A woman-centred, tailored SMS-delivered multi-component intervention for weight loss and maintenance of weight loss in the postpartum period: intervention adaptation and pilot RCT.

Authors: Caroline McGirr[1], Ciara Rooney[1], Dunla Gallagher[1], Stephan U Dombrowski[2], Annie S Anderson[3], Christopher R Cardwell[1], Caroline Free[4], Pat Hoddinott[5], Valerie A Holmes[1], Emma McIntosh[6], Camilla Somers[6], Jayne V Woodside[1], Ian S Young[1], Frank Kee[1], Michelle C McKinley[1]

Corresponding author:
Dr Michelle McKinley
Reader
Centre for Public Health, Queen's University Belfast
Institute of Clinical Sciences Block A (1st floor)
Grosvenor Road
Belfast, BT12 6BJ, UK
Email: m.mckinley@qub.ac.uk
Tel: (0044) 2890 97 8936

Authors' Affiliations
[1]Centre for Public Health, School of Medicine, Dentistry & Biomedical Sciences, Queen's University Belfast, UK.
[2]Faculty of Kinesiology, University of New Brunswick, Canada.
[3]Centre for Research into Cancer Prevention and Screening, Cancer Division, Medical Research Institute, Ninewells Medical School, Dundee, UK.

[4]Clinical Trials Unit, Department for Population Health, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, London, UK.
[5]Nursing, Midwifery and Allied Health Professions Research Unit, Faculty of Health Sciences and Sport, University of Stirling, UK.
[6]Health Economics and Health Technology Assessment, Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK.

Competing Interests

The following competing interests were declared by Co-Authors:

Prof E McIntosh is a member of the NIHR PHR Research Funding Board.

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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 to 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 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

To adapt and pilot test an evidence and theory-based tailored short message service (SMS) delivered intervention supporting behaviour change for weight loss and weight loss maintenance in postpartum women with overweight or obesity.

Overall Objectives

- To review behaviour change techniques (BCTs) 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 an SMS-delivered weight management intervention in postpartum women who are overweight or obese.

- To create a library of SMS messages, with personal and public involvement (PPI), 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 (RCT) of the SMS-delivered intervention.
- To conduct a pilot RCT to: test recruitment and randomisation strategies (including willingness to be randomised to an active control; retention and attrition rates between groups); examine fidelity of implementation and acceptability of the intervention and active control treatments; identify valid and PPI acceptable research instruments to be used in a full RCT; provide variability data on weight loss and weight loss maintenance on which to base a formal power calculation for a full RCT; and, to assess outcome data collection processes.
- To assess pilot data in relation to pre-defined stop/ go progression criteria for a full RCT (see *below*) to inform the decision of whether to proceed to a full RCT.

The main research questions for the pilot RCT

- 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 SMS-delivered intervention?
- Can data for the proposed endpoints 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 RCT?
- What sample size would be required in a full RCT?

Design

The study had two stages:

Stage one- development of a library of SMS messages to support weight loss and weight loss maintenance, with PPI involvement, focusing on diet and physical activity with embedded BCTs informed by behaviour change theory and evidence. Programming of an SMS platform to allow fully automated intervention delivery.

Stage two- 12-month, single-centre, two-arm, pilot, RCT with an active control. Ethical approval for the pilot RCT was granted by Queen's University Belfast School of Medicine, Dentistry and Biomedical Sciences Research Ethics Committee (Reference number 16.49).

Setting

Northern Ireland; women recruited via community-based approaches.

Participants

One hundred women with Body Mass Index ≥25 kg/m^2 who had given birth within the last 24-months.

Intervention and active control

The intervention group received an automated SMS intervention about weight loss and maintenance of weight loss for 12-months. The evidence and theory-based intervention consisted of a library of SMS messages focused on diet and physical activity with embedded BCTs known to be positively associated with weight management. Messages included bi-directional messages, interactive features and the intervention was fully automated.

The active control received automated SMS 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 PPI input.

Main outcome measures

Outcome assessments were collected at baseline, three, six, nine and 12-months during home visits and 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 (reading not visible to participant) for one-week at each study visit. Qualitative interviews were conducted with women at three 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 RCT based on evaluation of whether the following pre-specified progression criteria were met:

- Feasibility of recruitment– recruitment of at least 80% of pilot RCT target (i.e. at least n= 80) and across the socio-economic spectrum.
- Retention rate consistent with, or superior to, other weight loss interventions in overweight/ obese postpartum women with overweight or obesity, i.e. at least 65% retention in the intervention group and 60% retention in the control group.
- No evidence of substantial, differential attrition between the intervention and active control groups; a difference in attrition rate between groups of less than 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 one of the study, close consultation with postpartum women was used to develop a set of initial test SMS messages and then to subsequently review and refine the full library of SMS messages. The PPI informed the tone, length, style and content of the messages and, importantly, was used to get an instant reaction from women if they felt any messages were unsuitable/jarring. An iterative process of writing and feedback was used to develop the messages for the intervention group and active control. In total, the final SMS library consisted of n=588 intervention messages and n=312 active control messages. As well as message development, additional programming was added to the SMS platform to allow provision of feedback to participants. The results of stage one was a fully automated SMS intervention and library of SMS for the active control.

For stage two, the pilot RCT, women were recruited via community groups aimed at mothers of young children located in an urban area (Belfast) and 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 was achieved; the majority (n=67, 67%) were recruited via social media. Recruitment took five months, one month longer than anticipated. The sample ranged in age between 22 and 44-years and n=99 (99%) were of white ethnicity. Nearly half n=48 (48%) of the women recruited were less than six-months-postpartum, a further n=22 (22%) were six to 12-months-postpartum and n=30 (30%) were between 12 and 24-months-postpartum. The majority of the sample were married or living with a partner n=92 (92%) and n=42 (42%) were first-time mothers. Most participants were employed n=87 (87%), n=65 (65%) were educated to degree level and n=28 (28%) of the sample had a household income less than £30,000.

Fifteen women became pregnant during the follow-up (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 SMS messages according to their group allocation. Both groups indicated a high level of satisfaction with the SMS they received, and perceived there to be benefits to both the intervention and active control conditions. Satisfaction ratings with the intervention and active control were high; between 82% and 97% of participants indicated that they found the SMS to be easy to understand, helpful, interesting, and appropriate in terms of the amount 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 SMS 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 received. Women were able to readily recall specific details about the SMS content and the different styles of

messages. Some women also appreciated the anonymity of the delivery via SMS but, at the same time, they discussed a feeling of accountability. The active control SMS 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 intervention and active control at 12-months, adjusting for baseline, of -1.67 kg (95% CI -4.88 to 1.55)]. Eight percent (n=3) of women in the intervention group gained 5 kg or more compared to 20% (n=8) of women in the active control group. Women in the intervention group who engaged most with weekly SMS messages that asked them to self-weigh and send back their weight, or the SMS messages that asked women for a 'Yes/No' reply, were more successful in their weight loss efforts.

Conclusions

An evidence and theory-based SMS-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 RCT. Progression criteria were met and a full RCT 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 RCT in preparation for conducting a full RCT. The findings of this pilot RCT 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

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