weight maintenance is also a growing area of research endeavour. Lifestyle behavioural interventions usually involve asking participants to make changes to their dietary habits and/or increase their physical activity levels using cognitive and behavioural strategies, such as goal-setting, restraint of eating, self-regulation, relapse prevention and finding social support. A systematic review[67] of weight loss interventions involving obese and overweight adults reported that a combination of a low-energy diet and participation in physical activity was more effective for weight loss than diet-only interventions.

Several systematic reviews have demonstrated the effectiveness of group-based commercial weight loss programmes.[68,69] The group setting of these programmes is preferred by many, as it instils group social support that can facilitate behaviour change.[70] In 2006, both NICE and the Department of Health and Social Care recommended that primary care clinicians identify people affected by overweight and obesity and offer assistance with weight management.[71,72] Despite the evidence of effectiveness and cost-effectiveness of commercial weight loss programmes, this approach is not currently offered as treatment by many Clinical Commissioning Groups.[73,74] However, NICE guidance still recommends that people living with obesity or those most at risk of developing type 2 diabetes mellitus should be referred by their general practitioner (GP) to locally available weight loss programmes.[75] Weekly attendance at these programmes may not be suitable for all patients, however, owing to the cost of attendance and the high level of commitment required to attend weekly group meetings. Furthermore, this approach might not be suitable for those who have caring responsibilities, such as postnatal women.

Postnatal weight management interventions

Research shows that, irrespective of age or ethnicity, postnatal women would prefer to weigh less, are interested in implementing strategies to lose weight and would like help to do so.[76–78] During pregnancy and soon after childbirth, women may be more open to receiving support/advice about weight management; this may, therefore, be an ideal time to encourage the development of healthy lifestyle habits.[79] Weight management interventions may not only help women to lose any weight gained during pregnancy, but also have the potential to create a healthier environment for the whole family, providing further value and benefits.[80,81] Evidence has also highlighted that women would welcome additional weight management support after having a baby, as very little support is currently offered by the NHS.[82–84]

Evidence from systematic reviews of randomised controlled trials in the postnatal period

Many studies, adopting a variety of methodological designs, have tested a range of weight loss interventions during the postnatal period.[85,86] To provide a comprehensive up-to-date quantitative

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summary of the evidence, the authors of this report (AD and HP) completed a systematic review[86] in which the specific purpose was to both descriptively and statistically (using a mega meta-analysis) summarise the findings of systematic reviews of randomised controlled trials (RCTs) that have examined the effectiveness of behavioural lifestyle interventions for weight loss in postnatal women. A mega meta-analysis can be useful because it provides a comprehensive statistical summary of all of the available evidence across eligible systematic reviews. Mega meta-analysis is also helpful when previous systematic reviews have not been able to perform meta-analysis and/or subgroup analyses because of a lack of trials.

Nine systematic reviews of RCTs were eligible for inclusion in the review and 22 unique trials from across the nine systematic reviews were eligible for inclusion in the mega meta-analysis. *Table 1* shows details of the inclusion and exclusion criteria used in the review. Women who were randomised to a lifestyle intervention had a significantly lower body weight than comparators at the last follow-up visit (mean difference −1.7 kg, 95% CI −2.3 to −1.1 kg) (*Figure 1*). The results by subgroup are shown in *Figure 2*. Of interest here, the review did not find any RCTs that tested an intervention that was embedded in routine health-care appointments for postnatal women, and the review concluded that this might be a pragmatic way to offer support to all postnatal women who wish to lose weight after giving birth.

Analysis showed that interventions that involved both diet and physical activity interventions, physical activity interventions alone and dietary interventions alone were moderately effective in reducing weight relative to comparator groups, although there was only one trial in the diet-only analysis. That said, the amount of weight loss does not need to be large to bring health benefits.[109,110] Modelling has shown that even if a small amount of weight is lost, this weight loss remains cost-effective if the weight regained occurs on a lower weight trajectory.[111] Furthermore, as the relationship between obesity and mortality is linear, even small amounts of weight loss may be clinically important.[38,112,113] Clinical guidance from NICE suggests that weight loss of approximately 2 kg can contribute towards a meaningful reduction in cardiovascular disease risk and type 2 diabetes mellitus.[109]

It is important to highlight, however, that many of the RCTs included in the systematic reviews recruited small samples of participants, many of whom were white and middle class.[114,115] Furthermore, many of the tested interventions were intensive lifestyle-based programmes, were tailored to each

TABLE 1 Inclusion and exclusion criteria for selection of systematic reviews

Selection criteria	Inclusion criteria	Exclusion criteria
Study type	• Systematic reviews that included a summary of evidence from RCTs and/or quasi-RCTs	• Systematic reviews comprising non-RCT studies (other study designs) • Not published in English • Animal studies • Economic studies
Population	• Adult postnatal women • Included breastfeeding or formula-feeding women or both • Included those with or without comorbidities (i.e. gestational diabetes) • No restriction on BMI	
Intervention	• Lifestyle (dietary, physical activity or behavioural) intervention compared with usual care or another intervention to help manage weight after childbirth • Any setting • Group-based or individual intervention	• Surgery • Medications
Main outcome	• Weight-related data at baseline and follow-up • Postnatal weight loss	

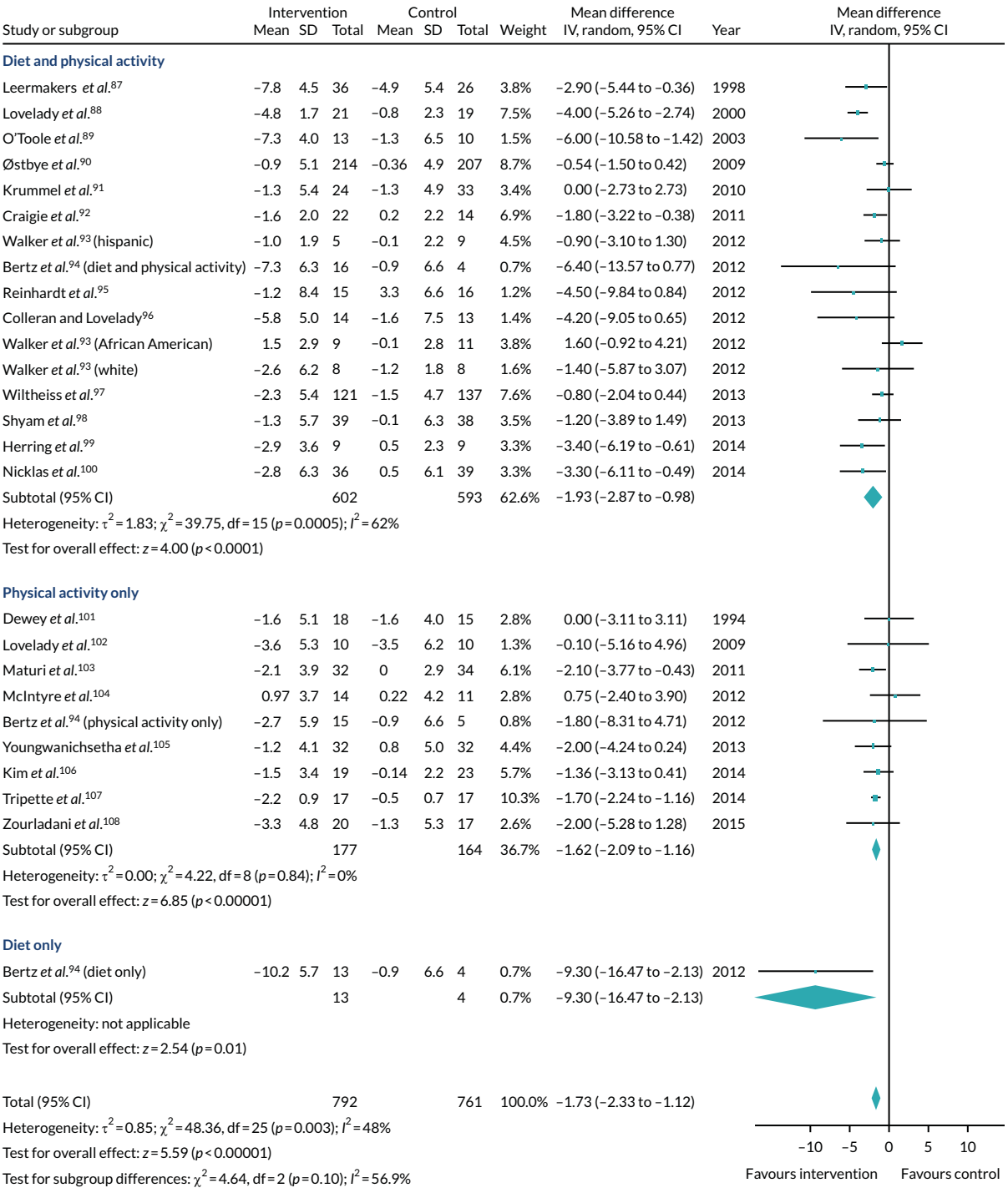

FIGURE 1 Overall mean difference in weight change (kg) and subgroup analysis (intervention type). This figure has been reproduced with permission from Ferguson JA, Daley AJ, Parretti HM. Behavioural weight management interventions for postnatal women: a systematic review of systematic reviews of randomized controlled trials. Obesity Reviews.[86] © 2019 World Obesity Federation.

individual woman and were frequently delivered by skilled health professionals, such as psychologists and dieticians.[116–118] Despite evidence suggesting that some of these interventions were effective, these intensive interventions require substantial resources to be scaled up to offer them to every postnatal woman in the UK who would benefit from them. Resource-intensive interventions cannot be delivered to all 820,000 women who give birth each year in the UK, 520,500 of whom will be overweight.[119] Furthermore, the acceptability of some of the interventions tested could be questioned given their reported high drop-out rates and/or poor levels of intervention attendance.[87,92,120] Attempts have been

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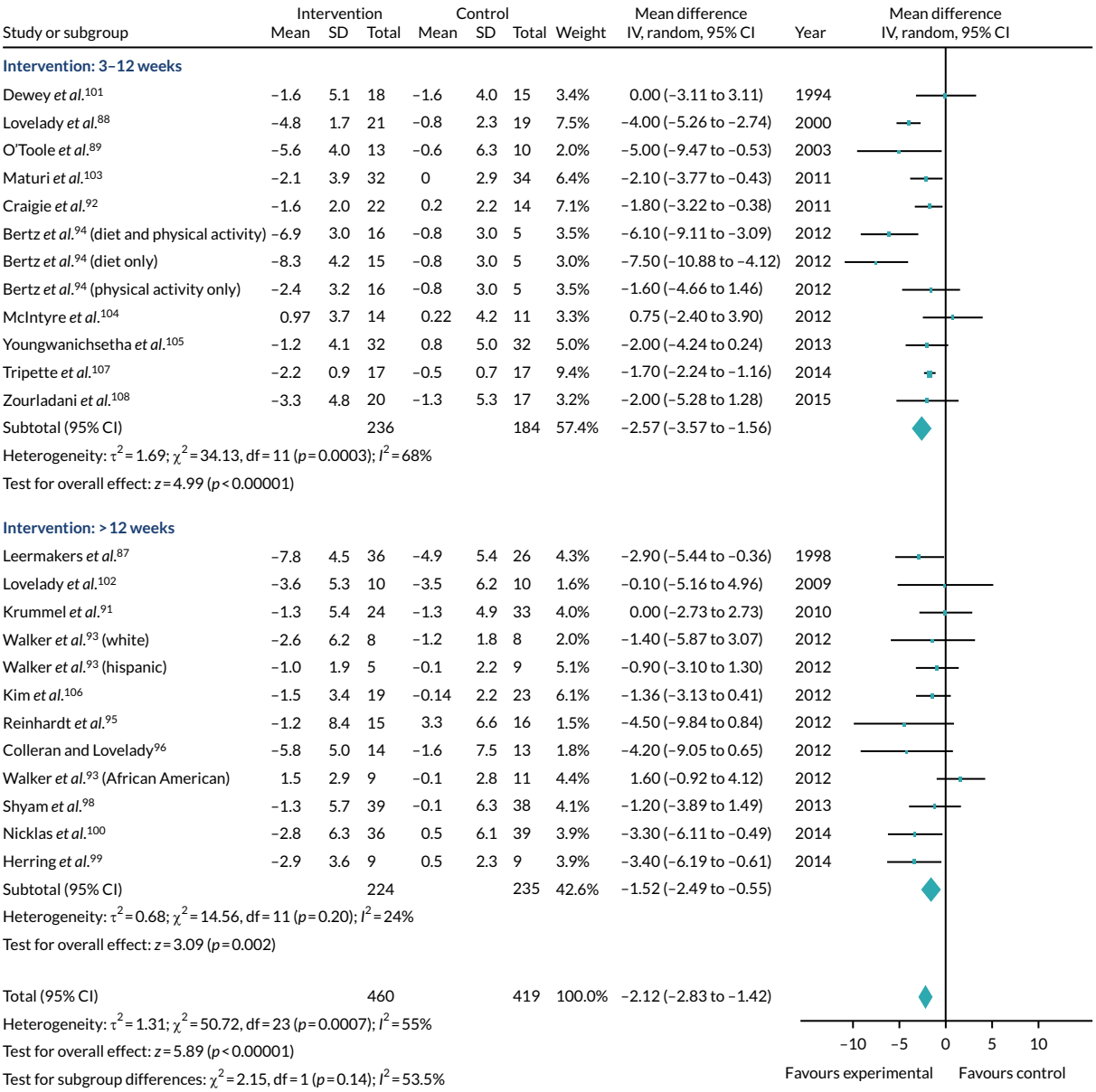

FIGURE 2 Mean difference in weight change (kg) by subgroup analysis (length of intervention). Note that this analysis was based on end-of-intervention weights recorded in the trials and two trials[90,97] were excluded (as no end of data were reported). Therefore, the figures in this forest plot differ to those shown in *Figure 1*. This figure has been reproduced with permission from Ferguson JA, Daley AJ, Parretti HM. Behavioural weight management interventions for postnatal women: a systematic review of systematic reviews of randomized controlled trials. Obesity Reviews.[86] © 2019 World Obesity Federation.

made to conduct studies that might be more appealing to a broader range of women from different ethnicities and socioeconomic backgrounds; however, they have also reported poor adherence and high drop-out rates.[121] Taken together, this evidence has highlighted the need for more high-quality RCTs that examine more acceptable and effective weight management interventions, designed to be suitable for postnatal women.[122] There is also a need for data regarding the cost-effectiveness of weight management interventions for postnatal women.

Self-management and self-regulation of weight

One solution that avoids the need for intensive resources to deliver postnatal behavioural weight management interventions is the provision of interventions that encourage self-management and self-regulation of weight. Research evidence has been inconsistent regarding the preferences of

postnatal women for different types of weight management interventions, with some reporting that women prefer to attend group-based sessions[123,124] and others reporting that home-based self-care interventions are preferred owing to issues such as time constraints, convenience and child care requirements.[92,125] Self-help interventions may, therefore, be attractive to this population of women, given that they are a low-cost, varied, flexible option that can be tailored to their specific needs. Given that many postnatal women may find it difficult to attend formal weight loss programmes and some have expressed a preference for home-based programmes, self-help interventions for postnatal weight loss are worthy of consideration.[86] In a systematic review[126] of RCTs that aimed to determine the effectiveness of self-help interventions for weight loss (self-help defined as interventions that could be delivered without person-to-person support, including formats such as smartphone, web and print), analyses showed that self-help interventions that require no human input for delivery led to a small, but significantly greater, weight loss than unsupported attempts to lose weight at 6 months compared with minimal interventions (−1.9 kg, 95% CI −2.9 to −0.8 kg). However, results were variable and the reasons for this heterogeneity were unknown. In addition, in the small number of studies providing data at 12 months weight loss was no longer significant; the effect size was comparable with that achieved at 6 months, suggesting that self-help interventions on their own may not be useful for sustaining long-term weight loss, and that additional components within weight loss interventions are required. Nonetheless, given the potential scalability and relatively low cost of this type of intervention, self-help programmes may be a useful component within a broader intervention to treat women who are overweight in primary care.

Self-monitoring of weight

Trials of self-management interventions for weight loss can inform our knowledge about which types of self-directed weight loss strategies are most effective and which may be usefully highlighted to the public and policy-makers as scalable, low-cost interventions. One such intervention that has shown promise in helping people manage their weight is regular weighing to check progress against a target: a form of self-monitoring. Self-monitoring is defined as the procedure by which individuals record their own target behaviours.[127]

The potential efficacy of regular weighing (either by the individual or by someone else) has been based on the principles of self-regulation theory.[128,129] Self-regulation has been described as a process that has three distinct stages: self-monitoring, self-evaluation and self-reinforcement. Self-monitoring is a method of systematic self-observation, periodic measurement and recording of target behaviours, with the goal of increasing self-awareness. The awareness fostered during self-monitoring is considered an essential initial step in promoting and sustaining behaviour change.

Strong evidence supports the role of self-monitoring as an effective strategy that leads to decreases in unwanted behaviours and increases in desired behaviours in many health areas, including diet and physical activity.[130] Self-monitoring is often described as a central component of behavioural treatment for weight loss,[131] which may include monitoring food intake, physical activity and other outcomes, such as weight, size and body shape.[132] Reviews by Michie *et al.*[133,134] of effective behavioural techniques for healthy eating, physical activity and reduction in alcohol consumption reported that self-monitoring was effective alone, but when combined with other techniques the effect size nearly doubled. In a systematic review of RCTs by Madigan *et al.*,[135] to examine the effectiveness of self-weighing as a strategy for weight loss, one of the included studies examined self-weighing as a single strategy and found it to be ineffective (−0.5 kg, 95% CI −1.3 to 0.3 kg); however, adding self-weighing/self-regulation techniques to programmes resulted in a significant difference of −1.7 kg (95% CI −2.6 to −0.8 kg). Multicomponent interventions, including self-weighing compared with no/minimal control, also resulted in mean differences of −3.7 kg (95% CI −4.6 to −2.9 kg).[135] With regard to postnatal women specifically, a systematic review to determine effective behaviour change techniques in physical activity interventions for this population found that effective interventions always included self-monitoring and goal-setting.[136]

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Accountability/audit and feedback for weight loss

External support for weight management has been shown to be a key factor in successful weight loss because of the feeling of accountability that it can foster.[137–139] Having to explain one's actions to another individual can change behaviour and keep individuals motivated and focused on their weight loss goals.[140,141] In practical terms, if people know that their weight is being monitored externally, they may feel more obligated to try and adhere to their weight loss goals. Bovens[142] has suggested that two concepts of accountability exist: one is a virtue and the other is a mechanism. Here the focus is on accountability as a mechanism and, therefore, consists of 'an obligation to explain and justify conduct'.[142] The concept of accountability is well versed in the areas of business and organisational change management literature, in which it has been shown to keep individuals engaged and focused on their task and ensure that goals are achieved. In recent years, the role of accountability has also been applied in the health sector, particularly in relation to weight management. For example, research has shown that couples or 'buddies' can positively influence the health behaviours of the other partner.[143–145] In the review of self-weighing and weight loss by Madigan *et al.*,[135] there was some evidence suggesting that adding accountability to a self-weighing programme improves effectiveness.

Participants in group weight loss programmes often report that it is the weekly weigh-in that is the most salient component of the programme that provides external accountability and keeps them committed to their diet and physical activity plan.[146] In practical terms, if a person knows that their weight will be monitored they are more likely to make healthy lifestyle choices and, therefore, are more motivated to stick to their weight loss goals. Related to this, Gardner *et al.*[147] have conducted a systematic review examining similar behaviour change techniques to accountability, called audit and feedback. They investigated whether or not audit and feedback changed health-care professionals' behaviour and found a significant effect (odds ratio 1.43 kg, 95% CI 1.28 to 1.61 kg). Audit and feedback are similar to accountability in that participants are aware of being observed. Based on this evidence, it can be hypothesised that adding accountability/audit to self-help and self-monitoring interventions could further facilitate weight loss.

Raising the topic of weight

Health professionals working in primary care have access to a wide proportion of the population and the ability to offer a range of important information as a trusted source of advice and support; therefore, they are well positioned to address overweight and obesity in the population, as most people are registered with a general practice. NICE Clinical Guideline 189[109] suggests that health-care providers should use their clinical judgement to decide when to opportunistically weigh patients, but few do.[148] NICE gives guidance on the appropriate weight management advice and treatment options to offer to patients who are overweight or obese; however, this tends to occur at the discretion of the health-care provider. Evidence has suggested that GPs and nurses are apprehensive about raising the topic of weight with their patients.[149] Some of the reasons given for this reluctance include a fear of causing offence, not feeling that they have the skills to raise the topic and a lack of appropriate treatment pathways.[150–153] Research has also identified that health professionals consider weight management unrewarding and are pessimistic about patients' motivation to lose weight.[153]

The provision of more weight management interventions in primary care settings may enable more people to receive treatment. Furthermore, it may also make it easier for the topic to be discussed because it 'normalises' the process of raising the topic. Having these conversations more routinely may also help to remove some of the societal stigma associated with overweight and obesity.[154,155] It is also interesting to highlight that research with GPs has suggested that, when raising the topic of weight, most patients are not offended, with such discussions being perceived as helpful by patients.[156]

The use of a brief intervention by health professionals to raise a specific health topic has been shown to be 10 times more useful for initiating a behaviour change programme than leaving the responsibility exclusively to the patient.[157] The use of brief interventions involving health-care professionals signposting patients presenting in primary care to seek weight management support shows promise of effectiveness. This trial found that a simple approach of GPs raising the topic of weight and referring obese adult patients to commercial weight management programmes during routine consultations was effective in facilitating weight loss.[156] Nevertheless, postnatal women are a unique subgroup of the population who experience many challenges and barriers that may impact their ability, willingness and motivation to regularly attend commercial weight loss programmes, for example availability of child care, cost, child-feeding routines, reduced mental health and disrupted sleeping patterns.

Technology and weight management

Various health policies have identified digital technologies as a promising vehicle for health behaviour change. NHS England's *Next Steps on the NHS Five Year Forward View*[158] strategy highlighted that better use of information and technology to help people manage and improve their own health can help meet the health need of the growing and ageing population, and reduce pressure on services.[158] The use of technology for behaviour change has also been identified as an opportunity in Public Health England's 5-year strategy.[159] Observational studies have reported that, irrespective of age or socioeconomic status, about 91% of new mothers use the internet as a source of information, with weight loss as the fourth most-searched topic.[160] Technology-based interventions offer self-regulatory features with the opportunity to promote self-awareness of health behaviours, and they can include a tracking system to enhance self-evaluation and self-reinforcement through monitoring devices.[161,162] Moreover, technology offers the potential to offer women a flexible approach to the management of their weight, providing the opportunity to access regular help and support.

Systematic reviews of eHealth or web-based interventions[163–166] for weight loss and/or maintenance in adults have found that these interventions can result in modest weight loss in overweight/obese adults. For example, a systematic review ($n = 224$ studies)[164] reported that internet/mobile telephone interventions improved diet, physical activity, obesity, tobacco use and alcohol use up to 1 year. Health professional involvement may also improve the effectiveness of digital or mHealth interventions.[165] More specifically, a systematic review[166] reported that internet-based weight management interventions for postnatal women appeared to be beneficial in reducing weight. This evidence suggests that it would be appropriate and potentially beneficial to include the assistance of technology in the development of weight management programmes for postnatal women.

Primary care settings, child immunisations and weight management

Primary care serves as a gateway into the NHS for the population, which means that the public have regular contact with health professionals in this context. As primary care operates throughout the UK, it can provide the opportunity and framework through which large-scale weight management interventions can be delivered, with the added potential of being able to access hard-to-reach populations, thereby reducing health inequalities. Public Health England recommends that all children under the age of 5 years in the UK receive a schedule of routine immunisations that include measles, mumps, rubella, polio, tetanus, diphtheria, pertussis, *Haemophilus influenzae* type b, meningococcal groups B and C, hepatitis B, rotavirus gastroenteritis and pneumococcal disease (13 serotypes).[167] These immunisations are provided by general practices and are usually administered by practice nurses.

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During their first year, babies receive immunisations when they are 8, 12 and 16 weeks old, as well as at 1 year. In 2019, 92.1% of children had completed the primary course of immunisations by their first birthday.[167] Each child is provided with a personal child health record book, or 'red book' at birth, in which health-related information, including immunisations, is recorded. Parents are asked to bring this red book with them to each child immunisation appointment so that delivery of the immunisation can be recorded. Given that the vast majority of postnatal women will have regular contact with primary care services to have their child immunised, these types of contacts provide an opportunity to reach all postnatal women to offer weight management interventions. This also aligns well with the ambition of the NHS to 'Make Every Contact Count': to deliver health behaviour change interventions to the population during routine health-care consultations.

Trial rationale

Given the consequences of obesity, the large numbers of women having babies each year who retain weight gained during pregnancy and the NHS resource implications of later health-care needs, there is a need to evaluate pragmatic, low-cost interventions that could facilitate postnatal weight loss at a population level. Moreover, NICE has highlighted the low quality of previous research as a limitation to developing clinical guidance in this area.[47,168] There is a need to intervene routinely and early in the postnatal period, to help women to manage their excess weight after having a baby and to minimise the long-term physical and mental health risks. This may also have additional benefits by reducing weight at the start of subsequent pregnancies. Interventions to promote a healthy diet and physical activity may also raise awareness of the importance of healthy lifestyle habits that will also be of benefit to the baby. Developing and testing postnatal interventions is also important, given that lifestyle interventions during pregnancy have had only modest success to date in preventing excessive gestational weight gain.[169,170]

The intervention proposed here will be delivered in the context of the national child immunisation programme in primary care to minimise the costs to the NHS and to avoid the need for additional contacts with health professionals at this busy time in women's lives. In the UK, infants are vaccinated four times in the first year of life as part of the child immunisation programme, which has a coverage rate of 92%.[167] We propose to embed a simple and brief intervention into this national child immunisation programme. The intervention does not require additional visits or expenses for postnatal women; thus, the sustainability of the intervention is likely to be high and income and/or ethnicity will not be barriers to participation. This approach also provides the opportunity for early intervention to reduce the possibility of women gaining further weight after childbirth. Although we expect our intervention approach to result in a smaller effect than the intensive interventions tested in previous trials, because of its widespread applicability and scalability it could have a larger population-level impact.

Aims of this study

The primary aim of this study was to produce evidence that a large-scale Phase III cluster RCT of a weight management intervention in which women engage in managing their own weight, by self-monitoring their weight and by accessing an existing online weight loss programme for support, is feasible. Should the intervention be feasible and acceptable, the ambition was to undertake a large-scale Phase III cluster RCT to assess the clinical effectiveness and cost-effectiveness of the intervention in facilitating long-term weight loss.

Objectives

The objectives of this research were to:

- assess the feasibility of delivering an intervention to promote self-management of weight loss through self-monitoring of weight and signposting to an online weight management programme by practice nurses as part of the UK child immunisation programme in women who have recently given birth
- assess recruitment to ensure that a full-scale Phase III cluster trial is feasible
- determine levels of adherence to the intervention (acceptability)
- determine the extent of participant burden in completing the trial questionnaires
- collect data on immunisation uptake rates (to check that the study does not have a detrimental effect on rates)
- determine the potential risk for intervention contamination (whether or not participants in the control group have spontaneously accessed the online programme) to assess if the main trial sample size will need to be adjusted to account for this
- provide estimates of the variability in the primary outcome (weight) to inform the sample size for the Phase III trial
- assess the impact of the intervention on breastfeeding rates and psychological health in both groups
- explore practice nurses' views about delivering the intervention and explore any variation in intervention delivery to ascertain if any adjustment to nurse training is required using semistructured interviews
- explore the acceptability of the intervention based on feedback from participants through semistructured interviews
- explore the acceptability/validity of the ICEpop CAPability measure for adults (ICECAP-A) for the cost-effectiveness analysis in the Phase III trial.

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Chapter 2 Methods

Design considerations

Before undertaking a large-scale Phase III cluster RCT to assess the clinical effectiveness and cost-effectiveness of an intervention, it is important to assess the feasibility and acceptability of such a trial. Although individually randomised trials can be less prone to selection bias and cheaper than cluster trials, a cluster design helps avoid the possibility of contamination in the comparator group. In this trial, practice nurses were trained to deliver the intervention. If an individual-randomisation design had been used, nurses could potentially use aspects of their training with participants assigned to the usual-care group. It is also possible that women registered at the same practice or living near each other (by virtue of being registered at the same practice) could potentially share information or intervention resources. Cluster randomisation helps to avoid the possibility of this contamination in usual-care participants.

Practices (clusters) were randomised to either the weight management intervention or the comparator trial group. To avoid the possibility of selection bias, which can be a concern in cluster trials, it is recommended that the randomisation of the clusters (in this case practices) occurs once the participants have been identified and recruited into the trial. In this trial, it was not possible to allocate practices to the trial groups after participants were recruited because the required number of births per practice could occur over several months, meaning that we would miss the immunisation visits in which the intervention is being delivered.

Setting

This trial took place in Birmingham, where about one-third of the population are of non-white ethnicity (compared with 13% in England). Birmingham has high levels of socioeconomic deprivation, with 40% of the population living in super output areas in the 10% most deprived areas in England.

Ethics approval and study sponsor

Favourable ethics approval for this study was obtained from Black Country Ethics Committee (reference number 236462). The University of Birmingham (UoB) was the sponsor for this trial. The day-to-day management of the trial was co-ordinated by the Birmingham Clinical Trials Unit (BCTU) at the UoB. BCTU is fully registered as a UK Clinical Research Collaboration clinical trials unit.

Trial Steering Committee

The Trial Steering Committee (TSC) met six times during the course of the study to assess its progress. The TSC included five independent members.

Patient and public involvement

As part of the Collaborations for Leadership in Applied Health Research and Care – West Midlands, a maternity Public and Researchers Involvement in Maternity and Early Pregnancy (PRIME) group was established to support and guide maternity-related research. The application proposal for this study was presented to six members of the PRIME group prior to submission and their views were

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incorporated into the application. Two members of the public, both of whom were married, mothers to three children, of white ethnicity and employed, were invited to join the study management group and attended all of the TSC meetings either in person or occasionally by teleconference. Their purpose and role were to help guide the research team and offer their experiences during both the trial and the qualitative study. Both patient and public involvement (PPI) representatives had recently given birth and were, therefore, able to offer feedback based on their very recent experiences of attending their general practice to have their child immunised. One of the representatives also had a personal interest in weight management after giving birth. All of the patient-facing trial documentation was viewed and commented on by the PPI representatives, and their feedback was incorporated into the documents. The PPI representatives were consulted regularly throughout all stages of the study, particularly regarding their views about different approaches to participant recruitment, their thoughts on the questions to be included in the interview topic guide and their views on planning for a subsequent Phase III trial. The research team found the feedback from the PPI representatives very useful; it kept the team 'grounded' and realistic in their expectations of participants. In a future trial, it would be important to invite mothers from non-white ethnic backgrounds to join the PPI group, to ensure that the views of women from a range of ethnic backgrounds are embedded in the management of the trial. The PPI representatives were reimbursed in line with the INVOLVE guidelines.

Design

A cluster randomised controlled feasibility trial design was used to assess the feasibility and acceptability of the intervention. General practice was the unit of randomisation. All women who had recently given birth and registered at participating practices were invited to take part. Group allocation was concealed from participants until baseline data were collected. To mitigate against selection bias, all women registered at general practices who gave birth at Birmingham Women's Hospital (BWH) were sent an invitation letter inviting them to take part in the study. The trial has been reported in line with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for the reporting of trials.

Eligibility criteria

A complete list of all of the inclusion and exclusion criteria is detailed in the following sections, and these were applied at various stages during the recruitment process.

Inclusion criteria

- Women aged $\geq$ 18 years.
- Women who were at least 4-weeks postnatal and who had not yet attended their first child immunisation appointment.
- Women planning to have their child immunised as part of the national immunisation programme.
- Women with a BMI of $\geq$ 25kg/m^2 at the time of recruitment at the baseline home visit.
- Women able and willing to provide written informed consent.

Exclusion criteria

- Women whose babies had died or had been removed from their care at birth.
- Women who indicated that they were already actively involved in a weight loss programme or weight management trial to lose weight.
- Women who were unwilling to give consent to notify their GP of their involvement in this study.
- Women who had been diagnosed with a serious mental health difficulty requiring hospitalisation or with anorexia and/or bulimia in the past 2 years.

Methods of recruitment

Screening via Birmingham Women's Hospital

Computerised systems at BWH allowed for systematic identification of all postnatal women who had recently given birth, regardless of socioeconomic status and ethnicity, which reduced the potential for recruitment and selection bias. Every 2 weeks, BWH conducted searches of women aged ≥ 18 years who had recently given birth and were registered at participating practices. A trial invitation letter and participant information sheet were mailed to these women from BWH asking them to contact the study researchers if they were interested in the trial. Women did not receive their letter of invitation until at least 4 weeks post delivery. BWH applied the following initial screening criteria before sending study letters of invitation to women:

- confirmed that the participant was aged ≥ 18 years
- confirmed that the participant had given birth at least 4 weeks previously
- confirmed that the participant was registered at one of the participating practices
- excluded mothers whose babies had died or had been removed from their care at birth.

The invitation letter and participant information sheet included a telephone number that potential participants could call if they were interested in the trial. Alternatively, potentially eligible participants were asked to complete a screening reply slip and return it to the research team in the post using a free-post envelope. Between September and December 2018, women who had not responded within 10 days of being sent the invitation letter and participant information sheet received a follow-up call from the research team at BWH to ask if they were interested in taking part. As the study was recruiting from practices mostly located in high-deprivation communities with ethnically diverse patient lists, it was felt that women may respond better to a telephone call in which they could talk to a researcher regarding the trial rather than by a letter alone, particularly if their literacy was low. Further screening by telephone was conducted by the research team prior to the baseline home visit. Assessment of full eligibility was completed at the baseline home visit (see *Establishing full eligibility at the baseline home visit and informed consent*).

Direct recruitment through general practices

Towards the end of the study recruitment period, recruitment via BWH was supplemented with recruitment strategies directly via practices. Posters advertising the trial were displayed in waiting rooms at participating practices. Posters were also made available for viewing on general practice waiting room television screens. Participants who heard about the trial through this route were asked to telephone the research team for further information, and the study invitation letter and participant information sheet were mailed to interested women, if women had not already received one. If women were still interested after receiving the invitation/participant information sheet, they contacted the research team again, either by telephone or by returning a reply slip sent to them requesting a follow-up call. During this second telephone call, initial eligibility screening checks were completed. If all initial screening eligibility criteria were met, an appointment was made for a researcher to visit potentially eligible participants at home to fully confirm eligibility and collect baseline data.

There was also the opportunity for participants to be informed about the trial directly from baby check clinics, from postnatal check-ups or at any other appointment with the GP or other health-care professional post delivery and prior to the 2-month immunisation appointment. Some GPs in participating practices were asked to give a letter of invitation and participant information sheet directly to participants whom they may have seen at postnatal check-up consultations and who may have been eligible. In practices that held baby clinics, a researcher attended these clinics on an ad hoc basis. In this instance, the researcher attending the baby clinics was not the first point of contact for participants, as these participants had already received at least one letter of invitation from BWH and/or a health-care professional at their practice. When this occurred, the researcher provided potential participants with the letter of invitation and participant information sheet directly, either to read at the practice or to take home. If, after having

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read these documents, women remained interested, they were screened at the practice by the researcher or telephoned at a later time to establish initial eligibility (see *Screening prior to baseline home visit*). If all of the initial screening criteria were met, an appointment was made for a researcher to visit their home to fully confirm eligibility and collect baseline data.

Screening prior to baseline home visit

Regardless of how women were notified about the trial or how they were approached, prior to the baseline home visit all potential participants were initially screened for eligibility by a researcher over the telephone, when verbal permission was requested to collect some screening information to establish eligibility. Screening by the researcher prior to the baseline home visit established the following:

- reconfirmed that the participant was aged ≥ 18 years
- reconfirmed that the participant had given birth at least 4 weeks previously
- reconfirmed that the participant was registered at one of the participating general practices
- collected self-reported data on participants' height and weight to calculate an approximate BMI
- confirmed that participants were planning to have their child immunised
- confirmed that participants had not yet attended the first child immunisation appointment
- confirmed that participants were not already actively involved in a weight loss programme or a weight management trial to lose weight
- confirmed that participants were willing to give consent to notify their GP of their participation in the trial.

An appointment was arranged for a researcher to visit the home of participants who fulfilled the initial screening criteria and who were interested in taking part in the study. The baseline visit was arranged to take place between 6 and 7 weeks postnatally, no earlier than 4 weeks and before the first immunisation visit at 2 months.

Establishing full eligibility at the baseline home visit and informed consent

Written informed consent was a two-stage process. At the baseline home visit, prior to any trial measurements being undertaken, a researcher obtained written informed consent to collect further screening data to fully confirm eligibility. If women consented to screening, the researcher measured participants' height and weight to confirm the BMI eligibility criteria. As part of the eligibility criteria, the researcher confirmed that participants had not been diagnosed with a serious mental health difficulty requiring hospitalisation or been diagnosed with anorexia and/or bulimia in the past 2 years. Participants were given the opportunity to ask questions about the trial before signing and dating the screening informed consent form. Written informed consent was obtained from participants not deemed eligible at the home visit to keep any data collected about them from the screening process.

Participants who met all of the eligibility criteria at the baseline home visit were asked if they consented to be enrolled into the main trial. The trial was explained to them again verbally, and written informed consent was obtained for enrolment. The baseline assessments were then undertaken. Participants were then notified of the trial group to which their general practice was allocated. Researchers stressed to women that participation was voluntary and that they were free to refuse to take part and could withdraw from the trial at any time.

Written informed consent was obtained for the qualitative studies with women and practice nurses/GPs after they had completed either receiving or delivering the intervention.

Randomisation

The unit of randomisation was the practice (cluster). Linked practices that shared clinical staff were considered a single practice/cluster. Linked practices that did not share staff were considered

independent practices. Practices in Birmingham and Solihull were invited to participate in the trial. The practices were randomised in a 1 : 1 ratio to the weight management intervention or to no intervention (usual care), using minimisation for practice list size (large, ≥ 6000 patients; small, < 6000 patients) and Index of Multiple Deprivation (IMD) score. The IMD was based on the postcode of the practice; the IMD score ranges from 1 to 32,844 and was divided into tertiles of high, medium and low levels of deprivation. The trials unit created a computer-generated randomisation list to allocate practices to the two trial groups. The randomisation list was held securely by the clinical trials unit. Once all of the necessary approvals were in place, practices were randomised centrally at BCTU by the trial statistician, and those practices randomised to the intervention group received the required training to deliver the intervention prior to opening for the trial. To maintain allocation concealment at the start of the study, randomisation of the first practices occurred when three practices were ready to open (except for need for trial intervention training). Thereafter, practices could be randomised sequentially.

Masking

It was not possible to mask participants or those providing the intervention to group allocation. It was also not possible to mask the outcome assessor, as the researcher needed to undertake both the baseline and the follow-up home visit to collect data. We do not believe that this would have introduced bias because the aim of this study was to assess the feasibility of undertaking a large Phase III cluster RCT, and these outcomes are not affected by knowledge of group allocation, and the data relating to the feasibility outcomes were not collected during the home visits.

Intervention

Overview summary

The intervention group were offered brief support that encouraged active self-management of weight in the postnatal period when they attended their practice to have their child immunised during the first year of life. In their first year, babies are routinely immunised at 2, 3, 4 and 12 months of age; the intervention was embedded in these routine immunisation contacts, so no additional visits by participants were required. The intervention involved nurses who encouraged participants to make healthier lifestyle choices through self-monitoring of their weight and signposting to an online weight management programme [Positive Online Weight Reduction (POWeR)] for support.[171] Nurses were asked not to provide any lifestyle counselling; their role was to only provide encouragement, provide regular external accountability (i.e. so that women were mindful that their weight was being monitored by someone else) and signpost women to the POWeR programme for weight loss information. The intervention was deliberately designed to be multicomponent because evidence suggests that such interventions lead to more favourable weight management during the postnatal period.[172]

The intervention behaviour change techniques were mapped in accordance with the CALO-RE taxonomy checklist (*Table 2*).[173] The content of the intervention has also been mapped against the Template for Intervention Description and Replication (TIDieR) checklist.[174]

Women were asked to weigh themselves weekly and record this on a weight record card that was attached to their child's health record red book, in which infant immunisations are recorded, or using the online programme. This is because nurses needed to be able to check that women were weighing themselves regularly, and the POWeR programme provides personalised information based on weight gain/loss progress. The intervention ran until the third immunisation (when the child was approximately 4 months old).

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TABLE 2 Intervention components using the CALO-RE behaviour change taxonomy[173]

Behavioural technique	Definition
Instruction on how to perform the behaviour	The practice nurse instructed participants to weigh themselves once per week. Participants were encouraged to weigh themselves on the same day and at the same time every week. The POWeR online programme also encouraged regular self-weighing, as well as giving information on how to make changes to eating and physical activity
Credible source	Participants were given an information leaflet at the start of the trial and were directed to the POWeR online programme
Social support (general)	Advice on using social support was included in the POWeR programme as were 'POWeR stories' from previous successful users of the programme
Goal-setting (behaviour)	Participants were asked to self-weigh and record their weight once per week. The POWeR online programme also allowed personalised eating and physical activity goals to be set each week
Goal-setting (outcome)	Participants were advised to aim for 0.5- to 1-kg weight loss per week, as advised by NICE for a general population
Self-monitoring of outcome(s) of behaviour	Participants were instructed to record their weight once per week on a record card that was attached to their child's red book. Participants could also record their weight weekly on the POWeR online programme
Feedback of outcome(s) of behaviour	Participants were weighed at each immunisation appointment by the practice nurse and given feedback by the nurse with their weight recorded on the record card attached to their baby's red book. The POWeR online programme also gave feedback on participant's own review of their weekly self-weight
Review behaviour goal(s)	Previously set personalised eating and physical activity goals were reviewed in the POWeR online programme
Use of follow-up prompts	Participants were directed to the POWeR online programme, which provides weekly e-mail messages to prompt participants to access the programme. Participants were also prompted to self-weigh when seen by the nurse at the child immunisation appointments

Weight loss goals

No clinical guidelines that specify rates of healthy weight loss for postnatal women are available, but for the general adult population NICE recommends 0.5–1 kg per week.[75] Participants were, therefore, advised to aim for 0.5- to 1-kg weight loss per week until they had achieved a BMI of < 25 kg/m^2 and were no heavier than their pre-pregnancy weight.

Accountability

As outlined above, practice nurses did not provide any counselling about diet/physical activity; they simply weighed participants at each child immunisation visit and recorded this weight, as a source of regular external accountability for weight monitoring. Someone who is regularly weighed is more likely to maintain weight goals when they know that their progress will be monitored by another individual.

Online weight loss programme (POWeR)

Nurses signposted women to the POWeR online weight loss programme for weight loss support and assistance with goal-setting, action planning and implementation of changes to their lifestyle (https://powerpimms.lifeguidehealth.org; accessed July 2019). Women were given their own unique username and were asked to set their own secure password. The POWeR programme is an existing programme and has been shown to result in clinically effective weight loss in overweight primary care patients when combined with brief nurse support.[171] The POWeR programme is a self-guided, online, theory- and evidence-based intervention to support weight management over 12 months, and was designed to be appropriate for people in most situations, including postnatal women. Participants choose either a low-energy eating plan (a reduction of around 600 calories per day) or a low-carbohydrate eating plan. Users are also encouraged to increase their physical activity levels by choosing either a walking plan or a self-selected mixture of other physical activities. The POWeR programme focuses principally on fostering users' self-regulation skills for autonomously self-managing

their weight, rather than providing detailed dietetic advice. Users of the programme are taught active cognitive and behavioural self-regulation techniques ('POWeR tools') to overcome problems, such as low motivation, confidence and relapse. Evidence is provided for the effectiveness of these techniques and examples given of how others have successfully used them ('POWeR stories'). The POWeR programme emphasises forming healthy eating and physical activity habits that should become non-intrusive and require little effort to sustain. Information about breastfeeding and weight loss was added to the programme for the purpose of this trial.

Participants were encouraged to continue to use the website weekly to track their weight, set and review eating and physical activity goals, and receive personalised advice. After entering their weight and whether or not they had achieved the goals they had set themselves the previous week, users received tailored feedback giving encouragement if they had maintained their weight loss (e.g. reminders of health benefits accrued) and met their goals. Weight gain and failing to meet goals triggered automated personalised advice, such as appropriate goal-setting and planning, boosting motivation, overcoming difficulties and recovering from lapses.

Training of practice nurses

All nurses who administered child immunisations at intervention practices were trained to deliver the intervention following a standard protocol. Training took about 20–25 minutes to complete, given that nurses' involvement was very simple and brief. Nurses were also trained in the research trial procedures. A training manual provided information on the importance of adhering to the protocol, information on the consequences of postnatal weight retention, instructions about how to weigh and record weight in the appropriate place in the child health red book, and tips and phrases for encouraging women to weigh themselves weekly (see *Report Supplementary Material 1*). The nurse training also addressed any concerns nurses may have had about raising the topic of weight.

Intervention fidelity

Written informed consent was obtained from participants to audio-record their immunisation/intervention consultations so that intervention fidelity against a checklist could be assessed. Only the parts of the consultation relevant to the intervention were recorded. This process was also included to allow assessment from a practical and logistical perspective on how well the intervention fitted within immunisation visits and to also inform nurse training for any subsequent main trial. This also allowed the research team to calculate how long the intervention took nurses to deliver.

Usual-care comparator group

Women allocated to the usual-care comparator group received brief written information about following a healthy lifestyle and no other intervention at the baseline home visit.

Outcome measures and trial procedures

Primary outcome

The primary aim of the trial was to assess the feasibility of undertaking a full-scale Phase III cluster RCT. This was assessed via specific questions:

- whether or not the trial was appealing to postnatal women (via assessment of the recruitment rate to ensure that a full Phase III trial is feasible)
- whether or not the intervention was acceptable (via assessment of adherence to weekly self-weighing and registration with the POWeR online weight management programme)
- whether or not the intervention had any adverse impact on infant immunisation rates (recorded attendance by practices)
- the number of women who completed the trial and completed the trial questionnaires (follow-up).

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BodyTrace weighing scales

The intervention group were given a set of real-time weight-tracking scales (BodyTrace scales, BodyTrace Inc., Palo Alto, CA, USA) as an objective process measure of adherence to weekly self-weighing (www.bodytrace.com/; accessed 12 November 2019). Each time a participant used the scales to weigh themselves, their data were sent to the research team in real time via wireless cellular data transfer. Participants who did not have wireless internet access in their homes, or did not want their weight to be transmitted to the team in real time, were given UPS ION scales (ION Health, Richmond, UK) that store 100 weight recordings on a Universal Serial Bus (USB) stick attached to the scales; with participants permission, these weight data were downloaded from the scales at the follow-up visit. The scales were delivered to participants' homes and were set up by the research team. Women were informed that their weight data would be transferred to the research team but that they would not receive feedback regarding their weight from the research team.

Other outcomes

Although this feasibility trial was not powered to detect meaningful differences in outcome measures, it provided the opportunity to ensure that there were no issues with the completion of these measures in preparation for the main trial. All measures were assessed at baseline and follow-up in both groups unless stated otherwise. Weight and body fat were assessed using a Tanita SC-240MA analyser (Tanita Europe BV, Amsterdam, The Netherlands). Depression and anxiety were assessed using the Hospital Anxiety and Depression Scale (HADS).[175] Body image was measured using the Body Image States Scale (BISS).[176] Self-reported physical activity was assessed using the postnatal version of the Pregnancy Physical Activity Questionnaire (PPAQ).[177] Weight control strategies were assessed at follow-up [Weight Control Strategies Scale (WCSS)].[178] Using the revised Three-Factor Eating Questionnaire (TFEQ), the variables of conscious cognitive energy restraint of eating, uncontrolled eating and emotional eating were measured.[179] Questions from Steinberg *et al.*'s[180] perceptions of self-weighing questionnaire were used to measure perceptions of regular monitoring in the intervention group at follow-up only.[180]

Health economics

Relative to routinely used economic quality-of-life measures, such as the EuroQol-5 Dimensions,[181] the ICECAP-A has only recently been developed.[182] We assessed the acceptability of the ICECAP-A in the feasibility trial to inform the economic evaluation design in a full trial. It was seen as an important measure to include, as the benefits of weight loss are not confined to health alone and ICECAP-A offers the potential to capture well-being benefits in an economic framework.

Adverse events and serious adverse events

The collection and reporting of adverse events (AEs) was conducted in accordance with the Research Governance Framework for Health and Social Care and the requirements of the Health Research Authority (HRA). The investigator assessed the seriousness and causality (relatedness) of all AEs experienced by trial participants, and if AEs occurred they were documented in the source data with reference to the protocol. No risks were expected to arise from taking part in the trial. The intervention was considered low risk, given that it consisted only of self-monitoring of weight, goal-setting and using an online weight loss programme, all of which have been used in other populations and settings without evidence of harm. There may be certain AEs that are commonly expected in participants undergoing a weight management programme. However, as these events are well characterised, it was highly unlikely that this trial would have revealed any new safety information relating to this intervention. Therefore, AEs were not collected. AEs related to the newborn baby were not collected either.

No serious adverse events (SAEs) were anticipated as a consequence of participation in the study, but reporting requirements were outlined in the trial protocol. Safety was assessed continuously throughout the study. The following were expected SAEs and were not reported as SAEs:

- SAEs that were related to a pre-existing condition (pre-existing conditions are medical conditions that existed before entering the trial, as we intend to monitor the safety of the intervention by capturing severe, unexpected occurrences, in relation to the intervention).
- Death as a result of a pre-existing medical condition. The protocol stipulated that all deaths should be reported to the trials office immediately on becoming aware so that no correspondence (patient questionnaires or queries, etc.) were sent to the participant or their family.

Investigators were required to only report SAEs that were attributable to the trial intervention. The above events were not considered related to the trial intervention and were, therefore, excluded from notification to the trial office as SAEs. The protocol was that these events should be recorded in the medical records in accordance with local practice.

Demographic-, lifestyle- and pregnancy-related information (both groups)

Information on age, ethnicity, pre-pregnancy weight, timing of cessation of breastfeeding, infant feeding practices and sleeping patterns of the mother were collected. Some women resume smoking and alcohol consumption after pregnancy, which might affect their weight; therefore, these behaviours were recorded. Data on whether or not participants in both groups had attended any formal weight loss programmes during their involvement in the trial were collected, as were data on any specific weight loss strategies or diets that participants might have used. Data relating to participants' mode of delivery, participants' pregnancy complications and how many children they had given birth to were collected. Data on marital status were collected to ascertain participants' general level of social support in their lives. Data on employment status and financial status were collected to provide descriptive profile data on women who agreed to participate.

Objective assessment of self-weighing (intervention group)

As an objective measure of adherence to self-weighing, the intervention group were given weighing scales (BodyTrace, www.bodytrace.com/; accessed 12 November 2019) that objectively recorded their weight every time they weighed themselves, and this information was remotely transmitted back to the research team by wireless transfer. These weighing scales were given to women at the baseline home visit by researchers. These scales were included as an objective process measure to assess adherence to frequency of self-weighing in the intervention group; we did not provide any feedback to participants, nor did we monitor fluctuations or changes in weight during the trial.

Weight record cards (intervention group)

The intervention group were asked to complete weight record cards that were collected from participants as a measure of intervention implementation at the end of the intervention. The record cards allowed us to measure how much of the intervention was delivered per protocol by practice nurses. We obtained data from the POWeR programme for participants who chose instead to record their weight on the online programme.

Use of the POWeR online programme (intervention group)

Using participants' e-mail addresses the online POWeR software automatically recorded their usage of the website (i.e. registration, number of logins, time spent on the POWeR website, progress through the POWeR programme and the number and value of weight measurements entered).

Attendance at immunisation appointments

The intervention was delivered at child immunisation appointments at 2, 3 and 4 months postnatally. Monitoring of immunisation uptake rates in the intervention group was an explicit role of the TSC. Practices were asked to provide data on all immunisations attended by both groups, and any missed

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appointments were investigated and a reason allocated. We also collected patient-reported attendance at the immunisation appointments at the follow-up visit.

Intervention fidelity via audio-recording of immunisation appointments

If consent to do so was provided, immunisation appointments were audio-recorded to gauge delivery of the intervention to protocol by practice nurses. These consultations were transcribed by a researcher (NTM) and read to assess, by use of a checklist, whether or not the nurses were delivering the intervention in accordance with their training and the protocol. The specific criteria checklist for nurses were as follows:

- weighed and recorded participants' weight on weight record card
- checked that participants had been weighing themselves on a weekly basis
- asked participants if they had accessed the POWeR website
- verbally signposted participants to the POWeR website.

Intervention contamination

The possibility of intervention contamination in the usual-care group was assessed by asking participants if they knew any other women participating in the trial and whether or not they had accessed the POWeR website.

Trial procedures

Table 3 outlines all of the assessments and outcomes measured in this trial, the time points at which they were measured and the groups that were assessed. Baseline home visits took

TABLE 3 Schedule of assessments

	Visit						
			Immunisation visits at general practice (intervention group only) (postnatally)				
Assessment	Screening: 4 weeks postnatally (no earlier than 4 weeks)	Baseline home visit: 6–7 weeks postnatally (before the first immunisation)	2 months	3 months	4 months	Follow-up home visit: 3 months post randomisation (–1 week to approximately 4 weeks)	Post follow-up
Identification of potential participants	✗						
Eligibility check	✗	✗					
Valid informed consent for screening		✗					
Height (cm)	✗	✗					
Weight (kg)	✗	✗	✗	✗	✗	✗	
Per cent body fat		✗				✗	
BMI (kg/m^2)	✗	✗					
Valid informed consent for full trial		✗					
Pregnancy and family details		✗					
Feeding of baby		✗				✗	
Sleep patterns		✗				✗	

TABLE 3 Schedule of assessments (*continued*)

Assessment	Visit						
	Screening: 4 weeks postnatally (no earlier than 4 weeks)	Baseline home visit: 6–7 weeks postnatally (before the first immunisation)	Immunisation visits at general practice (intervention group only) (postnatally)			Follow-up home visit: 3 months post randomisation (–1 week to approximately 4 weeks)	Post follow-up
			2 months	3 months	4 months		
Marital status		✗					
Employment and financial status		✗					
Smoking status		✗				✗	
Alcohol consumption		✗				✗	
HADS[175]		✗				✗	
ICECAP-A questionnaire[182]		✗				✗	
TFEQ[179]		✗				✗	
BISS[176]		✗				✗	
PPAQ[177]		✗				✗	
WCSS[178]						✗	
Immunisation record from participant						✗	
Weight loss resources used						✗	
Intervention group only: self-weighing data						✗	
Intervention group only: BodyTrace weight data						✗	
Intervention group only: POWeR programme[171] data						✗	✗
Intervention group only: trial acceptability						✗	
Immunisation records from GP							✗
Qualitative study interviews							✗

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place between 6 and 7 weeks postnatally and before the first child immunisation visit at 2 months, and took about 30–45 minutes to complete. Participants were visited at home by a researcher, where:

- Screening consent was obtained.
- Height, weight and percentage body fat were measured, and BMI was calculated.
- Eligibility (inclusion/exclusion criteria) was reviewed.
- Informed consent was obtained for eligible participants.
- The baseline health questionnaire booklet was completed/collected. The baseline questionnaire booklet was posted prior to the baseline home visit to allow the participant to complete the booklet in their own time prior to the visit.
- Participants were informed which group of the trial they were allocated to.
- The usual-care group were issued with the healthy lifestyle leaflet and advised that they would receive usual care at their child immunisation appointments.
- The intervention group were issued with the healthy lifestyles leaflet, the weight record card was attached to the red immunisation book, a trial sticker was placed on the front of the red book, and participants were given BodyTrace scales and instructed on use (issued instruction leaflet). The intervention group were provided with details instructions and individual login details for the online weight management programme.

Follow-up home visit

Follow-up visits took place 3 months after participants entered the trial and took approximately 30 minutes to complete. Participants were visited at home by a member of the research team and the following tasks were completed:

- Weight and percentage body fat measured, BMI calculated.
- Follow-up questionnaires collected. Questionnaires were posted to participants 5–7 days in advance (for collection by the researcher).
- Confirmation of attendance at immunisation appointments obtained.
- Intervention group only – willingness to participate in a semistructured interview about experiences of participating in the study; collection or photograph of the weight record card; collection of BodyTrace weighing scales.

Participant incentives

A £20 high-street shopping voucher was offered to all participants as reimbursement for any inconvenience that trial participation may have caused them. This voucher was offered at the follow-up home visit once all follow-up clinical report form (CRF) questions and health questionnaires had been completed.

Data monitoring

Given that this was a feasibility trial that was designed to test whether or not a definitive trial was feasible, a Data Monitoring and Ethics Committee was not established. Oversight of the trial was provided by the TSC.

Data management

Processes were employed to facilitate the accuracy of the data included in the final report. These processes were detailed in the trial-specific data management plan. Coding and validation were agreed between the trial manager, the statistician and the programmer, and the trial database was signed off once the implementation of these had been assured. The trial office checked incoming CRFs for compliance with the protocol, data consistency, missing data and timing. For CRFs completed by the chief investigator (or delegate) at the general practice, sites were asked for missing data or clarification of inconsistencies or discrepancies. Participant questionnaires, and patient-specific data from the baseline and follow-up CRFs, were reviewed on receipt at the trial office and inconsistent and/or missing data were queried with the participant. To ensure that participants did not feel harassed,

a single letter was sent to participants outlining the discrepancy and/or missing data and requesting this information. Occasionally, participants were telephoned to request or clarify missing or ambiguous data queries (if participants consented to be telephoned). All data were entered into the trial database by suitably trained staff. Informed consent forms, CRFs and questionnaires were stored in lockable filing cabinets in a secure, swipe access part of the UoB. Trial data were kept on password-protected electronic databases, on secure UoB servers, where access was limited to staff working on the trial only. The database had ranges applied to data items if suitable and appropriate.

Data collected through the POWeR website were electronically securely transferred from the University of Southampton to the trial office at the UoB throughout the trial. This was uploaded through the trial database.

Data security

The security of the data system was governed by the policies of the UoB. The university's Data Protection Policy and the Conditions of Use of Computing and Network Facilities set out the security arrangements under which sensitive data should be processed and stored. All studies at the UoB must be registered with the Data Protection Officer and data held in accordance with the Data Protection Act. The UoB has Data Protection Registration to cover the purposes of analysis and for the classes of data requested. The University's Data Protection Registration number is Z6195856.

Sample size

Given that this was a feasibility trial, a formal sample size calculation was not conducted. The trial was not designed or powered to detect a statistically significant difference in efficacy between the two trial groups. Sample sizes of at least 70 participants have been recommended.[183] A recruitment target of 80 women from 10–12 practices recruited over 8 months was set.

Recruitment

The recruitment rate is presented as a percentage based on the number of participants who took part in the trial divided by the target recruitment ($n = 80$). BWH provided data on the number of invitation letters sent, along with data on the age and ethnicity (in summary format) of the women who were sent an invitation letter.

Adherence/acceptability

The quantitative assessment of whether or not the intervention was acceptable to participants was based on the adherence to weekly self-weighing. The trial included three sources of data regarding the frequency of self-weighing: objective recording using the BodyTrace scales, self-reported in the child health red book and recordings using the POWeR programme. In the first instance, the objective recording of weight on the BodyTrace scales was used as the authoritative source of data to assess the frequency of self-weighing/adherence. As a secondary assessment of frequency of self-weighing and adherence, weight data from all three sources were included.

Immunisation rates

To check that the intervention had no adverse impact on infant immunisation rates, practices provided data on all immunisation appointments attended during the trial. The trial took place over the first three immunisation appointments. The proportion of babies who attended all three immunisation appointments was reported. Originally, the immunisation rate for each practice in the trial was to be compared with the normal immunisation rate for that practice. However, owing to low recruitment, the immunisation data have been presented overall by trial group and compared with national uptake rates.

Decision to progress to the Phase III trial

For the Phase III trial to take place, there needed to be evidence from this feasibility trial of meeting prespecified stop–go criteria. The trial was too small to include meaningful and sensitive stop–go criteria regarding the impact of the intervention on immunisation rates. However, we checked

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that the intervention had not adversely affected immunisation rates. The decision to proceed to the Phase III trial was, therefore, based on three criteria using a traffic-light system: (1) the recruitment rate, (2) adherence to weekly self-weighing and (3) registration with the online weight loss programme (POWeR).

In the traffic-light system, the green-light criteria were as follows:

- recruitment rate of $\geq 80\%$ of the target ($n = 80$; i.e. recruit at least 64 women)
- $\geq 50\%$ of the intervention group weigh themselves weekly $\geq 60\%$ of the time
- $\geq 60\%$ of participants registered with the online POWeR programme.

If all three criteria are met, we will proceed to an application for the full trial with the protocol unchanged (unless there is a clear message from the interviews that would improve the protocol).

The amber-light criteria were as follows:

- recruitment rate of 50–79% of the target ($n = 80$; i.e. recruit between 40 and 63 women)
- 40–49% of the intervention group weigh themselves weekly 40–59% of the time
- 40–59% of the intervention group registered with the online POWeR programme.

If one or more of our amber-light criteria are met, we will plan to adapt the protocol in the light of the feedback from the interviews and our experience to improve whichever criteria are not at the 'green-light' level before proceeding to the application for the full trial. In discussion with the TSC, we will assess whether or not adaption of the protocol will require further assessment before progressing.

The red-light criteria were as follows:

- recruitment rate of $< 50\%$ of the target ($n = 80$; i.e. recruit < 40 women)
- $< 40\%$ of the intervention group weigh themselves weekly 40–59% of the time
- $< 40\%$ of the intervention group registered with the online POWeR programme.

If one or more of these criteria are met, we would consider the current protocol not feasible and would not progress to an application for a full RCT with the current design. An additional red-light criterion would be concerns from the TSC that immunisation rates were adversely affected.

Data analysis

Analysis of outcome measures

A detailed statistical plan can be found in the *Report Supplementary Material 2*. A brief outline of these analyses is given below in relation to the proposed stop–go criteria and the outcome data collected. The stop–go criteria are based on recruitment, adherence to weekly self-weighing and registration to the POWeR programme (see above). The recruitment rate is presented as a percentage based on the number of participants who took part in the trial divided by the target recruitment ($n = 80$). The percentage of women in the intervention group who adhered to weekly self-weighing (according to the stop–go criteria) and who registered with the POWeR programme is also presented. The binomial normal approximation was used to calculate the corresponding 95% CIs.

All primary analyses of outcome data were by intention to treat. Participants were analysed in the intervention group to which they were allocated (according to the randomisation of the practice), and all participants were included whether or not they received the allocated intervention. The primary comparison groups were those in the weight management intervention group and those in the usual-care group. The analysis of outcome data focused on CI estimation. Continuous outcomes

(except the PPAQ; see below) were summarised using means and standard deviations (SDs). Adjusted mean differences between groups and the corresponding 95% CIs were estimated from generalised linear mixed models that included adjustment for baseline values (if available) and the minimisation variables (practice size and IMD), and practice (cluster) as a random effect. Data from the PPAQ are presented as medians with interquartile ranges (IQRs), and the unadjusted difference between the median in each group was reported along with the 95% CI that was calculated using bootstrapping methods. All estimates of differences between groups are presented with two-sided 95% CIs and no *p*-values are presented.

Use of the POWeR website was assessed through the number of times that participants logged on to POWeR, the number of times that participants recorded their weight on POWeR and the time spent browsing, with data presented as medians with IQRs. These data were also tabulated at each intervention week to assess usage over time. Progress through the POWeR programme is assessed by tabulating the number of stages that participants completed and the number of participants who completed each stage.

Qualitative study

Semistructured interviews with women were completed after trial follow-up to explore their views about the intervention. Practice nurses were also interviewed to understand more about their experiences of delivering the intervention during child immunisation appointments. These two interview studies are described in more detail in *Chapters 5* and *6*.

Changes to the protocol

Minor and substantial changes to the protocol and conduct of the trial are outlined in *Table 4*. One of the most important changes to note relates to the change in approach to calculating the trial recruitment rate. During the trial, we found out that BWH were sending letters to all women who had

TABLE 4 Protocol amendments

Amendment number	Date of amendment	Protocol version number	Type of amendment
1.0	***5 December 2017***	***2.0***	***Substantial***
Summary of amendment			

Substantial changes:

- Removal of the eligibility criteria screening for use of illicit drugs or alcohol dependence
- Clarification of the eligibility criteria screening for serious mental health difficulties and eating disorders
- Clarification of the recruitment process
- Clarification on the collection and analysis of the immunisation attendance data
- Clarification on safety reporting
- Addition to the instructions on the baseline questionnaire booklet front sheet
- Changes to the patient invitation letter
- Changes to the participant information sheet and GP poster
- Changes to the screening consent form, full informed consent form A and full informed consent form B
- Change to the baseline appointment letter

Non-substantial changes:

- Minor changes to the baseline and follow-up questionnaire booklets
- Minor changes to the weight card
- Change to the TSC's contact details and change to the timings of the TSC meetings
- Amended statement of activities and schedule of events
- Minor typographical corrections

continued

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TABLE 4 Protocol amendments (*continued*)

Amendment number	Date of amendment	Protocol version number	Type of amendment

Other modified documents approved	Previous version	New version
Invitation letter and reply slip	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Participant information sheet	Version 2.0 (16 November 2017)	Version 3.0 (5 December 2017)
Screening consent form	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Full informed consent form A	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Full informed consent form B	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
GP poster	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Baseline appointment letter	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Questionnaire baseline	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Questionnaire follow-up A	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Questionnaire follow-up B	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Weight card	Version 1.0 (12 October 2017)	Version 2.0 (5 December 2017)
Statement of activities (BWH)	Version 1.0	Version 2.0
Statement of activities (GPs)	Version 1.0	Version 2.0
Schedule of events (BWH)	Version 1.0	Version 2.0
Schedule of events (GPs)	Version 1.0	Version 2.0

2.0	***1 February 2018***	***4.0***	***Substantial***

Summary of amendment

Substantial changes:

- Changes to the participant information sheet, as requested by the HRA
- Changes to sections 8.6 and 16 of the protocol to reflect changes to the participant information sheet
- Changes to the full informed consent form B, participant interview consent form, nurses interview participant information sheet and nurses interview consent form

Non-substantial changes:

- Change of chief investigator title
- Addition of the International Standard Randomised Controlled Trial Number (ISRCTN) to protocol and trial documentation
- Reformatting of the trial number to incorporate site identification number
- Addition of trial number and correction to the weight record card
- Correction to one question on questionnaire follow-up B
- Amended statement of activities and schedule of events as requested by the HRA

TABLE 4 Protocol amendments (*continued*)

Amendment number	Date of amendment	Protocol version number	Type of amendment

Other modified documents approved	Previous version	New version
Participant information sheet	Version 3.0 (5 December 2017)	Version 5.0 (1 February 2018)
Invitation letter and reply slip	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Screening consent form	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Full informed consent form A	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Full informed consent form B	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
GP letter	Version 1.0 (12 October 2017)	Version 3.0 (1 February 2018)
GP poster	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Healthy lifestyle leaflet	Version 1.0 (12 October 2017)	Version 3.0 (1 February 2018)
Baseline appointment letter	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Follow-up appointment letter	Version 1.0 (12 October 2017)	Version 3.0 (1 February 2018)
Questionnaire baseline	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Questionnaire follow-up A	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Questionnaire follow-up B	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Weight record card	Version 2.0 (5 December 2017)	Version 4.0 (1 February 2018)
Nurses interview participant information sheet	Version 3.0 (22 November 2017)	Version 5.0 (1 February 2018)
Nurses interview consent form	Version 1.0 (12 October 2017)	Version 3.0 (1 February 2018)
Nurses interview schedule	Version 1.0 (12 October 2017)	Version 3.0 (1 February 2018)
Participant interview consent form	Version 1.0 (12 October 2017)	Version 3.0 (1 February 2018)
Participant interview schedule	Version 1.0 (12 October 2017)	Version 3.0 (1 February 2018)
Statement of activities (BWH)	Version 2.0	Version 3.0
Statement of activities (GPs)	Version 2.0	Version 3.0
Schedule of events (BWH)	Version 2.0	Version 3.0
Schedule of events (GPs)	Version 2.0	Version 3.0

3.0	*20 March 2018*	*5.0*	*Minor*

Summary of amendment

Non-substantial changes:

- Change to section 6.2. Clarification on the IMD score calculated for the general practice
- Change to section 13.2.1. Correction on the data collected on participants invited to participate
- Amended statement of activities and schedule of events as requested by the HRA

continued

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TABLE 4 Protocol amendments (*continued*)

Amendment number	Date of amendment	Protocol version number	Type of amendment

Other modified documents approved	Previous version	New version
Statement of activities (BWH)	Version 3.0	Version 4.0
Statement of activities (BWH)	Version 4.0	Version 5.0
Statement of activities (GPs)	Version 3.0	Version 4.0
Schedule of events (BWH)	Version 3.0	Version 4.0
Schedule of events (GPs)	Version 3.0	Version 4.0

4.0	***10 May 2018***	***6.0***	***Substantial***

Summary of amendment

Substantial changes:

- Submission of participant POWeR registration card
- Submission of participant instructions for the POWeR programme
- Submission of participant FAQs for the POWeR programme
- Submission of participant instructions for BodyTrace weighing scales

Non-substantial changes:

- Addition of a 'date completed' to the questionnaire baseline
- Addition of a 'date completed' to the questionnaire follow-up A
- Addition of a 'date completed' to the questionnaire follow-up B

Other modified documents approved	Previous version	New version
Participant POWeR registration card	N/A	Version 1.0 (10 May 2018)
Participant instructions for the POWeR programme	N/A	Version 1.0 (10 May 2018)
Participant FAQs for the POWeR programme	N/A	Version 1.0 (10 May 2018)
Participant instructions for BodyTrace weighing scales	N/A	Version 1.0 (10 May 2018)
Questionnaire baseline	Version 4.0 (1 February 2018)	Version 5.0 (10 May 2018)
Questionnaire follow-up A	Version 4.0 (1 February 2018)	Version 5.0 (10 May 2018)
Questionnaire follow-up B	Version 4.0 (1 February 2018)	Version 5.0 (10 May 2018)

5.0	***5 November 2018***	***7.0***	***Substantial***

Summary of amendment

Substantial changes:

- Change of grant holder and chief investigator employer from UoB to University of Loughborough
- Addition to the TSC details
- Changes to the recruitment process
- Submission of a GP flyer cover letter and GP flyer
- Submission of a GP version of the invitation letter and reply slip

Non-substantial changes:

- Minor typographical corrections

TABLE 4 Protocol amendments (*continued*)

Amendment number	Date of amendment	Protocol version number	Type of amendment

Other modified documents approved	Previous version	New version
GP flyer cover letter	N/A	Version 1.0 (5 November 2018)
GP flyer	N/A	Version 1.0 (5 November 2018)
Invitation letter and reply slip: GP version	N/A	Version 1.0 (5 November 2018)

6.0	*5 February 2019*	*8.0*	*Minor*

Summary of amendment

Non-substantial changes:

- Correction to three questions on the PIMMS-WL questionnaire baseline
- Correction to three questions on the PIMMS-WL questionnaire follow-up A
- Correction to three questions on the PIMMS-WL questionnaire follow-up B
- Addition of a question to the PIMMS-WL participant interview schedule

Other modified documents approved	Previous version	New version
Questionnaire baseline	Version 5.0 (10 May 2018)	Version 6.0 (5 February 2019)
Questionnaire follow-up A	Version 5.0 (10 May 2018)	Version 6.0 (5 February 2019)
Questionnaire follow-up B	Version 5.0 (10 May 2018)	Version 6.0 (5 February 2019)
Participant interview schedule	Version 3.0 (1 February 2018)	Version 4.0 (5 February 2019)

7.0	*16 July 2019*	*9.0*	*Minor*

Summary of amendment

Non-substantial changes:

- Clarification of the stop–go criteria
- Clarification on masking
- Clarification on the POWeR programme in the control group
- Clarification on data received from BWH
- Clarification on recruitment rate
- Update of trial staff and contact information

FAQ, frequently asked question; N/A, not applicable; PIMMS-WL, Postnatal IMMunisationS Weight Loss.

given birth at the hospital who were registered at general practices taking part in the trial, but they were unable to screen against key trial entry criteria, such as weight/BMI, because they did not have this information. This meant that letters were being sent to both eligible and ineligible women and it was, therefore, not possible to present the recruitment result as a proportion of the eligible participants invited to take part. We, therefore, changed the recruitment result so that it was presented as a proportion of the target. This was discussed and agreed with the TSC in October 2018, as well as with the Health Technology Assessment programme; this change was made to the protocol.

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Chapter 3 Results

Recruitment of practices and participants

Fourteen practices (clusters) were recruited to participate in this study: seven were randomised to deliver the weight management intervention and seven were randomised to deliver usual care. For randomisation by minimisation, practices were categorised according to list size and IMD score (*Table 5*).

A total of 368 letters were sent by BWH to potentially eligible women from the 14 participating practices. Of women who completed the initial telephone screening process, most participants were made aware of the trial via letter from BWH (87.5%). A total of 28 women consented to participate between July 2018 and April 2019 (10 months) at an average rate of 2.8 participants per month. Sixteen women were registered at practices that were delivering the weight management intervention and 12 women were registered at practices that were delivering usual care. Recruitment at each practice is detailed in *Table 6*. Four of the usual-care practices recruited no participants.

TABLE 5 Randomisation minimisation variables by practice and participants

Variable	Trial group		
	Intervention (*N* = 7)	Usual care (*N* = 7)	Overall (*N* = 14)
Minimisation variables (practice level, as per randomisation process)			
General practice list size, *n*			
Large (≥ 6000 patients)	3	3	6
Small (< 6000 patients)	4	4	8
IMD, *n*			
Low	0	0	0
Medium	1	0	1
High	6	7	13
Minimisation variables (participant level)	**N = *16***	**N = *12***	**N = *28***
General practice list size, *n* (%)			
Large (≥ 6000 patients)	8 (50)	9 (75)	17 (61)
Small (< 6000 patients)	8 (50)	3 (25)	11 (39)
IMD, *n* (%)[a]			
Low	0 (0)	0 (0)	0 (0)
Medium	1 (6)	0 (0)	1 (4)
High	15 (94)	12 (100)	27 (96)

a The IMD rank score ranges from 1 to 32,844 and has been divided into tertiles of high (1–10,948), medium (10,949–21,896) and low (21,897–32,844) levels of deprivation.

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TABLE 6 Recruitment of practices by trial group

Trial group	Number recruited
Intervention	
Practice A	1
Practice B	1
Practice C	2
Practice D	1
Practice E	4
Practice F	2
Practice G	5
Total	16
Usual care	
Practice H	0
Practice J	0
Practice K	3
Practice L	8
Practice M	0
Practice N	0
Practice O	1
Total	12

Withdrawals, loss to follow-up and missing data

One participant who was allocated to the intervention group withdrew from the trial because they decided not to have their child immunised. All remaining participants ($n = 27$) completed the follow-up visit for assessment of outcomes; however, one participant allocated to the intervention group did not complete the follow-up questionnaires. Return rates for the trial CRFs and health questionnaire booklets by trial group are detailed in *Table 7*. All expected baseline and follow-up CRFs were returned, and only one baseline (usual care) and one follow-up (intervention) health questionnaire booklet were not returned. Data regarding attendance at child immunisation appointments were not provided by practices for three participants (intervention, $n = 2$; usual care, $n = 1$). Weight record cards were returned blank (considered not returned) for three participants (intervention group). *Table 8* shows how well each outcome questionnaire was completed. Generally, $\geq$ 85% of received forms were completed in full. The PPAQ had the most missing items (five at baseline and three at follow-up were partially completed).

Participant trial flow

Figure 3 illustrates the flow of participants through the trial. The most common reason for non-recruitment related to potentially eligible women having already attended their first child immunisation appointment ($n = 5$) or having a BMI of < 25 kg/m^2 ($n = 4$).

TABLE 7 Data return status by trial group

Data	Trial group, *n* (%)					
	Intervention (*N* = 16)			Usual care (*N* = 12)		
	Expected	Returned	Not returned	Expected	Returned	Not returned
Baseline case report form	16	16 (100)	0 (0)	12	12 (100)	0 (0)
Baseline health questionnaire	16	16 (100)	0 (0)	12	11 (92)	1 (8)[a]
Follow-up CRF	15	15 (100)	0 (0)	12	12 (100)	0 (0)
Follow-up health questionnaire	15	14 (93)	1 (7)	12	12 (100)	0 (0)
Immunisation data form	15	13 (87)	2 (13)	12	11 (92)	1 (8)
Weight record card (intervention only)	15	12 (80)	3 (20)[b]			

a Participant reported that they had posted the questionnaire but it was not received by the trials unit, so it has been considered not returned.
b These three weight record cards were collected by the researcher at the 3-month visit, but the cards were completely blank so have been treated as if not returned because they provided no usable data.

TABLE 8 Questionnaire completion rates at baseline and follow-up

Questionnaire	Baseline (expected: *N* = 28[a]), *n* (%)			3-month follow-up (expected: *N* = 27[b]), *n* (%)		
	Received	Fully completed	Partially completed	Received	Fully completed	Partially completed
HADS[175]	27	26 (96)	1 (4)	26	25 (96)	1 (4)
TFEQ[179]	27	23 (85)	4 (15)	26	26 (100)	0 (0)
BISS[176]	27	26 (96)	1 (4)	26	25 (96)	1 (4)
[c]PPAQ[177]	27	22 (81)	5 (19)	26	23 (88)	3 (12)
ICECAP-A[182]	27	27 (100)	0 (0)	26	26 (100)	0 (0)
WCSS[178]				26	22 (85)	4 (15)
[d]Self-weighing perceptions[180]				14	13 (93)	1 (7)

a One participant did not return the questionnaire at the baseline visit.
b One participant withdrew from the trial.
c It is instructed that women only complete the work domain of the PPAQ if they are currently working, so these domain items are not considered missing if a woman is not working. The PPAQ does not specifically ask whether or not the woman is working, but owing to the trial population it is appropriate to assume that if the work domain was left completely blank that the woman was not working, and these are not considered missing data items. Of the 22 women who are considered to have completed the PPAQ in full at baseline, seven (32%) did not answer any questions in work domain. Of the 23 women who are considered to have completed the PPAQ in full at follow-up, 12 (52%) did not complete the work domain. It was assumed that these women were not currently working.
d Completed by intervention group only (expected *n* = 15).

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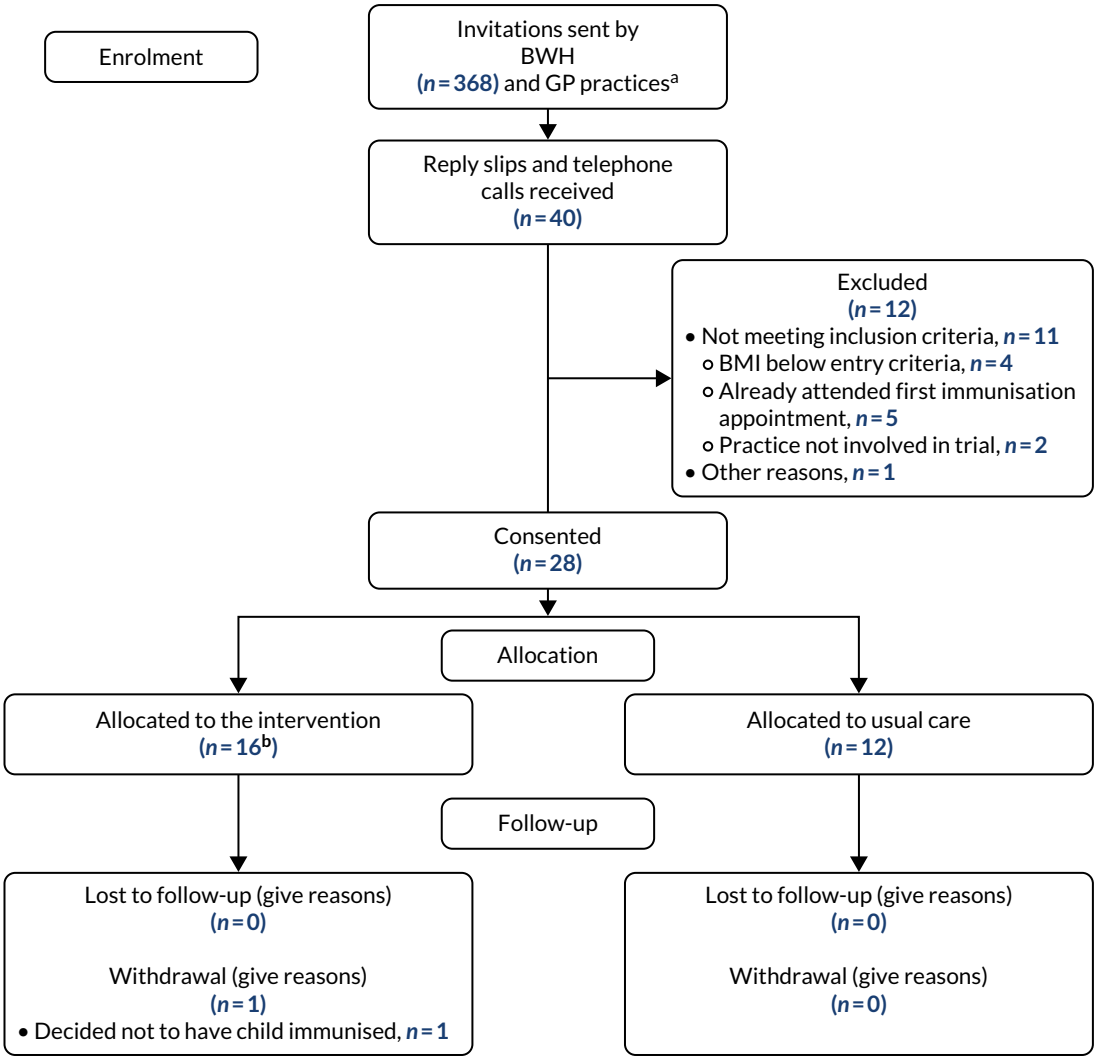

FIGURE 3 Participant flow through the trial. a, The total number of general practice invitations sent is unknown. Only two sites were able to provide information on the number of invitation that they had sent: one practice sent out 12 invitations and one sent out five invitations. b, One woman withdrew from the intervention owing to the study tasks being an inconvenience, but they agreed to continue in the trial and complete the follow-up assessment.

Participant characteristics at baseline

The average age of participants was 32.1 years (SD 5.7 years). Forty-six per cent of participants ($n = 13$) were of white ethnicity, with the remaining 54% ($n = 15$) from non-white ethnic groups. Most participants were married or living with their partner (74%, $n = 20$). The average weight and BMI of participants at baseline were 83.6 kg (SD 17.1 kg) and 31.8 kg/m^2 (SD 6.9 kg/m^2), respectively. Most participants had given birth to two children (43%, $n = 12$) and had tried to breastfeed the baby from their most recent pregnancy (96%, $n = 27$). Fifteen women (53%) were exclusively breastfeeding. On average, participants reported that they had 3.2 hours (SD 1.1 hours) of uninterrupted sleep per night (*Table 9*).

Adherence to self-weighing (intervention group)

Table 10 shows the number of weeks (as per the schedule of assessment) that participants weighed themselves, as recorded objectively using the BodyTrace weighing scales. Most participants (62.5%, $n = 10$) weighed themselves in at least eight of the weeks over the intervention period.

TABLE 9 Baseline characteristics by trial group

Characteristic	Trial group		Overall (*N* = 28)
	Intervention (*N* = 16)	Usual care (*N* = 12)	
Demographic and other baseline variables			
Age (years)			
Mean (SD), *n*	32.9 (6.1), 16	31.0 (5.3), 12	32.1 (5.7), 28
Minimum–maximum	22–41	24–42	22–42
Ethnic group, *n* (%)			
White	5 (31)	8 (67)	13 (46)
Pakistani	3 (19)	0 (0)	3 (11)
Other Asian	3 (19)	0 (0)	3 (11)
Black Caribbean	0 (0)	1 (8)	1 (3)
Black African	1 (6)	2 (17)	3 (11)
Other	4 (25)	1 (8)	5 (18)
Current marital status, *n* (%)			
Single (living alone)	1 (6)	3 (27)	4 (15)
Single (living with partner)	3 (19)	3 (27)	6 (22)
Married	11 (69)	3 (27)	14 (52)
Divorced/separated (living alone)	0 (0)	1 (9)	1 (4)
Other[a]	1 (6)	1 (9)	2 (7)
Missing, *n*	0	1	1
Current employment status, *n* (%)			
In paid employment	9 (56)	6 (55)	15 (56)
Unemployed	1 (6)	2 (18)	3 (11)
Student	1 (6)	0 (0)	1 (4)
Looking after the home/family	5 (31)	1 (9)	6 (22)
Sick/disabled	0 (0)	1 (9)	1 (4)
Other[b]	0 (0)	1 (9)	1 (4)
Missing, *n*	0	1	1
Current financial status, *n* (%)			
Normally have enough money	9 (56)	0 (0)	9 (35)
Enough money if I plan carefully	6 (38)	4 (40)	10 (38)
Enough money for basic things	1 (6)	3 (30)	4 (15)
Basic things hard to afford	0 (0)	3 (30)	3 (12)
Missing, *n*	0	2	2
Clinical information			
Average number of cigarettes smoked per day, *n* (%)			
None	16 (100)	9 (90)	25 (96)
Five or less	0 (0)	0 (0)	0 (0)
Between 6 and 10	0 (0)	1 (10)	1 (4)
Missing, *n*	0	2	2

continued

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TABLE 9 Baseline characteristics by trial group (*continued*)

Characteristic	Trial group		
	Intervention (*N* = 16)	Usual care (*N* = 12)	Overall (*N* = 28)
Drank alcohol in last week, *n* (%)			
Yes	4 (25)	2 (18)	6 (22)
No	12 (75)	9 (82)	21 (78)
Missing, *n*	0	1	1
Mean number of units			
Mean (SD), *n*	5.7 (3.5), 3	4.0 (2.8), 2	5.0 (3.0), 5
Minimum–maximum	2–9	2–6	2–9
Missing, *n*	1	0	1
Weight (kg)			
Mean (SD), *n*	81.6 (13.7), 16	86.2 (21.2), 12	83.6 (17.1), 28
Minimum–maximum	58.8–106.7	66.7–148.8	58.8–148.8
Height (cm)			
Mean (SD), *n*	161.2 (9.1), 16	164.0 (6.2), 12	162.4 (8.0), 28
Minimum–maximum	147.3–178.4	153.0–174.9	147.3–178.4
BMI (kg/m^2)			
Mean (SD), *n*	31.6 (6.1), 16	32.1 (8.0), 12	31.8 (6.9), 28
Minimum–maximum	25.5–47.2	26.3–56.4	25.5–56.4
Percentage body fat (%)			
Mean (SD), *n*	40.9 (4.0), 16	41.6 (6.0), 12	41.2 (4.8), 28
Minimum–maximum	34.6–46.8	32.5–56.1	32.5–56.1
Pregnancy details			
Weight before pregnancy (kg) (self-reported)			
Mean (SD), *n*	75.0 (14.6), 13	83.9 (31.0), 10	78.9 (23.0), 23
Minimum–maximum	55.5–104.0	50.0–154.6	50.0–154.6
Missing, *n*	3	2	5
Number of children given birth to, *n* (%)			
1	6 (37)	1 (8)	7 (25)
2	7 (44)	5 (42)	12 (43)
3	3 (19)	3 (25)	6 (21)
≥ 4	0 (0)	3 (25)	3 (11)
Number of children living in household, *n* (%)			
1	6 (37)	1 (8)	7 (25)
2	7 (44)	5 (42)	12 (43)
≥ 3	3 (19)	6 (50)	9 (32)
Health complications during this pregnancy? *n* (%)			
Yes	8 (50)	3 (25)	11 (39)
No	8 (50)	9 (75)	17 (61)

TABLE 9 Baseline characteristics by trial group (*continued*)

Characteristic	Trial group		Overall (*N* = 28)
	Intervention (*N* = 16)	Usual care (*N* = 12)	
If yes (*n* = 11) (note: not mutually exclusive), *n* (%)			
Gestational diabetes mellitus	1 (12.5)	2 (67)	3 (27)
Pre-eclampsia	1 (12.5)	0 (0)	1 (9)
Gestational hypertension	4 (50)	0 (0)	4 (36)
Pre-term delivery	1 (12.5)	0 (0)	1 (9)
Neonatal intensive care/special care	1 (12.5)	0 (0)	1 (9)
Other[c]	2 (25)	2 (67)	4 (36)
Type of delivery, *n* (%)			
Normal vaginal delivery	10 (63)	8 (67)	18 (64)
Instrumental vaginal delivery	1 (6)	0 (0)	1 (4)
Elective caesarean section	1 (6)	1 (8)	2 (7)
Emergency caesarean section	4 (25)	3 (25)	7 (25)
Pregnancy and breastfeeding			
Tried to breastfeed baby, *n* (%)			
Yes	16 (100)	11 (92)	27 (96)
No	0 (0)	1 (8)	1 (4)
Current method of feeding, *n* (%)			
Exclusively breastfeeding	11 (69)	4 (33)	15 (53)
Exclusively formula feeding	3 (19)	5 (42)	8 (29)
Both breastmilk and formula	2 (12)	3 (25)	5 (18)
If breastfeeding, intended time to continue breastfeeding: *n* (%)	(*N* = 13)	(*N* = 7)	(*N* = 20)
Up to 3 months	0 (0)	0 (0)	0 (0)
Up to 6 months	2 (15)	1 (14)	3 (15)
Up to 9 months	1 (8)	0 (0)	1 (5)
Up to 12 months	1 (8)	1 (14)	2 (10)
> 1 year	5 (38)	3 (43)	8 (40)
As long as possible	4 (31)	2 (29)	6 (30)
Sleep			
Average amount of uninterrupted sleep per night (hours)			
Mean (SD), *n*	3.0 (1.2), 16	3.5 (0.9), 12	3.2 (1.1), 28
Minimum–maximum	1–6	2–5	1–6

a Others (*n* = 2): living with partner and not living with partner.
b Others (*n* = 1): in paid employment and a student.
c Others (*n* = 4): pelvic pain (on crutches from 37/40), hyperemesis and excess water, hyperemesis, and high-risk embolism/thrombosis.

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TABLE 10 Frequency of self-weighing (objective data)

Number of times[a]	Weekly self-weighing according to schedule of assessments (*N* = 16), *n* (%)
1	2 (12.50)[b]
2	1 (6.25)
3	1 (6.25)[c]
4	1 (6.25)
5	1 (6.25)
6	0 (0)
7	0 (0)
8	1 (6.25)
9	0 (0)
10	1 (6.25)
11	1 (6.25)
12	0 (0)
≥ 13	7 (43.75)

a The number of times refers to the number of weeks during follow-up that participants weighed themselves as per the schedule of assessments. Data were collected until the scales were retrieved (minimum of 3 months).
b One participant subsequently withdrew from the intervention as they found study tasks an inconvenience, but they completed follow-up.
c One participant subsequently withdrew from the trial as they decided not to get their child immunised.

Table 11 shows the number of participants who weighed themselves in each of the scheduled weeks. Follow-up was conducted until the BodyTrace scales were collected (minimum 3 months).

Table 12 presents the number of participants who weighed themselves ≥ 60% of the time, between 40% and 59% of the time and < 40% of the time.

Self-weighing using objective and self-reported data

Multiple sources of frequency of self-weighing data were collected. The intervention group completed weight record cards and some participants recorded their weight on the POWeR online programme. Although these additional self-reported measures of weight are not direct evidence of self-weighing, they are an indication of adherence to the intervention. As a secondary assessment of the frequency of self-weighing, the self-reported weight data were used in combination with the objective transmitted weight data from the BodyTrace scales (*Tables 13–15*).

Use of the POWeR online weight management programme (intervention group)

A total of 9 out of 16 (56%) intervention group participants registered to use the POWeR online programme (objective data). The median number of times that these participants logged onto the POWeR website over the follow-up period was four times (IQR 2–9 times, range 1–21 times).

TABLE 11 Number of participants self-weighing (objective data)

Week number	Number of participants who self-weighed (*N* = 16), *n* (%)
1	15 (93.75)[a]
2	12 (75)
3	12 (75)
4	9 (56.25)
5	11 (68.75)
6	9 (56.25)
7	8 (50)
8	10 (62.5)
9	9 (56.25)
10	8 (50)
11	9 (56.25)
12	7 (43.75)
13	9 (56.25)
14	8 (50)
15	4 (25)
16	2 (12.5)
17	0 (0)
18	1 (6.25)
19	0 (0)
20	1 (6.25)

a One participant could not get a signal to transmit the weights using the BodyTrace scales at the baseline visit; their weights were subsequently recorded on a USB stick during the follow-up period (only one weight at week 4 was recorded).

TABLE 12 Self-weighing (objective data) according to percentage adherence categories

Adherence categories	Intervention group (*N* = 16), *n* (%)
Number of participants who weighed themselves weekly ≥ 60% of the time	10 (62.5)
Number of participants who weighed themselves weekly 40–59% of the time	0 (0)
Number of participants who weighed themselves weekly < 40% of the time	6 (37.5)

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TABLE 13 Frequency of self-weighing (all available evidence of self-weighing)

Number of times[a]	Weekly self-weighing according to schedule of assessments (*N* = 16), *n* (%)
1	1 (6.25)
2	1 (6.25)
3	1 (6.25)
4	1 (6.25)
5	0 (0)
6	1 (6.25)
7	0 (0)
8	1 (6.25)
9	0 (0)
10	0 (0)
11	0 (0)
12	1 (6.25)
≥ 13	9 (56.25)

a The number of times refers to the number of weeks during the intervention period that participants weighed themselves. Data were collected until the scales were retrieved (minimum 3 months).

TABLE 14 Number of participants self-weighing at scheduled week (all available evidence)

Week number	Number of participants self-weighing (*N* = 16), *n* (%)
1	16 (100)
2	13 (81.25)
3	13 (81.25)
4	12 (75)
5	13 (81.25)
6	10 (62.5)
7	10 (62.5)
8	11 (68.75)
9	10 (62.5)
10	10 (62.5)
11	10 (62.5)
12	9 (56.25)
13	11 (68.75)
14	10 (62.5)
15	5 (31.25)
16	4 (25)
17	0 (0)
18	1 (6.25)
19	0 (0)
20	1 (6.25)

TABLE 15 Self-weighing according to percentage adherence categories (all available data)

Adherence categories	Intervention group ($N = 16$), *n* (%)
Number of participants who weighed themselves weekly ≥ 60% of the time	11 (69)
Number of participants who weighed themselves weekly 40–59% of the time	1 (6)
Number of participants who weighed themselves weekly < 40% of the time	4 (25)

Registered participants recorded their weight on the POWeR programme a median of two times over follow-up (IQR 1–7 times) and spent a median of 102.8 minutes in total on the POWeR programme over follow-up (IQR 58.4–189.4 minutes). Four of the nine participants who registered on the POWeR programme completed stage 1 (44%), two completed stage 2 (22%) and no participants completed all three stages (*Tables 16–18*). Data are reported in medians owing to skewness in the data.

TABLE 16 Total number of POWeR[171] logins in each week of follow-up

Week number	Total number of POWeR logins[a]
1	13
2	5
3	6
4	6
5	4
6	1
7	4
8	3
9	6
10	6
11	3
12	2
13	2
14	1
15	1
16	1
17	2
18	0
19	0
20	1

a Data are for all participants in each given week.

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TABLE 17 Total number of weights recorded on the POWeR programme[171] in each week of follow-up

Week number	Total number of weights recorded on the POWeR programme[a]
1	3
2	5
3	3
4	4
5	4
6	1
7	3
8	3
9	2
10	3
11	1
12	1

a Data are for all participants in each given week of the intervention period.

TABLE 18 Total number of minutes spent on the POWeR programme[171] in each week

Week number	Total number of minutes that the POWeR programme was used[a]
1	340.6
2	125.8
3	86.1
4	240.6
5	120.8
6	6.5
7	31.7
8	19.3
9	51.5
10	52.7
11	70.1
12	29.1
13	15.6
14	4.6
15	12.1
16	4.4
17	13.3
18	0.0
19	0.0
20	0.4

a Data are for all participants in each given week of the intervention period.

Stop–go criteria to proceed to a Phase III trial

Table 19 details the outcomes of the trial in relation to the prespecified traffic-light stop–go criteria. Adherence to self-weighing as per the stop–go criteria was based on the objective weight data recorded on the BodyTrace scales.

Weight management resources and support to lose weight (intervention group)

At follow-up, participants were asked about resources that they had used to help them manage their weight and whether or not they had received any support to lose weight (*Table 20*).

TABLE 19 Stop–go criteria results

Stop–go criteria	Estimate (95% CI)	Target met
Recruitment rate	28/80, 35% (95% CI 25% to 45%)	Red
Adherence to intervention (self-weighing):[a] weighed weekly ≥ 60% of the time	10/16,[b] 63% (95% CI 39% to 86%)	Green
Adherence to intervention: registered with the POWeR programme[171]	9/16, 56% (95% CI 32% to 81%)	Amber

a Data based on objective assessment of weight as measured via the BodyTrace weighing scales.
b One participant withdrew from the trial.

TABLE 20 Weight management resources and support (intervention group)

Adherence categories	Intervention group ($N = 15$[a]), n (%)
Have you accessed or used any resources to help with your weight loss?	
Yes	6 (40)
No	9 (60)
If yes ($n = 6$)	
Online programme[b]	1 (17)
Exercise[c]	2 (33)
Diet[d]	3 (50)
Do you feel that there are people you know among your friends and family who support and encourage you with your postnatal weight loss?	
Yes	11 (73)
No	4 (27)
Self-reported accessing the POWeR programme[171]	
Yes	10 (67)
No	5 (33)
Do you know anyone else taking part in the study?	
Yes	1 (7)
No	14 (93)

a One intervention group participant withdrew from the trial prior to follow-up.
b Online programme ($n = 1$): programme not specified.
c Exercises ($n = 2$): the Dia method, postnatal exercises/yoga and Zumba at home.
d Diet changes ($n = 3$): no dairy/soya/egg products, general healthy eating – more fruit/vegetables, and low calorie, HelloFresh (Berlin, Germany).

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From *Table 19*, nine participants registered to use the POWeR programme; however, in *Table 20*, 10 participants self-reported accessing the POWeR programme. Of the 10 women in *Table 20* who self-reported accessing the POWeR programme, eight of these are included in the nine participants for whom there is a digital record of POWeR programme access. Two participants have self-reported access to the POWeR programme, but there is no digital record of this. Another participant had not self-reported accessing the POWeR programme, but there is a digital record of them registering to use this.

Single items relating to the acceptability of the intervention to participants

The intervention group were asked a series of single questions to assess their views on the acceptability of the study/intervention, for which scores could range from 1 to 8, with higher scores being more favourable. The mean score for the question 'would you recommend this study to your friends?' was 6.2 out of 8. On average, the usefulness of being weighed by the practice nurse was scored 5.3 out of 8 and the usefulness of weekly self-weighing was scored 5.8 out of 8 by participants. Overall, participants felt that it was appropriate for the nurse to weigh them at child immunisation visits (6/8). To assess the impact of the intervention on participants' mental health, a question that assessed whether or not the intervention made women anxious about their weight was included; the average response score was 3.8 out of 8 (*Table 21*).

TABLE 21 Views on the acceptability of the intervention

Adherence categories	Intervention group ($N = 15$[a,b])
Would you recommend this study to a friend?	
Mean (SD), *n*	6.2 (1.9), 13
Minimum–maximum	1–8
Missing, *n*	2
How helpful has being weighed by the nurse been for managing your weight?	
Mean (SD), *n*	5.3 (1.8), 13
Minimum–maximum	2–8
Missing, *n*	2
How helpful has weighing yourself weekly been for managing your weight?	
Mean (SD), *n*	5.8 (2.2), 13
Minimum–maximum	1–8
Missing, *n*	2
How appropriate was it for the nurse to weigh you at your baby immunisation appointment?	
Mean (SD), *n*	6.1 (2.3), 13
Minimum–maximum	1–8
Missing, *n*	2
How anxious did the study make you feel about your weight?	
Mean (SD), *n*	3.8 (2.5), 13
Minimum–maximum	1–8
Missing, *n*	2

a One participant in the intervention group withdrew prior to follow-up.
b Scores range from 1 to 8 on a Likert scale, with higher scores being more favourable.

Delivery of the intervention by practice nurses

Table 22 provides data on the delivery of the intervention by practice nurses at each immunisation appointment, as reported on the weight record card in the child health red book. Weight record cards were available for 12 of the 16 participants in the intervention group. Delivery of the intervention components (weighing the women at the immunisation appointment, asking the women if they were weekly self-weighing and reminding the women about using the POWeR website) by practice nurses was high across all immunisation appointments.

TABLE 22 Delivery of the intervention by nurses at immunisation appointments

Adherence categories	Intervention group ($N = 12$[a,b]), *n* (%)
2-month immunisation appointment	
Appointment attended by participant	
Yes	12 (100)
No	0 (0)
When participant was weighed in relation to the immunisation of the child	
Before	5 (71)
After	2 (29)
Declined	0 (0)
Missing	5
Weight recorded by nurse at immunisation appointment	
Yes	12 (100)
No	0 (0)
Participant reminded by nurse about the POWeR programme	
Yes	12 (100)
No	0 (0)
Participant asked by nurse if they were following weekly self-weighing	
Yes	12 (100)
No	0 (0)
Missing	0 (0)
3-month immunisation appointment	
Appointment attended by participant	
Yes	11 (100)
No	0 (0)
Missing	1[c]
When participant weighed in relation to the immunisation of the child	
Before	4 (100)
After	0 (0)
Declined	0 (0)
Missing	8

continued

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TABLE 22 Delivery of the intervention by nurses at immunisation appointments (*continued*)

Adherence categories	Intervention group ($N = 12^{a,b}$), *n* (%)
Weight recorded by nurse at immunisation appointment	
Yes	11 (100)
No	0 (0)
Missing	1
Participant reminded by nurse about the POWeR programme	
Yes	11 (100)
No	0 (0)
Missing	1
Participant asked by nurse if they were following weekly self-weighing	
Yes	11 (100)
No	0 (0)
Missing	1
4-month immunisation appointment	
Appointment attended by participant	
Yes	10 (100)
No	0 (0)
Missing	2[d]
When participant weighed in relation to the immunisation of the child	
Before	2 (100)
After	0 (0)
Declined	0 (0)
Missing	10
Weight recorded by nurse at immunisation appointment	
Yes	10 (100)
No	0 (0)
Missing	2
Participant reminded by nurse about the POWeR programme	
Yes	9 (100)
No	0 (0)
Missing	3
Participant asked by nurse if they were following weekly self-weighing	
Yes	9 (100)
No	0 (0)
Missing	3

a One participant in the intervention group withdrew prior to follow-up visit, which is when the weight record card is collected.
b Three of the 15 participants who reached the end of the trial returned a completely blank weight record card.
c Appointment was attended by mother according to follow-up form and GP records.
d Appointment was attended by the mother ($n = 1$) and grandparent ($n = 1$) according to follow-up form and GP records.

Attendance at immunisation visits

To check that the intervention did not adversely affect attendance at immunisation appointments (rates), practices provided data on attendance from participants' medical records. *Table 23* shows the number of immunisation appointments attended in each trial group and for each immunisation appointment. Practices provided immunisation data on 24 participants (expected data on 27 participants, as one woman withdrew from the study because they decided not to get their child immunised). There was no evidence that the intervention deterred participants from attending their child immunisation appointments, with 12 out of the 13 women (92%) in the intervention group for whom these data were provided attending all three child immunisation appointments and having their baby immunised.

Intervention contamination

Intervention contamination in the usual-care group was assessed through usual-care participants' self-reporting of whether they had accessed the POWeR website or used other resources to help with weight loss. *Table 24* shows the weight management questions asked at follow-up to usual-care participants. Only one participant reported using portion-control methods to help them lose weight and no participants reported accessing the POWeR website. Three participants reported knowing someone else taking part in the study.

Clinical and participant-reported outcomes

Descriptive data relating to clinical and questionnaire outcomes are detailed in *Weight and body composition*. Given that this was a feasibility study, no hypothesis testing was conducted and no inferences from these data can be made regarding the success of the intervention.

Weight and body composition

The usual-care group were 7.5 kg heavier (adjusted mean difference) in weight than the intervention group (95% CI −13.8 to −1.3 kg) at follow-up. The within-group profile of weight over time showed that the intervention group, on average, lost weight (unadjusted mean change −3.3 kg), whereas the usual-care group gained weight (unadjusted mean change 1.9 kg). The intervention group had lower BMI and percentage body fat scores than the usual-care group at follow-up (*Table 25*).

TABLE 23 Number of immunisation appointments attended (based on data provided by practices)

	Trial group, *n* (%)	
Adherence categories	**Intervention (*N* = 15[a])**	**Usual care (*N* = 12)**
Number of participants for whom data on immunisation attendance were not provided by practices	2	1
Immunisation appointment	***(N = 13)***	***(N = 11)***
2 months	13 (100)	11 (100)
3 months	13 (100)	11 (100)
4 months	12 (92)	11 (100)

a One woman in the intervention group withdrew from the trial because she decided not to have her child immunised.

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TABLE 24 Weight management in the usual-care group

Adherence categories	Usual-care group (*N* = 12), *n* (%)
Have you accessed or used any resources to help with your weight loss?	
Yes	1 (8)
No	11 (92)
If yes (n = 1):	
Portion control[a]	1 (100)
Do you feel that there are people you know, among your friends and family, who support and encourage you with your postnatal weight loss?	
Yes	10 (83)
No	2 (17)
Self-reported accessing the POWeR website[171]	
Yes	0 (0)
No	12 (100)
Do you know anyone else taking part in the study?	
Yes	3[b] (25)
No	9 (75)

a Portion control, reduce carbohydrates, more fruit.
b Two participants knew each other, the other participant could not remember who she knew.

TABLE 25 Body composition

Adherence categories	Baseline		3-month follow-up		Adjusted mean difference[b] (95% CI)
	Intervention (*N* = 16)	Usual care (*N* = 12)	Intervention (*N* = 15[a])	Usual care (*N* = 12)	
Weight (kg)					
Mean (SD), *n*	81.6 (13.7), 16	86.2 (21.2), 12	78.3 (13.5), 15	88.1 (23.9), 12	−7.5 (−13.8 to −1.3)
Minimum–maximum	58.8–106.7	66.7–148.8	60.5–106.7	64.1–154.3	
Percentage body fat					
Mean (SD), *n*	40.9 (4.0), 16	41.6 (6.0), 12	39.6 (4.7), 15	42.4 (7.1), 12	−3.2 (−6.3 to −0.1)
Minimum–maximum	34.6–46.8	32.5–56.1	34.5–48.9	30.5–57.0	
BMI (kg/m^2)[c]					
Mean (SD), *n*	31.6 (6.1), 16	32.1 (8.0), 12	30.2 (6.0), 15	32.8 (8.8), 12	−3.1 (−5.8 to −0.3)
Minimum–maximum	25.5–47.2	26.3–56.4	24.5–47.2	24.0–58.4	
Healthy (18.5–24.9), *n* (%)	0 (0)	0 (0)	2 (13)	1 (8)	
Overweight (25–29.9), *n* (%)	8 (50)	6 (50)	8 (53)	5 (42)	
Obese (30–39.9), *n* (%)	6 (37.5)	5 (42)	4 (27)	5 (42)	
Morbidly obese (> 40), *n* (%)	2 (12.5)	1 (8)	1 (7)	1 (8)	

a One intervention group participant withdrew prior to follow-up.
b Values of < 0 favour the intervention. Adjusted for practice (random effect), the two minimisation variables (GP size list and IMD), and baseline for value for each outcome.
c BMI at the 3-month follow-up was calculated using the height recorded at baseline and the 3-month follow-up weight.

Mental health outcomes

Table 26 shows the data for the assessment of anxiety and depression. The intervention group reported higher anxiety scores than the usual-care group at follow-up (adjusted mean difference 3.7, 95% CI 0.9 to 6.4). The intervention group reported marginally higher depression scores than the usual-care group at follow-up (adjusted mean difference 0.5, 95% CI −1.9 to 2.9). The intervention group reported a more favourable body image score than the usual-care group at follow-up (adjusted mean difference 0.9, 95% CI −0.5 to 2.4) (*Table 27*).

TABLE 26 Anxiety and depression (assessed by HADS[175])

	Baseline		3-month follow-up		
Adherence categories	**Intervention (*N* = 16)**	**Usual care (*N* = 12)**	**Intervention (*N* = 15[a])**	**Usual care (*N* = 12)**	**Adjusted mean difference[b] (95% CI)**
HADS: depression[c]					
Mean (SD), *n*	5.9 (4.9), 16	5.0 (3.0), 11	6.3 (4.0), 14	5.5 (2.5), 12	0.5 (−1.9 to 2.9)
Minimum–maximum	0–15	1–10	0–15	2–10	
Missing, *n*	0	1	1	0	
HADS: anxiety					
Mean (SD), *n*	6.1 (3.8), 16	6.3 (3.7), 11	8.4 (4.1), 14	5.2 (3.6), 12	3.7 (0.9 to 6.4)
Minimum–maximum	0–11	1–13	1–14	1–13	
Missing, *n*	0	1	1	0	

a One intervention group participant withdrew prior to follow-up.
b Values of < 0 favour the intervention. Adjusted for general practice (random effect), the two minimisation variables (GP size list and IMD), and baseline score.
c HADS domain scores range from 0 to 21, with higher scores indicating more severe anxiety/depression.

TABLE 27 Body image (assessed by BISS[176])

	Baseline		3-month follow-up		
Adherence categories	**Intervention (*N* = 16)**	**Usual care (*N* = 12)**	**Intervention (*N* = 15[a])**	**Usual care (*N* = 12)**	**Adjusted mean dfference[b] (95% CI)**
BISS: overall measure[c]					
Mean (SD), *n*	3.5 (0.9), 15	3.3 (1.0), 11	3.9 (1.4), 13	3.0 (1.5), 12	0.9 (−0.5 to 2.4)
Minimum–maximum	1.8–4.8	1.8–4.8	1.2–6.0	1.0–5.2	
Missing, *n*	1	1	2	0	

a One intervention group participant withdrew prior to follow-up.
b Values of > 0 favour the intervention. Adjusted for practice (random effect), the two minimisation variables (practice list size and IMD), and baseline score.
c BISS domain scores range from 1 to 9, with higher scores being more favourable.

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Eating behaviours

The intervention group reported higher cognitive restraint of eating and uncontrolled eating scores than the usual-care group at follow-up. The usual-care group reported more favourable emotional eating scores than the intervention group at follow-up. Data and results for these outcomes are detailed in *Table 28*.

Self-reported physical activity and sedentary behaviour

Physical activity-related outcomes and time engaged in sedentary behaviour are reported in *Table 29*. Data are reported in medians owing to skewness in the data, and unadjusted differences in medians are reported. The intervention group reported participating in more moderate-intensity physical activity [difference 22.3 metabolic equivalent of task (MET) hours per week, 95% CI −71.4 to 116.0 MET hours per week] but less light-intensity physical activity (difference −19.6 MET hours per week, 95% CI −84.9 to 45.7 MET hours per week) than the usual-care group at follow-up. The intervention group spent more time sedentary than the usual-care group (difference 8.4 MET hours per week, 95% CI −23.7 to 40.5 MET hours per week). Full details of all of the physical activity subdomains can be found in *Table 29*.

Weight control strategies (intervention group)

At follow-up, average scores for engagement in individual item weight control strategies were comparable across the groups (*Table 30*).

TABLE 28 Eating behaviour (assessed by TFEQ[179])

	Baseline		3-month follow-up		
Adherence categories	Intervention (*N* = 16)	Usual care (*N* = 12)	Intervention (*N* = 15[a])	Usual care (*N* = 12)	Adjusted mean difference[b] (95% CI)
TFEQ: cognitive restraint domain[c]					
Mean (SD), *n*	38.7 (15.0), 16	44.1 (28.1), 11	47.6 (12.7), 14	48.6 (23.3), 12	5.4 (−8.9 to 19.6)
Minimum–maximum	16.7–66.7	11.1–77.8	22.2–72.2	0–72.2	
Missing, *n*	0	1	1	0	
TFEQ: uncontrolled eating domain					
Mean (SD), *n*	47.9 (26.3), 16	43.0 (23.7), 11	50.3 (25.6), 14	41.0 (27.9), 12	−0.03 (−15.4 to 15.4)
Minimum–maximum	7.4–88.9	7.4–88.9	14.8–85.2	3.7–81.5	
Missing, *n*	0	1	1	0	
TFEQ: emotional eating domain					
Mean (SD), *n*	47.9 (26.5), 16	48.5 (32.7), 11	56.3 (34.4), 14	43.5 (32.3), 12	9.1 (−25.9 to 44.0)
Minimum–maximum	0–100	0–88.9	0–100	0–88.9	
Missing, *n*	0	1	1	0	

a One intervention group participant withdrew prior to follow-up.
b Values of < 0 favour the intervention, except for the cognitive restraint domain for which values of > 0 favour the intervention. Adjusted for general practice (random effect), the two minimisation variables (GP size list and IMD), and baseline score.
c TFEQ domain scores range from 0 to 100, with higher scores indicating more positive behaviour in the cognitive restraint domain and more negative behaviour in the uncontrolled eating and emotional eating domains.

TABLE 29 Physical activity and sedentary behaviour (assessed by PPAQ[177])

Adherence categories	Baseline		3-month follow-up		
	Intervention (*N* = 16)	Usual care (*N* = 12)	Intervention (*N* = 15[a])	Usual care (*N* = 12)	Difference in medians[b] (95% CI)
Intensity domains					
PPAQ: sedentary activity (MET hours/week)					
Median (IQR)	60.2 (30.6–88.5)	66.0 (28.0–97.1)	48.1 (21.0–56.9)	39.7 (22.4–60.8)	8.4 (−23.7 to 40.5)
Minimum–maximum	9.5–108.2	22.4–146.3	5.1–98.7	11.6–109.9	
Missing, *n*	2	1	2	0	
PPAQ: light-intensity activity (MET hours/week)					
Median (IQR)	119.2 (87.7–154.9)	154.9 (135.5–166.1)	110.8 (81.2–178.0)	130.4 (107.8–183.9)	−19.6 (−84.9 to 45.7)
Minimum–maximum	49.5–198.1	110.4–206.3	48.8–193.6	73.9–229.8	
Missing, *n*	1	1	2	1	
PPAQ: moderate-intensity activity (MET hours/week)					
Median (IQR)	116.4 (58.5–168.6)	141.5 (70.8–188.7)	150.8 (82.3–199.4)	128.5 (56.5–167.0)	22.3 (−71.4 to 116.0)
Minimum–maximum	10.6–210.4	58.6–206.5	50.2–266.1	55.1–361.3	
Missing, *n*	0	1	1	1	
PPAQ: vigorous-intensity activity (MET hours/week)					
Median (IQR)	0 (0–5.8)	0 (0–0)	1.6 (0–9.8)	3.3 (0–7.5)	−1.6 (−8.2 to 4.9)
Minimum–maximum	0–9.8	0–30.0	0–10.1	0–37.0	
Missing, *n*	0	1	1	0	
Activity-type domains					
PPAQ: household/caregiving activity (MET hours/week)					
Median (IQR)	202.6 (121.8–241.5)	224.2 (169.6–272.8)	181.0 (134.4–283.6)	219.5 (150.9–309.1)	−38.5 (−159.3 to 82.3)
Minimum–maximum	22.4–371.4	146.5–353.9	72.5–425.8	119.6–401.8	
Missing, *n*	1	1	2	0	
PPAQ: occupational activity (MET hours/week)					
Median (IQR)	0 (0–69.9)	0 (0–71.1)	0 (0–35.9)	0 (0–18.0)	0 (−19.9 to 19.9)
Minimum–maximum	0–138.8	0–158.6	0–239.8	0–109.4	
Missing, *n*	0	1	0	1	
PPAQ: sports/exercise activity (MET hours/week)[c]					
Median (IQR)	6.3 (0–20.3)	2.4 (0.8–22.0)	18.0 (5.3–29.6)	9.1 (6.4–17.0)	8.9 (−5.0 to 22.8)
Minimum–maximum	0–34.2	0–53.4	0–43.2	2.3–37.8	
Missing, *n*	0	1	1	0	
Total activity					
PPAQ: total activity (MET hours/week)					
Median (IQR)	289.7 (224.2–416.2)	345.6 (328.1–421.3)	265.4 (224.8–434.6)	278.6 (212.8–409.7)	−13.2 (−209.1 to 182.7)
Minimum–maximum	114.2–456.9	265.4–438.6	123.2–498.6	178.0–652.8	
Missing, *n*	3	1	3	1	

continued

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TABLE 29 Physical activity and sedentary behaviour (assessed by PPAQ[177]) (*continued*)

Adherence categories	Baseline		3-month follow-up		Difference in medians[b] (95% CI)
	Intervention (*N* = 16)	Usual care (*N* = 12)	Intervention (*N* = 15[a])	Usual care (*N* = 12)	
PPAQ: total activity (excluding work domain[d]) (MET hours/week)					
Median (IQR)	289.7 (181.0–323.0)	328.1 (271.1–362.4)	237.3 (178.9–396.2)	301.5 (217.0–401.4)	−64.2 (−213.1 to 84.6)
Minimum–maximum	71.2–456.9	261.0–423.6	123.2–498.6	178.0–543.4	
Missing, *n*	3	1	3	0	

a One woman in the weight management group withdrew prior to follow-up.
b Values of > 0 favour the intervention, except for PPAQ: sedentary activity for which values of < 0 favour the intervention.
c Three women at baseline and two women at follow-up indicated that they had undertaken something else for exercise but did not indicate what this exercise was. It is assumed that the unspecified exercises undertaken had a moderate intensity (MET value: 4.45). A sensitivity analysis performed assuming that these exercises were of low intensity (MET value: 2.9) and vigorous intensity (MET value: 6) gave very similar results to those presented here.
d Work domain (questions 33–37 answered only by those in work at the time of completion) are excluded here.

TABLE 30 Weight control strategies at the 3-month follow-up[178]

Adherence categories	Trial group		Adjusted mean difference[b] (95% CI)
	Intervention (*N* = 15[a])	Usual care (*N* = 12)	
WCSS: total WCSS score[c]			
Mean (SD), *n*	1.6 (0.6), 13	1.5 (0.6), 9	−0.04 (−0.7 to 0.6)
Minimum–maximum	0.8–2.7	0.5–2.2	
Missing, *n*	2	3	
WCSS: dietary choices score[c]			
Mean (SD), *n*	2.3 (0.7), 13	2.5 (0.8), 12	−0.2 (−0.8 to 0.3)
Minimum–maximum	1.2–3.7	0.6–3.4	
Missing, *n*	2	0	
WCSS: self-monitoring strategies score[c]			
Mean (SD), *n*	0.9 (0.9), 14	0.6 (0.7), 12	0.4 (−0.7 to 1.5)
Minimum–maximum	0–2.7	0–2.1	
Missing, *n*	1	0	
WCSS: physical activity score[c]			
Mean (SD), *n*	1.4 (0.8), 14	1.2 (0.6), 11	0.2 (−0.5 to 0.9)
Minimum–maximum	0–2.7	0.3–2.2	
Missing, *n*	1	1	
WCSS: psychological coping score[c]			
Mean (SD), *n*	1.5 (0.5), 13	1.5 (0.7), 10	−0.03 (−0.5 to 0.4)
Minimum–maximum	0.7–2.7	0.6–2.6	
Missing, *n*	2	2	

a One intervention group participant withdrew prior to follow-up.
b Values of > 0 favour the intervention. Adjusted for general practice (random effect) and the two minimisation variables (GP size list and IMD).
c WCSS domain scores range from 0 to 4, with higher scores being more favourable.

Perceptions of self-weighing (intervention group)

Overall, participants in the intervention group reported positive perceptions of regular self-weighing at 3 months, with an average score of 5.1 out of 8. Individual item scores for perceptions of self-weighing ranged from 4.2 to 5.8 out of 8 (*Table 31*).

TABLE 31 Individual item scores for perceptions of self-weighing[180]

Adherence categories	Intervention group ($N = 15^{a,b}$)
Over the past 3 months, how difficult was it to weigh yourself regularly?	
Mean (SD), *n*	5.1 (2.6), 13
Minimum–maximum	1–8
Missing, *n*	2
Over the past 3 months, how difficult was it to remember to weigh yourself regularly?	
Mean (SD), *n*	5.2 (2.6), 13
Minimum–maximum	1–8
Missing, *n*	2
Over the past 3 months, how helpful did you find regular self-weighing?	
Mean (SD), *n*	5.8 (2.3), 13
Minimum–maximum	2–8
Missing, *n*	2
Over the past 3 months, how frustrating was it to weigh yourself regularly?	
Mean (SD), *n*	5.2 (2.5), 13
Minimum–maximum	1–8
Missing, *n*	2
Over the past 3 months, how anxious did you feel because of weighing yourself regularly?	
Mean (SD), *n*	4.5 (2.6), 13
Minimum–maximum	1–8
Missing, *n*	2
Over the past 3 months, how self-conscious did you feel because of weighing yourself regularly?	
Mean (SD), *n*	4.2 (2.6), 13
Minimum–maximum	1–8
Missing, *n*	2
Over the past 3 months, I found weighing myself regularly to be a positive/negative experience	
Mean (SD), *n*	5.7 (1.7), 13
Minimum–maximum	4–8
Missing, *n*	2
How likely are you to weigh yourself regularly after this study ends?	
Mean (SD), *n*	5.2 (2.8), 13
Minimum–maximum	1–8
Missing, *n*	2

a One participant in the intervention group withdrew prior to follow-up.
b Scores range from 1 to 8, with higher scores being more favourable.

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Infant feeding and sleeping

Information relating to rates of breastfeeding and sleep patterns are presented in *Tables 32* and *33*, respectively. At follow-up, rates of breastfeeding were higher in the intervention group (67%, $n = 10$) than in the usual-care group (33%, $n = 4$). Hours of uninterrupted sleep per night were similar in both groups at follow-up.

Intervention fidelity assessed by audio-recordings of consultations

A total of 17 audio-recordings from immunisation appointments were completed, involving 10 mothers from six intervention practices. The aim was to audio-record as many appointments as possible; these data reflect those appointments for which both participants and nurses consented to having the consultation audio-recorded. Data from the audio-recordings indicated that the intervention took < 2 minutes to deliver in 11 consultations, between 2 and 3 minutes in five consultations and between 3 and 4 minutes in one consultation. The results show evidence of a high level of intervention fidelity

TABLE 32 Infant feeding

Adherence categories	Baseline, *n* (%)		3-month follow-up, *n* (%)	
	Intervention (*N* = 16)	Usual care (*N* = 12)	Intervention (*N* = 15[a])	Usual care (*N* = 12)
Current feeding method				
Exclusively breastfeeding	11 (69)	4 (33)	10 (67)	4 (33)
Exclusively formula feeding	3 (19)	5 (42)	4 (27)	7 (59)
Both breastmilk and formula	2 (12)	3 (25)	1 (6)	1 (8)
Have you been breastfeeding then stopped?				
Yes			4 (100)	6 (86)
No			0 (0)	1 (14)
Missing			11	5

a One intervention group participant withdrew prior to follow-up.

TABLE 33 Sleep patterns

Adherence categories	Baseline		3-month follow-up	
	Intervention (*N* = 16)	Usual care (*N* = 12)	Intervention (*N* = 15[a])	Usual care (*N* = 12)
Average hours of uninterrupted sleep per night				
Mean (SD), *n*	3.0 (1.2), 16	3.5 (0.9), 12	4.2 (1.8), 15	4.8 (1.4), 12
Minimum–maximum	1–6	2–5	2–8	3–8

a One intervention group participant withdrew prior to follow-up.

by practice nurses against the intervention checklist. In one case, it was clear from the conversation that the participant had forgotten their child's red book and, therefore, the nurse was not able to record that they had delivered the trial protocol. The overall results are displayed in *Table 34*.

Safety

No SAEs were reported during the study.

TABLE 34 Results from audio-recordings of the intervention consultations

Adherence categories	Completed by nurse/GP, *n* (%)	Not completed by nurse/GP, *n* (%)	Not clear from recording,[a] *n* (%)	N/A, *n* (%)
Weighed and recorded weight in child health red book	15 (88.2)	1 (5.9)	0	1 (5.9)
Checked participant was weighing weekly	15 (88.2)	2 (11.8)	0	0
Asked if accessed the POWeR[171] website	15 (88.2)	1 (5.9)	1 (5.9)	0
Signposted to the POWeR[171] website	13 (76.5)	3 (17.6)	1 (5.9)	0

N/A, not applicable.
a Not clear: did not hear direct evidence of this in the audio-recording but this task may have been completed after the recorder was switched off.

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Chapter 4 Discussion of trial findings

Main findings

This study examined the feasibility and acceptability of a multicomponent brief weight management intervention delivered to women at child immunisation appointments in primary care. The quantitative assessment of feasibility and acceptability of the intervention was based on prespecified traffic-light stop–go criteria. The recruitment target was not met (red), highlighting that changes to the methods of recruitment are required before proceeding to a Phase III trial. The target for adherence to regular self-weighing was met (green), albeit with wide CIs. Participants regularly recorded their weight on the weight record card, demonstrating that they adhered well to the main intervention component. The stop–go criteria for use of the POWeR website were categorised as amber; therefore, some additional strategies may need to be considered to assist participants in engaging with an online weight management programme. There was also an indication that the intervention may help women to successfully lose weight.

One participant withdrew from the study because they decided not to have their child immunised (intervention) and another participant withdrew from the intervention after deciding that the study tasks were an inconvenience, but agreed to remain in the trial and complete follow-up. No participants were lost to follow-up. The intervention did not have an adverse effect on attendance at immunisation appointments. This provides evidence of the feasibility and acceptability on the intervention. Most participants said that they would recommend the study to their friends. The intervention took practice nurses, on average, 2 minutes to deliver and the intervention fidelity by nurses was high, suggesting that the intervention can be delivered during child immunisations appointments in primary care.

Recruitment

Slower than expected recruitment rates are not uncommon in postnatal weight management studies[184,185] and recruitment proved difficult in this study; there may be several explanations for this. A total of 13 out of 14 practices were located in areas of high deprivation (based on IMD) serving a high proportion of ethnic minority patients. This is also evidenced by the number of participants who reported ‘difficult financial status’ (65%) and the high proportion of participants from non-white ethnic backgrounds (54%). Recruitment to clinical trials from these communities is known to be difficult; therefore, our recruitment experiences are likely to present a ‘worst-case scenario’. Information about the trial was sent to participants in English; in any subsequent trial, it will be important to translate the trial documentation into other languages (e.g. Urdu and Punjabi) so that information is accessible to all women from a range of ethnic backgrounds. Recruitment was also hampered by a change in the computer system at BWH in the last 6 weeks of the recruitment period. This computer system change made it difficult for the hospital to continue to systematically send invitation letters to potentially eligible women, and there was insufficient time for the research team to introduce new recruitment methods prior to the end of the recruitment phase.

Participants received their study invitation letter around 4–6 weeks after giving birth. This is a time during which mothers and their families are adjusting to life with a small baby and, therefore, weight loss may not be considered a priority at this time. There was a maximum period of 4 weeks available between women receiving their invitation letter and women being able to complete the baseline assessment. Women could not be recruited prior to 4 weeks postnatally and the baseline visit had to be completed before the first immunisation (when the child is about 2 months old). This short time framework may have deterred some women from participating in the trial at this busy time in their lives.

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Therefore, rather than recruiting women postnatally, an alternative approach may be to consider recruiting women antenatally towards the end of pregnancy, when women do not have the same distractions and demands on their time. Recruiting antenatally may also be useful because it provides time for women to start to think about weight loss and to mentally prepare for changes to their lifestyle behaviours before the baby arrives and the intervention commences postnatally. In a trial ($n = 656$) conducted by the authors of this report (AD, SJ and KJ) that assessed a weight management intervention during pregnancy and in which women were recruited at routine antenatal appointments in the community, a recruitment rate of 80.4% was reported, demonstrating that there is an appetite among women to be approached to participate in weight management trials prior to giving birth.[186]

Given the short window of opportunity available to recruit women and the cluster randomised research design adopted, it may be that an 'opt-out' approach to recruitment would be a more efficient method and would allow the trial to be better embedded into routine health-care practice. This may also allow for more timely translation and implementation should the intervention be shown to be effective. Evidence has suggested that higher response and recruitment rates may be obtained when studies employ opt-out methods.[187] Although acknowledging the ethics challenges that may arise in an 'opt-out' recruitment approach, such an approach would fit well with the cluster randomisation design; cluster trials more readily allow for an 'opt-out' recruitment process because a whole practice is allocated to one group allocation.

It might be the case that recruitment via other health-care professionals involved in the care of postnatal women and young babies might be useful in aiding recruitment, such as community midwives and health visitors. These routes of recruitment should be considered in future research studies.

Based on the recruitment response to this study, it is also possible that women do not want a weight management intervention shortly after giving birth; however, this is not consistent with literature that has reported that women do want early intervention. For example, longitudinal evidence has reported that, by 8 weeks postnatally, 84% of women were already attempting to, or were ready to start, managing their weight.[188] Similarly, an online survey that recruited 1015 women who had given birth in the previous 2 years and had joined Slimming World (Alfreton, UK) for the first time after having their baby, reported that approximately 45.6% ($n = 463$) of women began attending meetings between 1 and 7 months postnatally,[189] the time frame over which this intervention was delivered. The research team discussed recruitment methods with the PPI contributors throughout the trial; further engagement with contributors would be completed to optimise the recruitment strategy to the Phase III trial.

Adherence to self-weighing

Regular self-weighing has been shown to be an important strategy in facilitating weight loss, particularly when part of multicomponent weight loss interventions.[90,190–192] Once participants are recruited, engagement and later adherence are the most important determinants of effectiveness in lifestyle interventions. Low engagement rates in weight loss interventions may result in a non-significant outcome, despite the number of contacts offered/delivered.[193] In this trial, adherence to weekly self-weighing was good, demonstrating that women are keen to engage in this behaviour to manage their weight. Data collected via the objective recording BodyTrace scales showed that 63% of the intervention group weighed themselves weekly $\geq$ 60% of the time during the intervention, meeting the green stop–go criteria. When all available data (self-report and objective) from the BodyTrace scales, the weight record cards and the weight data reported in the POWeR programme were combined, adherence to weekly self-weighing increased to 69% over the scheduled intervention weeks. Collectively, these data show that postnatal women are motivated to engage in regular self-weighing soon after childbirth, a strategy that has been shown to be instrumental in facilitating weight loss in other populations and contexts.[130–135] One of the attractions of self-management-based interventions is that they are flexible, are individualised and can be engaged in by women at a time

that suits their daily lives. Although evidence shows that women engaged very well with self-weighing and recording of their weight, the CIs for frequency of self-weighing were wide; strategies to enhance this outcome could be considered to further increase engagement with this behaviour. Technology, such as text message reminders, may be useful in this regard.

Use of the POWeR online weight management programme

The use of technology to deliver lifestyle interventions has grown exponentially over the past decade. Technology-based interventions offer some key advantages over traditional behaviour change interventions: they have the ability to reach a large number of people at a relatively low cost; they offer increased access to the public at a time and place that suits their preferences, including the ability to overcome the need to attend face-to-face sessions to receive the intervention; and they are a way of encouraging self-care and self-management of health, which reduces NHS costs.

Participant engagement is critical to the success of any technology intervention. In total, 56% of participants registered to use the POWeR website and the amber stop–go criteria for progression was met. To have met the green stop–go criteria, $\geq$ 60% of participants needed to have registered with POWeR (56% achieved), which suggests that, prior to a subsequent Phase III trial, women would benefit from some additional support in using technology to support weight loss. Ideas for achieving this were raised in the qualitative interviews, such as making the POWeR website available as a mobile telephone application (hereafter referred to as app) and including more pages that are specifically relevant to postnatal women (see *Chapter 5*). It might also be the case that branded online weight loss programmes developed by commercial companies, such as those developed by Weight Watchers (New York, NY, USA) and Slimming World, may be useful.[194]

The small number of times that participants recorded a weight on the POWeR website is likely to be related to the weight record card being used instead. Given that weights on the record card were reviewed at the immunisation appointment (external accountability), participants were, therefore, more likely to record their weight on the record card than on the POWeR website. Engagement with the POWeR programme reduced over time and any future digital programme would probably need some additional strategies to sustain engagement. However, it should also be noted that engagement with the POWeR programme varied, with some women continuing to use it after the end of follow-up.

The clinical effectiveness of the overall intervention in any future trial will depend on the uptake, the ongoing engagement with the programme and the effectiveness of the programme. Here, we have data on only the first two of these elements. A previous trial has shown that the POWeR intervention was associated with weight loss at 1 year, but that this was not statistically greater than the control.[171] There have been considerable developments in digital weight management programmes since the initial decision to use the POWeR programme as the specific weight loss tool. Prior to a definite trial, an up-to-date review of the available resources will be conducted to identify the programme that is likely to best meet the needs of women, for example available in app format, and that also has evidence of effectiveness at least in general population samples of people who are overweight. Given the proportion of women recruited from ethnic minorities, it will also be important to consider programmes that are available in several languages.

Adverse effects from self-weighing

There has been debate in the literature on whether or not encouraging regular self-weighing might lead to adverse psychological health outcomes, including eating disorders and obsessive thoughts about body weight.[195–198] However, systematic reviews and studies do not support such a view.[199–201] Nevertheless, some consideration should be given to a small amount of evidence that has suggested

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that self-weighing could have an impact on psychological health. A systematic review by Pacanowski *et al.*[202] reported that self-weighing was associated with negative outcomes in young women. Of relevance here, Hartmann-Boyce *et al.*[203] reported a polarisation of views in relation to participants' attitudes and beliefs regarding the long-term use of self-monitoring techniques; some expressed experiencing a reduction in attentiveness, shame and even fear over time, whereas others claimed that self-monitoring increased levels of self-accountability, self-control and self-efficacy. Although participants in this trial were broadly supportive of encouraging women to self-weigh themselves regularly, there was also some evidence that it may lead to some participants feeling anxious about their weight; this will need to be investigated in greater depth in a subsequent larger trial and strategies put in place to mitigate occurrence.

Delivery of the intervention by nurses at child immunisation appointments

The UK guidelines advise all health-care professionals to screen for obesity and encourage weight loss via the provision of information and signposting to available weight management services.[71,75] However, evidence has shown that health-care professionals are reluctant to raise the topic of weight with their patients for fear of negative consequences, such as causing offence.[155,204] Kaplan *et al.*[205] have suggested that health-care providers were comfortable raising the topic of weight, but that time constraints prevented this during routine appointments. This study has provided data to show that practice nurses were able to 'raise the topic of weight' and deliver the intervention as per protocol.[205] Nurses delivered all components of the intervention with high fidelity. Furthermore, audio-recordings of the immunisation appointments demonstrated that, overall, nurses delivered the intervention well and in accordance with the protocol. This provides reassurance that the nurse training methods worked well and that the intervention can be delivered as intended during child immunisation appointments.

Intervention contamination

A cluster RCT methodology was adopted to minimise the potential for intervention contamination in usual care. Nevertheless, it is still possible for contamination to occur, and this trial aimed to assess this possibility of mitigating any potential effect(s) in a subsequent trial. In the usual-care group, only one participant (8%) reported that they had accessed or used resources to help them lose weight, none had accessed the POWeR website and three (25%) indicated that they knew another participant in the study. These data have indicated that the risk of intervention contamination is low, but that some consideration should be given to the possibility that contamination may occur.

Clinical outcomes

Several clinical and patient-reported outcome measures were included in this study to assess their completion rates for use in the subsequent effectiveness trial. However, this study was not powered to detect meaningful differences between the groups for these outcomes. All participants (except the participant who withdrew) provided weight data at follow-up and, similarly, there were few missing data for questionnaire-based outcomes, ranging from 0% to 15%. Missing data were primarily because of participants inadvertently not completing a specific item on questionnaires, rather than because they declined to complete them or found them difficult to understand. These findings are encouraging and provide confidence to include these questionnaires/outcomes in a larger trial. With respect to the health economics measures, the ICECAP-A was fully completed and, therefore, would form part of the economic evaluation design alongside the larger trial.

Assessments of weight, anxiety, depression, eating habits (TFEQ) and self-reported physical activity were included. Data regarding weight, body composition, participation in moderate-intensity physical activity and body image generally favoured the intervention group compared with the usual group at follow-up.

The intervention group reported higher anxiety and depression scores (marginal) and lower participation in light-intensity physical activity than the usual-care group at follow-up.

Implications

The intervention was deliberately developed with the ambition of the NHS to 'Make Every Contact Count' in mind.[206] The implementation of a multicomponent intervention that was embedded into routine health care may ensure accessibility to all women who give birth. This approach to intervention delivery seeks to ensure that hard-to-reach women, for example those with low levels of education, those living in deprived communities and ethnic minorities, who are perhaps more likely to be affected by obesity, are given the opportunity to receive weight management support after having a baby. Embedding a weight management intervention into routine child immunisation appointments presents an opportunity to routinely identify and treat more women with obesity to improve their potential weight trajectories during their reproductive years and beyond. The intervention tested here is brief and simple to deliver, which, if proven effective in a Phase III trial, may be cost-effective for the NHS.

Most people who lose weight will regain their weight loss within 1–3 years, highlighting the difficulties of sustaining health behaviour changes once active intervention is completed.[207–209] Related to this, in postnatal women, the needs of their child change during the first year, which can mean that barriers shift and new strategies are needed over time. Weight management interventions, therefore, need to be dynamic and flexible to address the barriers that this population of women may face over time. Such approaches might be to consider including text message support and/or further support at routine health-care contacts, given that many women will continue to engage with the NHS throughout the early years of their children's lives.

Most of the women recruited had more than one child; therefore, it is possible that the intervention is more appealing to these women who may be less likely than new mothers to be overwhelmed by the impact of a new child on their lives.

Strengths and limitations

This study has several methodological strengths and makes a unique contribution to the literature. To the best of our knowledge, this is the first study worldwide to assess the merits of a weight loss intervention embedded in a national child immunisation programme. This study was appealing to both first-time and multiparous mothers, suggesting that weight management during the postnatal period is a concern to women irrespective of the number of children that they have given birth to previously. Although the recruited sample was small, women varied in terms of their socioeconomic status, ethnicity and employment status, suggesting that the experiences of a wide range of women are represented in these findings. Importantly, the sample included a high proportion of women from more deprived areas. Practice nurses were trained to deliver the intervention following standardised procedures ensuring that the intervention had the best opportunity to be successful, and evidence shows that nurses adhered well to the protocol. The trial was conducted and reported in line with CONSORT guidelines to ensure that the trial methods were transparent and reproducible.

Process evaluations are often not included when evaluating complex health behaviour change interventions, but they can be very useful in helping to provide knowledge of 'how' the intervention is being delivered in practice. Several approaches to process evaluation were included in this study in relation to its setting, intervention delivery and the acceptability and implementation of the intervention. A selection of immunisation appointments in which the intervention was delivered were audio-recorded, and this provided objective 'real-time' naturalistic data on the interactions between

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participants and nurses to further enhance our understanding of how the intervention can be refined to maximise its effectiveness. The inclusion of the BodyTrace weighing scales allowed objective data on the frequency at which women weighed themselves each week to be collected, providing further real-time objective process evaluation data.

Many weight management studies rely on self-reported weight as outcome data at baseline and follow-up. By contrast, in this study assessments of weight were objectively measured by a researcher to ensure that these outcome data were accurate and not prone to bias or under-reporting. This approach also minimised the probability of missing data. Weight loss studies can often experience high loss to follow-up rates, but we were able to collect weight data on all participants who completed follow-up (27/28; one participant withdrew), demonstrating that the strategies used to ensure minimal loss to follow-up were effective. These strategies included conducting home visits for data collection at baseline and follow-up and providing a £20 financial incentive; these strategies should be used in subsequent research. We conducted semistructured interviews to obtain further understanding about the trial processes and the intervention components from both the participants' and the nurses' perspectives (see *Chapters 5* and *6*). The findings from the interviews provide important information in which the results of this trial can be understood and interpreted; the qualitative data collected can assist with the development of a more acceptable and potentially effective intervention in a subsequent Phase III trial.

Objective data on attendance at immunisation appointments were collected from medical records, so that the impact of the intervention on immunisation rates could be objectively assessed. This study provides reassurance that the intervention will not adversely affect immunisation uptake rates, which is critical to the integrity and safety of the intervention.

This study should also be interpreted in the light of some methodological limitations. By using a centralised hospital records system to invite all women who had recently given birth to take part in the study, the aim was to reduce the likelihood of recruiting only women who were highly motivated to lose weight, but we cannot discount the possibility that atypical women were recruited. Similarly, study procedures that involved home visits at baseline and follow-up may have resulted in recruitment of more motivated women. The characteristics of the sample may not be representative of the eligible populations, and those recruited may have responded to the intervention more favourably than might be the case for postnatal women more generally. Data collection on the views of women who declined to participate would have been useful in developing our understanding of the acceptability of the intervention. As this was a feasibility trial, the sample size was small and the findings should be interpreted with this in mind. Women self-reported their physical activity behaviour; therefore, the data may be prone to bias and over-reporting. Future studies should consider including an objective assessment of physical activity. A more detailed analysis of body composition would have been useful, as some studies have reported fluctuations in body fat percentage during the year following childbirth.

We assessed the intervention over only the first three immunisation appointments at 1, 3 and 4 months; the intervention was not delivered at the 12-month child immunisation appointment, so the longer-term effects of the intervention were not assessed. Nevertheless, it is important to consider that, as mothers become more accustomed to a routine with their new baby, they may be able to dedicate more time to their own health and well-being,[209] which may translate into a greater lifestyle behaviour change over time. An opportunity to measure greater change in health behaviours may have been missed, and in any subsequent trial this later 12-month immunisation appointment should be included in the intervention.

Sleep deprivation is common for many women during the postnatal period and can affect mood and energy levels.[210] Weight loss has also been linked to sleep duration and quality.[211–213] To attain more accurate and detailed data on this variable, future studies should include an objective measure of sleep, ideally through a tracker watch that records these data in real time each day.

Conclusions

This trial has provided evidence that a brief weight loss intervention focused on promoting self-management of weight that was delivered by nurses during routine child immunisations visits was acceptable to women who were recruited. Practice nurses were able to deliver the intervention with high fidelity, indicating that the intervention is feasible to deliver during child immunisation appointments. Adherence by participants to the self-weighing component was generally good. Uptake of the weight management programme was acceptable, although there is scope for improvement. However, recruitment was a challenge and the methods used to recruit postnatal women were not successful, and alternative approaches need to be tested prior to progressing to a Phase III trial.

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Chapter 5 Qualitative study (participants)

Introduction

After giving birth, a window of opportunity opens in which women may be motivated to lose weight.[214,215] Although many weight loss interventions for postnatal women have been tested and shown to have varying levels of effectiveness,[216] few studies have explored the views of women who participate in such interventions as well as simultaneously exploring the experiences of those who deliver these interventions to women. The Medical Research Council have advocated the use of feasibility and acceptability studies prior to more comprehensive and costly evaluations of complex health-care interventions.[217] This process allows any potential issues that might affect the delivery and acceptance of the intervention to be identified and resolved early on in the research process.[217] The use of nested qualitative research has been shown to be beneficial when addressing issues relating to the acceptability and practicality of an intervention.[218,219] It was intended that the findings from this qualitative study and the interviews with practice nurses who delivered the intervention would be understood alongside the trial data to provide a comprehensive multiperspective assessment of the feasibility and acceptability of the intervention. This chapter will explore the views of women who participated in the intervention. *Chapter 6* reports the views of practice nurses who delivered the intervention during child immunisation visits. This study (chapter) had the following objectives to:

- explore whether or not child immunisation appointments are an appropriate setting for postnatal mother's weight to be monitored
- capture intervention participants' views about how useful the intervention was in helping them manage their weight
- determine what elements of the intervention facilitated and/or impeded its acceptability
- investigate what aspects of the intervention were acceptable and unacceptable to participants, as well as the reasons for these feelings and opinions
- assess which components of the intervention may need to be amended, if any, and invite feedback from participants about how the intervention might be improved
- assess if the intervention led to participants experiencing any psychological harm relating to their weight.

Methods

Semistructured interviews were used to explore women's views of the intervention. Interviews were held after women had completed the intervention. Interviews were used, rather than focus groups or observation, because this study was focused on exploring women's individual views and experiences, rather than views that might be revealed in a group format or through their 'presentation of self' in front of others.[220] Semistructured interviews were chosen for several further reasons. Interviews provide the opportunity for key questions to be asked of participants, which allows comparison of question responses with others who have also experienced the intervention as well as the participant group as a whole. This process allows for patterns of variation to be explored while still allowing flexibility.[221] We aimed to gain a thorough understanding of and be able to describe trial participants' and nurses' experiences of an intervention embedded in an existing service; therefore, we used a 'generic approach' rather than following a specific theoretical perspective.[222] This study has been reported in line with the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines for the reporting of qualitative studies.

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Recruitment of participants

During the follow-up home visit at 3 months post enrolment, participants in the intervention group were asked if they were willing to participate in an interview to talk about their experiences of the trial intervention. Those willing to participate were asked to sign a separate written consent form prior to the interview taking place.

Interview topic guide and interview procedures

Before any interviews were conducted, topic guides with broad, open-ended questions were piloted to ensure that the questions were easily understood and coherent. The interview topic guide comprised open-ended questions and prompts to explore participants' reflections of key elements of the intervention, including their experience of regular self-weighing; their experience of being weighed by the practice nurse during child immunisation appointments; their thoughts on being referred to a website for weight management advice and information; and their general views of the intervention, including its timing (see *Appendix 1*). Participants were met once and given the freedom to expand on areas of interest and concern to them. If required, the questions were modified by the researcher to allow them to be better understood by participants, and their responses clarified and expanded on should they appear to be relevant to the study. Interviews lasted between 30 and 61 minutes. Natalie Tyldesley-Marshall conducted the interviews face to face in participants' homes, usually with the baby present. The transcripts were anonymised with unique participant identification numbers. Natalie Tyldesley-Marshall is female with many years' experience of qualitative research and has a Master's degree in Social Research. Participants received a £20 high-street shopping voucher to cover any out-of-pocket expenses associated with taking part in this study.

Data analysis

Data collected during the interviews were digitally recorded on an encrypted audio-recording device. Field notes were taken immediately after the interviews and integrated into the transcripts. Data were transcribed by a commercial company. A confidentiality agreement between the UoB (sponsor) and the transcription company was in place prior to any data being sent. Interviews were recorded and transcribed verbatim with the permission of participants. Interview transcripts were thematically analysed using the framework method, a recognised tool for collating data and facilitating its interpretation.[223] Data management was facilitated by using QSR International's NVivo 12 Plus. A list of overall and individual themes for trial participants was compiled to allow for cross-group/individual comparison.

An early transcript was independently reviewed by four authors (NTM, AD, HP and SG) (each with different disciplinary backgrounds: sociology, psychological and general practice) to develop the coding frame. Interviews were read and listened to at least two or three times to allow the study lead researcher (NTM) to become familiar with the raw data. Transcripts were analysed line by line and assigned codes, derived from the data, then assigned to themes identified. A framework 'matrix' (or grid) was developed with one horizontal row for each participant and one code for each vertical column, and was organised with codes under each theme on a new sheet. This enabled the researcher to immerse themselves in the data. Each transcript extract was entered into the matrix and summarised, with transcript page and line reference provided to allow comparison of participants by codes and themes by the same researcher (NTM), and to provide transparency in the coding and analysis process.[223]

Regular meetings were held with the qualitative study team to discuss additional codes and ideas to achieve consensus that would improve both the quality and the rigour of the study. This was useful because an experienced qualitative researcher (SG) was in the team, who guided the framework analysis process. Early thoughts about coding, themes and the direction of the analysis were also made and kept for increased transparency and rigorousness of the research. A record was also kept of the

coding, themes and any changes throughout the analysis.[223] Early transcripts were read to understand whether or not newer codes could be applied to earlier transcripts, and once interviews produced no new codes it was concluded that data saturation had been reached and no new knowledge would be obtained from further interviews.[224] The coding book is available in *Report Supplementary Material 2*.

Results

There were 14 participants who were allocated to the intervention group, and one indicated during recruitment to the trial that she was not interested in participating in an interview. Of the 13 participants remaining, two were not available in the time frame of the study, one had no time available and one was not contactable in the time frame of the study. A total of nine participants from the intervention group took part in an interview. The sociodemographic profile of these participants is shown in *Table 35*. Three main themes emerged from the data with 18 subthemes (*Table 36*). Participants were randomly assigned numbers; these do not correspond to the order in which the interviews took place. Each quotation is followed by participants' assigned number.

Pre-pregnancy weight and alternatives to conventional approaches

All mothers had previously tried to lose weight and all mentioned having used diet and/or exercise to manage their weight, with over half trying both. No participants mentioned specific diets, such as the 5 : 2 diet and Atkins Diet, but rather they referred to calorie counting or cutting out high-calorie food, alcohol or snacks from their diet. Exercise was mentioned by most participants and physical activities included using a commercial gym, exercise classes and more ad hoc community-based exercise, such as walking:

> *Yeah, like there have been times before where I've gone through stages of kind of, of weighing myself and recording it and that kind of thing, but I've never done any kind of erm, like official like Weight Watchers erm, so yeah, never kind of really consistently or with any particular um kind of diet or a structure to it.*
>
> *Participant 5, lost weight*

However, two women reported trying to lose weight previously through 'shortcuts' or alternative methods, such as consumption of cider vinegar, Chinese tea and 'fat burners' (weight loss tablets). Both of these participants had also tried conventional dieting methods:

> *I was trying to diet before I got married and then it didn't work. So I joined, this, doctor in [city] who prescribed me some medication that . . . Fat burners, something like that, and it's meant to suppress your appetite.*
>
> *Participant 7, lost weight*

Reasons for participating in the trial

All of the women were motivated to join the study to lose weight; however, the reasons for this varied between non-specific reasons, such as wanting to lose weight, and more specific reasons related to amount of weight, for example wanting to return to their pre-pregnancy weight, or wanting to lose weight for a particular event, such as an upcoming holiday:

> *I want to lose weight. As soon as I had a baby I wanted to lose weight because I'm planning on a big holiday! So I want, I want to be able to go on the beach.*
>
> *Participant 2, no weight loss*

One participant was motivated to lose weight for medical reasons stemming from their current weight, and another participant recognised the health risks as a result of their weight in combination with their ethnicity.

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TABLE 35 Characteristics of the intervention participants who were interviewed

Age (years)	Ethnicity	Baseline BMI (kg/m^2)	Follow-up BMI (kg/m^2)	General practice (IMD rank)	Self-reported financial status [employment status]	Number of children	Marital status	Gained/lost weight
42	White	30.8	27.4	High	*I have enough money if I plan my spending carefully* [in paid employment]	1	Married	Lost
30	White	34.9	34.4	High	*I normally have enough money for whatever I want* [looking after the home/family]	2	Married	Lost
40	White	27.7	27.1	High	*I have enough money if I plan my spending carefully* [in paid employment]	3	Single (living with partner)	Lost
30	Black African	36.1	36.1	High	*I have enough money if I plan my spending carefully* [in paid employment]	3	Single (living alone)	Stayed the same
23	Other Asian	31.6	29.0	High	*I normally have enough money for whatever I want* [student]	2	Married	Lost
33	White	27.7	25.5	High	*I normally have enough money for whatever I want* [in paid employment]	1	Married	Lost
29	Other (Iraqi)	42.4	32.2	Medium	*I have enough money if I plan my spending carefully* [looking after the family/home]	2	Married	Lost
32	White	28.7	27.8	High	*I normally have enough money for whatever I want* [in paid employment]	1	Single (living with partner)	Lost
39	Other Asian	30.0	26.5	High	*I normally have enough money for whatever I want* [in paid employment]	2	Married	Lost

TABLE 36 Coding framework

Intervention participants' coding framework	Practice nurses' coding framework
Barriers to and facilitators of weight loss	
Barriers to weight loss	Perceived barriers to mothers' weight loss
Facilitators of weight loss	Perceived facilitators of mothers' weight loss
How to lose weight	How to lose weight
	Ideal time, space and role for weight loss and intervention
	Potential barriers to weight loss according to nurses
Evaluation of the trial	
Areas for improvement	Areas for improvement
Credibility of scales	
	Assessment of training
	Identifying trial participants
	Impact of the trial on appointments
Impact of the trial/intervention	Impact of the trial on participants
Importance of numbers	
Opt out	Rolling out the intervention
Positives of the intervention	Positives of the intervention
	Recording weight
Steps in appointment	Steps in appointment
Website content	Website
Website positives	
Feelings around weighing and weight loss	
Accountability: participants	
Emotional issues around losing weight	
Feelings knowing that they will be weighed	
Feelings when nurse weighs	Participants' feelings while weighing
Reasons for starting the trial	
Self-weighing feelings	Nurses' feelings when weighing participants

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Would I recommend the trial to other postnatal women?

All participants except one would recommend joining the study to other mothers, but with some considerations. The content of the website was the only reason that one participant would not recommend the trial:

> *I'd say no because of only the content of it. It wasn't . . . There were bits there . . . but once you've read the same thing . . . for the last 3 weeks it's the same again. There's no change to it.*
>
> *Participant 4, lost weight*

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One participant was concerned about those with eating disorders being recruited to the trial. Although most participants talked about the difficulties of being a mother to a newborn baby, only one would have started the intervention a few weeks later, so as not to place too much pressure on a mother (particularly first-time mothers) who could be going through a 'hard' time:

> *Err, yes, I, I would . . . But I would say to them though, ya know, it's it's . . . just . . . [slight sigh] if they're in the right space. As I said, I never realised how hard being a, a parent would be. It's really, really hard and um, . . . it, it I think if somebody was really struggling with, ya know, a new baby, I wouldn't recommend it 'cos I think it's, it's something they don't need to then be 'Oh, I'm sorry, but you're really fat, you need to lose weight as well'.*
>
> *Participant 3, lost weight*

When asked what sort of things would help other new mothers lose weight after pregnancy, almost all of the participants gave answers in terms of changing diet, increased exercise and a few specific exercises or strategies, such as cooking meals at home. These answers were typically tied into the notion of social support and having significant others (especially those whom they lived with) encourage them in their new weight loss behaviours, and support them in ways such as reminding them not to buy certain foods, caring for the baby while they exercised or buying aids that allowed them to exercise with their new baby:

> *So I think having some kind of support system in place . . . non-judgemental support system in place that isn't like 'Oh my gosh, you didn't lose weight. You must be eating too many Oreos, but instead like this is a common issue. Here are some steps you can take. Hang in there'.*
>
> *Participant 1, lost weight*

Barriers to weight loss for new mothers

Participants discussed several barriers to their weight loss. For most participants, their baby was a barrier to navigate around if they wanted to exercise, and it was hard to leave the house to exercise. Gyms did not always have breastfeeding facilities, crèches or mother and baby classes. If there was nowhere to 'store' the baby, then suitable child care (paid or unpaid) had to be found. Alternatively, 'baby-friendly' physical activity had to be found. Breastfeeding was seen as a barrier to weight loss, for example when gyms did not have facilities for breastfeeding and when increased hunger from breastfeeding led to increased calorie consumption:

> *[They are] not a once every 3-hour baby, [they're] a once every hour baby. Which makes it hard. [They don't] like bottles and so swimming I can do because I can run up ter [the local public swimming baths], swim fer a half hour, come back and be back for [their] next feed.*
>
> *Participant 1, lost weight*

> *The more I'm breastfeeding, I'm more hungry . . . than anything else because my [child], although now I'm trying to like give [them] solids, [they] don't want it. [They're] constantly on my breasts.*
>
> *Participant 2, no weight loss*

Three participants mentioned that tiredness from raising a newborn baby led to them making less healthy dietary choices; when fatigued, they chose less healthy options that required less effort to prepare. Similarly, having a newborn baby meant an unpredictable schedule and a necessity to plan and work around the schedule of the baby, which similarly led to participants choosing less healthy food options that were quicker to prepare:

> *It's tough . . . already. You have a new baby . . . that is depriving you of sleep. Erm, you have what, 2 hours sleep, interruptions overnight at times all you want is, ya know, cake, wine, takeaway and a few indulgences.*
>
> *Participant 3, lost weight*

> *Yeah! Easier to just go to [shop] and just [quieter] get a ready meal from M&S [London, UK] and put it in the microwave than spending 2 hours cooking.*
>
> *Participant 2, no weight loss*

Participants commented that continuing and maintaining behavioural changes was difficult (despite the perceived effectiveness of the intervention), and most of the participants talked about the temptation to 'fall off the wagon' and stop maintaining their weight loss efforts in the face of alternative pressures, such as stress and tiredness, or allowing themselves an 'indulgence'. The study was seen to help them keep 'on track':

> *It [being involved with PIMMS-WL] been good 'cos' it helped me to, stay in track of my weight 'cos' I see, weigh myself every week. So kinda like, this week if I lose weight I'm . . . happy, then next week if I put it on loads, I can't . . . I need to watch what I'm eating.*
>
> *Participant 2, no weight loss*

Facilitators of weight loss

Several comments were made about potential facilitators of weight loss. Some participants reported that being a new mother had brought more of a freedom from the restrictions on exercise during pregnancy and a time to restart exercise habits that their baby could join in with. One participant (who had a supportive partner who was able to look after their baby) was able to use the time when their baby slept to exercise and was of the view that they now had more time available to exercise than when they were employed. Another participant viewed being a new mother as liberating, given that they were restricted from exercising during pregnancy and had experienced a post-pregnancy condition that had restricted their exercise for a number of weeks thereafter:

> *Like I know some people have a really difficult time with babies with sleep and getting out of the house and all that kind of stuff. I don't know if I've been lucky because [they're] relatively easy to do things with, but that's allowed me to go out and do exercise.*
>
> *Participant 5, lost weight*

Although breastfeeding was viewed as a barrier to weight loss, in some instances it was also considered a facilitator in terms of the view that it can lead to more calories being 'burned':

> *I mean in, in my case I really do think that breastfeeding's helped a lot [towards weight loss].*
>
> *Participant 1, lost weight*

Having a newborn in the house made one mother think more about the impact that her own health behaviours were having on her baby; therefore, both she and her partner tried to model healthy eating behaviours to engrain 'good habits':

> *We want [them] to eat healthy, ya know, and it's all vegetables and fruits that we have [them] on, so that's nice ter- We eat [their] leftovers too. They're good for us too. We'll show [them] like 'Look, pear is good!'.*
>
> *Participant 1, lost weight*

Intervention components

Participants expressed a range of views about the intervention components and their feelings about how effective each component was in helping them to manage their weight. The following section provides a summary of the thoughts and opinions of the women; it is not an exhaustive list. *Table 37* provides an overview of participants' feelings on being weighed by practice nurses and self-weighing.

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TABLE 37 Participants' feelings about being weighed by nurses and self-weighing

Participant identity number	Feelings about self-weighing			Feelings when anticipating nurse weighing			Feelings during nurse weighing		
	Good	Indifferent	Bad	Good	Indifferent	Bad	Good	Indifferent	Bad
1	Good/ control/ pride		Fear	Excited/ pride	Fine	Fear	Good		Fear
2	Happy		Fear	Motivated				Fine	Fear
3			Worry		Unfazed			Unfazed	
4	Good	Unfazed			Unfazed			Unfazed	
5		Fine	Bad		Fine			Fine	
6	Control		Worry		Fine	Worry		Fine	
7	Excited/ good/pride			Good/ excited			Excited/ good/ motivated		
8	Good/ control		Worry		Fine		Happy		Worry
9	Pleased/ excited	Unfazed			Fine			Fine	

Being weighed at child immunisations

When anticipating being weighed by nurses at child immunisation appointments, most participants were unconcerned about being weighed. Two participants felt good or excited about being weighed and two felt anxious/scared when they expected to have gained weight. One participant commented that being weighed 'motivated' her to lose weight (Participant 7). At the appointments, most participants reported that they continued to feel unconcerned about being weighed. Two women continued to feel anxious when they recorded weight gain on the nurse scales:

> *They [the nurse weighing me] didn't bother me. I'm, I'm not bothered, yeah, so it's fine.*
>
> *Participant 4, lost weight*

Most participants reported that the nurse was supportive and/or 'non-judgemental' if they had maintained or gained weight. Participants commented that nurses tended to congratulate them on weight loss or say something encouraging, such as they would lose weight by the next immunisation, or suggest that they go to the POWeR website for more weight loss support, which many participants found a source of encouragement or motivation:

> *She would always tell me how well I did. And how great I looked and tell me I'm doing a great job and that, that weight's gonna to come right off. And um, and she was, she was always very positive.*
>
> *Participant 1, lost weight*

No participants thought that their baby's immunisation appointment was an inappropriate or unsuitable time for delivery of a weight loss intervention or to discuss weight-related issues. Some participants described it as a 'good time' to discuss weight (Participant 9) or said that it 'definitely worked' (Participant 5). Some women praised the convenience that they did not have to make an 'extra' trip out of the house with their baby:

> *Yeah, it seemed to work quite well as a way of doing it. Erm, and because . . . you're there every 4 weeks, it's a good . . . space of time where you can . . . ya know, you're going to be able to see a difference, in your*

> *weight, in that time, so it seemed, it seemed like a good, a good opportunity to do that that weigh in. Yeah. It was just kind of another point to check in on things.*
>
> *Participant 5, lost weight*

Two participants felt that there should be more support for weight loss for postnatal women from the NHS shortly after child birth and, therefore, that this intervention was ideal:

> *I'm happy for the attention on [them], but I feel like . . . um, postnatal care just kind of falls to the wayside fer, the mothers, and so, I was happy to get any attention at all, ya know what I mean? Like 'How are you feeling? Ya know, get on a scale,' instead of it just . . . Otherwise I would have just walked in, they would have given [them] a jab and I would have walked out.*
>
> *Participant 1, lost weight*

> *Because when you have a baby, you're on your own after that, after the midwife finished doing whatever . . . Even if you go to the doctor and wanna lose weight, they'll tell you 'Go diet.'. That's what they tell you. They don't even tell you how you can do it. They just tell you . . . 'Go diet.'. 'Diet I tried is not working. Give me another advice!'.*
>
> *Participant 2, no weight loss*

Only one mother was concerned that the nurse appeared busy and had many mothers queuing outside the consultation room, so felt that if they had questions about weight loss they would not ask them:

> *But when the lady came to my house, the PIMMS lady, then I was quite happy to talk to her an' . . . have a conversation, whereas I think in the, in the setting of a busy GP practice I'm not sure . . . I would have . . . felt like I could really . . . sort of talk for a long or, ya know, ask questions or anything 'cos I feel, you just feel like, ya know, they're so busy you don't want ter . . . take up too much of their time.*
>
> *Participant 9, lost weight*

Weekly self-weighing and recording of weight

No participants objected to self-weighing and recording their weight at home. However, some participants reported problems with the reliability of the BodyTrace weighing scales, with some finding that the reported weight deviated by ≈ 1 kg, depending on the room, time of day or type of floor used when weighing. This led some women to view the scales that were used at the immunisation appointments or their own eyes (e.g. by looking at the fit of their clothes) as a more reliable measure of their weight loss progress. Almost all of the participants indicated that they were able to weigh themselves either every week or almost every week, although one participant decided to stop weighing herself after 4 weeks owing to technical problems with her scales. All of the participants found the process of self-weighing easy to remember, typically doing so on a specific day:

> *Yeah, it was fine. By just setting . . . the day and the time to do it it meant that I could just . . . yeah, just every Wednesday morning.*
>
> *Participant 9, lost weight*

Emotions and self-weighing

When weighing themselves, participants reported that their expectations of their weight affected their emotions; typically, they felt 'good' when they expected to see that their weight had gone down,

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whereas they felt worried, fearful or 'bad' if they expected an increase in their weight because of a 'bad week'. However, for two participants, self-weighing made them feel in control of their weight:

> *[I felt] good, when it showed that I'd lost sooo much.*
>
> *Participant 7, lost weight*

> *Yeah. Ermmm, some weeks I felt a bit anxious if I hadn't . . . done well.*
>
> *Participant 6, lost weight*

> *I guess just like on days when I weigh myself and my weight has gone down, I feel great and like, I'm in control of things. Do you know what I mean? Like I'm directing the ship [NTM laughs] and it's going in the right direction.*
>
> *Participant 1, lost weight*

All of the participants reported finding self-weighing useful. Most participants reported finding the weight displayed on the scales as an important way to see that their weight loss efforts were having an effect and that they were making progress. For some participants, the scales changed their point of reference for their weight. Rather than comparing their current weight with, for example, their weight before becoming a mother, perhaps in their 20s, they compared their current weight with their weight at the start of the intervention:

> *I guess it [weighing yourself regularly] kind of helped you, um, know how you were progressing.*
>
> *Participant 3, lost weight*

> *And if I hadn't . . . had that [figure] to compare against I would just always feel like I was . . . 'I'm heavier than I used to be.'. Instead of 'look how much I've lost in the last 6 weeks'.*
>
> *Participant 1, lost weight*

Some of the participants commented that the actual weight displayed on the scales was less important than other measures of progress, for example how their clothes fitted and their reflection in the mirror. For the most part, these views were likely to be expressed by participants who had experienced issues with the reliability of the scales:

> *I normally go off erm, how my clothes fit anyway. Because that's what they normally say anyway.*
>
> *Participant 4, lost weight*

> *How do the jeans feel ya know, when I'm wearing, wearing, wearing them or how do I kind of look in the mirror? Ya know, those, those are the ways that I, tell. And I can feel it in myself as well . . . So it's more on how I feel than necessarily a number, on the, scales, I guess.*
>
> *Participant 5, lost weight*

The POWeR website

All of the participants commented that they felt that it was acceptable for nurses to refer them to the POWeR website for support, rather than being given the information about weight management directly from the nurse at the immunisation appointment. The reason given for this view was that the website could be accessed more frequently from home at any time of the day, which was important because this allowed access to fit around the unpredictable schedule of the baby and while their baby was sleeping:

> *[It's] easier because you haven't gotta go out of the house to them. You know, go out of the house with a baby in tow. Um, and you can sort of do it at home. At your own pace sort of thing.*
>
> *Participant 4, lost weight*

> *Well, you don't meet the nurses often, right? While, with the website I can go on once a week. [baby interruption] But errr . . . with the website, I could go in and I could access it more often.*
>
> *Participant 1, lost weight*

The website was generally well regarded and found to provide useful information. One participant, however, pointed out that the website contained information that she had 'seen before' (Participant 5). Another participant commented that there were few 'bells and whistles' to it (Participant 1), although its appearance was not as important as its function:

> *There's quite a lot of info- helpful information on the, website, yeah. Gives you a list of all the um . . . ideas of if you want to do like a low-carb diet or a low-calorie diet an', things like that and it gives you like . . . guideline that you could follow.*
>
> *Participant 6, lost weight*

Two participants commented that the information on the POWeR website came from a 'trusted source' owing to its links with the NHS, and one participant valued that the website was free to use and free from advertising. One participant had been concerned and confused by many differing opinions from the internet and friends' opinions; therefore, they were very pleased to have advice that they could trust about which diets were safe:

> *Yeah. Yeah, it's very helpful for new mums and . . . maybe you can find the best way and . . . healthy way because not everything is healthy it's a very . . . helpful and safe website.*
>
> *Participant 8, lost weight*

Most of the participants were able to access the POWeR website, but one participant had technical difficulties related to their laptop computer. One participant had difficulties when they lost the password and another encountered a difficulty with the link to the POWeR website. Although most of the participants used a computer to access the website, one mother commented that the site could be more compatible with mobile telephones. Participants commented that, because they had a new baby, they were not always able to have immediate access to a laptop to access the POWeR website. By contrast, they always had access to their mobile telephone:

> *Ermmm, the only thing about it was I was doing it on my phone. And it's not like . . . erm, kind of phone compat-, compatible, so you have to like zoom in . . . On stuff it's just easier when I had like, a few minutes on my phone. 'Cos I've always got my phone with me I'd say that would make it better. Definitely.*
>
> *Participant 5, lost weight*

> *I'm still weighing myself and I put that in My Fitness Pal [Under Armour, Baltimore, MD, USA] app so I can see how much I've gained or lost.*
>
> *Participant 1, lost weight*

Some of the participants mentioned that the modules did not take long to read, that reading the modules could be started and dropped easily, and that the modules fitted around their baby's schedule. Two participants commented on the website being motivating:

> *It was nice that they weren't super lengthy. I think that was . . . the best part because if they were [NTM laughs] I wouldn't have had time to do it.*
>
> *Participant 1, lost weight*

> *Because you've just given birth you don't wanna do . . . erm, you've got no time for, so you do it at your own pace. Erm, no, I think it's, it's really good. An' it, an' it was easy.*
>
> *Participant 7, lost weight*

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> *I've actually made a, a concerted effort to . . . even abolish all freezer mixes like, ya know, fish and chips and just fings that are really quick, erm, to in replace of home-cooked/slow-cooked meals because now I just . . . cook batch and um, it lasts for ya know 3 or 4 days and it's healthy. So I think yeah, but that sort of incentive from, the PIMMS-WL, erm the POWeR ya know website, is, it's good. So that, all together has ya know helped me, lose weight.*
>
> *Participant 3, lost weight*

Entering a new goal every time that they logged on was found to be difficult by two participants; however, two other participants found that setting goals and regularly reviewing these goals was useful:

> *[My e-mail reminder] was kind of like 'Right, do you want to review any of your targets?' and I was kind of like 'Well, I've got targets there. Can I really be bothered to review them and change them?'. So there's probably not, that much that I'm getting out of it now.*
>
> *Participant 5, lost weight*

> *I liked the, setting goals. It had me set goals and then . . . then it would ask, you know, what was helpful and what wasn't or 'Were you able to hit your goals or not?' or 'Do you want to modify them?'. That was . . . I found the goal-setting really helpful.*
>
> *Participant 1, lost weight*

Two participants suggested that the content of the POWeR website could be more focused on postnatal-specific diet and exercise issues, such as having post-pregnancy complications that delay or restrict certain exercise and needing to avoid drastic calorie reductions because of breast milk production. A couple of participants thought that videos for 'exercise with baby' would have been useful, and one thought that other people's 'inspirational stories' would provide motivation:

> *Maybe personalising the website, more too . . . um, to, kind of the real dilemmas of . . . motherhood in the early years, ya know, in the early weeks and early months of . . . um, because like I wasn't physically ready to do some of it.*
>
> *Participant 1, lost weight*

> *I'm not sure if they had any like stories about other people, I can't remember. Like, things like that that you could just like read up inspirational things that you can like . . . Think, if you're having a bad day or read stories and it's a bit, it helps you a bit.*
>
> *Participant 6, lost weight*

Some participants liked that the POWeR website allowed them to personalise information for them. They were allowed a choice (primarily between a reduced-calorie and a reduced-carbohydrate diet) and to select the modules of interest to them:

> *Ermm, so yeah, you, you choose your plans. You choose your goals, which was good, and then. You review your goals at the end of the week.*
>
> *Participant 3, lost weight*

All participants would recommend the website to others, although a couple had provisos. One stated that it would be helpful only if the mothers did not already have basic knowledge of nutrition and diet, such as knowing which foods are carbohydrates and which foods have high calories:

> *I'd recommend it to a mum who had no idea at all about how to lose weight or how to eat healthily. I think if you've got a relatively good grasp, then I don't think it would be useful.*
>
> *Participant 5, lost weight*

Participants made several suggestions for improving the POWeR website, which included better compatibility with mobile telephones, inclusion of videos of exercises that could be undertaken with a baby and at home, and inspirational success stories of new mothers who had lost a lot of weight, ideally through the intervention.

Strengths of the intervention

Two participants advocated that the intervention should be rolled out to other hospitals:

> *Personally, I think women, would love the opportunity to be given to them, personally, but obviously I can't speak for every women. But personally I think it's a great opportunity to be . . . introduced . . . not, not just for the women in hospital. Across Birmingham.*
>
> *Participant 2, no weight loss*

Accountability, or the notion that they would have 'an obligation to explain and justify conduct', was mentioned by most participants:

> *Like even though you don't feel like you're being . . . I never felt like I was kind of being checked up on or pressured, but you kind of think 'Well, I've set myself these 12 or 16 weeks ter try and lose weight. I'm committed to doing it.'. Just by having an external, agency there who are aware and involved in it can potentially motivate you to do, to do more than if no one's going to know, if you've not, tried or not.*
>
> *Participant 5, lost weight*

> *Because obviously now I know that there's also, a third person who's watching me. It's not just . . . me . . . between the closed door or the researcher who's seeing whatever is, recording. Yak now, yeah, it was motivating.*
>
> *Participant 2, no weight loss*

About half of the participants commented that simply being part of the trial was a useful, regular reminder that they had to focus on losing weight and that they had to be continually mindful of their behaviour:

> *Yes 'cos obviously to lose weight these days . . . is difficult to do on your own than when you've got somebody there nagging you in the back of your head. You know you've got this programme that you're doing. It's like just going to Weight Watchers. You know every week you have to be going to be weighed. It's similar to dis as well. Every week you have to be weighed, so . . . you're keeping track of your weight.*
>
> *Participant 2, no weight loss*

Participants felt that a particular strength of the intervention was that it did not require women to make additional visits to the practice to be weighed. A few participants mentioned how little effort it required and that it was easy to integrate the intervention components into their existing behaviour. All participants found that the intervention, or some aspect of it, increased their motivation for or commitment to losing weight. Over half of the participants commented on the perceived effectiveness of the intervention for them, and two found this to be motivating:

> *That would be . . . quite inconvenient. Just to go there to be weighed. Because I'd have to take the baby, and. In the early days . . . ya know . . . It's more difficult to get out and about, so . . . I was happy to do it, 'cos I was there anyway.*
>
> *Participant 9, lost weight*

> *It hasn't, it hasn't been too kind of . . . too much work or effort or anything like that, like. [. . .] Yaknow, it was very much kind of fitting it in, alongside what I was kind of doing anyway.*
>
> *Participant 5, lost weight*

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Yeah, erm, it's made me more focused, made me more determined . . . to get back on it. To give me like the incentive. It's given me like a head start.

Participant 6, lost weight

It's very hellllll, helpful for us because when I check, my weight is going down and it helps me to continues.

Participant 8, lost weight

Most women reported liking the 'non-judgemental' delivery of the intervention, with reference to both the nurses and the POWeR website:

And um, it didn't make you feel bad . . . Like, yaknow, you didn't feel bad for having a bad week. It was actually very encouraging, like 'Yaknow, you've had a bad week, don't give up. Try this module on how to deal with slip-ups'.

Participant 3, lost weight

Later impact of the study

Most participants stated that they were now more confident that they would be able to manage their weight in the future and that they accepted that they could lose weight:

The fact that I did erm, is a positive thing and it shows that I do know, what I need to do to lose weight. It's just a case of maintaining it. Erm, soo . . . yeah.

Participant 5, lost weight

Thank you for the, thank you for this research. It's very, very helpful for me and I changed my life.

Participant 8, lost weight

One participant reported a change in perspective after the study, an increased awareness of the lifestyle choices that affected their weight. Some mothers found that taking part had instilled effective habits for weight loss:

I'm more conscience, conscious about what I eat. Brown bread. Yeah, like just changing like little things, like um, the olive oil instead of the regular and, not eating out as much.

Participant 7, lost weight

I did a lot of the stuff that, the trial encouraged has now become just a routine, so hence, erm that's an important part, is, erm, habit. So um, yeah, I'm fairly happy and confident that I should be able to, continue all the things that I've learned.

Participant 3, lost weight

General suggestions for improvement

One participant thought that self-weighing could be less frequent than weekly, which would allow a longer period between weighing and a larger, more noticeable difference in weight loss:

Erm, it was better, er, using the scales, as I said, erm, e- every few weeks in the immunisation. I found that more useful because every week you get obsessed with the, the tiny numbers, whereas if you weigh yourself every, almost every month you kind of . . . you appreciate I've actually lost a lot of weight, um, as opposed to 'Oh, I've lost a pound', 'I've lost yaknow two pounds'.

Participant 3, lost weight

A few participants believed that it would have been helpful to have someone contact them in between immunisation appointments to check their progress and encourage them to keep 'on track' with their weight loss targets:

> *I think someone should have called me or e-mailed me to like push me a little bit and threaten me a bit. Not threaten me, but like just say erm, 'We've noticed you haven't weighed yourself this week' something like that. Or 'Is there a problem with your scales?'.*
>
> *Participant 7, lost weight*

About half of the participants thought that it would have been useful to have a telephone number or an e-mail address to contact if they needed to ask something and did not want to wait until the next appointment. However, their responses suggested that this was more a need for regular contact with a supportive person to keep them motivated and continuing to adhere to their new behaviours, and all of these participants wanted this in addition to the website, not to replace it. One participant would also have liked to have something tangible, such as leaflets about weight loss, and not just website access:

> *I mean it is helpful um, having the website, but. I'd probably like a, maybe a bit more . . . um, personal support or sumfin. . . . If you had someone that you could call or text if you were having like a bad day or something, I think like something like that'd help just to know that you've got . . . a bit of extra support, to be honest.*
>
> *Participant 6, lost weight*

Two participants suggested that the trial could have been mentioned earlier to pregnant women to make them aware of its existence before attempting to recruit them after pregnancy:

> *Yeah. I fink . . . dis programme . . . like instead of just us having it after birth, I think . . . Yaknow like towards the end of the pregnancy, I think if . . . obviously I don't know if the midwives are going to agree to do it – but if your midwife can start talking to you about it [. . .] just give you information, like the leaflet for you to read, and then, next time when you go see them, then they can just ask the question 'What do you think about the leaflet I gave you?'.*
>
> *Participant 2, no weight loss*

It was also suggested that nurses could be supported by a health visitor or someone in a similar role, who would visit new mothers at home to discuss weight loss.

Changing the methods of recruitment to the trial

Participants were asked for their views in relation to changing the method of recruitment to opt-out. It was put to participants that trial practices could make the intervention routine care for all new mothers (which could be declined) and all women at practices would enter the trial. Their expectations of how new mothers would feel about this method of recruitment varied. Most thought that women would have no problem with this approach, given that they could always refuse to participate:

> *I don't think people have, a major problem with it . . . It might just be, if people aren't . . . losing the weight, because I know a lot of people struggle. I think it's a, a bit of postnatal care sort of thing, which'd be quite helpful for some people.*
>
> *Participant 4, lost weight*

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Some participants suggested that if an 'opt-out' method to recruitment was used, health-care staff should be mindful when approaching mothers because weight is a sensitive topic and women should be approached in a caring manner:

> *I think . . . maybe people would be alright with it. But I know people can be very sensitive about their weight, so. I think if you explain to them and just say 'Look, we're offering you the opportunity ter, have weigh-ins at each of your immunisations so that over the next 12 to 16 weeks if you would like to try and lose weight you could do that,' erm, then maybe people would go 'Oh yeah, that would be a good opportunity'.*
>
> *Participant 5, lost weight*

> *But then you have to bear in mind people with anorexia and stuff like that. That's the only thing. Yeah.*
>
> *Participant 7, lost weight*

Discussion

The study explored the views of participants who experienced the trial intervention. Most participants were keen to lose weight after having a baby and were motivated to join the trial for this reason. Using child immunisation appointments as a context for delivering weight management was viewed as acceptable and some viewed it as 'ideal'. All but one participant would recommend the intervention to their friends. Regular self-weighing and recording of weight was viewed as an acceptable and sustainable strategy for weight loss. Women also liked the use of technology to facilitate weight loss. Many participants talked about the difficulty of maintaining and persevering with their dietary and physical activity behaviours to facilitate weight loss, such as depriving themselves of their favourite 'indulgences' and choosing the most convenient dietary option rather than the healthy option. Social support for weight loss was considered important in terms of reminders not to buy particular foods and providing child care to allow participants to exercise. Some of these key themes are discussed in more depth in the following sections.

Weight loss after pregnancy

Studies have reported that women are motivated to lose weight after having a baby, and this was also the case for participants in this trial.[76–79] Participants expressed a strong desire to lose weight and welcomed support from the NHS via this trial to help them achieve this goal. Although women expressed several barriers to losing weight, such as lack of gym facilities, lack of child care and tiredness, the time after giving birth appears to be a good opportunity to engage by facilitating changes to their dietary practices and physical activity behaviours. This process may have additional benefits to women's health; for example, exercise is known to improve mental health and, specifically, postnatal depression, and weight loss has been associated with improved mood and body image.[226–228]

Self-weighing as a strategy for weight loss

Women were generally accepting of the instruction to weigh themselves and record their weight regularly. Participants reported that self-weighing and recording of weight was easy to do and they were able to remember to do so each week. Several women commented that they had used an implementation strategy (action plan) by weighing themselves at the same time and/or day each week. This is important because having an action plan is the cornerstone of long-term behaviour change and it can be critical to preventing relapse. These findings are also encouraging because there has been some concern in the literature that asking people to weigh themselves regularly might cause unintended negative psychological consequences, including disordered eating.[195] Consistent with these findings, several other studies have not found an association between self-weighing and negative psychological health outcomes.[197–200]

Using child immunisation appointments to offer a weight loss intervention

To the knowledge of the authors, no other published study has tested an intervention embedded in child immunisation appointments and, therefore, the intervention tested here was novel. The PPI representatives were involved in its development and they expressed some apprehension about how well the intervention would be received by mothers. Most of this concern was based on child immunisations being a stressful time for mothers and, therefore, a weight management intervention may not be well received at this time. However, participants in this study did not report a similar concern. Women reported that it was acceptable for practice nurses to deliver the intervention at child immunisation appointments and for nurses to serve as a source of external accountability for their weight management (see *Weighing by practice nurses and accountability*). No participants reported feeling that the intervention took time away from their baby or the immunisation. Participants commented that the intervention was convenient because it did not require any extra visits and that they welcome support from the NHS and, consequently, this type of intervention was ideal for them. Participants felt that nurses were supportive and having encouragement after a 'slip up' enabled the participants to continue with their behaviour, rather than viewing their efforts (and themselves) as a failure and reverting to a number of past unhealthy behaviours: to 'fall off the wagon'. All participants indicated that they would recommend the study to their friends, highlighting additional acceptability of the intervention.

Weighing by practice nurses and accountability

The intervention was deliberately designed to be brief and simple for nurses to deliver, so that it could be readily embedded in routine consultations in primary care. The centre piece of the intervention was the principle of 'accountability': the notion that someone other than yourself is observing and cares whether or not you reach your weight loss goals. The primary role of the nurse was to provide external accountability, not to provide detailed advice or counselling. Women reported that the nurses were supportive, and knowing that they would be weighed by nurses helped to keep them focused on their weight loss goals (external accountability) and motivated them to persevere with changes to their diet and physical activity behaviours.

Weight and emotions

Although self-weighing may help people manage their weight, there may be concerns that it will have adverse psychological consequences or lead to the adoption of unhealthy weight control behaviours. Some researchers have suggested that feedback about body size may lead to psychological distress and that self-weighing may have a negative impact on body image and/or mood by continually reinforcing to people that their current body size is not ideal, or result in unhealthy dietary behaviours, such as binge eating and skipping meals.[195,196] As highlighted earlier, there is little evidence to support these concerns, but it is still important that trials continue to monitor whether or not self-weighing leads to negative psychological events. The emotions experienced by participants when weighing themselves varied depending on the weight that they expected to see displayed on the scales: typically they felt 'good' when they expected to see that their weight had decreased, whereas they felt worried, 'fearful' or 'bad' if they expected an increase because of a 'bad week'. The results of this qualitative study are consistent with Hartman-Boyce *et al.*'s[202] synthesis of qualitative studies of self-weighing, in which viewing weight as a way to assess success or failure towards weight loss was found to lead to feelings of guilt, shame and disappointment, including avoidance of self-weighing in those who suspected that their weight was stable or had increased. Shifting perceptions of self-weighing as a means to self-knowledge and better understanding of weight and its fluctuations/changes, however, may remove the emotional impact associated with self-weighing. It is interesting to note that more participants reported stronger negative emotional responses to weighing themselves than being weighed by the nurses.

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Most participants were unconcerned about being weighed by the nurse, which may be related to participants feeling that their nurse was non-judgemental and supportive.

Using technology to assist with weight loss

Technology is increasingly being used to assist with health behaviour change in public health and NHS contexts. It was important for this study to capitalise on this and consider ways in which technology could be used in the intervention to assist both participants and practice nurses. None of the participants was concerned about being directed to a website for support and advice about weight loss rather than being given support directly from a nurse during the appointment. Moreover, some participants preferred the website because it could be accessed more frequently from home and at any time of the day, especially around their new baby's unpredictable schedule. Most participants liked the opportunity to personalise and make choices on the website; however, a few mothers thought that the content could be more tailored to postnatal mothers, taking into consideration post-pregnancy complications and providing advice on and videos of exercises that could be undertaken at home with a baby.

Using an opt-out method of recruitment

In preparation for the possibility of a subsequent Phase III trial, participants were asked for their views about a change to the recruitment process used here and adopting an a opt-out recruitment method. Most participants did not foresee any problem in 'rolling out' the intervention using an 'opt-out' approach to recruitment if the process was adequately explained to women in a sensitive manner.

Suggestions for improving the intervention

Overall, women found the intervention feasible and acceptable, while also suggesting several ways in which the intervention could be refined to make engagement and implementation easier for them. Rather than having to login to an online weight management website using a computer, it was suggested that it would be more convenient and practical if women were able to access the programme using a mobile telephone app, in which they could track their weight. Some mothers believed that it would have been helpful to have an additional contact with them to check their progress and encourage their efforts; this would also have the added benefit of providing further external accountability, which participants felt was motivating for them. It was suggested that successful case studies of women who had lost weight be included and that the research team provide a contact number or an e-mail address so that participants could ask questions about issues related to their lifestyle behaviours. Another suggestion was to provide women with information packs or leaflets about lifestyle behaviours that women could read at their leisure. Some participants suggested that it would be better to raise the topic of recruitment to this trial with women antenatally, before attempting to recruit postnatally.

Strengths and limitations

The findings from this study should be considered in the light of its methodological strengths and limitations. This nested qualitative study was important because it offered and contributed context to how the intervention was experienced and received by participants; an integral strategy when determining the feasibility and acceptability of a complex intervention.[229] This study provided additional in-depth data that contributed towards the process evaluation of the intervention. The experiences of women who had both lost and gained weight at follow-up are represented in the findings.

Women from a range of backgrounds were interviewed and at least one participant from each intervention practice was interviewed. A comprehensive approach to data analysis was undertaken involving four researchers (NTM, AD, HP and SG) ensuring consensus at each stage of the process. These findings can be used to make adjustments to the design, delivery and implementation of the intervention before it is tested in a Phase III RCT. A topic guide with set questions/topics and probes also ensured that each participant was interviewed in a consistent manner. The study also has some limitations. The number of participants interviewed was small and the views reported here may represent more motivated women. The interviews were held in participants' homes with a researcher and, therefore, they may have expressed more favourable views of the intervention than if the interviews had been conducted in a neutral environment with an independent researcher.

Conclusions

Participants were keen to lose weight after giving birth. Overall, participants reported that the intervention was acceptable to them and they welcomed the support to lose weight that was provided by the trial. Child immunisation appointments were viewed as an acceptable environment in which to offer postnatal women a weight management intervention, and this was not viewed as distracting from the health of the baby. Participants would recommend the intervention to their friends. Weekly self-weighing and recording of weight was seen as an acceptable and sustainable strategy for weight loss in postnatal women. Women also liked the use of technology to help them lose weight. Participants made several suggestions on how the intervention could be developed and refined to further enhance the applicability and longer-term implementation of the intervention in health routine care for all women who wish to lose weight after having a baby.

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Chapter 6 Nurses' experiences of delivering the intervention

Background

Health-care professionals can have an important impact on the health behaviours of the public. By raising the topic of weight loss, health professionals can provide information and support to help women lose weight. However, there are a number of barriers to health-care professionals raising the topic of weight loss during consultations, such as time and workload pressures; fear of offending; concerns about damaging ongoing relationships by raising this sensitive topic; a belief that obesity is not a medical problem or an appropriate topic for them to raise; and a lack of confidence in patients' ability to make behaviour changes.[153,230] An intervention embedded in routine health-care appointments could help to address many of the concerns that health professionals have and help to 'normalise' the topic of weight loss. This study aimed to assess the views of practice nurses who delivered the intervention described in *Chapter 2*. The objectives were to:

- explore nurses' views about women's perceptions of the intervention in practice
- investigate nurses' feelings about raising the topic of weight with postnatal women at child immunisation appointments
- capture nurses' views about delivering the intervention and the impact that it had on the structure and duration of child immunisation appointments
- gather suggestions from nurses about how to improve the delivery and content of the intervention, including the training provided for them.

Methods

Recruitment and data collection

Practice nurses who delivered the intervention were asked by telephone or e-mail to participate in a semistructured interview about their views on postnatal weight loss and their experiences of delivering the intervention during routine child immunisation appointments after all of the participants recruited from their practice had completed the study. Practice nurses provided written informed consent to participate in the study. Interviews took place either face to face or by telephone. For interviews that took place by telephone, nurses were verbally asked the questions on the nurse interview consent form and asked to state their agreement with each statement; their responses were audio-recorded. Semistructured interviews were chosen as the method of inquiry for all of the reasons outlined in *Chapter 6*. Nurses delivering the intervention were chosen for interview to provide accounts of the same phenomenon from different perspectives.[231] Nurses received a £10 high-street shopping voucher for any out-of-pocket expenses. This study has been reported in line with the COREQ guidelines for the reporting of qualitative studies.

Interview topic guide and interview procedures

The semistructured interview topic guide (see *Appendix 2*) explored nurses' reflections on delivering the intervention in practice. The questions covered general warm-up questions relating to nurses' careers and typical immunisation appointments, their thoughts on referring women to the POWeR website and their feedback on the training that they had received to deliver the intervention and on delivering the intervention in practice. Interviews lasted between 22 minutes and 66 minutes. Interviews were audio-recorded and professionally transcribed verbatim. (One interview was not audio-recorded at the request of the nurse and handwritten notes were made instead.) The transcripts were anonymised,

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with each nurse given a unique study identification number. Field notes were taken immediately after the interviews and integrated into the transcripts. Nurse transcripts were also anonymised by excluding the name of the general practice and the name of the nurse from the transcripts.

Data analysis

Data analysis followed the same processes detailed in *Chapter 5*. The coding book is available in *Report Supplementary Material 3*.

Results

Characteristics of the nurses/general practitioners and emergent themes

A total of six nurses and one GP who delivered the intervention agreed to participate in an interview from across all of the intervention practices (they are herein referred to as nurses, as the GP responses were not distinctly different from those of the nurses). None declined to participate in this interview study. Most of the nurses had been practice nurses for over 10 years and had been delivering immunisations for all of this time. Interviews were conducted one on one: three were completed face to face with the nurses at their practice and four were completed by telephone (three at their general practice and one at home). A total of 15 themes and five subthemes emerged from the nurses' data. Nurses were randomly assigned numbers that do not correspond to the order in which the interviews were undertaken. Each quotation is followed by the assigned number of the nurse in question and by the page number and line number from their transcript, to aid transparency.

Impact of being overweight or obese on participants

When nurses were asked about the impact that being overweight or obese had on mothers, most responded in terms of the increased risk of developing long-term conditions (diabetes or cardiovascular disease). Nurses were of the view that being overweight had an impact on mother's self-confidence, and two nurses referred to an increased risk of developing depression:

> *A lack of confidence from a physical point of view . . . I would say . . . um . . . they've more, more chances . . . of developing chronic diseases in later life.*
>
> *Nurse 3, p2, 50*

Losing weight after having a baby

All nurses thought that participants did not view being overweight as a problem or important soon after pregnancy. Most nurses stated that participants had raised the issue of weight management with them during an immunisation appointment. However, one nurse noted that there was an increasing general awareness that being overweight could negatively affect health:

> *So now their weight is a big issue, more normal really, so they are accepting and willing to cooperate. [. . .] Recently, yaknow, the knowledge is getting more and more. The people trying to lose weight, more people are coming forward, compared to before, yaknow.*
>
> *Nurse 7, p2, 69*

More than half of the nurses felt that mothers expected to gain weight with pregnancy, with two even describing resistance to weight loss from mothers that needed to be overcome. One nurse also highlighted that weight loss requires change and perseverance, which most people find difficult:

> *If you tell someone what to do it's not going to work. They're going to possibly do, the opposite. It's got to be the right time for them ter, ter want to do it.*
>
> *Nurse 5, p15, 589*

Most nurses commented that new mothers were focused on their baby and deprioritised other concerns, such as their own health and well-being:

> Nurse 5: *As, as a new mum. I think you put your erm, priority into your baby so.*
>
> (NTM): *Mmmm you put yourself second.*
>
> *Nurse 5, p2, 77*

Pregnancy myths and misconceptions

Nearly half of the nurses believed that participants held a number of pregnancy myths, such as 'eating for two', as well as unrealistic expectations about weight loss because of celebrities being able to return to their previous body shape and weight a short time after pregnancy:

> *Yaknow, when you see these celebs on the telly, and they've had a baby . . . and they come out 4 weeks later . . . looking as trim as anything Yeah. You think but what have you done to get that and should you have been doing that? A week after you've had a baby, you know? So I just think the pressure's on everybody.*
>
> *Nurse 4, p20, 762*

Post pregnancy as a vulnerable time

Just under half of the nurses described the postnatal period as a vulnerable time (especially for first-time mothers) in which mothers should not be 'burdened' with any 'pressure', such as goals to lose weight. One nurse commented that the mothers most concerned about their weight would stop bringing their child for immunisations, which would reduce immunisation rates:

> *Just relax for a bit. You've been through a really traumatic experience. You might already have two toddlers running you . . . ragged. I just think . . . sort of give them a break really, yaknow?*
>
> *Nurse 4, p20, 768*

Raising the topic of weight loss

Over half of the nurses were concerned about having enough time in the immunisation appointment to raise a potentially upsetting topic and then provide adequate support. Two nurses were also concerned about damaging their relationship with the mother:

> *In an appointment which is already quite full with the baby, you can't offer the mum the support that you want to offer her. You haven't got the time to say 'Well sit down, let's have a chat'. You know, you don't have the time for that [. . .] because I'd just feel awful if . . . somebody walked out and I was thinking 'Oh God, I hope they're alright'.*
>
> *Nurse 4, p5, 153*

> *I think if you're asking mom if she's fine, and she's feeling OK, to then say 'And how is your weight going?'. It's a little bit . . . rude I think.*
>
> *Nurse 4, p12, 425*

Breastfeeding was mentioned by two nurses as a facilitator of weight loss, as expressed below:

> *I notice myself that people who are, tend to breastfeed their babies [. . .], they're more likely to lose their weight, to go back to normal . . . if they're on their just normal diet. Avoiding just junk food, than somebody who's, yaknow, not on any breast . . . they don't do breastfeeding.*
>
> *Nurse 1, p18, 735*

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Potential barriers to weighing women at child immunisation appointments

All nurses reported that there was 'not enough time' in an appointment to add more tasks (regardless of how long their slots were); therefore, additional tasks could not be easily added. Most nurses commented about the purpose of the appointment being for child immunisations or the baby, and so weighing the mother was not as high a priority:

> *I mean, it would be great . . . if I had time ter, yaknow, give them the encouragement and spend more time on that, but the focus of the consultation was the child.*
>
> *Nurse 5, p7, 264*

Legitimising weighing at consultations

Although all nurses reported feeling comfortable and confident weighing people, and more than half stated that they were already weighing mothers in their surgery, nearly half mentioned that, because participants had consented to be in the trial, this provided justification for or legitimised them weighing participants at appointments:

> *Ummm . . . I wouldn't feel any concern about that [weighing PIMMS-WL mothers] because I would know, know that they'd given their consent. So . . . no concerns at all.*
>
> *Nurse 3, p6, 214*

> *I didn't mind. It's never uncomfortable to ask them because they obviously know what they've signed up for.*
>
> *Nurse 6, p10, 369*

Two nurses said that they would not feel comfortable approaching overweight new mothers to weigh them on an ad hoc basis, and one of these nurses stated that they would not feel comfortable weighing new mothers if it became standard practice:

> *I dunno whether it puts a little bit of pressure on because how quick's too quick and how slow is too slow, d'ya know what I mean? So yeah, I don't think I'd feel comfortable just . . . No, I don't think I would feel comfortable [weighing as standard practice].*
>
> *Nurse 4, p11, 406*

Most nurses commented that weighing women was not 'on their template'; that it is not a job-role task that they are expected to complete at immunisation appointments:

> *Well, personally I've never done it in baby imms and whenever I've worked with other nurses it's never been, it's never been part of the consultation.*
>
> *Nurse 4, p13, 469*

Weight loss as the mother's responsibility

Most of the nurses felt that, at least partly, weight loss was the responsibility of the mother:

> *Like . . . people know that they need to lose weight if they are overweight.*
>
> *Nurse 5, p15, 584*

> *I suppose you've got to have the motivation in wanting to do it [lose weight] as well, haven't you, to be fair.*
>
> *Nurse 6, p11, 413*

Two nurses commented that weight gain was expected and essentially unavoidable in mothers during pregnancy:

> *Yaknow, I realise it is a time in a woman's life when she does put, weight on.*
>
> *Nurse 5, p12, 470*

Trial training

Training for the trial was administered in person and took approximately 30 minutes to deliver. The training was adapted for the situation and ease of the nurses, so sometimes it was delivered by telephone and sometimes it was summarised for the nurse's convenience. Each nurse's experience and description of the training varied. Although one nurse thought that the training covered 'a lot of content' in a short amount of time (Nurse 2), two nurses felt that the training was very basic or insufficient (one of these nurses was trained by telephone):

> *So I wouldn't say I received any sort of training; it was just somebody on the phone talking through what I needed to do when the mums came in and what to look out for, what would be in the red book to suggest that they were on the trial.*
>
> *Nurse 4, p2, 53*

All but one nurse felt prepared to deliver the intervention after their training. Three nurses felt nervous until they had delivered the intervention to at least one mother and the training was no longer theoretical:

> *I would say I was, not . . . particularly prepared because . . . errrr, I tend to feel prepared when I've done something. After I'd seen the patient. I felt . . . better prepared to do it again, but I only saw one. So yeah. Not particularly prepared.*
>
> *Nurse 3, p3, 110*

Nearly half of the nurses rarely referred back to the manual: two because they did not feel the need to and the other because they did not have the time. Most nurses who referred back to the manual did so before seeing a participant or highlighted key parts in the manual for quick reference:

> *Obviously, 'cos' if you're doin' it all the time you don't . . . just comes second nature, but when you're just doing it every ad-hoc, it's just a good refresher just to remind you of the things you need to be asking.*
>
> *Nurse 6, p3, 101*

Delivering the intervention

Most of the nurses were able to identify intervention participants at immunisation appointments from the trial sticker on the front of the red book and/or by the insertion of the weight record card next to the immunisation record page in the red book. However, this method was reliant on participants remembering to show the booklet in enough time to be weighed during the appointment and for the nurse to recognise the trial sticker/record card. Two nurses expressed dissatisfaction at this and would have preferred to have been alerted much earlier, while two other nurses did not find these stickers useful or did not remember seeing them. Nurses relied on additional means to identify intervention participants, with some receiving e-mail reminders from the research team or being informed by their manager:

> *Ermmm, when you do a child vaccination, often a parent will not. Won't present: Mmmm. The stickers on the red book To you. It really depends on, on the mum. But . . . very often you're focusing on . . . the baby and the vaccination.*
>
> *Nurse 3, p4, 147*

About half of the nurses reported immunising the child before weighing participants because they wanted the immunisation to be completed quickly as it can be stressful for some mothers. Just under half of the nurses reported weighing before immunising, giving reasons such as delaying the baby crying until the end or not identifying a trial participant until seeing their sticker later in the appointment. Almost all of the nurses reported that it was easy to access the weight record card and it was straightforward to record the participants' weight in the red book.

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Most nurses described a non-judgemental and/or supportive attitude and ensured that they did not criticise participants or tell them to try harder when they had not lost weight. By stating that weight loss was a long-term goal or they believed that the participant would lose the weight by the next appointment, most nurses felt that they encouraged participants in a constructive manner:

> *So I'd just be giving them kinda general encouragement that . . . it is OK and weight loss is a, a long-term . . . a long-term process. Yaknow, you're not gonna see massive changes straightaway. And so it's just kinda gentle . . . encouragement.*
>
> *Nurse 5, p7, 277*

No nurses reported any irritation or upset from participants being directed to the POWeR website. One nurse found it convenient to refer participants to a website for weight loss advice, whereas another pointed out that they would have previously referred mothers to the NHS Choices website (a website covering a variety of health topics including weight loss, although not specifically designed for postnatal mothers). Two nurses also had concerns about the information technology literacy of some of the mothers, especially in minority ethnic communities, while another two nurses suggested diversifying the approach by providing physical information, such as leaflets, or more person-to-person advice, in addition to the website:

> *I think it's a good idea. But a-again . . . it really depends, on the person and whether they respond well to . . . written information . . . or whether they, they want a more personal approach . . . Some people just like . . . to have a chat with you . . . about their weight and the kind of foods that they should be eating . . .*
>
> *Nurse 3, p10, 392*

About half of the nurses highlighted the problems of participants accessing reliable and consistent advice on weight loss after pregnancy from the internet and were glad that participants had the POWeR website as an up-to-date source of correct information:

> *So I'd much rather that than them . . . just . . . Google [Google Inc., Mountain View, CA, USA] and find bits of what everyone's. So no, that, that was fine. It's just a shame we hadn't the opportunity to look at it to see what it was they were looking at, but we knew it was the right stuff.*
>
> *Nurse 4, p16, 606*

Almost all of the nurses reported that participants did not bring up the website in their conversations, although when the nurses asked participants whether or not they had been regularly visiting the website (as directed by the training), the comments surrounding the website were mixed. Many nurses reported that participants did not comment beyond saying that they used the website and how often, that they were having trouble accessing it or that they found it useful or easy to use:

> *Yeah, they said they'd both been on it and they found it easy to use, so. That was good we hadn't the opportunity to look at it to see what it was they were looking at, but we knew it was the right stuff.*
>
> *Nurse 5, p10, 405*

Participants' feelings about being weighed at immunisation appointments

When asked about how participants appeared to feel while being weighed, most nurses reported that they seemed comfortable, with one nurse reporting that their mother 'jumped on the scales' eagerly and appeared to enjoy finding out how much weight they had lost (Nurse 2). Two of the nurses reported that some of their participants were uncomfortable with being weighed, appearing embarrassed. Nearly half of the nurses reported that participants gave reasons before they were weighed by them about why they had or had not lost weight. Only one nurse reported that any (two)

of their participants declined to be weighed; both of these participants had not lost weight. Only one nurse reported mothers hesitating initially about getting on the weighing scales, but they were encouraged to do so with little difficulty:

> NTM: *And how comfortable do you think, the mothers were with you weighing them?*
>
> Nurse 1: *. . . It was OK. It was OK. They were quite errrr . . . alright.*
>
> *Nurse 1, p10, 392*

Role of health professionals in providing support for weight loss

When asked who should be providing new mothers with advice and information on how to lose weight, nurses felt that any health professional in contact with mothers would be appropriate. One nurse described their role as ideal, given that midwives or health-care visitors were focused on the baby and not the mother. One nurse referred to weight loss companies, such as Weight Watchers and Slimming World, that had more time and the ability to support new mothers in their weight loss efforts:

> *I think it's, probably everybody. While they're seeing the mother. Yeah. Who is the patient is feeling more comfortable with.*
>
> *Nurse 1, p19, 773*

However, just over half of the nurses stated that the 'ideal time' for raising the topic of weight loss with mothers was 6–8 weeks after pregnancy or the postnatal check; half of the nurses also thought that the topic should be raised during pregnancy. It was suggested that providing leaflets or information packs or couching the intervention in terms of 'healthier eating' or 'lifestyle choices' might be appropriate:

> *I just think . . . as a health-care provider I'd be more erm, open to having that discussion [about weight loss] at the postnatal check with the mum.*
>
> *Nurse 5, p13, 516*

Role of accountability in weight loss

Accountability is a sense of obligation, of not 'letting someone down', and of having to explain and justify conduct to another. This concept was mentioned by only two of the nurses and was linked in both cases to motivation to adhere to behaviours to lose weight:

> *I think it's more of an incentive. Especially knowing that they [the recruits] was being weighed.*
>
> *Nurse 6, p9, 332*

> *'Cos I suppose if they [the recruits] go anywhere and hand their red book over, their weight's in there for everybody to see, isn't it?*
>
> *Nurse 4, p15, 553*

Strengths of the intervention

All of the nurses commented on the intervention being a 'good idea' and/or likely to increase participants' motivation to lose weight. Three nurses reported that the intervention was not onerous or difficult to deliver. Three nurses were initially concerned that they would be inundated with questions about weight loss but that this had not been their experience.

Roll-out of the intervention to all postnatal women

Nurses were asked to imagine a scenario in which the intervention was rolled out to all postnatal women who attended their immunisation appointments and to comment on how they would feel if this were to happen. Two nurses thought that this would be unproblematic. Another nurse thought that

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this would take more time but would be 'manageable'. Three nurses commented on the potential logistical problem of having to electronically record the weight and logging in and out of the baby's and the mother's file to update both the mother and the infant records, given that immunisations are recorded in the child's record, not the mothers' record:

> *It wasn't really taking much of my time and, errrrrr yaknow, it's something they're here anyway. No, I didn't, it couldn't . . . it really doesn't make any difference.*
>
> *Nurse 1, p15, 594*

> *Ermmm, it would be difficult because you've got the baby on the, on your computer screen, so to go into the mother to record the weight in the computer . . . that, that would just take . . . too much . . . time. It's just . . . not very logistically easy.*
>
> *Nurse 5, p10, 387*

Two nurses thought that it would be difficult to roll the intervention out because of the additional time that weighing and recording women's weight would take.

> *We might be lucky to have 10, 15 minutes and otherwise . . . And that's just enough to do the baby. So if it was um . . . if there was something else it would be much harder.*
>
> *Nurse 6, p7, 276*

Suggestions for improving the trial

One nurse suggested that a digital copy of the nurses training manual would simplify searching for information. It was also suggested that the training could be split over two sessions or that 'refresher' sessions could be delivered at various times during the intervention. One nurse suggested that some consideration should be given to the idea of deferring the start of intervention until 12 weeks after childbirth or giving promotional literature about the trial antenatally.

Nurses' standard appointment slots at their surgeries varied from 10 to 20 minutes. Two nurses thought that a longer appointment time was needed to deliver the intervention. Just over half of the nurses perceived that the intervention added 5–10 minutes to their usual appointment length; however, one nurse thought that it took 2–5 minutes, another thought that it added only 1–2 minutes, and another thought that it did not take any extra time and that only reorganisation of the appointment was required:

> *I think the appointment should have been . . . made to be 20 minutes, but then that would mean that you'd see less, less babies, less mums. Ermm, that's the only thing, it did take a bit extra time.*
>
> *Nurse 5, p14, 551*

One nurse suggested that participants have their own booklet to record their weight, rather than recording their weight in the red book, and another suggested that an appointment just for the mother, not one targeted at the baby, might be helpful:

> *In an appointment which is already quite full with the baby, you can't offer the mum the support that you want to offer her. You haven't got the time to say 'Well sit down, let's have a chat'. You know, you don't have the time for that. So I think maybe it would be more appropriate if it was offered to mums in an appointment on their own.*
>
> *Nurse 4, p5, 153*

Two nurses thought that a more 'holistic' approach could be taken to the sessions. The focus would not be solely on the mother's weight and weight loss; instead, blood pressure and additional health checks could be made with the aim of assessing the general health of mothers:

> *Yaknow, I just think . . . for some mums it's a bit of pressure, but I think it'd be lovely if there was sort of like an 8-week check for mum . . . say a 16-week check with a nurse, to just say 'How ya doing?' where you would generally say to mum 'Well let's check your blood pressure, let's check your weight', because it's more of a health check, to see how they are.*
>
> *Nurse 4, p19, 724*

Discussion

Summary

Practice nurses expressed a range of views about postnatal weight loss and delivering the trial intervention during routine child immunisation appointments. Nurses commented that, in their opinion, mothers did not view being overweight as a concern soon after pregnancy. Nurses felt that new mothers were focused on their baby and not on their own health and well-being, and held unrealistic expectations about weight loss after childbirth. Some nurses felt that the postnatal period was a vulnerable time, particularly for first-time mothers, in which mothers should not be burdened with any pressure to lose weight. Some nurses were concerned about raising the topic of weight; it was considered a sensitive topic, and they felt that they did not have sufficient time to address concerns women might have and that it would affect their relationship with mothers. However, nurses also commented that the trial provided a basis on which they could raise the topic of weight and provided a platform to have these conversations.

Overall, nurses felt that the intervention was easy to deliver, that the intervention was a good idea, that women engaged well with the components, that the intervention was likely to increase motivation for weight loss and that the intervention appeared to be effective in increasing postnatal weight loss. Some nurses, however, felt that, if the intervention were to be rolled out, extra time would be required. Nurses believed that mothers appeared comfortable with being weighed by them.

Although some nurses had initial reservations about the intervention associated with concerns that women would want to have lengthy conversations or ask many questions about weight, in practice this was not the case. Moreover, nurses reported that participants were accepting of being directed to the POWeR website for support and advice, although there was some concern about the computer literacy skills of ethnic minority women whose first language was not English. Nurses made a number of practical suggestions for improving the conduct and later implementation of the trial. Some of the key issues raised by nurses and relevant to this trial intervention will be explored in more depth in the following sections.

Losing weight after having a baby

Studies have highlighted that women find it difficult to lose weight after having a baby.[42–44] Similarly, nurses highlighted that motherhood was a particularly vulnerable time and discussed the pressure or burden of trying to lose weight soon after birth as undesirable. This was linked to the possibility of increasing the risk of postnatal depression by two nurses. All nurses felt that new mothers did not view being overweight or obese as a health concern and most nurses thought that new mothers prioritised their baby's health over their own. There was a feeling among some nurses that mothers held unhelpful 'myths' and misconceptions about weight loss and pregnancy/childbirth that hindered their weight loss efforts.

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Raising the topic of weight

Research has reported that there are many barriers to health-care professionals raising the topic of weight loss, such as difficulty in raising a sensitive topic.[153,230] Nurses commented that they felt more comfortable raising the topic of weight and weighing participants because the participants had chosen to be involved in the trial and were expecting to be weighed at their appointment. One nurse stated that she would not feel comfortable if weighing all mothers became standard care. It was interesting to note that a lack of ability to lose weight was not specifically mentioned as a reason not to raise the topic with participants, but nurses did mention resistance to change/lack of engagement.

Training to deliver the intervention

Nurses mostly felt that they were well prepared to deliver the intervention, but that this was not fully the case until they had put their training into practice with their first participant. Nurses made some suggestions about how the training could be improved (see *Intervention roll-out and suggestions for developing the intervention*) to ensure that they felt confident in raising the topic of weight and successfully delivering the intervention. It is of note here that delivery of the intervention per protocol by nurses was very high (see *Chapter 3*).

Delivering the intervention in practice

In the UK, weighing pregnant women and new mothers has swung in and out of NHS policy several times over the past century, meaning that health professionals are likely to have become uncertain about the merit and role of regular weighing in health care. In the past few years, there has been increased evidence for the role of regular weighing as part of multicomponent weight management interventions; however, very recent evidence in pregnant women showed that weighing alone by midwives during pregnancy was not effective in preventing excessive gestational weight gain.[232] In this study, all of the nurses commented that the intervention was a 'good idea' and/or that the intervention would help to increase women's motivation to lose weight. When asked to recall how they delivered the intervention, most of the nurses listed most of the five steps from the training manual checklist. Interestingly, two nurses seemed to be 'reframing' weight loss to participants by changing their perceptions from weight loss being a short-term goal to weight loss being a more long-term ambition. This is a strategy found to be effective when used by those aiming to lose weight without professional support or a formal programme underpinning their efforts.[233]

Most nurses reported that mothers were comfortable with being weighed, with only a couple of nurses reporting that some of their participants felt embarrassed. Evidence has shown that people who are overweight often feel self-conscious about their bodies, 'ashamed and stigmatised'.[7,8,154] It is possible that such feelings might be mitigated, however, if regular weighing was integrated into routine care, as this would serve to normalise this process; overweight mothers might not feel that they are being 'singled out' or treated differently. This suggestion fits with another suggestion from the nurses that the intervention could be less focused on the weight and couched within a broader 'health check' after having a baby framework.

Most nurses were comfortable and confident in delivering the intervention, and some commented that they were already weighing some patients at their practice in relation to a practice-wide policy or on their own initiative. It is interesting to note, however, that these nurses were still uncomfortable with weighing mothers, referring to the additional 'pressure' or 'burden' on mothers at a particularly vulnerable time.

Intervention roll-out and suggestions for developing the intervention

Most nurses did not foresee any major problems related to the future roll-out of the intervention and thought that it was 'manageable'. No nurses reported any practical issues in delivering the intervention. Nurses suggested diversifying the approach by providing physical information, such as leaflets and more person-to-person advice, in addition to the website. However, the issue of having to switch between the mothers' and the baby's electronic records should be considered and raised in the training.

Practice nurses offered several strategies for developing the intervention, both in terms of improving women's experience of the intervention and in relation to their delivery of the intervention to women. It was suggested that nurses might benefit from refresher training sessions when there is a longer than expected gap between their training and their first participant. A digital copy of the training manual would also aid training before seeing a new participant.

Strengths and limitations

This study has a number of strengths and limitations that should be considered when interpreting the findings. The results provide additional information from which the results of the RCT can be interpreted. Because we tested a novel intervention for the first time, we have provided in-depth experiential data on a weight management intervention embedded in child immunisation visits in primary care. All of the nurses, from a range backgrounds and experiences as practice nurses, contributed to this study. The data presented here are based on nurses' personal experiences of delivering the intervention in practice, within their working lives, rather than hypothetical scenarios. The nurses were recruited from practices located in areas of very high deprivation with a high proportion of ethnic minority patients, which can lead to a challenging environment in which to deliver health care. Despite these challenges, nurses felt that they were able to deliver the intervention as per protocol. The study also has some limitations that should be considered. Only six nurses and one GP were interviewed; therefore, data represent the views of a small number of nurses who delivered the intervention. One of the interviews was not audio-recorded at the request of the nurse and notes were taken instead; it is possible that some comments were not recorded accurately.

Conclusion

Overall, nurses felt that they were able to raise the topic of weight because the trial provided a framework in which they could legitimately have conversations about this topic. However, some caveats to successful implementation were raised by nurses: they felt that the intervention was easy to deliver and that it would motivate women to lose weight. If the intervention were to be rolled out and integrated into routine care, nurses felt that extra time at child immunisation appointments would be required to deliver the intervention. Participants appeared accepting of being directed by nurses to the POWeR website for support and advice about weight loss, but nurses felt that more consideration should be given to ensuring computer literacy among ethnic minority women to allow them to access and benefit from the online weight management support.

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Chapter 7 Comparison of participants' and nurses' experiences

This brief chapter aims to draw together the findings from the interviews with participants and nurses presented in *Chapters 5* and *6*, to highlight the similarities and inconsistencies in their experiences and/or views about the intervention to assist with future refinements to the intervention.

Raising the topic of weight loss

The most commonly reported barriers to nurses raising the topic of weight loss were workload pressures; lack of time at immunisation appointments; fear of raising a potentially sensitive topic; viewing weight loss as the mother's responsibility; and perceiving weight management as being outside their typical tasks as a practice nurse. Several nurses commented that motherhood was a particularly vulnerable time and they wanted to avoid putting pressure on women to lose weight. However, although most participants discussed the difficult times of motherhood, unprompted and unrelated to weight loss, no participants reported weight loss being a sensitive or difficult topic for them to discuss with the nurse or any other health professional. By contrast, some mothers commented that they wanted the topic of weight loss to be raised or the weight loss intervention to have been discussed with them sooner.

Barriers to and facilitators of weight loss

The perceived facilitators of, and barriers to, new mothers' weight loss efforts offered by nurses were different from those offered by the participants. All of the nurses reported that, generally, new mothers did not view being overweight as a problem or viewed themselves as not being overweight. In addition, most nurses perceived a focus on the new baby to the exclusion of all else, including the mother's own health needs. However, participants had a different view of this impact of the baby on their lifestyle, and commented that they had to think about negotiating their diet and exercise behaviours around the baby's schedule, lack of sleep and breastfeeding, not that they did not have time to focus on these health behaviours.

Process involved in delivering the intervention

Nurses were asked to weigh participants and record this on the record card in the red book; to remind women to weigh themselves weekly and to record this in the red book; and to encourage use of the POWeR website and/or 'signpost' participants to do so. All of the nurses reported weighing the mothers and almost all reported that they checked whether or not participants had been self-weighing weekly by asking or checking the record card. All of the nurses reported that they signposted participants to the POWeR programme and most of the nurses had checked that the participants had visited the website. All of the participants reported being weighed by the nurse, but most did not mention being asked if they had been self-weighing weekly, and only about half of participants mentioned that they had been signposted to the POWeR website.

The nurses did not appear to view being supportive or encouraging as noteworthy, yet when prompted most nurses reported encouraging participants with weight loss. By contrast, most participants mentioned and appreciated the supportive and non-judgemental approach of the nurse to their weight loss, particularly when participants had gained weight.

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Accountability

Most participants mentioned accountability, that someone other than themselves was monitoring whether or not they were weighing themselves regularly and that they wanted to avoid 'letting down' the nurse; this provided them with a source of motivation to continue to adhere to a healthy lifestyle and weight loss. It is interesting to note that only two nurses discussed or raised the concept of accountability in their interview conversations.

The POWeR website

Most of the nurses reported that participants did not particularly bring up conversations about the POWeR website at appointments, but most mothers commented positively about the website, finding it useful and easy to use.

General thoughts about the study

All of the nurses commented that the intervention was a 'good idea' and participants similarly viewed the intervention favourably. One of the nurses felt that participants should have their own appointment rather than the intervention being offered at the child immunisation appointment, yet many participants reported that one of the things that they liked about the intervention was that no extra appointments were required and that attending extra appointments would be difficult, with one participant explicitly commenting that they would not attend extra appointments. In addition, no participants considered their baby's immunisation appointment to be an unsuitable time for them to receive a weight loss intervention.

Rolling out PIMMS-WL

Neither participants nor nurses believed that rolling out the intervention would be difficult or problematic to achieve. Women did not believe that there would be any objections from women if an 'opt-out' recruitment procedure was implemented, so long as it was made clear they still had the right to decline the study/intervention and nurses were tactful and sensitive when raising the topic of weight.

Chapter 8 Overall discussion

This final chapter aims to provide a broad synthesis of the study findings and includes recommendations for future research. This report has presented data from a RCT and two nested qualitative studies with participants and practice nurses. The trial tested the feasibility of a brief routine weight management intervention embedded in the national child immunisation programme and reported that adherence to the intervention was broadly acceptable, but that the primary method of recruitment was not successful.

The qualitative study with participants raised several considerations for research. Most of the participants commented that they were keen to lose weight after giving birth and were motivated to join the trial for this reason. Women liked the idea of using child immunisation appointments to receive a weight management intervention. Participants commented that they would recommend the intervention to their friends. Self-weighing and recording of weight were seen as an acceptable strategy for weight loss and participants liked the use of technology to help them lose weight. Many participants talked about the difficulty of maintaining and persevering with their dietary and physical activity behaviours to facilitate weight loss. Participants liked the idea that someone was monitoring their weight and there was someone who they were 'accountable' to for their weight loss progress.

Despite concerns about raising the topic of weight, most nurses felt that the intervention facilitated the conversation and could be embedded in routine child immunisation appointments. Nurses suggested that the length of child immunisation appointments could be extended to accommodate the intervention. Although some nurses in the qualitative study commented that the intervention added 10 minutes to the length of the immunisation appointments, audio-recordings of consultations indicated that the intervention took nurses/GPs approximately 2 minutes to implement. As nurses were being asked to deliver a new task, doing so may have been perceived to have taken longer.

Strengths and limitations of the programme of research

The specific strengths and limitations of each study have been previously discussed in *Chapters 4–6*; this chapter will take a broader perspective of the strengths and limitations of this research. The use of mixed methods was a particular strength because it provided the opportunity to collect different types of data and perspectives on the research questions. Completing the trial prior to conducting the semistructured interview studies provided information that could be fed into the interview topic guides in the qualitative studies, thus providing the opportunity to gain a deeper understanding about the feasibility and acceptability of the intervention. The inclusion of interviews with both participants and practice nurses provided simultaneous dual perspectives on the same processes of experiencing and implementing the intervention. The findings of this research can now be used to develop this intervention in a Phase III trial or to develop other research that aims to address brief interventions for postnatal women in primary care. The inclusion of the BodyTrace weighing scales as an objective process measure of frequency of self-weighing was a key methodological strength of the study, particularly in relation to providing evidence of intervention adherence.

To the best of our knowledge, the study reported here is the first to investigate the merits of the integration of a weight management intervention for postnatal women in existing primary care contacts with minimal costs to the NHS. This study, therefore, makes a unique contribution to the literature.

The study also had some wider limitations that should be considered when planning future studies. Although the study took place in Birmingham, which has a very diverse population, all of the study materials were in written in English and this may have prevented some women from participating.

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Although the completion rates for the questionnaires were high, the questionnaire booklet was relatively long, taking about 20 minutes to complete; this may have negatively affected the women's responses. Participants were not asked about their diet or diet quality and such data would be useful alongside data collected on weight, although it is recognised that dietary recall can be inaccurate.[234,235] Physical activity was collected by self-report and future studies should consider collecting these data using objective measurement devices, such as accelerometers. The scales and questionnaires used in this study to assess body image and body dissatisfaction scores were designed for use with the general population and not specifically with postnatal women. Future research should also consider including additional anthropometric measurements to assess body composition (e.g. waist circumference) that may be better placed to detect changes in this outcome. Some consideration should be given to the research that has suggested that people who participate in weight loss studies may not be representative of the general population.[236] Thus, it is possible that the study attracted more health-aware or health-conscious women and future studies should consider including a measure to assess this outcome.

Implications of the research and future research recommendations

NICE has called for more high-quality research in this area and this study directly addresses this gap. This study has contributed to research into obesity prevention and management by extending the evidence available on interventions to reduce postnatal weight retention and weight gain during the postnatal period. However, more high-quality research is necessary to ensure that the consistent development of policies and guidance for maternal weight gain and postnatal weight loss can be implemented. Attempts could be made to improve the design and conduct of RCTs in this topic to increase the quality of the evidence. There are several specific ways in which research on this question should be developed and improved, and these are outlined in the following sections.

The design of this trial resulted in a short time frame in which women could be recruited; this may have deterred some women from participating at a busy time in their lives. Therefore, rather than recruiting women postnatally, an alternative approach could be to recruit women antenatally, towards the end of their pregnancy, when women do not have the same distractions and demands on their time. Recruiting antenatally may also be beneficial because it provides time for women to begin to consider making changes to their health behaviours before their baby is born; the intervention can then commence postnatally. Furthermore, given the short window of opportunity available to recruit women, it may be that an 'opt-out' approach to recruitment would be a more efficient method and would also allow the trial to be better embedded in routine health-care practice. This may also allow for more efficient implementation in the NHS should the intervention be shown to be effective. Such an approach to recruitment is also supported by evidence that has suggested that higher response and recruitment rates may be obtained when studies use opt-out methods.[187] Data from the qualitative study with participants also showed some evidence that an opt-out approach to recruitment may be acceptable, but it may still be important to seek the views of more postnatal women on this question before a subsequent Phase III trial. It may be the case that recruitment via other health professionals involved in the care of postnatal women and young babies might be useful in aiding recruitment, such as community midwives and health visitors. These routes of recruitment could be considered in future research studies.

This trial took place in Birmingham, a very ethnically diverse city. The trial recruitment documents and intervention materials were not translated into different languages; this may have increased both the number of women recruited and the intervention adherence. Any future study should consider making all of the study documents available in several languages, particularly when they take place in large multi-ethnic cities.

This study did not gather information on the reasons why women did not take up the offer to participate. Future research could benefit from conducting in-depth qualitative research on the reasons why women decide not to participate in studies of this type.

As a feasibility trial, the intervention was assessed over the first three child immunisation appointments when the child was 1, 3 and 4 months old. The intervention was not delivered at the 12-month child immunisation appointment; therefore, the longer-term effects of the intervention were not assessed. Trials with long(er)-term follow-up would contribute to the evidence and the quality of that evidence.

Weighing patients during routine appointments may help alleviate the fear and concerns that many health-care professionals and patients can experience when discussing weight. Interventions, such as the one tested here, showcase the need for more research testing interventions involving weighing of patients during routine health-care appointments. Research would also be worthwhile that considers different ways in which health-care professionals can support women to lose weight after having a baby, for example via community midwives and health visitors.

The role of technology in postnatal weight loss might also be a useful avenue for future research endeavours because this allows intervention support to be delivered at scale. The inclusion of commercial weight loss programmes in broader weight loss interventions might also be worthwhile, as recent research has demonstrated that such approaches may be feasible and acceptable to postnatal women.[194] Specifically, it could be that referral or signposting by practice nurses to commercial weight loss programmes, in addition to weighing women at child immunisation appointments, could improve the effectiveness of the intervention; this would be an important question for future research to pursue.

Although evidence shows that women engaged well with self-weighing and recording of their weight, the CIs for frequency of self-weighing were wide; strategies to enhance this outcome could be considered to further increase engagement with this behaviour. Technology, such as text message reminders, may be useful in this regard and future research should consider including such prompts. It might also be the case that branded online weight loss programmes developed by commercial companies may be useful and could be used to support the face-to-face intervention consultations that the practice nurses delivered; future research that examines the role of commercial weight management programmes could be worthwhile.[194]

Women self-reported their physical activity and the data may be prone to bias and over-reporting. Future studies should consider including an objective assessment of physical activity. A more detailed analysis of body composition would have been useful because some studies have reported fluctuations in body fat percentage during the year following childbirth.

Conclusion

The findings of this study have demonstrated that it is possible for nurses to deliver a brief weight loss intervention to postnatal women, focused on promoting self-management of weight, during child immunisation appointments in primary care. Although women and nurses responded well to the intervention and adherence to weekly self-weighing was high, there is some scope to improve participants' engagement with the intervention. The recruitment of participants was challenging and the study sample was small, highlighting that the recruitment methods used were not successful. Alternative approaches to recruitment need to be explored prior to a Phase III trial.

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Publications

Daley AJ, Jolly K, Bensoussane H, Ives N, Jebb SA, Tearne S, *et al.* Feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme in primary care: randomised controlled cluster feasibility trial. *Trials* 2020;**21**:757.

Parretti HM, Ives N, Tearne S, Vince A, Greenfield SM, Jolly K, *et al.* Protocol for the feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme: randomised controlled cluster feasibility trial with nested qualitative study (PIMMS-WL). *BMJ Open* 2020;**10**:e033027.

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Data-sharing statement

The data sets used and analysed during this study are available from the corresponding author on reasonable request.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 Participant interview topic guide

The PIMMS-WL Trial

Feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme in primary care: randomised controlled cluster feasibility trial with nested qualitative study.

Interview Topic Guide – Mothers

Thank you again for meeting and agreeing to talk to me today. Are you comfortable and ready to get started?

I'd like to talk with you today because you've taken part in the PIMMS-WL trial and now we'd like to find out as much as we can about what you thought of the trial and what it was like for you to be a part of this trial.

With your permission, I will record our conversation and then combine all the interviews we conduct with mums in the trial and use this to summarise what mums thought of the PIMMS-WL weight management intervention. As I'll be recording our conversation and want to keep what you say anonymous, I will start the recording by mentioning your trial number and avoid addressing you by name while we chat. I will be recording our conversation on an encrypted digital recorder. After we finish up here, I'll take the recording to university then download and save it onto my desktop computer which is password protected. Any direct quotes from you may be used in reports or journal articles, if they are, they will be completely anonymous so that no one will be able to identify you.

Once we've finished talking (the interview), there will be an opportunity for you to raise any concerns you have, but you can stop me at any time and if you do not wish to answer a particular question or want to terminate the interview at any time that is absolutely fine.

Warm up

How old is your baby now?

How's it all going?

Pre-pregnancy weight maintenance

Now I'd like to talk about any previous weigh loss attempts you made before your last pregnancy.

- Before joining this trial, had you ever tried to lose weight?
- What type of things did you do to try and manage your weight in the past?

Reasons for participating in trial

- Can you tell me about what it's been like for you being involved in the PIMMS-WL trial?

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- What were you hoping to get out of being a part of PIMMS-WL?
- Why did you want to take part?

Self-weighing

- Could you tell me what you thought about having to weigh yourself once a week?
- Can you tell me how weighing yourself made you feel?
- How useful did you find weighing yourself regularly?
- Were you able to weigh yourself once a week?
  - Was it easy to remember to weigh yourself regularly?
- Can you tell me how important the number on the scales was for you and why?

Current weight management

- Are you still attempting to manage your weight?
- Can you tell me a bit about what you do to manage your weight presently?
- What do you use to help you measure/gauge your progress?

Immunisation appointments

I would now like to talk about what happened during baby's immunisation appointments.

- Could you describe a typical immunisation appointment? Could you walk me through what would happen during these appointments?
- You mentioned that the nurse….did the nurse ask if she could weigh you during these appointments?
- How did you feel when the nurse was weighing you?
- What did you think of having the nurse weigh you during your baby's immunisation appointment?
- Could you tell me a little bit about what the nurse said to you while she was weighing you?
- Did the nurse hold your baby while you were on the scales?
- Can you tell me how you felt knowing that you would be weighed at your baby's immunisation appointments?

POWeR website

Now I want to ask you about the POWeR website.

- Were you able to access the site?
- Can you tell me what sort of things you looked at on the website?
- What did you think of the website?
- What did you think about being referred to a website for weight management advice instead of being offered it during the immunisation appointment?

Additional questions

- Now that you've been involved in the PIMMS-WL trial, how do you feel about managing your weight?

- Can you tell me what sort of things we could have done differently to make things easier for you?
- Can you tell me what would you think we should have done to make being involved in the PIMMS-WL trial better for you?
- At the start of this study you completed a consent form to agree to participate. This means that only women like you who signed this consent form can take part and the nurse will only weigh women who filled in the consent form. In the next study we are thinking about not having a consent form and the nurse just weighing every woman who comes to each of the immunisation appointments and writing this in the red book as part of routine care after having a baby. The nurse would also encourage every woman to weigh themselves each week like we asked you to do. How do you think women would react to this? Or how would they feel about it?

  Prompt: Women could still refuse to be weighed it is just that the nurse will expect to do it routinely in all women unless they object – rather than having a consent form like you did?
- What sort of things do you think would help women lose weight after pregnancy?
- Would you recommend the trial to your friends or other new mums?
- Is there anything else you'd like to tell me?

Thank you so very much for your time and for raising such interesting points. On behalf of the entire PIMMS-WL research team, I would like to say thank you for taking part in our trial and inviting us in to your house.

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Appendix 2 Nurse interview topic guide

The PIMMS-WL Trial

Feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme in primary care: randomised controlled cluster feasibility trial with nested qualitative study.

Interview Topic Guide – Nurses

Thank you again for meeting and agreeing to talk to me today. Are you comfortable and ready to get started?

I'd like to talk with you today because you've taken part in the PIMMS-WL trial and now we'd like to find out as much as we can about what you thought of delivering the brief weight management intervention during baby immunisation appointments and what your experiences were of being a part of this trial.

With your permission, I will record our conversation and then combine all the interviews we conduct with nurses in the trial and use this to summarise what nurses thought of the PIMMS-WL weight management intervention. As I'll be recording our conversation and want to keep what you say anonymous, I will start the recording by mentioning your trial number and avoid addressing you by name while we chat. I will be recording our conversation on an encrypted digital recorder. After we finish up here, I'll take the recording to university then download and save it onto my desktop computer which is password protected. Any direct quotes from you may be used in reports or journal articles, if they are, they will be completely anonymous so that no one will be able to identify you.

Once we've finished talking (the interview), there will be an opportunity for you to raise any concerns you have, but you can stop me at any time and if you do not wish to answer a particular question or want to terminate the interview at any time that is absolutely fine.

Warm up

How long have you been a practice/ research nurse?

How long have you been giving immunisations for?

General Information

- Who usually brings the baby to these immunisation appointments?
- Since you've been working with new mums, what sort of impact do you think overweight and obesity has had on them?

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- When you meet new mums at these appointments, is the topic of weight and weight management commonly raised?

PIMMS-WL Nurses Training

Now I'd like to talk about the nurses training you received on how to deliver the intervention during the immunisation appointments.

- Could you describe the training you received for this trial?
- What did you think of the nurses training manual?
  - How often do you think you referred back to it?
- What do you think we could have added or changed about the training sessions to make them more effective for you
- After the training how prepared did you feel to deliver the intervention?

Immunisation appointments

I would now like to switch topics a little and talk about what happened during baby immunisation appointments with mothers involved in the PIMMS-WL trial.

- How easy was it to identify mothers who were taking part in the trial?
- Could you describe a typical immunisation appointment with a PIMMS-WL mum? Could you walk me through what would happen during these types of appointments?
- Can you tell me how you felt knowing that you would be asking to weigh mothers involved in the trial?
  - How comfortable/ confident did you feel?
- Could you tell me a little bit about what sort of things you'd say to the mum while you were weighing her?
  - How comfortable do you think the mothers were with you weighing them?
  - Did any women refuse to be weighted?
  - What sorts of reasons did they give for not wanting to be weighed?
- What sort of reactions did you get from mothers who attended these appointments alone compared to those who attended with their partners or mothers?
- Where did the baby get put while the mothers were on the scales and you were recording their weight?
  - Were there practical issues to consider when having to weigh the mothers?
- What did you think of having to record their weight in the red book?
  - Was it easy to remember?
  - Was the weight record card easily accessible?
- How much more time did appointments take when you had to weigh the mothers?
- Can you tell me what you think it would be like if you had to weigh every mother you saw during your baby immunisation clinics?

POWeR website

Now I want to ask you about the POWeR website.

- Can you tell me what sort of responses you received when you referred mothers who asked you for weight loss advice to the POWeR website?
- Can you tell me a bit about what the mothers told you about the POWeR website?
- Were you able to have a look at the POWeR website?
    - What did you think of the website?
- What did you think about referring mothers to a website for weight management advice during the immunisation appointment?

Additional questions

- Before taking part in this study, what did you tell mothers who asked you for weight loss advice?
- When do you think is the ideal time to try and encourage new mums to start thinking about trying to lose/manage their baby weight?
- What sort of things do you think would help women lose weight after pregnancy?
- Who do you think should be providing mothers with this advice?
- Can you tell me what sort of things we could have done differently to make things easier for you?
- Can you tell me what would you think we should have done to make being involved in the PIMMS-WL trial better for you?

Is there anything else you'd like to tell me?

Thank you very much for taking part. On behalf of the entire PIMMS-WL research team, I would like to thank you for helping us test the intervention and for taking time out of your busy day to sit here with me today and tell me what you thought about the trial. Thank you.

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