

Text messaging to help women with overweight or obesity lose weight after childbirth: the intervention adaptation and SMS feasibility RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The intervention adaptation and SMS feasibility RCT

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Scientific summary

Background

About half of women of childbearing age have overweight or obesity. Overweight and obesity in pregnancy are associated with adverse health outcomes in mothers and babies. Furthermore, excessive gestational weight gain and postpartum weight retention are established predictors of long-term obesity. The postpartum period offers an opportunity to intervene and shape new health behaviours, as women have shown motivation for weight loss during this time and may have a heightened awareness of their own and their families' health. However, women often struggle with weight management at this stage in life and face many barriers to taking positive action, such as lack of time, tiredness and prioritising their children's needs. Systematic review evidence highlights that gaps exist in the knowledge about effective and appropriate weight management interventions in women during the postpartum period. Effective and cost-effective weight management interventions that are acceptable to postpartum women are needed. Employing mobile technologies to change diet, weight and physical activity presents a promising and expanding area of behavioural research, but one that has not, to date, been rigorously tested in new mothers.

Overall aim

The aim was to adapt and pilot-test an evidence- and theory-based tailored intervention delivered by short message service that supported behaviour change for weight loss and weight loss maintenance in postpartum women with overweight or obesity.

Overall objectives

- To review behaviour change techniques used in the txt2stop intervention and, through assimilation of relevant systematic review evidence, behaviour change theories and the National Institute for Health and Care Excellence guidance, build a logic model for a weight management intervention delivered by short message service for postpartum women who are overweight or obese.
- To create a library of short message service messages with personal and public involvement, to support weight loss and weight loss maintenance in postpartum women with overweight or obesity.
- To develop an intervention manual, including a library of messages and recruitment materials, and a protocol for a pilot randomised controlled trial of the short message service-delivered intervention.
- To conduct a pilot randomised controlled trial to test recruitment and randomisation strategies (including willingness to be randomised to an active control, and retention and attrition rates between groups), examine fidelity of implementation and acceptability of the intervention and active control treatments, identify valid and acceptable (to personal and public involvement members) research instruments to be used in a full randomised controlled trial, provide variability data on weight loss and weight loss maintenance on which to base a formal power calculation for a full randomised controlled trial, and assess outcome data collection processes.
- To assess pilot data in relation to predefined stop/go progression criteria for a full randomised controlled trial (see *Main outcome measures*) to inform the decision of whether or not to proceed to a full randomised controlled trial.

The main research questions for the pilot randomised controlled trial

- Is the recruitment strategy appropriate?
- Is the retention rate acceptable?
- What are the views of postpartum women with overweight or obesity regarding the acceptability and perceived benefits of the short message service-delivered intervention?
- Can data for the proposed end points be successfully collected?
- Can all components of the trial be successfully delivered?
- What are the indicative effects of the intervention on weight loss and weight loss maintenance?
- What fine-tuning of the intervention content or delivery is required for a full randomised controlled trial?
- What sample size would be required in a full randomised controlled trial?

Design

The study had two stages:

- Stage 1 – development of a library of short message service messages to support weight loss and weight loss maintenance, with personal and public involvement, that focused on diet and physical activity with embedded behaviour change techniques informed by behaviour change theory and evidence; and programming of a short message service platform to allow fully automated intervention delivery.
- Stage 2 – a 12-month, single-centre, two-arm, pilot randomised controlled trial with an active control. Ethics approval for the pilot randomised controlled trial was granted by the Queen's University Belfast School of Medicine, Dentistry and Biomedical Sciences Research Ethics Committee (reference number 16.49).

Setting

The study was set in Northern Ireland; women were recruited through community-based approaches.

Participants

A total of 100 women with a body mass index of ≥ 25 kg/m² who had given birth in the previous 24 months were recruited.

Intervention and active control

The intervention group received an automated short message service intervention about weight loss and weight loss maintenance for 12 months. The evidence- and theory-based intervention consisted of a library of short message service messages that focused on diet and physical activity with embedded behaviour change techniques known to be positively associated with weight management. Messages included bidirectional messages and interactive features, and the intervention was fully automated.

The active control received automated short message service messages about child health and development for 12 months. An active control was chosen for this study to reduce the disappointment and attrition associated with being randomised to a control group in a weight management intervention. The intervention and active control were developed with personal and public involvement input.

Main outcome measures

Outcome assessments were collected at baseline and at 3, 6, 9 and 12 months via home visits; women received a voucher on completion of each of the five assessment visits in recognition of their participation in the research. Weight, waist circumference and blood pressure were measured by researchers at each visit using standard procedures and participants also completed a questionnaire booklet and wore a sealed pedometer (i.e. the reading was not visible to the participant) for 1 week at each study visit. Qualitative interviews were conducted with women at 3 and 12 months to gather feedback on the intervention and active control and the study procedures.

An independent Study Steering Committee advised on the decision to proceed to a full randomised controlled trial based on an evaluation of whether or not the following prespecified progression criteria were met:

- feasibility of recruitment – recruitment of at least 80% of the pilot randomised controlled trial target (i.e. at least $n = 80$ participants); participants must also be from across the socioeconomic spectrum
- retention rate consistent with, or superior to, other weight loss interventions in overweight/obese postpartum women with overweight or obesity, that is at least 65% retention in the intervention group and 60% retention in the control group
- no evidence of a substantial, differential attrition between the intervention and active control groups; a difference in attrition rate between groups of $< 20\%$
- acceptability of the intervention and active control (satisfaction ratings, qualitative views, willingness to be randomised)
- evidence of positive indicative effects – change in anthropometric measures over time.

Results

In stage 1 of the study, close consultation with postpartum women was used to develop a set of initial test short message service messages and then to subsequently review and refine the full library of short message service messages. The personal and public involvement group informed the tone, length, style and content of the messages and, importantly, was used to get an instant reaction from women if they felt that any messages were unsuitable/jarring. An iterative process of writing and feedback was used to develop the messages for the intervention and active control groups. In total, the final short message service library consisted of 588 intervention messages and 312 active control messages. As well as message development, additional programming was added to the short message service platform to allow provision of feedback to participants. The results of stage 1 were a fully automated short message service intervention and a library of short message service messages for the active control.

For stage 2, the pilot randomised controlled trial, women were recruited through community groups aimed at mothers of young children located in an urban area (Belfast) and a rural area (within County Tyrone) of Northern Ireland, as well as through placement of posters in libraries, word of mouth and social media advertisements.

The recruitment target of 100 participants was achieved; the majority [$n = 67$ (67%)] were recruited via social media. Recruitment took 5 months, which was 1 month longer than anticipated. The sample ranged in age from 22 to 44 years; 99 (99%) participants were of white ethnicity. Nearly half [$n = 48$ (48%)] of the women recruited were < 6 months post partum, a further 22 (22%) participants were 6–12 months post partum and 30 (30%) were between 12 and 24 months post partum. The majority [$n = 92$ (92%)] of the sample were married or living with a partner, and 42 (42%) participants were first-time mothers. Most participants were employed [$n = 87$ (87%)], 65 (65%) were educated to degree level and 28 (28%) had a household income of $< £30,000$ per annum.

Fifteen women became pregnant during the follow-up period (intervention, $n = 9$; control, $n = 6$) and had to cease participation in the study for this reason. In the remaining sample of 85 women, at 12 months two women withdrew from the study and eight were lost to follow-up, leaving a sample of 75 women; retention at 12 months was 85.7% (36/42) of women in the intervention group and 90.7% (39/43) of women in the active control group.

The intervention was delivered as intended; all women received all short message service messages according to their group allocation. Both groups indicated a high level of satisfaction with the short message service messages that they received, and the participants perceived benefits in both the intervention and the active control conditions. Satisfaction ratings with the intervention and active control were high; between 82% and 97% of participants indicated that they found the short message easy to understand, helpful, interesting and appropriate in terms of the number of messages sent during the study and timing (delivery at appropriate times of the day). The length, tone and clarity of the messages were all considered to be acceptable. In interviews, women in the intervention group commented favourably on the different types of messages they received and liked that messages also came at the weekend, when routines change and compliance with weight management efforts can be put to the test. The short message service messages were described as encouraging, non-judgemental, non-stigmatising, reassuring and empathetic. They acted as reminders to stay on track or to get back on track, and prompted positive behaviours. Importantly, women could engage with them at a time that suited them and also look back over previous messages they had received. Women were able to readily recall specific details about the short message service content and the different styles of messages. Some women also appreciated the anonymity of the delivery via short message service but, at the same time, they discussed a feeling of accountability. The active control short message service also elicited many positive responses from women in the interviews, including feeling supported, reassured and encouraged. Others appreciated increasing feelings of self-worth as a mother, indicating a potential benefit of these messages in their own right for postpartum women.

Based on the analysis of weight data for the population completing the follow-up at 12 months ($n = 75$), between baseline and 12 months, the intervention group lost on average 1.75 kg, whereas the active control group gained 0.19 kg [corresponding to a mean difference in weight change between the intervention and active control groups at 12 months, adjusting for baseline, of -1.67 kg (95% confidence interval -4.88 to 1.55 kg)]. Eight per cent ($n = 3$) of women in the intervention group gained ≥ 5 kg, compared with 20% ($n = 8$) of women in the active control group. Women in the intervention group who engaged most with weekly short message service messages that asked them to self-weigh and send back their weight, or the short message service messages that asked women for a 'yes/no' reply, were more successful in their weight loss efforts.

Conclusions

An evidence- and theory-based short message service-delivered intervention was successfully developed in conjunction with postpartum women with overweight and obesity. The intervention was acceptable to women and was feasible to implement in a 12-month pilot randomised controlled trial. Progression criteria were met and a full randomised controlled trial should examine the effectiveness and cost-effectiveness of the intervention. Some minor refinements need to be made to the intervention and trial procedures based on the findings of the pilot randomised controlled trial in preparation for conducting a full randomised controlled trial. The findings of this pilot randomised controlled trial support the idea that interventions employing technology may fit well with the lives of women at this stage of life. However, appropriately powered trials with good engagement and retention, longer-term follow-up and examination of cost-effectiveness and potential for scale-up, alongside effectiveness, are still lacking in this field.

Trial registration

This trial is registered as ISRCTN90393571.

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