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

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Scientific summary

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Background

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

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

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

Overall objectives

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

Main research questions and aims

This research had several aims and objectives:

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

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

Design

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

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

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

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

Setting

This study took place in Birmingham, UK.

Participants

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

Intervention

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

Usual care

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

Main outcome measures

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

Results

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

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

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

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

Conclusions

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

Trial registration

This trial is registered as ISRCTN12209332.

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