**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 a nested qualitative study.**

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**Abstract**

**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 impacts for women in later life and increases health risks during subsequent pregnancies.

**Objective**: The primary aim was to produce evidence of whether a phase III trial of a brief weight management intervention where 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 semi-structured interview studies with intervention participants, and practice nurses who delivered the intervention. Trial data were collected at baseline and three months later. The interview studies took place after trial follow-up.

**Setting**: Birmingham, England

**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 within 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 two, three and four months of age. The intervention involved motivation and support by nurses to encourage participants to make healthier lifestyle choices through self-monitoring of weight and signposting to an online 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 within the child health ‘red book’, or using the online programme. The behavioural goal was for women to lose 0.5 kg to 1 kg per week. Usual care 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 stop-go traffic light 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 the intervention was acceptable to them and they welcomed support to lose weight at their child immunisation appointments. Whilst some caveats to implementation were raised by nurses, they felt the intervention was easy to deliver and that it would motivate postnatal women to lose weight.

**Limitations**: Fewer participants were recruited than planned.

**Conclusions**: Whilst 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.

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# Alphabetical List of Abbreviations

|  |  |
| --- | --- |
| **Term** | **Description** |
| AE | Adverse Events |
| BCTU | Birmingham Clinical Trials Unit |
| BMI | Body Mass Index |
| BWH  CI | Birmingham Women’s Hospital  Confidence Interval |
| CCG | Clinical Commissioning Group |
| CONSORT | Consolidated Standards of Reporting Trials |
| COREQ  CLAHRC | Consolidated Criteria for Reporting Qualitative Research  Collaborations for Leadership in Applied Health Research and Care |
| CRF | Clinical Report Form |
| EQ-5D | EuroQol-5D |
| DMC | Data monitoring and Ethics Committee |
| GP | General Practitioner |
| HRA | Health Research Authority |
| ICECAP-A | ICEpop CAPability- Adults |
| IMD  Kg | Index of Multiple Deprivation  Kilogram |
| NHS | National Health Service |
| NICE | National Institute for Health and Care Excellence |
| NWCR | National Weight Control Registry |
| PCCRTU | Primary Care Clinical Research Trials Unit |
| PPI | Patient and Public Involvement |
| RCT | Randomised Controlled Trial |
| PIS, | Participant Information Sheet |
| POWeR | Positive Online Weight Reduction |
| SAE | Serious Adverse Event |
| PRIME | Public Researchers Involvement in Maternity & Early Pregnancy |
| TIDeR  TSC | Template for intervention Description and Replication  Trial Steering Committee |
| UK | United Kingdom |
| UoB | University of Birmingham |
| US | United States |
| USB | Universal Serial Bus |
| WCSS | Weight Control Strategies Scale |

**Plain English Summary**

After giving birth many women find it hard to lose the weight they have gained during pregnancy. Research so far has focused on testing intensive weight loss programmes which 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 within immunisation appointments and whether women followed the intervention. Women who were overweight/obese and had given birth at least four weeks ago were invited to participate. Women interested in participating were visited at home to measure their weight and collect information about them at the start and end of the study. Participants were allocated to the intervention or 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 ‘red book’ when they attended the practice to have their child immunised when their baby was two, three and four months old. Women were encouraged to use an online weight loss programme to help them lose weight and advised to aim to lose 0.5-1kg per week. 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, although women who did participate mostly followed the intervention well and weighed themselves weekly. Nurses liked the intervention and felt it could be incorporated within immunisation appointments and suggested some ideas for improvement. The study appeared feasible and acceptable but better ways of recruiting women are needed.

**Word count 298**

**Scientific Summary**

**Background**

After childbirth most women do not lose the extra weight that they have 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 living with overweight would prefer to weigh less, are interested in implementing weight loss strategies, and would like support to help them achieve this outcome as little support is offered by the NHS. Weight management interventions could not only help women to lose any weight gained during pregnancy but may have the potential to stimulate changes which 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 randomised to a lifestyle intervention had significantly lower body weight at last follow‐up than comparators (mean difference of −1.7 kg:95% CI, −2.3 to −1.1 kg). However, many of the interventions 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 were effective, the NHS lacks the resources to scale-up these intensive interventions. More specifically, resource intensive interventions cannot be delivered to all 820,000 women who give birth annually in the United Kingdom, 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, 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 within 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 within 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 a large-scale phase III cluster randomised controlled trial of a brief weight management intervention where 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.

**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, by 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 a phase III cluster trial is feasible;
* Determine levels of intervention adherence; ;
* Collect data on immunisation uptake rates to ensure there are no adverse consequences on 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 the usual care group spontaneously accessed the online weight management programme).

Through semi-structured 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 to 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 semi-structured interview studies involving intervention participants and practice nurses. The unit of randomisation was the practice, stratified by list size (small/ large) and practice index of multiple deprivation (low/medium/high). 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 had been collected. The aim was to recruit 80 women from 10 to 12 practices over eight months. Favourable ethical 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 coordinated 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 two weeks during the recruitment period Birmingham Women Hospital’s 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 four 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 six-seven weeks postnatally and before the first child immunisation appointment. Follow-up home visits took place three 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 semi-structured interview about their views and experiences after they had completed the intervention. After all their participants had completed the intervention, practice nurses (or GPs if they delivered immunisations) were also interviewed to understand more about their experiences of delivering and implementing the intervention within 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.

**Setting**

This study took place in Birmingham, West Midlands, UK.

**Participants**

Participants were eligible for the trial if they were aged ≥18 years; had given birth at least four weeks previously; registered as a patient at one of the participating practices; planning to have their child immunised and had not yet attended the first child immunisation appointment; had a body mass index ≥25kg/m2 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 GP regarding their participation in the trial; or they had been diagnosed with a serious mental health difficulty requiring hospitalisation in the past two years or with anorexia and/or bulimia in the past two years.

**Intervention**

The intervention group were offered brief support that encouraged active self-management of weight when they attended their practice to have their child immunised. In the United Kingdom within the child immunisation programme children are routinely immunised at two, three, four and twelve months of age. The intervention was embedded within the first three of these routine immunisation appointments so no additional visits by participants were required. The intervention involved 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 (POWeR) to support them to make healthier lifestyle choices. Nurses were asked not to provide any lifestyle counselling; their role was only to provide encouragement, regular external accountability through weighing at each visit (i.e. so participants were conscious that their weight was being monitored), and to signpost participants to using 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 the child health record (‘the red book’), or to record their weight using the online POWeR programme. The intervention ran until the third immunisation appointment, when the child was approximately four months old. Participants were advised to aim for a goal of 0.5-1 kg per week weight loss until they had achieved a body mass index less than 25 kg/m2 and were no heavier than their pre-pregnant 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.

**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 pre-specified traffic light stop-go criteria; recruitment to target; 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 collected included weight, percentage body fat, depression and anxiety (Hospital Anxiety and Depression Scale), body image (Body Image State Scale) and self-reported physical activity (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) 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 immunisations 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 semi structured 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 semi-structured 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 (16 intervention, 12 usual care) participants (from a planned recruitment of 80 participants; 35% of target) were 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 criteria 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 no 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. Whilst most participants indicated they would recommend the study to their friends and felt regular self-weighing was useful in managing their weight, there was some evidence that it may be associated with anxiety about weight in some women.

The usual care group were on average 7.5 kg (adjusted mean difference) heavier in weight than the intervention group (95% CI: -13.8 to -1.3) 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 intervention participants highlighted that most 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 for delivering weight management. 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 the postnatal period was a vulnerable time, where mothers should not be ‘burdened’ with any ‘pressure’ to lose weight. Some nurses were concerned about raising the topic of weight as they considered it a sensitive topic and they did not have time to address concerns women might have about their weight. However, nurses also commented 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 the intervention was easy to deliver, a good idea, that women engaged well with the components and it 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, within child immunisations appointments. Whilst 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.

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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  Gender 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 2014-2015 obesity cost the National Health Service (NHS) approximately £6.1 billion 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 since 2016 and 2017.5-6 Some people who are obese may also experience stigmatisation that 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

Women’s main child-bearing years (25–34 years) hold the highest risk of weight gain compared with men or women of other age groups.9 A pooled analysis of global body mass index (BMI) trends estimated that the average BMI for women increased by 0.59 kg/m² (0.49 to 0.70 kg) 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 and obese.12-13  This prevalence of overweight and obesity amongst 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 amongst women who experienced higher levels of socio-economic deprivation.16 It is estimated that on average women gain about 14-15 kg during pregnancy and at one year after birth 5-9 kg is retained, with an average BMI of 29.4 kg/m2.17-20 One explanation for excess weight gain during pregnancy is the traditional ideology of “eating for two”,21-22 a common explanation given by women who feel pregnancy is a time where they can eat what they chose 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 to the mother and the baby have been well documented.25-28 Many of the health risks are interrelated and include the development of gestational diabetes, pre-eclampsia and gestational hypertension for the mother. There may also be perinatal complications for the baby such as macrosomia, new born hypoglycaemia, jaundice, shoulder dystocia, asphyxiation and stillbirth.29-31 A systematic review of 11 cohort studies, which included data from almost one million women reported that an increase in BMI (by one unit or more) was associated with a 60% increased risk (95% CI 1.48 to 1.96) 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 2011-2013, approximately 50% of the women who died during pregnancy in the UK had complications associated with being overweight or obesity.33 Another systematic review and meta-analysis identified a 264% increase in the odds of child obesity when mothers have obesity before conception.34.

**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.40-42 A UK-based prospective cohort study (n=2,559) of postnatal women noted that by six months postnatally, about 73% of women retained at least some of the weight gained during pregnancy.43 Prospective observational studies have reported that among women who have a healthy BMI prior to pregnancy, 30% are overweight one year after giving birth. Of women who are overweight prior to conception, 44% are obese by one year after giving birth, while 97% of women who are obese prior to pregnancy remain so at one 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 one to two years following childbirth.44 Of note, evidence has also indicated that women who lost all pregnancy weight within six 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 10 years follow-up.45 Findings from a systematic review involving 17 studies reported that postnatal weight retention was more attributable to excessive gestational weight gain, than pre-pregnancy BMI.46 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..47-49 The National Institute for Health and Care Excellence (NICE) public health guidance has highlighted gaps in the evidence about acceptable and effective weight management interventions for postnatal women.50 Of interest here, in 2018, the Royal College of Obstetrics and Gynaecology acknowledged that more women were conceiving whilst being overweight or obesity, and that women of childbearing age with a BMI 30 kg/m2 or greater should receive information and advice about the risks of obesity during pregnancy and childbirth, and be supported to lose weight before conception and between pregnancies, in line with NICE guidance.50-51 More specifically, women should be supported to lose weight in the postnatal period and women who are overweight should be offered referral to weight management services where available.

**Postnatal weight retention and mental health**

There is good evidence of an association between mood/postnatal depression and postnatal weight retention.52-53 Low mood or elevated depressive symptomatology can negatively impact on the bonding relationship between the mother and her child.54 This relationship is more pronounced in women who were obese prior to pregnancy.55 These findings are relevant because poor bonding can have long term consequences for the child, including delays in social, cognitive and emotional development.56

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 childcare duties.57-59 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, recovering from childbirth, and the physical and emotional effects of recent pregnancy and childbirth.60-61 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.62-63

The postnatal period, particularly the first six months, is often characterised by sleep deprivation for the mother, which can consequently impact on decisions about health behaviours. Evidence from systematic reviews has identified an inverse association between the amount of sleep and postnatal weight retention.64 In addition, if women initiate poor health behaviours during the early postnatal period, there is a risk they may become established as new behaviours within mothers’ new routine with their baby and the wider family.65-66 Moreover, studies involving a range of populations have shown that sleep deprivation is related to poor eating behaviours and weight gain.67-69 Sleep deprivation and fatigue is 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 of weight loss interventions involving obese and overweight adults reported that a combination of a low-energy diet and participation in physical activity were more effective for weight loss compared to diet only interventions.70

Several systematic reviews have demonstrated the effectiveness of group based commercial weight loss programmes.71-72 The group setting of these programmes is preferred by many as it instils group social support which can facilitate behaviour change.73 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.74-75 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 (CCGs).76-77 However, NICE guidance still recommends that people living with obesity or those most at risk of developing type 2 diabetes, should be referred by their GP to locally available weight loss programmes.78 Weekly attendance to these programmes may not be suitable to all patients however, due 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. 79-81 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.82 Weight management interventions may not only help women to lose any weight gained during pregnancy but may also have the potential to create a healthier environment for the whole family, providing further value and benefits.83-84 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.85-87

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

Many studies, that have adopted a variety of methodological designs, have tested a range of weight‐loss interventions during the postnatal period.88-89 To provide a comprehensive up-to date quantitative summary of the evidence the authors of this report (AD, HP) completed a systematic review where 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.89 Mega meta‐analysis can be useful because it provides a comprehensive statistical summary of all 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.

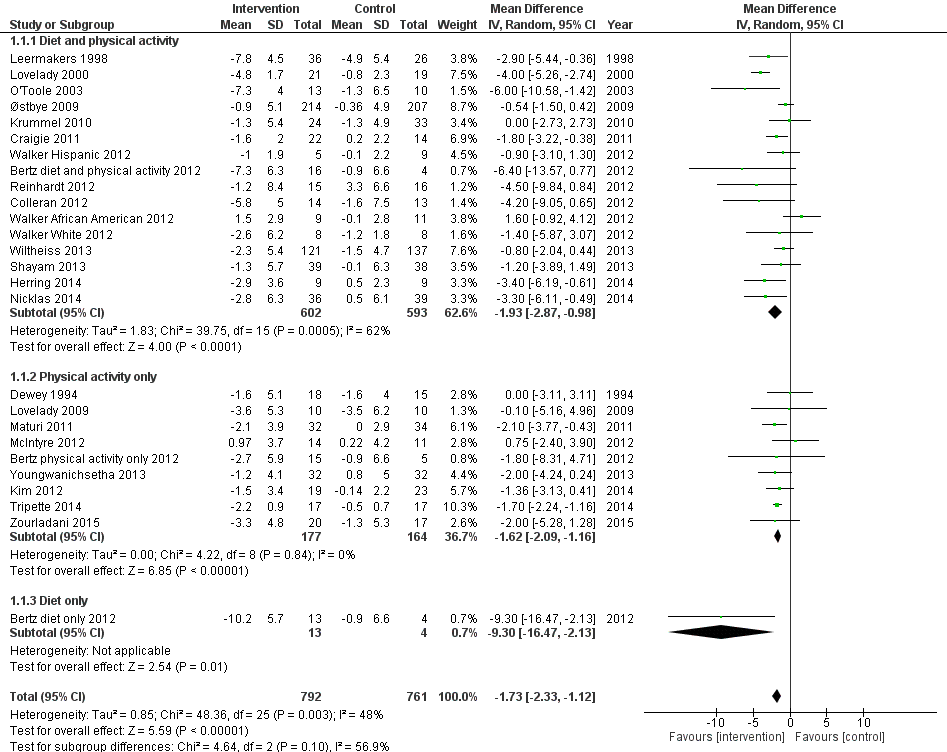
Nine systematic reviews of RCTs were eligible for inclusion in the review and 22 unique trials from across the nine systematic reviews were eligible for inclusion in the mega meta‐analysis. See Table 1 for details regarding the inclusion and exclusion criteria used in the review. Women randomised to a lifestyle intervention had significantly lower body weight at last follow‐up than comparators (mean difference of −1.7 kg (95% CI, −2.3 to −1.1 kg)) (Figure 1). The results according to subgroups can be found in Figure 2. Of interest here, the review did not find any RCTs that had tested an intervention embedded within 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 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, weight loss does not need to be large to bring health benefits.90-91 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.92 Furthermore, as the relationship between obesity and mortality is linear, even small amounts of weight loss may be clinically important.93-95 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.90

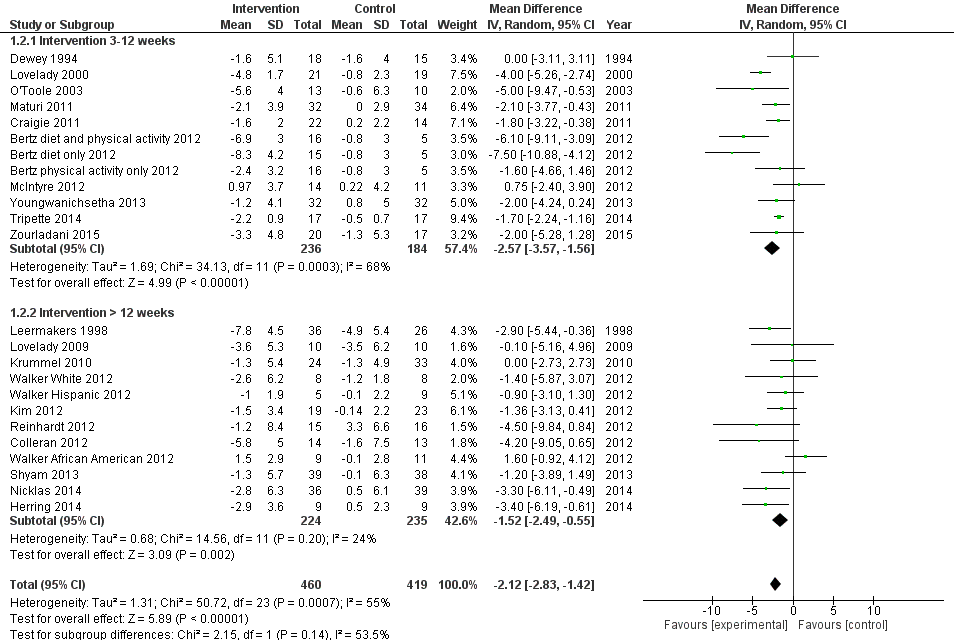
It is important to highlight, however, that many RCTs included in the systematic reviews recruited small samples, many of whom were white and middle-class.96-97 Furthermore, many of the tested interventions were intensive lifestyle-based programmes; were tailored to each individual woman and were frequently delivered by skilled health professionals such as psychologists and dieticians.98-100 Despite evidence suggesting that some of these interventions were effective, the NHS lacks the resources to scale-up these intensive interventions to offer them to every postnatal woman in the UK that 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.101 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.102-104 Attempts have been made to conduct studies that might be more appealing to a broader range of women from different ethnicities and socio-economic backgrounds, but they have also reported poor adherence and high drop-out rates.105 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.106 There is also a need for data regarding the cost-effectiveness of weight management interventions for postnatal women.

Table 1: Inclusion and exclusion criteria for selection of systematic reviews

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| --- | --- | --- |
| **Selection Criteria** | **Inclusion Criteria** | **Exclusion Criteria** |
| Study type | * Systematic reviews that included a summary of evidence from RCTs and/or quasi-RCTs | * Systematic reviews comprised of non-RCT studies (other study designs) * Not published in English * Animal studies * Economic studies |
| Population | * Adult postnatal women * Including 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 to 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)89**



**Figure 2: Mean difference in weight change (kg) by subgroup analysis (length of intervention)89**

Note: This analysis was based on end of intervention weights recorded in the trials and two trials107-108 were excluded (as no end of data were reported). Therefore the figures in this forest plot differ to those shown in Figure 1.

**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 about the preferences of postnatal women for different types of weight management interventions with some reporting that women prefer to attend group‐based sessions,109-110 while others found that home‐based self-care interventions are preferred due to issues such as time constraints, convenience, and childcare requirements.111-112 Self‐help interventions may therefore be attractive to this population of women given they are a low cost, varied, flexible option that can be tailored to their specific needs. Given 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..(89) In a systematic review of RCTs to determine the effectiveness of self-help interventions for weight loss,113 (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 small, but significantly greater weight loss than unsupported attempts to lose weight at six months compared with minimal interventions (−1.9 kg, 95% CI, −2.9 to −0.8). 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 six 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 policymakers 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.114

The potential efficacy of regular weighing (either by the individual or someone else) has been based on the principles of self-regulation theory.115-116  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.117 Self-monitoring is often described as a central component of behavioural treatment for weight loss,118 which may include monitoring food intake, physical activity, and other outcomes such as weight, size and body shape.119 Reviews by Michie et al of effective behavioural techniques for healthy eating, physical activity and reduction of alcohol consumption reported that self-monitoring was effective alone, but when combined with other techniques the effect size nearly doubled.120-121 In a systematic review of RCTs by Madigan et al 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 it was ineffective (-0.5 kg, 95% CI: -1.3 to 0.3), but adding self-weighing/self-regulation techniques to programmes resulted in a significant difference of -1.7 kg (95% CI -2.6 to -0.8).122 Multi-component interventions including self-weighing compared to no/minimal control also resulted in mean differences of -3.7 kg (95% CI -4.6 to -2.9).122 Regarding postnatal women specifically, a systematic review to determine effective behavioural change techniques in physical activity interventions for this population found that effective interventions always included self-monitoring and goal setting.(123)

**Accountability/audit and feedback for weight loss**

External support for weight management has been shown to be a key factor for successful weight-loss because of the feeling of accountability it can foster.124-126 Having to explain one’s actions to another individual can change behaviour and keep individuals motivated and focused on their weight loss goals.127-128 In practical terms, if people know their weight is being monitored externally, they may feel more obligated to try and adhere to their weight loss goals. Bovens has suggested that two concepts of accountability exist, one is a virtue and the other a mechanism.129 Here the focus is on accountability as a mechanism and therefore consists of “an obligation to explain and justify conduct”.129 The concept of accountability is well versed in the areas of business and organisational change management literature, where it has been shown to keep individuals engaged and focused on their task and ensuring 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.130-132 In the review of self-weighing and weight loss by Madigan et al, there was some evidence suggesting that adding accountability to a self-weighing programme improves effectiveness.122

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.133 In practical terms, if a person knows 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 and colleagues have conducted a systematic review examining similar behaviour change techniques to accountability called audit and feedback.134 They investigated whether audit and feedback changed healthcare professionals’ behaviour and found a significant effect (odds ratio (OR)=1.43, 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 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, and so are well positioned to address overweight and obesity in the population, as most people are registered with a general practice. NICE CG189 suggests that healthcare providers should use their clinical judgement to decide when to opportunistically weigh patients, but few rarely do so.90, 135 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 healthcare provider. Evidence has suggested that GPs and nurses are apprehensive about raising the topic of weight with their patients.136 Some of the reasons given for this reluctance include a fear of causing offence, not feeling they have the skills to raise the topic and lack of appropriate treatment pathways.137-140 Research has also identified that health professionals consider weight management unrewarding and are pessimistic about patients’ motivation to lose weight.140

The provision of more weight management interventions in primary care settings may enable more people to receive treatment, but 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.141-142. It is also interesting to highlight that research with GP’s has suggested that when raising the topic of weight, most patients are not offended, with such discussion being perceived as helpful by patients.143

The use of a brief intervention by health professionals to raise a specific health topic has shown to be ten times more useful for initiating the use of a behaviour-change programme compared to leaving the responsibility exclusively to the patient.144 The use of brief interventions involving healthcare professionals signposting patients presenting in primary care to seek weight management support shows promise of effectiveness. This trial found that a simple approach of raising the topic of weight and referral of obese adult patients to commercial weight management programmes by GPs during routine consultations was effective in facilitating weight loss.143 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 childcare, 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’ 2017 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.145 The use of technology for behaviour change has also been identified as an opportunity in Public Health England’s 5-year strategy (From Evidence into Action, Opportunities to Protect and Improve the Nation’s Health).146 Observational studies have reported that irrespective of age or socio-economic status, about 91% of new mothers use the internet as a source of information with weight loss as the fourth most searched topic.147 Technology based interventions offer self-regulatory features with the opportunity to promote self-awareness of health behaviors and they can include a tracking system to enhance self-evaluation and self-reinforcement through monitoring devices.148-149 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 for weight loss and/or maintenance in adults have found that these interventions can result in modest weight loss in overweight/obese adults.150-153 As examples, a systematic review (n=224 studies) reported that internet/mobile phone interventions improved diet, physical activity, obesity, tobacco and alcohol use up to one year.151 Health professional involvement may also improve the effectiveness of digital or mHealth interventions.152 More specifically, a systematic review reported that internet-based weight management interventions for postnatal women appeared to be beneficial in reducing weight.153 This evidence suggests that it would be appropriate and potentially beneficial to include the assistance of technology within 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, meaning the public have regular contact with health professionals in these contexts. 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 five years old in the UK receive a schedule of routine immunisations, which include measles, mumps, rubella, polio, tetanus, diphtheria, pertussis, haemophilus influenza type b, Meningococcal groups B and C, hepatitis B, rotavirus gastroenteritis and pneumococcal (13 serotypes).154 These immunisations are provided by general practices and are usually administered by practice nurses. During their first year, babies receive immunisations at eight weeks, 12 weeks old, 16 weeks old, as well as at one year. In 2019, 92.1% of children had completed the primary course of immunisations by their first birthday.154 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. As 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 within 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 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 have highlighted the low quality of previous research as a limitation to developing clinical guidance in this area.(50, 155) 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 which will be of benefit to the baby too. Developing and testing postnatal interventions is also important given that lifestyle interventions during pregnancy have only had modest success to date in preventing excessive gestational weight gain.156-157

The intervention proposed here will be delivered within 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%.154 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 where 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 effectiveness and cost-effectiveness of the intervention in facilitating long-term weight loss.

**Objectives**

The objectives of this research were:

* In women who have recently given birth, assess the feasibility of delivering an intervention to promote self-management of weight loss, by self-monitoring of weight and signposting to an online weight management programme by practice nurses as part of the UK child immunisation programme;

Assess recruitment to ensure 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 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;
* To 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;
* Using semi-structured interviews explore practice nurses’ views about delivering the intervention and to explore any variation in intervention delivery to ascertain if any adjustment to nurse training is required;
* Based on feedback from participants through semi- structured interviews explore the acceptability of the intervention;
* Explore the acceptability/validity of the ICECAP-A for the cost-effectiveness analysis in the phase III trial.

**CHAPTER 2 METHODS**

**Design considerations**

Before undertaking a large-scale phase III cluster RCT to assess the clinical and cost-effectiveness of an intervention, it is important to assess the feasibility and acceptability of such a trial. While 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 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 have been recruited because the required number of births per practice could occur over several months, meaning we would miss the immunisation visits where 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 to 13% in England). Birmingham has high levels of socio-economic deprivation, with 40% of the population living in Super Output Areas in the 10% most deprived areas in England.

Ethical approval and study sponsor

Favourable ethical approval for this study was obtained from Black Country Ethics Committee (Reference Number: 236462). The University of Birmingham was the Sponsor for this trial. The day-to-day management of the trial was coordinated by the Birmingham Clinical Trials Unit (BCTU) at the University of Birmingham. BCTU is fully registered as a UKCRC clinical trials unit.

Trial Steering Committee (TSC)

The TSC met six times during the course of the study to assess its progress. The TSC included five independent members.

**PPI involvement**

As part of the CLAHRC-West Midlands, a maternity Public & 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 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 the trial steering committee meetings either in person or occasionally by teleconference. Their purpose and role were to help guide the research team and offer their experiences both during the trial and qualitative study. Both 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 the patient facing trial documentation was viewed and commented upon by the PPI representatives and their feedback was incorporated into the documents. The PPI representative were consulted regularly throughout all stages of the study, particularly regarding their views about different approaches to participants 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 representative 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 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. GP 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 had been collected. To mitigate against selection bias, all women registered at GP 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 CONSORT guidelines for the reporting of trials.

Eligibility criteria

A complete list of all the inclusion and exclusion are detailed below and these were applied at various stages during the recruitment process.

Inclusion criteria

* Aged ≥18 years
* Women who were at least four weeks postnatal and who had not yet attended the first child immunisation appointment
* Planning to have their child immunised within the national immunisation programme
* BMI 25kg/m2 or more at the time of recruitment at the baseline home visit
* Able and willing to provide written informed consent

Exclusion criteria

* Mothers whose babies had died or had been removed from their care at birth
* Women who indicated they were already actively involved in a weight loss programme or weight management trial to lose weight
* 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 two years

**Methods of recruitment**

**Screening via Birmingham Women’s Hospital**

Computerised systems at Birmingham Women’s Hospital (BWH) allowed for systematic identification of all postnatal women who had recently given birth, regardless of socio-economic status (SES) and ethnicity, which reduced the potential for recruitment and selection bias. Every two 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 (PIS) 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 four weeks post-delivery. BWH applied the following initial screening criteria before sending study letters of invitation to women:

1. Confirmed the participant was aged ≥18 years
2. Confirmed the participant had given birth at least four weeks previously
3. Confirmed the participant was registered at one of the participating practices
4. Excluded mothers whose babies had died or had been removed from their care at birth

The invitation letter and PIS included a telephone number which 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 PIS received a follow-up call from the research team at Birmingham Women’s Hospital to ask if they were interested in taking part.  As the study was recruiting from practices located in mostly high deprivation communities with ethnically diverse patient lists, it was felt women may respond better to a phone call where they could talk to a researcher regarding the trial, rather than by a letter alone, particularly if there was low literacy. 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 later section).

**Direct recruitment through GP 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 GP practice waiting room TV 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 PIS was mailed to interested women, if women had not already received one. If women were still interested after receiving the invitation/PIS 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, postnatal check-ups or at any other appointment with the GP or other health care professional post-delivery and prior to the two month immunisation appointment. Some GPs in participating practices were asked to give a letter of invitation and PIS 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. Where this occurred, the researcher provided potential participants with the letter of invitation and PIS directly, either to read at the practice, or to take home. If, after having reading 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 visit section below). If all 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, where 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:

1. Reconfirmed the participant was aged ≥18 years;
2. Reconfirmed the participant had given birth at least four weeks previously;
3. Reconfirmed the participant was registered at one of the participating GP practices;
4. Collected self-reported data on participants’ height and weight to calculate an approximate BMI;
5. Confirmed participants were planning to have their child immunised;
6. Confirmed participants had not yet attended the first child immunisation appointment;
7. Confirmed participants were not already actively involved in a weight loss programme or a weight management trial to lose weight;
8. Confirmed participants were willing to give consent to notify their GP of their participation in the trial;

For participants who fulfilled the initial screening criteria and were interested in taking part in the study, an appointment was arranged for a researcher to visit their home for the baseline visit. The baseline visit was arranged to take place between six and seven weeks postnatally, no earlier than four weeks and before the first immunisation visit at two 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 two 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 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. Participant were then notified of the trial group to which their GP 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 as 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 no intervention (usual care) using minimisation for practice list size (large: 6000 or more; small: under 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 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 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 because 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 the first year, babies are routinely immunised at two, three, four and twelve months of age; the intervention was embedded within these routine immunisation contacts so no additional visits by participants were required. The intervention involved nurses encouraging participants to make healthier lifestyle choices through self-monitoring of their weight and signposting to an online weight management programme (POWeR) for support.158 Nurses were asked not to provide any lifestyle counselling; their role was only to provide encouragement, regular external accountability (i.e. so women were mindful their weight was being monitored by someone else) and to signpost women to using POWeR for weight loss information.The intervention was deliberately designed to be multi-component because evidence suggests that such interventions lead to more favourable weight management during the postnatal period.159

The intervention behaviour change techniques were mapped according to the CALO-RE taxonomy checklist160 See Table 2. The content of the intervention has also been mapped against the TiDier checklist.161

**Table 2:** Intervention components using the CALO-RE behavioural change taxonomy160

|  |  |
| --- | --- |
| **Behavioural technique** | **Definition** |
| Instruction on how to perform the behaviour | The practice nurse instructed participants to weigh themselves once a week.  Participants were encouraged to weigh themselves on the same day and time every week. 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 also 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 a week. 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 0.5-1kg weight loss a week as advised by NICE for a general population. |
| Self-monitoring of outcome(s) of behaviour | Participants were instructed to record their weight once a week on a record card that was attached to the 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 the 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 POWeR online programme. |
| Use of follow up prompts | Participants were directed to POWeR online programme, which provides weekly email 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. |

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

**Weight loss goals**

No clinical guidelines that specify rates of healthy weight loss for postnatal women are available, but for the adult general population NICE recommend 0.5 kg to 1 kg per week.78 Participants were therefore advised to aim for 0.5 kg to 1 kg per week weight loss until they had achieved a BMI less than 25 kg/m2 and were no heavier than their pre-pregnant 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 their progress will be monitored by another individual.

**Online Weight Loss Programme (POWeR: Positive Online Weight Reduction)**

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) and 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.158 POWeR 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 a 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. POWeR 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 or relapse. Evidence is provided for the effectiveness of these techniques and examples given of how others have successfully used them (‘POWeR stories’). POWeR 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 they had achieved the goals they had set themselves the previous week, users received tailored feedback giving encouragement if maintaining weight loss (e.g. reminders of health benefits accrued) and meeting goals. Weight gain and failing to meet goals triggered automated personalised advice such as appropriate goal setting and planning, boosting motivation, overcoming difficulties, 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 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 (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 comparison 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 the trial was appealing to postnatal women (via assessment of the recruitment rate to ensure a full phase III trial is feasible);
* whether the intervention was acceptable (via assessment of adherence to weekly self-weighing and registration with the POWeR online weight management programme);
* whether 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).

**BodyTrace weighing scales**

The intervention group were given a set of real time weight tracking scales (BodyTrace scales) as an objective process measure of adherence to weekly self-weighing (https://www.bodytrace.com/). 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 which store 100 weight recordings on a 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 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

While 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. Depression and anxiety were assessed using the Hospital Anxiety and Depression Scale.(162) Body image was measured using the Body Image States Scale.(163) Self-reported physical activity was assessed using the postnatal version of the Pregnancy Physical Activity Questionnaire.164 Weight control strategies were assessed at follow-up (Weight Control Strategies Scale).165 Using the revised three-factor eating questionnaire the variables of conscious cognitive energy restraint of eating, uncontrolled eating and emotional eating were measured.166 Questions from Steinberg and colleagues perceptions of self-weighing questionnaire were used to measure perceptions of regular monitoring in the intervention group at follow-up only167.

**Health economics**

Relative to routinely used economic quality-of-life measures, such as the EQ5D,168 the ICECAP-A has only recently been developed.169 We assessed the acceptability of the ICECAP-A within the feasibility trial to inform the economic evaluation design within 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 wellbeing benefits within 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 this occurred it was 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 since it only consisted 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 which 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. Adverse events 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 only required to 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 according to 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 impact on weight therefore these behaviours were recorded. Data on whether participants in both groups had attended any formal weight loss programmes during their involvement in the trial was collected as was data on any specific weight loss strategies or diets that participants might have used. Data relating to participants’ mode of delivery, pregnancy complications and how many children they had given birth to were collected. Data on marital status was collected to ascertain participants’ general level of social support in their lives. Data on employment status and financial status was 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, USA) (https://www.bodytrace.com/) that objectively recorded 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 and these 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 by practice nurses per protocol. We obtained data from POWeR for participants who chose instead to record their weight on the online programme.

**Use of the POWeR Online Programme (intervention group)**

Using participants email address the online POWeR software automatically recorded participants’ usage of the website (i.e. registration, number of logins, time spent on POWeR, progress through POWeR, number and value of weight measurements entered).

**Attendance at immunisation appointments**

The intervention was delivered at child immunisation appointments at two, three and four 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 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**

Where 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 then read to assess, by use of a checklist, whether the nurses were delivering the intervention according to their training and the protocol. These 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 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 usual care participants had accessed the POWeR website.

Table 3: Schedule of assessments

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Visit* | *Screening* | *Baseline*  *Home Visit* | *Immunisation visits at GP practice*  *(INTERVENTION GROUP ONLY)* | | | | *Follow-up Home Visit* | | *Post Follow-up* |
|  | *4 weeks*  *postnatally*  *(no earlier than 4 weeks)* | *6-7 weeks*  *postnatally*  *(before the 1st immunisation)* | *2 months*  *postnatally* | *3 months*  *postnatally* | *4 months*  *postnatally* | *3 months post-randomisation*  *(-1 week to approx +4 weeks)* | |  | | |
| *Identification of potential participants* | **X** |  |  |  |  |  | |  | | |
| *Eligibility check* | **X** | **X** |  |  |  |  | |  | | |
| *Valid informed consent for screening* |  | **X** |  |  |  |  | |  | | |
| *Height* | **X** | **X** |  |  |  |  | |  | | |
| *Weight* | **X** | **X** | **x** | **x** | **x** | **x** | |  | | |
| *% body fat* |  | **X** |  |  |  | **x** | |  | | |
| *BMI* | **X** | **X** |  |  |  |  | |  | | |
| *Valid informed consent for full trial* |  | **X** |  |  |  |  | |  | | |
| *Pregnancy and family details* |  | **X** |  |  |  |  | |  | | |
| *Feeding of baby* |  | **X** |  |  |  | **x** | |  | | |
| *Sleep patterns* |  | **X** |  |  |  | **x** | |  | | |
| *Marital status* |  | **X** |  |  |  |  | |  | | |
| *Employment and financial status* |  | **X** |  |  |  |  | |  | | |
| *Smoking status* |  | **X** |  |  |  | **x** | |  | | |
| *Visit* | *Screening* | *Baseline*  *home visit* | ***Immunisation visits at GP practice***  ***(INTERVENTION GROUP ONLY)*** | | | | *Follow-up*  *home visit* | | *Post follow-up* |
|  | *4 weeks*  *postnatally*  *(no earlier than 4 weeks)* | *6-7 weeks postnatally (before 1st immunisation* | *2 months*  *postnatally* | *3 months*  *postnatally* | *4 months*  *postnatally* | *3 months post-randomisation*  *(-1 week/+4 weeks)* | |  | | |
| *Alcohol consumption* |  | **X** |  |  |  | **x** | |  | | |
| *HADS Questionnaire162* |  | **X** |  |  |  | **x** | |  | | |
| *ICECAP-A Questionnaire169* |  | **X** |  |  |  | **x** | |  | | |
| *Eating Habits Questionnaire166* |  | **X** |  |  |  | **x** | |  | | |
| *Body Image Questionnaire163* |  | **X** |  |  |  | **x** | |  | | |
| *PPAQ Questionnaire164* |  | **X** |  |  |  | **x** | |  | | |
| *Weight Control Strategies Scale165* |  |  |  |  |  | **x** | |  | | |
| *Immunisation record from participant* |  |  |  |  |  | **x** | |  | | |
| *Weight loss resources used* |  |  |  |  |  | **x** | |  | | |
| *Intervention only – Self-weighing data* |  |  |  |  |  | **x** | |  | | |
| *Intervention only – BodyTrace weight data* |  |  |  |  |  | **x** | |  | | |
| *Intervention only – POWeR programme158 data* |  |  |  |  |  | **x** | | **x** | | |
| *Intervention only – Trial Acceptability* |  |  |  |  |  | **x** | |  | | |
| *Immunisation records from GP* |  |  |  |  |  |  | | **x** | | |
| *Qualitative Study Interviews* |  |  |  |  |  |  | | **x** | | |

Trial Procedures

Table 3 outlines all 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 place between 6-7 weeks postnatally and before the first child immunisation visit at two months and took about 30-45 minutes to complete. Participants were visited at home by a researcher where;

* Screening consent was obtained
* Height, weight, percentage body fat were measured, BMI calculated
* Eligibility (inclusion/exclusion criteria) was reviewed
* Informed consent was obtained foreligible participants
* 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
* Usual care group were issued with the healthy lifestyle leaflet and advised that they would receive usual care at their child immunisation appointments.
* Intervention group were issued with the healthy lifestyles leaflet, the weight record card was attached to 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 three 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, 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 semi-structured 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 trial participation may have caused them. This voucher was offered at the follow-up home visit once all follow-up the case report forms (CRFs) questions and health questionnaires had been completed.

Data monitoring

As this was a feasibility trial designed to test whether a definitive trial was feasible a Data Monitoring and Ethics Committee (DMEC) 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, statistician and programmer and the trial database was signed off once the implementation of these has 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 GP 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 was 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 (where participants have consented to be telephoned). All data was entered onto 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 University of Birmingham (UoB). Password protected electronic databases, on secure UoB servers, for trial data have limited access to staff working on the trial. The database had ranges applied to data items where suitable and appropriate.

Data collected through the POWeR website was electronically securely transferred from the University of Southampton to the Trial Office at the University of Birmingham 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 University of Birmingham. 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 University of Birmingham must be registered with the Data Protection Officer and data held in accordance with the Data Protection Act. The University of Birmingham 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

As 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.170 A recruitment target of 80 women from 10-12 practices recruited over eight 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 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 was 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 is reported. Originally, the immunisation rate for each practice in the trial was to be compared with the normal immunisation rate for that practice. However, due to low recruitment, the immunisation data has 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 pre-specified 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 that the intervention had not adversely affected immunisation rates. The criteria to proceed to the phase III trial was therefore based on three criteria; the recruitment rate; adherence to weekly self-weighing and registration with the online weight loss programme (POWeR) using a traffic light system.

Green light

* Recruitment rate ≥80% of the target (n=80; i.e. recruit at least 64 women), ≥50% of the intervention group weigh themselves weekly ≥60% of the time and ≥60% of participants have 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).

Amber light

* 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 and 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 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 adaption of the protocol will require further assessment before progressing.

Red light

* Recruitment rate of <50% of the target (n=80; i.e. recruit less than 40 women), <40% of the intervention group weigh themselves weekly 40-59% of the time and <40% of the intervention group have registered with the online POWeR programme. If one or more of these criteria are met, we would consider the current protocol not feasible and not progress to an application for a full RCT with the current design. Additional red-light criteria would be concerns from the TSC that immunisation rates have been adversely affected.

**Data analysis**

Analysis of outcome measures

A detailed statistical plan can be found in the additional material. 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 is based on recruitment, adherence to weekly self-weighing and registration to POWeR (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 POWeR is also presented. The binomial normal approximation was used to calculate the corresponding 95% confidence intervals.

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 involved those in the weight management intervention group versus those in the usual care group. The analysis of outcome data focused on confidence interval estimation. Continuous outcomes (except the Pregnancy Physical Activity Questionnaire; see below) were summarised using means and standard deviations. Adjusted mean differences between groups and the corresponding 95% confidence intervals were estimated from generalised linear mixed models which included adjustment for baseline values (where available) and the minimisation variables (practice size and index of multiple deprivation), and practice (cluster) as a random effect. Data from the Pregnancy Physical Activity Questionnaire are presented as medians with inter-quartile ranges, and the unadjusted difference between the median in each group was reported along with the 95% confidence interval calculated using bootstrapping methods. All estimates of differences between groups are presented with two-sided 95% confidence interval and no p-values are presented.

Use of the POWeR website was assessed through the number of times participants logged on to POWeR, recorded their weight on POWeR and time spent browsing, with data presented as medians with interquartile ranges. 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 participants completed and the number of participants who completed each stage.

Qualitative study

Semi-structured 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 within child immunisation appointments. These two interview studies are described in more detail in Chapters 5 and 6.

**Changes to protocol**

Minor and substantial changes to the protocol and conduct of the trial are outlined below in Table 4. One of 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 given birth at the hospital who were registered at GP practices taking part in the trial, and they were unable to screen against key trial entry criteria e.g. weight/BMI, as 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 Trial Steering Committee in October 2018, and also with the HTA, and this change was made to the protocol.

Table 4: Protocol amendments

|  |  |  |  |
| --- | --- | --- | --- |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** |
| **1.0** | **5th Dec 2017** | **2.0** | **Substantial** |
| **Summary of amendment** | | | |
| **Substantial changes:**   * Removal of the eligibility criteria screening for use of illicit drugs or alcohol dependence * Clarification to 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 * 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 TSC contact details and change to the timings of TSC meetings * Amended statement of activities and schedule of events * Minor typographical corrections | | | |
| |  |  |  | | --- | --- | --- | | **Other modified documents approved** | **Previous version** | **New version** | | Invitation Letter and Reply Slip | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Participant Information Sheet | Version 2.0 (16th Nov 2017) | Version 3.0 (5th Dec 2017) | | Screening Consent Form | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Full Consent Form A | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Full Consent Form B | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | GP Poster | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Baseline Appointment Letter | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Questionnaire Baseline | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Questionnaire Follow-up A | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Questionnaire Follow-up B | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 2017) | | Weight Card | Version 1.0 (12th Oct 2017) | Version 2.0 (5th Dec 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 | | | | |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** |
| **2.0** | **1st Feb 2018** | **4.0** | **Substantial** |
| **Summary of amendment** | | | |
| **Substantial changes:**   * Changes to the Participant Information Sheet as requested by the HRA * Changes to section 8.6 and 16 of the protocol to reflect changes to the Participant Information Sheet * Changes to the Full Consent Form B, Participant Interview Consent Form, Nurses Interview PIS and Nurses Interview Consent Form   **Non-substantial changes:**   * Change of CI title * Addition of ISRCTN number to protocol and trial documentation * Re-formatting of the Trial Number to incorporate site ID * 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 | | | |
| |  |  |  | | --- | --- | --- | | **Other modified documents approved** | **Previous version** | **New version** | | Participant Information Sheet | Version 3.0 (5th Dec 2017) | Version 5.0 (1st Feb 2018) | | Invitation Letter and Reply Slip | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Screening Consent Form | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Full Consent Form A | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Full Consent Form B | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | GP Letter | Version 1.0 (12th Oct 2017) | Version 3.0 (1st Feb 2018) | | GP Poster | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Healthy Lifestyle Leaflet | Version 1.0 (12th Oct 2017) | Version 3.0 (1st Feb 2018) | | Baseline Appointment Letter | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Follow-up Appointment Letter | Version 1.0 (12th Oct 2017) | Version 3.0 (1st Feb 2018) | | Questionnaire Baseline | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Questionnaire Follow-up A | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Questionnaire Follow-up B | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Weight Record Card | Version 2.0 (5th Dec 2017) | Version 4.0 (1st Feb 2018) | | Nurses Interview PIS | Version 3.0 (22nd Nov 2017) | Version 5.0 (1st Feb 2018) | | Nurses Interview Consent Form | Version 1.0 (12th Oct 2017) | Version 3.0 (1st Feb 2018) | | Nurses Interview Schedule | Version 1.0 (12th Oct 2017) | Version 3.0 (1st Feb 2018) | | Participant Interview Consent Form | Version 1.0 (12th Oct 2017) | Version 3.0 (1st Feb 2018) | | Participant Interview Schedule | Version 1.0 (12th Oct 2017) | Version 3.0 (1st Feb 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 | | | | |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** |
| **3.0** | **20th Mar 2018** | **5.0** | **Minor** |
| **Summary of amendment** | | | |
| **Non-substantial changes:**   * Change to section 6.2. Clarification on the IMD score calculated for the GP 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 | | | |
| |  |  |  | | --- | --- | --- | | **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 | | | | |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** |
| **4.0** | **10th May 2018** | **6.0** | **Substantial** |
| **Summary of amendment** | | | |
| **Substantial changes:**   * Submission of participant POWeR registration card * Submission of participant instructions for POWeR * Submission of participant FAQs for POWeR * 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 (10th May 2018) | | Participant Instructions for POWeR | N/A | Version 1.0 (10th May 2018) | | Participant FAQs for POWeR | N/A | Version 1.0 (10th May 2018) | | Participant Instructions for BodyTrace weighing scales | N/A | Version 1.0 (10th May 2018) | | Questionnaire Baseline | Version 4.0 (1st Feb 2018) | Version 5.0 (10th May 2018) | | Questionnaire Follow-up A | Version 4.0 (1st Feb 2018) | Version 5.0 (10th May 2018) | | Questionnaire Follow-up B | Version 4.0 (1st Feb 2018) | Version 5.0 (10th May 2018) | | | | |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** |
| **5.0** | **5th Nov 2018** | **7.0** | **Substantial** |
| **Summary of amendment** | | | |
| **Substantial changes:**   * Change of grant holder and CI employer from University of Birmingham to University of Loughborough * Addition to 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 | | | |
| |  |  |  | | --- | --- | --- | | **Other modified documents approved** | **Previous version** | **New version** | | GP Flyer Cover Letter | N/A | Version 1.0 (5th Nov 2018) | | GP Flyer | N/A | Version 1.0 (5th Nov 2018) | | Invitation Letter and Reply Slip – GP Version | N/A | Version 1.0 (5th Nov 2018) | | | | |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** |
| **6.0** | **5th Feb 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 (10th May 2018) | Version 6.0 (5th Feb 2019) | | Questionnaire Follow-up A | Version 5.0 (10th May 2018) | Version 6.0 (5th Feb 2019) | | Questionnaire Follow-up B | Version 5.0 (10th May 2018) | Version 6.0 (5th Feb 2019) | | Participant Interview Schedule | Version 3.0 (1st Feb 2018) | Version 4.0 (5th Feb 2019) | | | | |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** |
| **7.0** | **16th July 2019** | **9.0** | **Minor** |
| **Summary of amendment** | | | |
| **Non-substantial changes:**   * Clarification of the stop/go criteria * Clarification on masking * Clarification on POWER in the control group * Clarification on data received from BWH * Clarification on recruitment rate * Update of trial staff and contact information | | | |
|  | | | |

**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. See Table 5.

**Table 5: Randomisation minimisation variables by practice and participants**

|  | | **Intervention (N=7)** | **Usual Care**  **(N=7)** | **Overall**  **(N=14)** |
| --- | --- | --- | --- | --- |
| **Minimisation variables (centre level as per randomisation process)** | | | | |
| GP practice list size | Large  (≥6000 patients) | 3 | 3 | 6 |
| Small  (<6000 patients) | 4 | 4 | 8 |
| Index of multiple deprivation | Low | 0 | 0 | 0 |
| Medium | 1 | 0 | 1 |
| High | 6 | 7 | 13 |
| **Minimisation variables (participant level)** | | | | |
|  |  | **Intervention**  **N=16** | **Usual care**  **N=12** | **Total**  **N=28** |
| Index of multiple deprivation1 | Low | 0 (0%) | 0 (0%) | 0 (0%) |
| Medium | 1 (6%) | 0 (0%) | 1 (4%) |
| High | 15 (94%) | 12 (100%) | 27 (96%) |
| GP practice list size | Large  (≥6000 patients) | 8 (50%) | 9 (75%) | 17 (61%) |
| Small  (<6000 patients) | 8 (50%) | 3 (25%) | 11 (39%) |

1 Index of multiple deprivation 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.

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 were 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 which were delivering the weight management intervention, and 12 women were registered at practices delivering usual care. Recruitment at each practice is detailed in Table 6. Four of the usual care practices recruited no participants.

**Withdrawals, loss to follow-up and missing data**

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

**Table 6: Recruitment of practices by trial group**

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

**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 below 25 kg/m2 (n=4).

Invitations sent by Birmingham Women Hospital (n=368) and GP practices1

**Figure 3: Participant Flow through the trial**

1Totalnumberof GP practice invitations sent is unknown. Only two sites were able to provide information on the number of invites that they had sent; one practice sent out 12 invitations and one sent out five invitations. 2One woman withdrew from the intervention due to the study tasks being an inconvenience, but they agreed to continue in the trial and complete the follow-up assessment.

Enrolment

Lost to follow-up (give reasons) (n=0)

Withdrawal (give reasons) (n=0)

Allocated to usual care (n=12)

Lost to follow-up (give reasons) (n=0)

Withdrawal (give reasons) (n=1)

* Decided not to have child immunised (n=1)

Consented (n=28)

Excluded (n=12)

Not meeting inclusion criteria (n=11)

* + BMI below entry criteria (n=4)
  + Already attended first immunisation appointment (n=5)
  + Practice not involved in trial (n=2)
* Other reasons (n=1)

Allocated to intervention (n=162)

Follow-Up

Allocation

Reply slips and telephone calls received (n=40)

**Table 7: Data return status by treatment group**

|  | **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%) | 11 (8%) |
| Follow-up case report form | 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%) | 32 (20%) |  |  |  |

1Participant reported that they had posted the questionnaire, but it was not received by the trials unit, so it has been considered not returned.2These three weight record cards were collected by the researcher at the three month visit, but the cards were completely blank so have been treated as if not returned as they provided no usable data.

**Table 8: Questionnaire completion rates at baseline and follow-up**

|  | **Baseline**  (Expected=281) | | | **3-month follow-up**  (Expected=272) | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Received** | **Fully completed** | **Partially**  **complete** | **Received** | **Fully completed** | **Partially**  **Complete** |
| Hospital Anxiety and Depression Scale (HADS)162 | 27 | 26 (96%) | 1 (4%) | 26 | 25 (96%) | 1 (4%) |
| Three factor eating questionnaire166 | 27 | 23 (85%) | 4 (15%) | 26 | 26 (100%) | 0 (0%) |
| Body image state scale163 | 27 | 26 (96%) | 1 (4%) | 26 | 25 (96%) | 1 (4%) |
| Pregnancy physical activity questionnaire (PPAQ)3 164 | 27 | 22 (81%) | 5 (19%) | 26 | 23 (88%) | 3 (12%) |
| ICEpop CAPability measure for adults (ICECAP-A)169 | 27 | 27 (100%) | 0 (0%) | 26 | 26 (100%) | 0 (0%) |
| Weight control strategies scale165 |  |  |  | 26 | 22 (85%) | 4 (15%) |
| Self-weighing perceptions4 167 |  |  |  | 14 | 13 (93%) | 1 (7%) |

1One participant did not return questionnaire at baseline visit. 2One participant withdrew from the trial. 3It 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 the woman is working or not, but due 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, 7 (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. 4Completed by intervention group only (expected N=15).

**Participant characteristics at baseline**

The average age of participants was 32.1 years (SD=5.7). Forty-six percent 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 was 83.6 kg (SD=17.1) and 31.8 kg/m2 (SD=6.9) 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 breast feeding. On average participants reported they had 3.2 hours (SD=1.1) of uninterrupted sleep per night. See Table 9.

**Table 9: Baseline characteristics by trial group**

| **Demographic and other baseline variables** | | **Intervention**  **(N=16)** | **Usual Care**  **(N=12)** | **Overall**  **(N=28)** |
| --- | --- | --- | --- | --- |
| Age (years) | Mean (SD, N) | 32.9 (6.1, 16) | 31.0 (5.3, 12) | 32.1 (5.7, 28) |
| Min-Max | 22-41 | 24-42 | 22-42 |
| Ethnic group | 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 | 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%) |
| Other1 | 1 (6%) | 1 (9%) | 2 (7%) |
| Missing | 0 | 1 | 1 |
| Current employment status | 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%) |
| Other2 | 0 (0%) | 1 (9%) | 1 (4%) |
|  | Missing | 0 | 1 | 1 |
| Current financial status | 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 | 0 | 2 | 2 |
| **Clinical Information** | | | | |
| Average number of cigarettes smoked each day | None | 16 (100%) | 9 (90%) | 25 (96%) |
| 5 or less | 0 (0%) | 0 (0%) | 0 (0%) |
| 6-10 | 0 (0%) | 1 (10%) | 1 (4%) |
| Missing | 0 | 2 | 2 |
| Drank alcohol in last week | Yes | 4 (25%) | 2 (18%) | 6 (22%) |
| No | 12 (75%) | 9 (82%) | 21 (78%) |
|  | Missing | 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) |
|  | Min-Max | 2-9 | 2-6 | 2-9 |
|  | Missing | 1 | 0 | 1 |
| Weight (kg) | Mean (SD, N) | 81.6 (13.7, 16) | 86.2 (21.2, 12) | 83.6 (17.1, 28) |
| Min-Max | 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) |
| Min-Max | 147.3-178.4 | 153.0-174.9 | 147.3-178.4 |
| BMI (kg/m2) | Mean (SD, N) | 31.6 (6.1, 16) | 32.1 (8.0, 12) | 31.8 (6.9, 28) |
| Min-Max | 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) |
| Min-Max | 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) |
| Min-Max | 55.5-104.0 | 50.0-154.6 | 50.0-154.6 |
| Missing | 3 | 2 | 5 |
| Number of children given birth to | 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 | 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 | Yes | 8 (50%) | 3 (25%) | 11 (39%) |
| No | 8 (50%) | 9 (75%) | 17 (61%) |
| *If yes (n=11, note: not mutually exclusive):* | 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%) |
| Other3 | | 2 (25%) | 2 (67%) | 4 (36%) |
| Type of delivery | 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 | Yes | 16 (100%) | 11 (92%) | 27 (96%) |
| No | 0 (0%) | 1 (8%) | 1 (4%) |
| Current method of feeding | 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:* |  | *(n=13)* | *(n=7)* | *(n=20)* |
| Intended time to continue breastfeeding | 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) |
| Min-Max | 1-6 | 2-5 | 1-6 |

1Others (n=2): living with partner; not living with partner. 2Others (n=1): In paid employment and a student. 3Others (n=4): pelvic pain (on crutches from 37/40); hyperemesis and excess water; hyperemesis; and high-risk embolism/thrombosis

**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 10: Frequency of self-weighing (objective data)**

|  |  |
| --- | --- |
| **Number of Times1** | **Weekly self-weighing according to schedule of assessments**  **(N=16)** |
| 1 | 22(12.50%) |
| 2 | 1 (6.25%) |
| 3 | 13 (6.25%) |
| 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%) |

1The number of times refers to the number of weeks during follow-up that participants weighed themselves as per the schedule of assessments. Data was collected until the scales were retrieved (minimum three months). 2One participant subsequently withdrew from the intervention as they found study tasks an inconvenience, but they completed follow-up. 3One participant subsequently withdrew from the trial as they decided not to get their child immunised.

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

**Table 11: Number of participants self-weighing (objective data)**

|  |  |
| --- | --- |
| **Week Number** | **Number of participants who self-weighed**  **(N=16)** |
| 1 | 151 (93.75%) |
| 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%) |

1One participants could not get a signal to transmit the weights using the BodyTrace scalesat the baseline visit; their weights were subsequently recorded on a USB stick during follow-up period (only one weight at week 4 was recorded).

Table 12 presents the number of participants weighing themselves at least 60% of the time, between 40-59% of the time and less than 40% of the time.

**Table 12: Self-weighing (objective data) according to percentage adherence categories**

|  |  |
| --- | --- |
|  | **Intervention group**  **(N=16)** |
| 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%) |

**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 was used in combination with the objective transmitted weight data from the BodyTrace scales. See Tables 13-15.

**Table 13: Frequency of self-weighing (all available evidence of self-weighing)**

|  |  |
| --- | --- |
| **Number of Times1** | **Weekly self-weighing according to schedule of assessments (N=16)** |
| 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%) |

1Thenumber of times refers to the number of weeks during the intervention period that participants weighed themselves. Data was collected until the scales were retrieved (minimum three months).

**Table 14: Number of participants self-weighing at scheduled week (all available evidence)**

|  |  |
| --- | --- |
| **Week Number** | **Number of participants self-weighing (N=16)** |
| 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)**

|  |  |
| --- | --- |
|  | **Intervention group**  **(N=16)** |
| 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%) |

**Use of the POWeR online weight management programme (Intervention group)**

A total of 9/16 (56%) of the intervention group participants registered to use the POWeR online programme (objective data). The median number of times these participants logged onto POWeR over the follow-up period was 4 (IQR 2-9, range 1-21). Registered participants recorded their weight on POWeR a median of two times over follow-up (IQR 1-7) and spent a median of 102.8 minutes in total on POWeR over follow-up (IQR 58.4-189.4). Four of the nine participants who registered on POWeR completed stage 1 (44%), two completed stage 2 (22%) and no participants completed all three stages. See Tables 16-18. Data are reported in medians due to skewness in the data.

**Table 16: Total number of POWeR158 logins in each week of follow-up**

|  |  |
| --- | --- |
| **Week** | **Total Number of POWeR logins1** |
| 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 |

1Data are for all participants in each given week

**Table 17: Total number of weights recorded on POWeR158 in each week of follow-up**

|  |  |
| --- | --- |
| **Week** | **Total Number of Weights Recorded on POWeR1** |
| 1 | 3 |
| 2 | 5 |
| 3 | 3 |
| 4 | 4 |
| 5 | 4 |
| 6 | 1 |
| 7 | 3 |
| 8 | 3 |
| 9 | 2 |
| 10 | 3 |
| 11 | 1 |
| 12 | 1 |

1Data are for all participants in each given week of the intervention period

**Table 18: Total number of minutes spent on POWeR158 in each week**

|  |  |
| --- | --- |
| **Week** | **Total Number of Minutes POWeR Used1** |
| 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 |
| 19 | 0 |
| 20 | 0.4 |

1Data 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 pre-specified 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.

**Table 19: Stop-Go criteria results**

|  |  |  |
| --- | --- | --- |
| Stop-Go Criteria | **Estimate (95% Confidence Interval)** | **Target met** |
| Recruitment rate | 28/80 (35%, 95% CI: 25% to 45%) | Red |
| Adherence to intervention (self-weighing)1: weighed weekly ≥60% of the time | 10/162 (63%, 95% CI: 39% to 86%) | Green |
| Adherence to intervention: registered with POWeR158 | 9/16 (56%, 95% CI: 32% to 81%) | Amber |

1Data based on objective assessment of weight as measured via the BodyTrace weighing scales. 2One participant withdrew from the trial.

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

At follow-up participants were asked about resources they had used to help them manage their weight and whether they had received any support to lose weight. See Table 20.

**Table 20: Weight management resources and support (Intervention group)**

|  |  |  |
| --- | --- | --- |
|  | | **Intervention group**  **(N=151)** |
| Have you accessed or used any resources to help with your weight loss? | Yes | 6 (40%) |
| No | 9 (60%) |
| *If yes (n=6):* |  |  |
|  | Online programme2 | 1 (17%) |
|  | Exercise3 | 2 (33%) |
|  | Diet4 | 3 (50%) |
| Do you feel there are people you know, amongst your friends and family who support and encourage you with your postnatal weight loss? | Yes | 11 (73%) |
| No | 4 (27%) |
| Self-reported accessing POWeR158 | Yes | 10 (67%) |
| No | 5 (33%) |
| Do you know anyone else taking part in the study? | Yes | 1 (7%) |
| No | 14 (93%) |

1One intervention group participant withdrew from the trial prior to follow-up. 2Online programme (n=1): programme not specified. 3Exercises (n=2): DIA method post-natal exercises/yoga; Zumba at home. 4Diet changes (n=3): no dairy/soya/egg products; general healthy eating - more fruit/veg; and low calorie, Hello Fresh.

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

**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 where scores could range from 1-8 where higher scores were more favourable. The mean score for the question ‘would you recommend this study to your friends?’ was 6.2/8. On average the usefulness of being weighed by the practice nurse was scored 5.3/8 and usefulness of weekly self-weighing scored 5.8/8 by participants. Overall participants felt 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 the intervention made women anxious about their weight was included and the average response score was 3.8/8. See Table 21.

**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 inserted 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.

**Attendance at immunisation visits**

To check that the intervention did not adversely impact on attendance at immunisation appointment (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 as they decided not to get their child immunised). There was no evidence that the intervention deterred participants from attending their child immunisation appointment, with 12 of the 13 women (92%) in the intervention group for whom this data was provided attending all three child immunisation appointments and having their baby immunised.

**Table 21: Views on the acceptability of the intervention**

|  | **Intervention group**  **(N=151,2)** |
| --- | --- |
| Would you recommend this study to a friend? | |
| Mean (SD, N) | 6.2 (1.9, 13) |
| Minimum-Maximum | 1-8 |
| Missing | 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 | 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 | 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 | 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 | 2 |

1One participant in the intervention group withdrew prior to follow-up. 2Scores range from 1 to 8 on a likert scale, where higher scores are more favourable.

**Table 22: Delivery of the intervention by nurses at immunisations**

|  | | **Intervention**  **(N=121,2)** |
| --- | --- | --- |
| **2-month immunisation appointment** |  |  |
| Appointment attended by participant | Yes | 12 (100%) |
| No | 0 (0%) |
| When participant 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 POWeR | Yes | 12 (100%) |
| No | 0 (0%) |
| Participant asked by nurse if 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 | 13 |
| When participant weighed in relation to the | Before | 4 (100%) |
| immunisation of the child | After | 0 (0%) |
|  | Declined | 0 (0%) |
|  | Missing | 8 |
| Weight recorded by nurse at immunisation appointment | Yes | 11 (100%) |
| No | 0 (0%) |
| Missing | 1 |
| Participant reminded by nurse about POWeR | Yes | 11 (100%) |
|  | No | 0 (0%) |
|  | Missing | 1 |
| Participant asked by nurse if following weekly | Yes | 11 (100%) |
| self-weighing | No | 0 (0%) |
|  | Missing | 1 |
| **4-month immunisation appointment** |  |  |
| Appointment attended by participant | Yes | 10 (100%) |
|  | No | 0 (0%) |
|  | Missing | 24 |
| When participant weighed in relation to the | Before | 2 (100%) |
| immunisation of the child | 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 POWeR | Yes | 9 (100%) |
|  | No | 0 (0%) |
|  | Missing | 3 |
| Participant asked by nurse if following weekly | Yes | 9 (100%) |
| self-weighing | No | 0 (0%) |
|  | Missing | 3 |

1One participant in the intervention group withdrew prior to follow-up visit which is when the weight record card is collected. 2Three of the 15 participant who reached the end of the trial returned a completely blank weight record card.3Appointment was attended by mother according to follow-up form and GP records. 4Appointment was attended by mother (n=1) and grandparent (n=1) according to follow-up form and GP records.

**Table 23: Number of immunisation appointments attended (based on data provided by practices)**

|  |  |  |
| --- | --- | --- |
|  | **Intervention (N=151)** | **Usual Care (N=12)** |
| Number of participants for whom data on immunisation attendance was not provided by practices | 2 | 1 |
| Participant attendance at immunisation appointments | | |
|  | (N=13) | (N=11) |
| 2 Months | 13 (100%) | 11 (100%) |
| 3 Months | 13 (100%) | 11 (100%) |
| 4 Months | 12 (92%) | 11 (100%) |

**1**One woman in the intervention group withdrew from the trial as they decided not to have their child immunised.

**Intervention contamination**

Intervention contamination in the usual care group was assessed through usual care participants self-reporting whether they had accessed the POWeR website or used other resources to help with weight loss. Table 24 gives information on 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 POWeR. Three participants reported knowing someone else taking part in the study.

**Table 24: Weight management in the usual care group**

|  |  |  |
| --- | --- | --- |
|  | | **Usual Care**  **(N=12)** |
| Have you accessed or used any resources to help with your weight loss? | Yes | 1 (8%) |
| No | 11 (92%) |
| *If yes (n=1):* |  |  |
|  | Portion control1 | 1 (100%) |
| Do you feel there are people you know, amongst your friends and family who support and encourage you with your postnatal weight loss? | Yes | 10 (83%) |
| No | 2 (17%) |
| Self-reported accessing POWeR158 | Yes | 0 (0%) |
| No | 12 (100%) |
| Do you know anyone else taking part in the study? | Yes | 32 (25%) |
| No | 9 (75%) |

1Portion control, reduce carbohydrates, more fruit. 2Twoparticipants knew each other, the other participant could not remember who she knew.

**Clinical and participant reported outcomes**

Descriptive data related to clinical and questionnaire outcomes are detailed below. As this was a feasibility study no hypothesis testing was conducted and no inferences from this 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) 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) while the usual care group gained weight (unadjusted mean change: +1.9 kg). The intervention group had lower BMI and percentage body fat scores than usual care at follow-up (see Table 25).

**Mental health outcomes**

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

**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 is reported in medians due to skewness in the data, and unadjusted differences in medians are reported. The intervention group reported participating in more moderate intensity physical activity at follow-up (difference = 22.3 MET hours/week: 95% CI: -71.4 to 116.0), but less light intensity physical activity (difference = -19.6 MET hours/week: 95% CI: -84.9 to 45.7) than usual care. The intervention group spent more time sedentary than usual care (difference = 8.4 MET hours/week: 95% CI: -23.7 to 40.5). Full details of all the physical activity sub-domains 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. See Table 30.

**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 5.1/8. Individual item scores for perceptions of self-weighing ranged from 4.2 to 5.8/8. See Table 31.

**Infant feeding and sleeping**

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | **Baseline** | | **3-month follow-up** | | |
|  | | **Intervention**  **(N=16)** | **Usual Care**  **(N=12)** | **Intervention**  **(N=151)** | **Usual Care**  **(N=12)** | **Adjusted mean difference2**  **(95% CI)** |
| 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, -1.3) |
|  | Min-Max | 58.8-106.7 | 66.7-148.8 | 60.5-106.7 | 64.1-154.3 |
| % 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, -0.1) |
|  | Min-Max | 34.6-46.8 | 32.5-56.1 | 34.5-48.9 | 30.5-57.0 |
| BMI (kg/m2)3 | 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, -0.3) |
|  | Min-Max | 25.5-47.2 | 26.3-56.4 | 24.5-47.2 | 24.0-58.4 |
|  |  |  |  |  |  |  |
| BMI (kg/m2) | Healthy (18.5-24.9) | 0 (0%) | 0 (0%) | 2 (13%) | 1 (8%) |  |
|  | Overweight (25-29.9) | 8 (50%) | 6 (50%) | 8 (53%) | 5 (42%) |
|  | Obese (30-39.9) | 6 (37.5%) | 5 (42%) | 4 (27%) | 5 (42%) |
|  | Morbidly Obese(>40) | 2 (12.5%) | 1 (8%) | 1 (7%) | 1 (8%) |
|  |  |  |  |  |  |  |

**Table 25: Body composition**

1One intervention group participant withdrew prior to follow-up. 2Values <0 favour the intervention. Adjusted for practice (random effect), the two minimisation variables (GP size list and index of multiple deprivation), and baseline for value for each outcome. 3BMI at 3-month follow-up calculated using the height recorded at baseline and 3-month follow-up weight.

**Table 26: Anxiety and depression (HADS162)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Baseline** | | **3-month follow-up** | | |
| **Intervention**  **(N=16)** | **Usual Care**  **(N=12)** | **Intervention**  **(N=151)** | **Usual Care**  **(N=12)** | **Adjusted mean difference2**  **(95% CI)** |
| HADS: Depression3 | | | | | |
| 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, 2.9) |
| Minimum-Maximum | 0-15 | 1-10 | 0-15 | 2-10 |
| Missing | 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, 6.4) |
| Minimum-Maximum | 0-11 | 1-13 | 1-14 | 1-13 |
| Missing | 0 | 1 | 1 | 0 |  |

1One intervention group participant withdrew prior to follow-up. 2Values <0 favour intervention. Adjusted for GP practice (random effect), the two minimisation variables (GP size list and index of multiple deprivation), and baseline score. 3HADS domain scores range from 0 to 21, where higher scores indicate more severe anxiety/depression.

**Table 27: Body image (BISS163)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Baseline** | | **3-month follow-up** | | |
| **Intervention**  **(N=16)** | **Usual Care**  **(N=12)** | **Intervention**  **(N=151)** | **Usual Care**  **(N=12)** | **Adjusted mean dfference2 (95% CI)** |
| BISS: overall measure3 | | | | | |
| 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, 2.4) |
| Min-Max | 1.8-4.8 | 1.8-4.8 | 1.2-6.0 | 1.0-5.2 |
| Missing | 1 | 1 | 2 | 0 |  |

1One intervention group participant withdrew prior to follow-up. 2Values >0 favour intervention. Adjusted for practice (random effect), the two minimisation variables (practice list size and index of multiple deprivation), and baseline score. 3BISS domain scores range from 1 to 9, where higher scores are more favourable.

**Table 28: Eating behaviour (TFEQ166)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Baseline** | | **3-month follow-up** | | |
| **Intervention**  **(N=16)** | **Usual Care**  **(N=12)** | **Intervention**  **(N=151)** | **Usual Care**  **(N=12)** | **Adjusted Mean Difference2**  **(95% CI)** |
| TFEQ: Cognitive restraint domain3 | | | | | |
| 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, 19.6) |
| Minimum-Maximum | 16.7-66.7 | 11.1-77.8 | 22.2-72.2 | 0-72.2 |
| Missing | 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, 15.4) |
| Minimum-Maximum | 7.4-88.9 | 7.4-88.9 | 14.8-85.2 | 3.7-81.5 |
| Missing | 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, 44.0) |
| Minimum-Maximum | 0-100 | 0-88.9 | 0-100 | 0-88.9 |
| Missing | 0 | 1 | 1 | 0 |  |

1One intervention group participant withdrew prior to follow-up. 2Values <0 favour intervention, except for the cognitive restraint domain where values >0 favour intervention. Adjusted for GP practice (random effect), the two minimisation variables (GP size list and index of multiple deprivation), and baseline score. 3TFEQ domain scores range from 0 to 100, where higher scores indicate more positive behaviour in the cognitive restraint domain and higher scores indicate more negative behaviour in the uncontrolled eating and emotional eating domains.

**Table 29: Physical activity and sedentary (PPAQ164)**

|  | | **Baseline** | | **3-month follow-up** | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Intervention**  **(N=16)** | **Usual Care**  **(N=12)** | **Intervention**  **(N=151)** | **Usual Care**  **(N=12)** | **Difference in Medians2 (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, 40.5) |
| Minimum-Maximum | | 9.5-108.2 | 22.4-146.3 | 5.1-98.7 | 11.6-109.9 |
| Missing | | 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, 45.7) |
| Minimum-Maximum | | 49.5-198.1 | 110.4-206.3 | 48.8-193.6 | 73.9-229.8 |
| Missing | | 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, 116.0) |
| Minimum-Maximum | | 10.6-210.4 | 58.6-206.5 | 50.2-266.1 | 55.1-361.3 |
| Missing | | 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, 4.9) |
| Minimum-Maximum | | 0-9.8 | 0-30.0 | 0-10.1 | 0-37.0 |
| Missing | | 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, 82.3) |
| Minimum-Maximum | 22.4-371.4 | | 146.5-353.9 | 72.5-425.8 | 119.6-401.8 |
| Missing | 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, 19.9) |
| Minimum-Maximum | | 0-138.8 | 0-158.6 | 0-239.8 | 0-109.4 |
| Missing | | 0 | 1 | 0 | 1 |  |
| PPAQ: Sports/Exercise activity (MET hours/week)3 | | | | | | |
| 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, 22.8) |
| Minimum-Maximum | | 0-34.2 | 0-53.4 | 0-43.2 | 2.3-37.8 |
| Missing | | 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, 182.7) |
| Minimum-Maximum | | 114.2-456.9 | 265.4-438.6 | 123.2-498.6 | 178.0-652.8 |
| Missing | | 3 | 1 | 3 | 1 |  |
| PPAQ: Total Activity (excluding work domain4) (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, 84.6) |
| Minimum-Maximum | | 71.2-456.9 | 261.0-423.6 | 123.2-498.6 | 178.0-543.4 |
| Missing | | 3 | 1 | 3 | 0 |  |

1One woman in the weight management group withdrew prior to follow-up. 2Values >0 favour intervention, except for PPAQ: Sedentary Activity where values <0 favour intervention.3 Three women at baseline and two women at follow-up indicated that they had done 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). 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. 4Work domain (questions 33-37 only answered by those in work at the time of completion) are excluded here.

**Table 30: Weight control strategies165**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **3-month follow-up** | | |
| **Intervention (N=151)** | **Usual Care (N=12)** | **Adjusted mean difference2 (95% CI)** |
| WCSS: Total WCSS Score3 | | | |
| Mean (SD, N) | 1.6 (0.6, 13) | 1.5 (0.6, 9) | -0.04 (-0.7, 0.6) |
| Minimum-Maximum | 0.8-2.7 | 0.5-2.2 |
| Missing | 2 | 3 |  |
| WCSS: Dietary Choices score3 | | | |
| Mean (SD, N) | 2.3 (0.7, 13) | 2.5 (0.8, 12) | -0.2 (-0.8, 0.3) |
| Minimum-Maximum | 1.2-3.7 | 0.6-3.4 |
| Missing | 2 | 0 |  |
| WCSS: Self-Monitoring Strategies score3 | | | |
| Mean (SD, N) | 0.9 (0.9, 14) | 0.6 (0.7, 12) | 0.4 (-0.7, 1.5) |
| Minimum-Maximum | 0-2.7 | 0-2.1 |
| Missing | 1 | 0 |  |
| WCSS: Physical Activity score3 | | | |
| Mean (SD, N) | 1.4 (0.8, 14) | 1.2 (0.6, 11) | 0.2 (-0.5, 0.9) |
| Minimum-Maximum | 0-2.7 | 0.3-2.2 |
| Missing | 1 | 1 |  |
| WCSS: Psychological Coping score3 | | | |
| Mean (SD, N) | 1.5 (0.5, 13) | 1.5 (0.7, 10) | -0.03 (-0.5, 0.4) |
| Minimum-Maximum | 0.7-2.7 | 0.6-2.6 |
| Missing | 2 | 2 |  |

1One intervention group participant withdrew prior to follow-up. 2Values >0 favour intervention. Adjusted for GP practice (random effect) and the two minimisation variables (GP size list and index of multiple deprivation). 3WCSS domain scores range from 0 to 4, where higher scores are more favourable.

**Table 31: Individual item scores for perceptions of self-weighing167**

|  | **Intervention group**  **(N=151,2)** |
| --- | --- |
| 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 | 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 | 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 | 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 | 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 | 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 | 2 |
| Over the past 3 months, I found weighing myself regularly to be positive/negative experience | |
| Mean (SD, N) | 5.7 (1.7, 13) |
| Minimum-Maximum | 4-8 |
| Missing | 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 | 2 |

1One participant in the intervention group withdrew prior to follow-up. 2Scores range from 1 to 8, where higher scores are more favourable.

**Table 32: Infant feeding**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **Baseline** | | **3- month follow-up** | |
| **Intervention**  **(N=16)** | **Usual care**  **(N=12)** | **Intervention**  **(N=151)** | **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 |

1One intervention group participant withdrew prior to follow-up.

**Table 33: Sleep patterns**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **Baseline** | | **3-months follow-up** | |
| **Intervention**  **(N=16)** | **Usual Care**  **(N=12)** | **Intervention**  **(N=151)** | **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) |
| Min-Max | 1-6 | 2-5 | 2-8 | 3-8 |

1One intervention group participant withdrew prior to 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 and this data reflects those where both participants and nurses consented to having the consultation audio recorded. Data from the audio recordings indicated that the intervention took less than two minutes to deliver in eleven consultations, between two and three minutes in five consultations and between three and four minutes in one consultation. The results show evidence of a high level of intervention fidelity by practice nurses against the intervention checklist. In one case it was clear from the conversation that the participant had forgotten their child 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.

## **Table 34: Results from audio records of intervention consultations**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Completed by nurse/GP** | **Not completed by nurse/GP** | **Not clear from recording\*** | **N/A** |
| Weighed & 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 POWeR158 website | 15 (88.2%) | 1 (5.9%) | 1 (5.9%) | 0 |
| Signposted to POWeR158 | 13 (76.5%) | 3 (17.6%) | 1 (5.9%) | 0 |

\*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

**Safety**

No serious adverse events were reported during the study.

**CHAPTER 4: DISCUSSION OF TRIAL FINDINGS**

**Main findings**

This study examined the feasibility and acceptability of a multi-component 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 pre-specified 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 confidence intervals. 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 was categorised as amber, therefore some additional strategies may need to be considered to assist participants with 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 as 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 of the intervention. Most participants said they would recommend the study to their friends. The intervention took practice nurses on average two minutes to deliver and intervention fidelity by nurses was high suggesting that the intervention can be delivered within child immunisations appointments in primary care.

**Recruitment**

Slower than expected recruitment rates are not uncommon in postnatal weight management studies.(171-172) and recruitment proved difficult in this study; there may be several explanations for this. A total of 13/14 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 & 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 Birmingham Women’s Hospital in the last six 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 at about 4-6 weeks after giving birth. This is a time in 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 four weeks available between women receiving their invitation letter and being able to complete the baseline assessment. Women could not be recruited prior to four weeks postnatally and the baseline visit had to be completed before the first immunisation (when the child is about two months old). This short time framework may have deterred some women from participating at this busy time in their lives. 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, KJ), that assessed a weight management intervention during pregnancy, and where 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.173

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.174 Whilst acknowledging the ethical 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 a ‘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, although this is not consistent with literature that has reported women do want early intervention. For example, longitudinal evidence has reported that by eight weeks postnatally, 84% of women were already attempting to, or were ready to start managing their weight.175 Similarly, an online survey recruited 1,015 women who had given birth in the previous two years and had joined Slimming World for the first time after having their baby, reported that approximately 45.6% (n=463) began attending meetings between one to seven months postnatally,(176) the timeframe over which this intervention was delivered. The research team discussed recruitment methods with the PPI contributors throughout the trial and 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.107, 177-179 Once participants are recruited, engagement and later adherence are the most important determinant 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.180 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 Body Trace scales showed that 63% of the intervention group weighed themselves weekly ≥60% of the time during the intervention, meeting the green stop-go criteria. When all available data (self-report and objective) from the Body Trace scales, weight record cards and the weight data reported on the POWeR programme were combined, adherence to weekly self-weighing increased to 69% over 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.(117-122) One of the attractions of self-management-based interventions is that they are flexible, individualised and can be engaged in by women at a time that suits their daily lives. While evidence shows that women engaged very well with self-weighing and recording of their weight, the confidence intervals 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, 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, reducing NHS costs.

Participant engagement is critical to the success of any technology intervention. 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, ≥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 phone app, 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 and Slimming World, may be useful.181

The low number of times participants recorded a weight in POWeR is likely related to the weight record card being used instead. As weights on the record card were reviewed at the immunisation appointment (external accountability) participants were therefore more likely to record their weight on the card than on POWeR. Engagement with POWeR reduced over time and any future digital programme would likely need some additional strategies to sustain engagement. However, it should also be noted that engagement with POWeR 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, ongoing engagement with the programme and the effectiveness of the programme. Here we only have data on the first two of these elements. A previous trial has shown that the POWeR intervention was associated with weight loss at one year, but this was not statistically greater than control.158. There have been considerable developments in digital weight management programmes since the initial decision to use POWeR 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 which is likely to best meet the needs of women, for example, available in app format, and which 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 as to whether encouraging regular self-weighing might lead to adverse psychological health outcomes, including eating disorders and obsessive thoughts about body weight.182-185 However, systematic reviews and studies do not support such a view.186-188 Nevertheless, some consideration should be given to a small amount of evidence that has suggested that self-weighing could impact psychological health. A systematic review by Pacanowski and colleagues reported that self-weighing was associated with negative outcomes in young women.189 Of relevance here, Hartmann-Boyce reported a polarisation of views in participants’ attitudes and beliefs in relation to the long-term use of self-monitoring techniques; some expressed experiencing a reduction in attentiveness, shame and even fear over time, whereas others claimed self-monitoring increased levels of self-accountability, self-control and self-efficacy.190 Whilst 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**

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.74, 78 Yet evidence has shown that health professionals are reluctant to raise the topic of weight with their patients for fear of negative consequences such as causing offence.191-192 Kaplan and colleagues have suggested that health care providers were comfortable raising the topic of weight but that time constraints prevented this during routine appointments.193 This study has provided data to show that practice nurses were able to ‘raise the topic of weight’ and deliver the intervention per protocol. 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 according to the protocol. This provides reassurance that the nurse training methods worked well and that the intervention can be delivered as intended within child immunisations.

**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 to mitigate 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%) women indicated they knew another participant in the study. These data have indicated 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 outcomes 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 missing data for questionnaire-based outcomes was low, ranging from 0% to 15%. Missing data was primarily due to 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 (three-factor eating questionnaire) 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 usual care at follow-up.

**Implications**

The intervention was deliberately developed with the ambition of the NHS to ‘Make Every Contact Count’ in mind.194 The implementation of a multicomponent intervention, which 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, 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.195-197 Related to this, in postnatal women, the needs of their child change during the ﬁrst year and this can mean that barriers shift and new strategies are needs 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 the intervention is more appealing to these women who may be less likely to be overwhelmed by the impact of a new child to their lives, than new mothers.

### Strengths and limitations

This study has several methodological strengths and makes a unique contribution to the literature. This is the first study worldwide to assess the merits of a weight loss intervention embedded within a national child immunisation programme. This study was appealing to both first-time and multiparous women, suggesting that weight management during the postnatal period is a concern to women irrespective of the number of children they have given birth to previously. Whilst the recruited sample was small, women varied in terms of their socio-economic status, ethnicity and employment status, suggesting that the experiences of a wide range of women are represented in the 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 nurses adhered well to the protocol. The trial was conducted and reported in line with CONSORT guidelines to ensure 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 where the intervention was delivered were audio-recorded and this provided objective ‘real time’ naturalistic data on the interactions between 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. In contrast, in this study, assessments of weight were objectively measured by a researcher to ensure this outcome data was 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; 1 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 and these strategies should be used in subsequent research. We conducted semi structured interviews to obtain further understanding about the trial processes and the intervention components, from both the participants and 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 was 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 impact 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 highly motivated to lose weight, but we cannot discount the possibility that atypical women were recruited. Similarly, the study procedures that involved home visits at baseline and follow up may also 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 only assessed the intervention over the first three immunisation appointments at one, three and four 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 wellbeing,(197) which may translate into 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 levels198  Weight loss has also been linked to sleep duration and quality.199-201 To attain more accurate and detailed data on this variable, future studies should include an objective measure of sleep, ideally through a tracker watch the records this 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 within routine child immunisations visits was acceptable to women recruited. Practice nurses were able to deliver the intervention with high fidelity indicating the intervention is feasible to deliver within child immunisation appointments. Adherence by participants to the self-weighing component was generally good. Uptake of the weight management programme was acceptable though 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.

**CHAPTER 5: QUALITATIVE STUDY (PARTICIPANTS)**

**Introduction**

After giving birth, a window of opportunity opens, where women may be motivated to lose weight.202-203 Whilst many weight loss interventions for postnatal women have been tested and shown to have varying levels of effectiveness,204 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 healthcare interventions.205 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.205 The use of nested qualitative research has been shown to be beneficial when addressing issues relating to the acceptability and practicality of an intervention.206-207 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 multi perspective assessment of the feasibility and acceptability of the intervention. This chapter will explore the views of women who participated in the intervention. The following chapter reports the views of practice nurses who delivered the intervention within child immunisation visits. This study (chapter) had the following objectives:

•Explore whether 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**

Semi-structured 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 revealed in a group format, or through their ‘presentation of self’ in front of others.208 Semi-structured interviews were chosen for several further reasons. Interviews provide the opportunity for key questions to be asked of participants, allowing 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.209. We aimed to gain a thorough understanding of, and be able to, describe trial participants and nurses’ experiences of an intervention embedded within an existing service therefore used a ‘generic approach’, rather than following a specific theoretical perspective.210 This study has been reported in line with the COREQ guidelines for the reporting of qualitative studies.

**Recruitment of participants**

During the follow-up home visit at three 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 the questions were easily understood and coherent. The interview topic guide was comprised of open-ended questions and prompts to explore participants’ reflections of key elements of the intervention, including: their experience of regular self-weighing; being weighed by the practice nurse during child immunisation appointments; thoughts on being referred to a website for weight management advice and information and their general views of the intervention including its timing (Appendix 1). Participants were met once and given the freedom to expand upon 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 upon, should they appear to be relevant to the study. Interviews lasted between 30 and 61 minutes. NTM conducted the interviews face-to-face in participants homes, usually with the baby present. The transcripts were anonymised with participant unique identification numbers. NTM is female with many years’ experience of qualitative research and a Masters 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 was 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 University of Birmingham (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. Interviews transcripts were thematically analysed using the Framework Method, a recognised tool for collating data and facilitating its interpretation.211 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 (each with different disciplinary backgrounds: sociology, psychological, general practice) (NTM, AD, HP, SG) 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 assigned 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, 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, 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.211

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 rigour of the study. This was useful as the team included an experienced qualitative researcher (SG) 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.211 Early transcripts were read to understand whether 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.212 The coding book is available in Report Supplementary Material 2.

**Results**

There were 14 participants were allocated to the intervention group, and one indicated during recruitment to the trial that she was not interested in the participating in an interview. Of the 13 remaining, two were not available in the timeframe of the study; one had no time available; and one was not contactable in the timeframe of the study. A total of nine participants from the intervention group completed an interview. The socio-demographic profile of these participants is shown in Table 5. Three main themes emerged from the data with 18 sub-themes (Table 36). Participants were randomly assigned numbers; these do not correspond to the order that the interviews were undertaken. Each quote is followed by participants’ assigned number, then the page number and line number from their transcript.

**Table 35: Characteristics of intervention participants who were interviewed**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Age** | **Ethnicity** | **Baseline BMI** | **Follow-up BMI** | **GP 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 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 and facilitators of weight** | |
| Barriers to weight loss | Perceived barriers in mothers to weight loss |
| Facilitators for weight loss | Perceived facilitators in mothers to weight loss |
| How to lose weight | How to lose weight |
|  | Ideal time, space and role for weight loss and intervention |
|  | Potential barriers in nurses to weight oss |
| **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 to be weighed |  |
| Feelings when nurse weighs | Participants feelings while weighing |
| Reasons for starting the trial |  |
| Self-weighing feelings | Nurses’ feelings when weighing participants |

**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, 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 having previously tried to lose weight 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 trial**

All the women were motivated to join the study to lose weight, though these reasons varied between non-specific reasons, such as wanting to lose weight, to 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. One participant was motivated to lose weight for medical reasons which their current weight complicated; and another participant recognised the health risks due to their weight in combination with their ethnicity

“*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

## **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 three weeks it’s the same again. There’s no change to it.”* **Participant 4, lost weight**

One participant was concerned about those with eating disorders being recruited to trial. Whilst most participants talked about the difficulties of being a mother to a new-born baby, only one would have started the intervention a few weeks later, so as not to place too much pressure on 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, yaknow, 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 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 that 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 related to their weight. 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 breast-feeding facilities, crèches, or mother and baby classes. If there was nowhere to ‘store’ the baby, then suitable childcare (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 breast feeding and increased hunger from breastfeeding leading to increased calorie consumption.

“*[They are] not a once every three 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 breast feeding, 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 new-born baby meant an unpredictable schedule, and a necessity to plan and work around the schedule of the baby, which similarly led to 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, two 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 and S and put it in the microwave than spending two hours cooking*.” **Participant 2, lo weight loss**

Participants commented that continuing and maintaining behavioural changes was difficult (despite the perceived effectiveness of the intervention), and most talked about the temptation to ‘fall off the wagon’ and to stop maintaining their weight loss efforts in the face of alternative pressures, such as stress or tiredness, or allow 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 to weight loss

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

Whilst breast feeding was viewed as barrier, 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 new-born in the house made one mother think more about the impact her own health behaviours were having on her baby and so 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 women; it is not an exhaustive list. Table 37 provides an overview of participants’ feelings on being weighed by practice nurses and self-weighing.

**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 led to them feeling “motivated” for weight loss. At the appointments, most participants reported that they continued feeling 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-judgmental” 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 suggested 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, or that it “*definitely worked*”. 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 four 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 ba-by, 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.

“*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 of weight at home. However, some participants reported problems with the reliability of the BodyTrace weighing scales, with some finding that the weight reported deviated by a ~1 kg, depending on the room, time of day, or type of floor used when weighing. This led some women to view the scales used at the immunisation appointments, or their own eyes (for example, the fit of their clothes) as a more reliable measure of their weight loss progress. Almost all participants indicated they were able to weigh themselves either every week or almost every week, though one participant decided to stop weighing herself after four weeks due to technical problems with their scales. All participants found the process of self-weighing easy to remember; typically doing so on a specific day.

*M: 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 their expectations of their weight affected their emotions; typically they felt “good” when expecting to see that their weight had gone down, while being worried, fearful or “*bad*” if they expected an increase in weight, due to a “*bad week*”. While 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 [NT laughs] and it’s going in the right direction*.” **Participant 1, lost weight**

All 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 they were making progress. For some participants the scales changed their point of reference for their weight. Rather than comparing their current weight against, for example, their weight before becoming a mother, perhaps in their twenties, they compared to 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 six weeks.’*” Participant 1, lost weight

Some 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 mirror was more important. These views were mostly 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 Iiii 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

**Table 37: Participants’ feelings about being weighed by nurses and self-weighing**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ID | **Feeling on self-weighing** | | | **Feelings 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 |  |

## **POWeR website**

All participants commented that they felt 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*”. Another commented that there were few “*bells and whistles*” to it, though 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 POWeR came from a “*trusted source*” due 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 so 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 participants were able to access the POWeR website but one had had technical difficulties related to their laptop computer. One participant had difficulties when they lost the password; and another when they had difficulty with the link to the POWeR site. While most participants used computers to access the website, one mother commented that the site could be more compatible for accessing by mobile phone. Participants commented that because they had a new baby they were not always able to have immediate access to a laptop to access POWeR. In contrast, they always had access to their mobile phone.

“*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 m 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 app so I can see how much I’ve gained or lost”* **Participant 1, lost weight**

Some participants mentioned that the modules did not take long to read and reading the modules could be started and dropped easily and they fitted around their baby’s schedule. Two 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 [NT 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**

*“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 three or four 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 they logged on was found difficult by two participants, though two other participants found setting goals and regularly reviewing these goals was useful.

*“[My email 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 POWeR could be more focussed on postnatal-specific diet and exercise issues, such as having post-pregnancy complications that delay or restrict certain exercise; or needing to avoid drastic calorie reductions for breast milk production. A couple of participants thought that videos for ‘exercise with baby’ would have been useful, and one thought 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 choice (primarily between a reduced calorie and a reduced carbohydrate diet) and 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, though a couple had provisos. One stated that it would only be helpful if the mothers did not already have basic knowledge of nutrition and diet, such as knowing which foods are carbohydrates, 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 POWeR. Which included better compatibility with mobile phones, inclusion of videos of exercises that can be done with baby, 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

“B*ecause 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 participants commented that simply being part of the trial was a useful, a 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 the intervention, or some aspect of it, increased their motivation or commitment to losing weight. Over half of 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 inn, alongside what I was kind of doing anyway.”* Participant 5, lost weight

“*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 helllll, 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-judgmental” delivery of the intervention, both with reference to 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 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, about the lifestyle choices that impacted on 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, allowing a longer period between weighing and a bigger, 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 emailed 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 participants thought that it would have been useful to have a phone number or email address to contact if they needed to ask something and did not want to wait until the next appointment. Though 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 trial could have been raised 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 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, since 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

Some participants suggested that if an ‘opt-out’ method to recruitment was used healthcare staff should be mindful when approaching mothers as 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. Manyparticipants 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”, or choosing the most convenient dietary option, rather than the healthy option. Social support for weight loss was considered as important in terms of reminders not to buy particular foods and providing childcare 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.79-82 Participants expressed a strong desire to lose weight and welcomed support from the NHS via this trial to help them achieve this goal. Whilst women expressed several barriers to losing weight, such as lack of gym facilities, childcare 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, specifically postnatal depression and weight loss has been associated with improved mood and body image.213-215

**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 corner stone to long term behaviour change and it can be critical to preventing relapse. This finding is 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.182 Consistent with these findings several other studies have not found an association between self-weighing and negative psychological health outcomes.184-187

**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 within 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 around 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 below). No participants reported feeling that the intervention took time away from their baby, or the immunisation. Participants commented that the intervention was convenient as 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 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 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 within routine consultations in primary care. The centre piece of the intervention was the principal of ‘accountability’, the notion that someone other than yourself is observing and cares whether 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 goals (external accountability) and motivated them to persevere with changes to their diet and physical activity behaviours.

**Weight and emotions**

Whilst 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, 182-183  As highlighted earlier, there is little evidence to support these concerns, but it is still important that trials continue to monitor whether self-weighing leads to negative psychological events. The emotions experienced by participants when weighing themselves varied depending on the weight they expected to see displayed on the scales; typically they felt “good” when they expected to see that their weight had decreased, while being worried, “fearful” or “bad” if they expected an increase, due to a “bad week”. The results of this qualitative study are consistent with Hartman-Boyce *et al.*’s synthesis of qualitative studies of self-weighing, where viewing weight as a way to assess success or failure towards weight loss was found to lead to feelings of guilt, shame, disappointment, including avoidance of self-weighing in those that suspected their weight was stable, or had increased.189. 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. Most participants were unconcerned about being weighed by the nurse and this 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 within public health and NHS contexts. It was important for this study to capitalise on this and consider ways in which technology could be used within the intervention, to assist both participants and practice nurses. None of the participants were 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 since 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, though a few mothers thought that the content could be more tailored to postnatal mothers, taking into consideration post-pregnancy complications and advice and videos for exercises that could be done 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 their views about a change to the recruitment process used here and to adopting an a opt-out recruitment method. Most participants did not foresee any problem ‘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, whilst 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 phone app, where 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 to include successful case studies of women who had lost weight and the research team should provide a contact number or email address so that participants could ask questions about issues related to the 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 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 light of its methodological strengths and limitations. This nested qualitative study was important as 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.216 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, 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 that 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 into health routine care for all women who wish to lose weight after having a baby.

# CHAPTER 6: NURSES EXPERIENCES OF DELIVERING THE INTERVENTION

# Background

Healthcare 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 healthcare professions raising the topic of weight loss within consultations, such as time and workload pressures; fear of offending, or concerns around 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 to make behaviour changes.140, 217 An intervention embedded within routine healthcare appointments could help to address many of the concerns health professionals have and help to ‘normalise’ the topic. 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
* To investigate nurses’ feelings about raising the topic of weight with postnatal women at child immunisation appointments.
* To capture nurses’ views about delivering the intervention and the impact it had on the structure and duration of child immunisation appointments
* To 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 phone or email to participate in a semi-structured interview about their views on postnatal weight loss and their experiences of delivering the intervention within routine child immunisation appointments after all 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 and their responses were audio recorded. Semi structured interviews were chosen as the method of inquiry for all the reasons previously outlined in Chapter 6. Nurses delivering the intervention were chosen for interview to provide accounts of the same phenomenon from different perspectives.218 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 semi-structured 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’ career and typical immunisation appointments; their thoughts on referring women to the POWeR website; and their feedback on the training they had received to deliver the intervention and of delivering the intervention in practice. Interviews lasted between 22-66 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 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 nurses/GP 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 nurses at their practice, and four by telephone (three at their general practice; one at home). A total of 15 themes and five sub-themes emerged from the nurses' data. Nurses were randomly assigned numbers; that do not correspond to the order that the interviews were undertaken. Each quote is followed by their assigned number, then by page number and line number from their transcript, in order 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 nurses responded in terms of increased risk of developing long-term conditions (diabetes or cardiovascular disease). Nurses viewed 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 noted that there was an increasing general awareness that being overweight could negatively impact 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 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 wellbeing.

*“As, as a new mum. I think you put your erm, priority into your baby so”.*

*(NT): “Mmmm You put yourself second.”* **Nurse 5, p2, 77**

#### Pregnancy myths and misconceptions

Nearly half the nurses believed that participants held a number of pregnancy myths such as ‘eating for two’; as well as unrealistic expectations about weight loss from celebrities 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 four 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 nurses described the postnatal period as a vulnerable time (especially for first-time mothers), where they 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, and this 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 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 the 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 okay, 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 for weight loss as expressed below.

*“I notice my-self 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**

#### Potential barriers to weighing women at child immunisations

All nurses reported that there was ‘not enough time’ in an appointment to add more tasks (regardless of how long their slots were), so 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**

Whilst 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 provide justification 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 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 phone, and summarised for the nurse’s convenience. Each nurse’s experience and description of their training varied. While one nurse thought the training covered “*a lot of content*” in a short amount of time; two felt the training was very basic or insufficient (one of these nurses was trained by phone.)

*“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. with three nurses feeling 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 nurses rarely referred back to manual; two because they did not feel the need to; 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 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 be 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; some having email 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 nurses reported immunising the child before weighing participants, since they wanted the immunisation over 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 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.

Most nurses described a non-judgemental and or/supportive attitude, where they ensured 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 that they believed 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 okay 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 gentlle... 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, while another pointed out that they would have previously referred mothers to the NHS Choices website (website covering a variety of health topics including weight loss, though not specifically designed for postnatal mothers). Two nurses also had concerns about the IT 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 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 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 the nurses reported that participants did not bring up the website in their conversations, although when the nurses asked participants whether they 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 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. Two nurses reported that some of their participants were uncomfortable with being weighed, appearing embarrassed. Nearly half 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.

*“NT: And how comfortable do you think, the mothers were with you weighing them?*

*PN: ...It was okay. It was okay. 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, since midwives or healthcare visitors were focused on the baby, not the mother. Another referred to weight loss companies, such as Weight Watchers and Slimming World, that had more time and 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 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 healthcare 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 only mentioned by two of the nurses and was linked in both cases to motivation to adhere with 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 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 where 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 thought that 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 participants and infant records, since immunisations are recorded in the child’s record, not the participants’ (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 out the intervention because of the additional time weighing and recording women’s weight would take.

“*We might be lucky to have ten fifteen 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 child-birth or giving promotional literature about the trial antenatally.

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

*“I think the appointment should have been... made to be twenty 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 weight in the red book, and another suggested 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 with the sessions. The focus would not be solely about the mother’s weight and weight loss, but that 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 eight week check for mum… say a sixteen 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 within 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 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, where they 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 that they felt 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 it provided a platform to have these conversations.

Overall nurses felt that the intervention was easy to deliver, a good idea, that women engaged well with the components, that it was likely to increase motivation for weight loss and that it 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 needed. Nurses believed that mothers appeared comfortable with being weighed by them.

While 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 below.

**Losing weight after having a baby**

Studies have highlighted that women find it difficult to lose weight after having a baby.44-46 Similarity, 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 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.

**Raising the topic of weight**

Research has reported that there are many barriers to healthcare professionals raising the topic of weight loss such as difficulty in raising a sensitive topic.140, 217 It was commented by nurses that they felt more comfortable raising the topic of weight and weighing participants because they had chosen to be involved in the trial and participants 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 the resistance to change/lack of engagement.

**Training to deliver the intervention**

Nurses mostly felt 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 later section) to ensure they felt confident in raising the topic of weight and then 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, the weighing of pregnant women and new mothers has swung in and out of NHS policy several times over the last century meaning that health professionals are likely to have become uncertain about the merit and role of regular weighing within healthcare. In the past few years there has been increased evidence for the role of regular weighing as part of multicomponent weight management interventions, although very recent evidence in pregnant women showed that weighing alone by midwives during pregnancy was not effective in preventing excessive gestational weight gain.219 In this study all the nurses commented that the intervention was a ‘good idea’ and/or would help to increase women’s motivation to lose weight. When asked to recall how they delivered the intervention, most nurses listed most of the five steps from the training manual checklist. Interestingly, two nurses seem to be ‘reframing’ weight loss to participants through changing their perceptions from weight loss being a short-term goal, to 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.220

Most nurses reported 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, 141 It is possible that such feelings might be mitigated however, if regular weighing was integrated in to routine care as this would serve to normalise this process; overweight mothers might feel they are not 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 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 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 future roll out of the intervention and 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, or more person-to-person advice, in addition to the website. However, the issue of having to switch between the mothers and 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 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 by which the results of the RCT can be interpreted. As 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 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 healthcare. Despite these challenges, nurses felt able to deliver the intervention per protocol. The study also has some limitations that should be considered. Only six nurses and one GP were interviewed therefore data represents 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 and it is possible that some comments were not recorded accurately.

**Conclusion**

Overall nurses felt able to raise the topic of weight because the trial provided a framework in which they could legitimately have conversations about this topic. Whilst, some caveats to successful implementation were raised by nurses, they felt 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 extra time at child immunisations 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 more consideration needed to be given to the ensuring computer literacy in ethnic minority women to allow them to access and gain benefit from the online weight management support.

**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 the 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 of women to lose weight. However, while 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. On the contrary, 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 and facilitators to weight loss**

The perceived facilitators and barriers to new mothers’ weight loss efforts offered by nurses were different to those of participants. All nurses reported that generally new mothers did not view being overweight as a problem or viewed themselves as not being overweight. Additionally, 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 nurses reported weighing the mothers; and almost all reported that they checked whether participants had been self-weighing weekly by asking or checking the record card. All nurses reported that they signposted participants to POWeR; and most had checked that they had visited the website. All 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 they had been asked signposted to the POWeR website.

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

**Accountability**

Most participants mentioned accountability, that someone other than themselves was monitoring whether they were weighing themselves regularly or not 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 within their interview conversations.

**POWeR website**

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

**General thoughts about the study**

All 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 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 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 randomised controlled trial and two nested qualitative studies with participants and practice nurses. The trial tested the feasibility of a brief routine weight management intervention embedded into 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 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. Manyparticipants 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 into routine child immunisations. Nurses suggested the length of child immunisations could be extended to accommodate the intervention. Whilst some nurses in the qualitative study commented that the intervention added 10 minutes to the length of immunisations, audio recordings of consultations indicated that intervention took nurses/GPs approximately two 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 and 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 semi-structured 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 other research that aims to address brief interventions for postnatal women in primary care. The inclusion of the BodyTace 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.

The study reported here is the first to investigate the merits of the integration of a weight management intervention for postnatal women within 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. Whilst the study took place in Birmingham with a very diverse population, all the study materials were in written in English and this may have prevented some women from participating. While the completion rates for the questionnaires were high, the questionnaire booklet was relatively long taking about 20 minutes to complete; this may have impacted negatively on 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.221-222 Physical activity was collected by self-report and future studies should consider collecting this 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) which 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.223 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 the consistent development of policies and guidance for maternal weight gain and postnatal weight loss can be implemented. Attempts should 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 below.

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, then the intervention can 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 into routine health care practice. This may also allow for more efficient implementation into the NHS should the intervention be shown to be effective. Such an approach to recruitment is also supported by evidence that has suggested higher response and recruitment rates may be obtained when studies use opt-out methods.174 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 should 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 and this may have both increased the number of women recruited and intervention adherence. Any future study should consider making all 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 and future research would 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 one, three and four 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 within routine healthcare appointments. Research that considers different ways in which health care professionals can support women to lose weight after having a baby would also be worthwhile, for example via community midwives and health visitors.

The role of technology and 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 within broader weight loss interventions might also be worthwhile as recent research as demonstrated that such approaches may be feasible and acceptable to postnatal women.181 Specifically, it could be that referral or signposting by practice nurses to commercial weight loss programmes, in additional 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.

While evidence shows that women engaged well with self-weighing and recording of their weight, the confidence intervals 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 would be worthwhile.181

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 as 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, within child immunisations appointments in primary care. Whilst 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 the recruitment methods used were not successful. Alternative approaches to recruitment need to be explored prior to a phase III trial.

**Contributions of Authors**

Amanda J Daley (Chief Investigator, Professor of Behavioural Medicine and NIHR Research Professor in Public Heath) developed the original idea for the study and funding application, along with HMP and the co-investigators. She developed the research protocol with the other co-investigators, including the training manual for practice nurses. She oversaw the delivery of the trial and led the preparation of the final report (drafting, reviewing and editing).

Kate Jolly (Co-investigator, Professor of Public Health and Primary Care) contributed to development of the funding application and research protocol in collaboration with co-investigators. She contributed to the preparation of the final report (drafting, reviewing and editing).

Natalie Ives (Reader in Clinical Trials, Statistical Team leader) contributed to the development of the trial protocol in collaboration with co-investigators. She provided oversight regarding the statistical analysis plan and the conduct of the statistical analyses and contributed to the preparation of the final report (drafting, reviewing and editing).

Susan Jebb (Co-investigator, Professor of Diet and Population Health) contributed to development of the funding application and research protocol in collaboration with co-investigators. She contributed to the preparation of the final report (drafting, reviewing and editing).

Sarah Tearne (Trials Manager Team Leader) contributed to development of the trial protocol in collaboration with co-investigators. She was responsible for the management of the trial and contributed to the preparation of the final report (drafting, reviewing and editing).

Sheila Greenfield (Co-investigator, Professor of Medical Sociology) contributed to development of the funding application and research protocol in collaboration with co-investigators. She oversaw the development of the protocol for the qualitative studies and the preparation of the final report (drafting, reviewing and editing).

Lucy Yardley (Co-investigator, Professor of Health Psychology) contributed to development of the funding application and trial protocol in collaboration with co-investigators. She contributed expertise regarding the digital technology aspects of the intervention and to the preparation of the final report (drafting, reviewing and editing).

Paul Little (Co-investigator, Professor of Primary Care Research) contributed to development of the funding application and trial protocol in collaboration with co-investigators. He contributed to the preparation of the final report (drafting, reviewing and editing).

Natalie Tyldesley-Marshall (Research Associate) contributed to development of the qualitative study protocols in collaboration with co-investigators. She conducted the interviews and analyses for both qualitative studies and contributed to the preparation of the final report (drafting, reviewing and editing).

Hannah Bensoussane(Statistician) prepared the data for analysis and conducted the statistical analyses. She contributed to the preparation of the final report (drafting, reviewing and editing).

Ruth Pritchett (Co-investigator, Research Fellow) contributed to development of the funding application and research protocol in collaboration with co-investigators. She contributed to the preparation of the final report (drafting, reviewing and editing).

Emma Frew (Co-investigator, Professor of Health Economics), contributed to the development of the trial protocol in collaboration with co-investigators. She provided oversight regarding the health economics data and contributed to the preparation of the final report (drafting, reviewing and editing).

Helen M Parretti (Co-Chief Investigator, Senior Clinical Lecturer in Primary Care) contributed to development of the funding application and research protocol in collaboration with co-investigators. She provided clinical oversight, contributed to the delivery of the trial and to the preparation of the final report (drafting, reviewing and editing).

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**Data Sharing**

The datasets used and analysed during this study are available from the corresponding author on reasonable request, after a period of two years from the date of this publication.

**Patient Data**

This work uses data provided by patients and collected by the NHS as part of their care and support and would not have been possible without access to this data. The NIHR recognises and values the role of patient data, securely accessed and stored, both in underpinning and leading to improvements in research and care.

**Study Outputs up to November 2019**

Parretti HM, Ives N, Tearne S, Vince A, Greenfield SM, Jolly K, JebbSA, FrewE, Yardley L, Little P, Pritchett RV, DaleyAJ**. 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. doi: 10.1136/bmjopen-2019-033027**.**

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**AppendicesAppendix 1:** Participant interview topic guide

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|  | **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?
  + 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.

**Appendix 2:** Nurse interview topic guide

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|  | **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?
* 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.