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Effectiveness and cost effectiveness of an automated text message intervention for weight management in postpartum women with overweight or obesity: the Supporting MumS Randomised Controlled Trial

The Supporting MumS (SMS) study

This protocol has regard for the HRA guidance.

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PROTOCOL VERSION

Protocol version	Date	Changes since previous version
V1.0	30/11/2021	N/A
V2.0	07/03/2022	Research reference numbers added; changes to section 9.3 to clarify wording in SAE assessment and reporting; mental health component added to study design, sample size increased to account for higher estimated pregnancy rates in some populations of women, duplicate text removed from section 12.
V3.0	10/05/2023	Processes to 1) collect participant self-reported weight at 12 and 24 months (only in the case that it is not possible to collect researcher measured weight, and 2) provide a booklet of intervention content to the active control group after 24 months, were added.

RESEARCH REFERENCE NUMBERS

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PROTOCOL LANGUAGE

As per NICE Postnatal care guideline NG194[1], this protocol uses the terms 'woman' or 'mother' throughout. These should be taken to include people who do not identify as women but are pregnant or have given birth. Similarly, where the term 'parents' is used, this should be taken to include anyone who has main responsibility for caring for a baby.

The authors of this protocol appreciate that the language around weight is sensitive and preferences for terms vary from person to person. This protocol uses ‘people first language’ to respectfully address people living with chronic diseases, rather than labelling them by their illness. People first language is recommended by major obesity organisations and can help reduce the challenge of stigma and discrimination. The use of people first language is widely accepted for most chronic diseases and disabilities.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's standard operating procedures (SOPs), and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:  Date: 30/11/2021

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i. LIST of CONTENTS

ii. LIST OF ABBREVIATIONS

AE	Adverse Event
APR	Annual progress report
AR	Adverse reaction
AUC	Area under the curve
BCT	Behaviour change technique
BiB	Born in Bradford
BiBBS	Born in Bradford Better Start
BMI	Adverse Reaction
CEAC	Cost-effectiveness analysis curve
CEA	Cost-effectiveness analysis
CI	Chief Investigator
CICI	Context and Implementation of Complex Interventions
CONSORT	Consolidated standards of reporting trials
COVID-19	Coronavirus disease 2019
CRF	Case Report Form
CTU	Clinical Trials Unit
CUA	Cost-utility analysis
DMC	Data Monitoring Committee
DMP	Data management plan
DPA	Data protection act
EPDS	Edinburgh postnatal depression scale
EQ-5D-5L	European Quality of Life 5-Dimensions 5-levels questionnaire
GAD-7	General Anxiety Disorder-7 questionnaire
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General practitioner
HAPA	Good Clinical Practice
ICECAP-A	ICEpop CAPability measure for Adults
ICER	Incremental cost-effectiveness ratio
ICMJE	International Committee of Medical Journal Editors
ISRCTN	International Standard Randomised Controlled Trials Number
LSHTM	London School of Hygiene and Tropical Medicine

MaMB	Me and My Baby Questionnaire
MaMC	Me and My Child Questionnaire
MORS	Mothers Object Relations Scale
MRC	Medical Research Council
NHS	National Health Service
NI	Northern Ireland
NICTU	Northern Ireland Clinical Trials Unit
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OR	Odds ratio
R&D	Research & Development
REC	Research Ethics Committee
PHQ-9	Patient Health 9-item Questionnaire
PHRP	Public Health Research and Practice
PI	Principal Investigator
PIS	Participant information sheet
PMH	Postnatal mental health
PMT	Project management team
PPI	Patient/Personal and Public Involvement
QALY	Quality-adjusted life years
QR	Quick response
QUB	Queen's University Belfast
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SAP	Statistical analysis plan
SES	Socio-economic status
SOP	Standard Operating Procedure
TMF	Trial Master File
TSC	Trial Steering Committee
UK	United Kingdom

iii. TRIAL SUMMARY

Trial Title	Effectiveness and cost effectiveness of an automated text message intervention for weight management in postpartum women with overweight or obesity: the Supporting MumS Randomised Controlled Trial (RCT)	
Short title	The Supporting MumS (SMS) study	
Trial Design	A UK wide multi-site, parallel, two-arm (intervention vs active control), RCT, with embedded process evaluation and cost-effectiveness analysis	
Trial Participants	Women with overweight or obesity who have had a baby in the last two years	
Planned Sample Size	888	
Intervention duration	12 months	
Follow up duration	24 months	
Planned Trial Period	46 months	
	Objectives	**Outcome Measures**
Primary	To conduct a 2-arm parallel group RCT comparing weight loss at 12 months for postpartum women with overweight or obesity who receive text messages about weight management or an active control.	Between group difference in weight change from baseline to 12 months (kg)
Secondary	To assess differences between groups in secondary outcomes.	Proportion of women gaining a substantial amount of weight (>5kg) during the 12 and 24 month follow-up
		Change in waist circumference
		Change in dietary intake
		Change in physical activity
		Infant feeding practices
	To assess the cost-effectiveness of the text message intervention.	Quality-adjusted life year (QALY) Incremental cost-effectiveness ratio (ICER)
	To conduct a process evaluation to explore women's experiences of the intervention, the pathways through which the intervention	Engagement with the intervention [response to the two-way text messages (weekly weight reporting and 'Yes/No' questions)]

	effects are mediated and contextual factors affecting the outcomes or future implementation of the intervention.	Reach - study records Dose – study records (e.g. if participants texted STOP) Semi-structured interviews at 6 and 12 months –experiences of receiving the intervention and active control, how they feel the intervention 'worked' or did not work for them (mechanism of impact), and suggestions for implementation (if the intervention was shown to be effective). Acceptability - participant rating of intervention, qualitative interviews, recruitment, retention and engagement with the two-way text messages Change in theory based mediators of behaviour change (HAPA items including action and coping planning and self-efficacy for diet and physical activity, habit behaviour, self-regulation of eating behaviour, self-monitoring diet, activity and weight, goal setting diet and activity, weight loss motivation, social support, self-esteem) Change in moderators of behaviour change (sleep, mental health - anxiety and depression, mother/child relationship, confidence, importance, desire for weight loss)
	To seek permission for linkage to routine data for long term health outcomes (mum and youngest child at time of signing up to the study).	Informed consent
	To examine the long-term effect of the 12 month intervention, at 24 months (i.e. 12 months after the intervention has ceased).	Between group difference in weight change from baseline to 24 months and weight change between 12 and 24 months.
	To conduct interviews with stakeholders to explore scale-up and implementation.	Semi-structured interviews with stakeholders.

iv. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The day-to-day management of the project is the responsibility of the Chief Investigator (CI, M McKinley). There will be five recruitment sites (Site Principal Investigators (PIs): Northern Ireland, M McKinley; Scotland, P Hoddinott; Wales, E Coulman; England, London, C Free; England, Bradford, S Bridges). The trial will be co-ordinated by the CI and Trial Manager who are based at the Centre for Public Health, Queen's University Belfast.

Each site lead will be responsible for the recruitment and management of research staff at their site and for recruitment and follow-up of participants at their site, including data collection, as well as facilitating relevant PPI activities and connections with stakeholders.

The trial is supported by the Northern Ireland Clinical Trials Unit who will be responsible for data management including database development.

Set-up of sites and discussion of relevant processes and progress will be facilitated by regular site team teleconferences (CI, site leads, Trial Manager, research staff) which will be more frequent at trial outset and then reduce in frequency (e.g. weekly/fortnightly to monthly) if good progress is being made. This will allow recruitment strategies to be modified in a timely manner if required. There will also be email contact between meetings as needed.

Other sub-group meetings will be scheduled as required at trial set-up and as the trial progresses through key milestones, e.g. qualitative research sub-group, data management sub-group, statistics and health economics sub-group, Personal and Public Involvement (PPI) sub-group.

The Project Management Team (all co-applicants, Trial Manager, PPI representative) will be the key decision-making group, providing oversight of the management and conduct of the trial and will report to the Trial Steering Committee (TSC). They will meet every quarter with email contact between meetings as needed, e.g. for troubleshooting purposes.

The responsibilities of each member of staff on the trial will be detailed in the delegation log.

Trial Steering Committee (TSC)

An independent TSC will be established. The TSC will provide overall supervision of the trial on behalf of the sponsor and funder and will ensure the trial is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The TSC will also formally review trial progress at two points as follows:

1. A traffic light system will be used to review study progression at the mid-point of the recruitment period with the following actions: proceed if >50% of target achieved; modify recruitment approach if 25-49% and consider stopping in discussion with the TSC, funder and sponsor if <25% of target recruited.[2]
2. The TSC in conjunction with NIHR will decide if the study should progress to Stage 3 (24 month follow-up and interviews with stakeholders) based on assessment of the 12 month primary outcome data and any other core outcome data required to make a fully informed decision at 12 months (end of intervention).

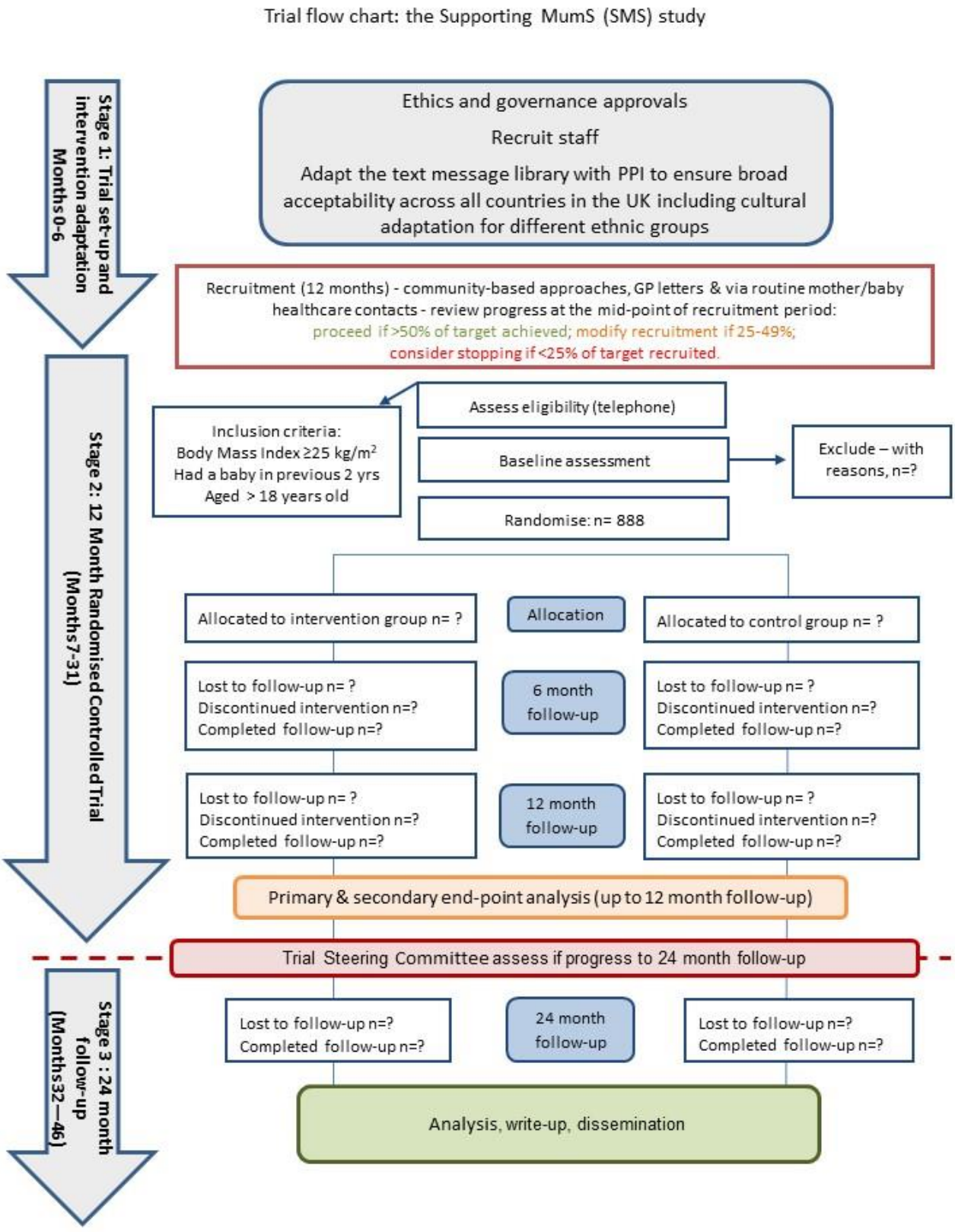
The Independent TSC will meet annually face-to-face or via teleconference and additional meetings will be convened as needed to consider the above progression points.

Data Monitoring (and ethics) Committee (DMC)

As this is a very low risk lifestyle behaviour change intervention, a DMC will not be convened. No evidence of harm has been reported in text message studies for other health behaviours or in our pilot RCT[3]. Data on serious adverse events, as detailed in section 9 of the protocol, will be reported to the TSC. Participant safety will be a standing item on the TSC agenda.

v. KEY WORDS: Women with overweight or obesity, postpartum, ethnically diverse, weight management, text messages, randomised controlled trial

vi. TRIAL FLOW CHART



1 BACKGROUND

Overweight and obesity are major 21st century public health challenges. Obesity has nearly doubled worldwide since 1980[4] and this has implications for maternal health. According to the Health Survey for England 2018, the proportion of overweight and obesity increases with age among women of childbearing age from 35% of 16-24 years old, to 53% and 61% of women aged 25-34 and 35-44 years old respectively[5]. Compared to women with a healthy weight, being classified as overweight or obese at the start of pregnancy is associated with an increased risk of gestational diabetes, pre-eclampsia, hypertension, depression, caesarean section, postpartum haemorrhage, induction of labour, pre-term birth, stillbirth, foetal defects, congenital abnormalities and infant death,[6-9] with an increased risk of offspring adiposity continuing into childhood.[10,11]

Women are at an increased risk for weight gain during the reproductive years.[12] About one in five women move into a higher body mass index (BMI) category at 18 months postpartum.[13] Weight gain between successive pregnancies is associated with increased risk of gestational diabetes mellitus, hypertensive disorders of pregnancy, caesarean section, high infant birth weight and perinatal mortality.[12] Systematic review evidence[14-17] and NICE (National Institute for Health and Clinical Excellence) Public Health Guidance[18] both highlight current gaps in knowledge about effective and appropriate weight management interventions in women during the postpartum period. We need to develop weight loss interventions that support postpartum women to improve their health before future pregnancies and they need to fit seamlessly into the busy lives of women during the postpartum period if they are to succeed[12]. Interventions must carefully consider the difficulties in reaching this population and the specific barriers to lifestyle behaviour change that come with having a baby; [3,19-23] failing to consider this has been a significant limitation of many previous studies in this area as described below.

Text message interventions have the advantage of high reach potential (approximately 95% of households in the UK own a mobile phone),[24] flexible scheduling and interactivity,[25] and convenience for mums with limited time, thus making them attractive to this group, and with the potential to help address health inequalities[3]. They have also been shown to be cost-effective and readily scalable.[26] Systematic reviews provide support for the use of text messaging in weight management interventions[27-31] but also indicate further work is required in this field.

Postpartum weight loss interventions

Systematic review evidence suggests that diet and physical activity interventions delivered postpartum have a moderate but positive influence on maternal weight[17-20] and that interventions combining diet and activity behaviour change[17,19,20] that include self-regulatory behaviour change techniques (BCTs), such as self-monitoring of weight[17] may be more successful.

Attrition is an issue for trials in this field. A review of systematic reviews and meta-analyses by Farpour-Lambert *et al.* (2018)[32] examined evidence for an effect of postpartum interventions on postpartum weight retention. Overall, combined diet and activity interventions reduced postpartum weight retention in women of any BMI (weighted mean difference -2.57 kg to -2.30 kg) but this was based on evidence judged to be very low quality. Dodd *et al.* (2018)[33] in their systematic review of weight loss in postpartum dietary and/ or physical activity intervention trials, reported overall participant withdrawal rate of 25% and the authors indicated a need to develop appropriate ways of recruiting and engaging with this population to achieve sustained behaviour change. Since these systematic reviews, several weight management trials in postpartum women have been published, the majority of which have been feasibility or pilot studies[34-38]. These studies highlight interventions that show promise in postpartum women and, in particular, the use of technology seems to be well received, perhaps because it fits better within the lives of women at this stage of life.[35,38] However, issues of poor recruitment and retention still affect some studies in this area[34,36,39] and we took steps to avoid this in our successful pilot RCT[3] (as described in sections 7.7 and 8.1). Even though recruitment rates may suggest that postpartum women

have similar interest in remotely delivered versus in-person weight management interventions,[40] the reality of engaging with in-person protocols remains an ongoing challenge in this field, particularly when considering health inequalities.[41-44] The intervention setting and mode of delivery are key considerations when developing postpartum weight management interventions because of the well-recognised barriers for new mums, such as lack of time and childcare and busy family schedules.[12] Interventions for women with overweight or obesity after pregnancy delivered in community settings, using group approaches, have presented difficulties for new mothers at this challenging time, and have raised concerns about reach and retention, particularly for disadvantaged groups,[17,41-43] creating a potential to increase health inequalities.[45,46] For example, despite high initial motivation to enrol in the active mothers postpartum study,[44] and the provision of group sessions multiple times per week, at various times of day, women found it difficult to attend owing to the competing needs of their baby, home- and work-life. Thus, despite considerable evidence that group approaches are associated with significant weight loss in the general population[61] they may not be feasible for a lot of women in the postpartum period. A highly flexible and individualised approach to weight loss interventions is needed in the postpartum period, shifting away from structured community based programmes, to home-based or more adaptable 'anytime, anyplace' approaches, as enabled by mobile technologies.[12]

The Supporting MumS pilot RCT[3]

To address the gaps discussed above, we developed a library of text messages to support weight loss and weight loss maintenance in the postpartum period, with personal and public involvement. The messages focus on diet and physical activity with embedded behaviour change techniques informed by behaviour change theory and evidence.

We then conducted a pilot RCT with 100 women with overweight or obesity who had given birth in the previous 24 months[3]. We chose an opt-in period of up to 24 months postpartum for a number of reasons. Studies of maternal weight trends through the initial two years postpartum highlight the problem of retention of gestational weight gain, as well as weight gain that originates solely within the postpartum period. Studies have shown that maternal weight gain is common after one year postpartum, thus reinforcing the need for interventions extending into this period, and recruiting women in the period from birth up to two years postpartum.[12] For example, Lipsky *et al.* (2012) examined weight change between one and two years postpartum in a cohort of 413 women in New York[47]. They found that about one in four women gained weight (more than 2.25kg) during this late post-partum phase. Women who were overweight or obese at the one year postpartum time point were more likely to gain weight between one and two years than women with a normal pre-pregnancy BMI (OR 2.38 and 2.92, respectively). The Active Mothers Postpartum Study[48] of 450 overweight and obese women assessed weight at 6 weeks and 12, 18 and 24 months and also showed an upwards trajectory for weight between 12 and 24 months, particularly for women in obese class II and III. Abebe *et al*.(2015)[49] found three groups of postpartum weight trajectories in the Norwegian Mother and Child Cohort study of nearly 50,000 mothers where weight had been measured at 0.5, 1.5 and three years. Most women (86%) had a low level of postpartum weight retention (0.5kg) and a slight gain in weight over three years (<2 kg), 5.6% had a high postpartum weight retention at six months (8kg) followed by marked weight loss over the next 2.5 years (2.63 kg per year on average), and 8.5% had high weight retention (5kg) at six months and an increase in weight over the next 2.5 years (by 1.43kg/year). In a recently reported analysis of the prospective cohort Project Viva[50] of 1359 mothers, based on weights at 1, 6, 12, and 24 months postpartum, women following a trajectory of 'little weight loss + slight gain' during the first 2 years postpartum had an adverse cardiometabolic profile 3 years after delivery. This extended postpartum period is particularly important as it represents the pre-conceptual period for a subsequent pregnancy[47] and so is an opportune timeframe for weight management interventions. NICE guidance supports weight management in the first year or two after birth as this is a time when women start to think about having another baby and a low cost intervention such as this could reasonably be made available to women up to 2 years postpartum. In addition to this, the lived experience of postpartum women, revealed in qualitative

research, shows that every woman's postpartum journey is different; women vary in how they feel about their postpartum body and shape and in their readiness to engage with weight management efforts[19-23]. Whilst some women may be ready to engage with weight management a few months after birth, others may not be ready to engage until much later. The optimal time to engage women in postpartum weight management is still unknown.[14,17] Based on what is known about vulnerability for weight gain in the extended postpartum period, together with insight from women about readiness to engage in weight management postpartum, we have allowed a window of two years postpartum as the trial inclusion criteria. As outlined in the statistical analysis section (section 10), we will examine weeks postpartum an effect moderator to inform the evidence base on whether there is an optimal time to engage women in postpartum weight management.

In our pilot study, one hundred postpartum women were randomised to receive our text messages about weight loss (intervention group) or text messages about child health and development (active control) for 12 months. The intervention was fully automated and was delivered as intended. Both the intervention and active control groups indicated a high level of satisfaction with the text messages they received, and perceived there to be benefits to both the intervention and active control conditions. Between 82% and 97% of participants indicated that they found the text messages 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. The text 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 received. Women were able to readily recall specific details about the content and the different styles of messages. Some women also appreciated the anonymity of the delivery via text message but, at the same time, they discussed a feeling of accountability. The active control text messages 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. Fifteen women became pregnant during the follow-up and stopped the study for this reason. Excluding these women, retention at 12 months was 85.7% and 90.7% in the intervention and control groups respectively. Based on the analysis of weight change 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% Confidence Interval (CI) -4.88 to 1.55)]. Women in the intervention group who engaged frequently with weekly messages that asked them to self-weigh and send back their weight, or the messages that asked women for a 'Yes/No' reply, were more successful in their weight loss efforts. For example, high engagers with 'Yes/No' messages lost 2.9kg at 12 months compared to 0.9kg for low engagers; for waist circumference, high engagers reduced their waist circumference by 9.4cm compared to 3.6cm for low engagers. The independent Trial Steering Committee (TSC) and all reviewers of the final report agreed that pre-specified progression criteria for proceeding to a full trial (i.e. successful recruitment, high retention and no differential attrition, high acceptability of the intervention, and evidence of positive indicative effects) had been met.

The effectiveness trial described here is based on the pilot RCT methodology[3]. The key changes from pilot to full trial are:

- Removing use of a sealed pedometer to assess physical activity as it was not acceptable to women.
- Removing the discussion forum component of the intervention as it was not used by participants in the pilot RCT.

Postnatal mental health

Poor postnatal mental health (PMH) (from birth to 2 years), defined as depression, anxiety and/or a poor mother-child relationship, are common and can have long-lasting effects on the woman, her child and wider family.[51] Providing specialist services for women with complex health needs is a priority in the NHS Long Term Plan; however, the prevalence, trajectories and predictors of poor PMH outcomes remain unknown, making it impossible for commissioners to implement appropriate services. In addition, whilst the NHS is bound by the Equality Act 2010 ensuring that people with protected characteristics have the same opportunities as do others, this is not currently the case; a recent systematic review integrating results from qualitative, quantitative and mixed-methods studies highlighted that women of low socio-economic status (SES) and/or ethnic minorities, particularly those who do not speak English, are less likely to have PMH issues identified and treated.[52]

NICE guidance[53] is clear that midwives, GPs and health visitors should consider screening for perinatal depression and anxiety at specific time points, and, where there are indications of concern, a more thorough assessment should be completed using standardised tools (PHQ-9[54] or EPDS[55] and GAD-7[56]). The outcomes of the screening and assessments for these PMH concerns is very poorly recorded in electronic care records meaning that prevalence rates, service needs and the identification of any inequalities in prevalence, identification or treatment are very difficult to research. Assessments of postpartum depression, depression and anxiety will be collected in this study.

NICE guidance for the postnatal period also states that health visitors should assess the mother and child relationship for potential concerns, but they offer no recommended standardised tool to complete this assessment in children <1 year old. Without standardised tools, it is impossible to identify prevalence, identify the need for service provision and/or look for inequalities in identification / access of support. A recent pilot of a standardised tool (the maternal postnatal attachment scale), in an ethnically diverse and low SES community, demonstrated that it was feasible to administer such a tool but the concepts were poorly understood by women.[57] In response a co-produced assessment tool has been developed with health visitors and the community and piloted – the Me and My Baby/Child (MaMB/MaMC tool[58]). This will be administered in the present study, along with the Mothers Object Relations Scale (MORS)[59] which is frequently used in interventions, to test the validity and reliability of the MaMB/MaMC[58] screening tool.

2 RATIONALE

The increased prevalence of obesity is currently estimated to cost the National Health Service (NHS) over £6 billion per year and, by 2050, if indirect costs are included, these costs are forecast to rise to nearly £50 billion.[60] Add to this the effect the COVID-19 pandemic has had on healthcare utilisation with BMI being directly associated with higher risk of serious illness, complications and hospitalisation from the virus. A UK- based study[61] found that a pregnant woman with a BMI of ≥25 kg/m^2 led to NHS costs of up to 37% more than a woman with a BMI between 18.5 kg/m^2 and 24.9 kg/m^2. Current guidance suggests that health professionals should advise women within two years of having a baby to eat healthily and keep active to encourage postpartum weight reduction[18,62]. NICE guidance on weight management before, during and after pregnancy[18] and its associated review of the cost-effectiveness of weight management interventions following childbirth,[63] both outline the potential of postpartum interventions to reduce the long-term risks of heart disease, cancer, obesity and diabetes. The postpartum period could be an ideal time to intervene to shape new health behaviours as women have shown motivation for weight loss during this time and may be more than usually receptive to information about their own and their families' lifestyle.[64] It is also a time when many start to prepare for the next pregnancy, so there is also the potential to set women on a positive course for subsequent pregnancies[12]. Women have highlighted a need for additional weight management support during the

postpartum period as little is currently provided.[65] NICE guidance[18] highlights the gap in knowledge about effective and appropriate weight management interventions in women during this period.

Some weight loss interventions can be resource intensive and expensive which can limit potential for scale-up and implementation,[66] while concerns have been raised that others could increase health inequalities.[45,46] Use of mobile phones and other technical devices have become integral to how individuals live their lives. Mobile phone ownership is widespread amongst all sectors of society, irrespective of socioeconomic status. Unlike web-based interventions or apps, which require ownership of a smartphone or tablet, and individuals taking the initiative to use them, text messaging is a relatively simple mode of communication that uses basic mobile technology. An intervention using text messaging can be delivered flexibly for sustained contact over the medium to long-term, can be reactive as well as proactive, and does not necessarily rely on initiation by the participant.[25,67] Using the real-time advantages offered by mobile technologies to deliver weight management support in the postpartum period has the potential to empower women and encourage behaviours that may improve maternal health in both the short and long-term.[68] The availability, adaptability and low cost of mobile technologies provide a promising format for delivering lifestyle intervention programmes on a sustained basis[25] and the NHS aims to embrace the potential of digital strategies for improving UK health.[69]

The Supporting MumS study adopts a fully automated approach to intervention delivery whilst still offering feedback to participants. The study makes a novel and important contribution to the field of text message interventions as there are currently few fully automated text message interventions, especially where text messaging is the main mode of delivery, and also a lack of interventions incorporating two-way messaging to encourage engagement and delivery of specific BCTs. Few incorporate weight loss and weight loss maintenance, few have lasted 12 months or more and few have an active control to minimise disappointment bias.[3]

This trial is not only relevant to women after pregnancy, but has the potential to be adapted for other population groups as one of the advantages of the approach is the unlimited potential for reach at low-cost. Such interventions could complement the weight management and lifestyle advice that is currently delivered across many areas of the health service to help ease the current burden on an over-stretched service. Testing the intervention in a multi-site RCT will enhance the generalisability of the findings to different ethnic and socioeconomic groups thus informing implementation.

In addition, the Supporting MumS cohort provides an opportunity to collect invaluable outcome data on PMH into the extended postpartum period, including postnatal depression, depression, anxiety and the mother/child relationship, in an ethnically and socioeconomically diverse sample from all four UK countries. This will expand our knowledge on prevalence and mental health trajectories across groups, to inform service need. The study also enables us to further test the validity and reliability of the MaMB/MaMC[58] screening tool which has been co-produced by health visitors and the community, to assess the mother and child relationship.

2.1 Assessment and management of risk

No evidence of harm has been reported in text message studies for other health behaviours or in our pilot RCT[3]. However, we will monitor any emerging safety issues or unintended consequences such as adverse impact on mental health and wellbeing and any such cases will be referred to their GP for appropriate treatment. Any adverse events or safety issues reported by participants at any stage during the trial will be recorded in the study records and reported to the TSC (participant safety will be a standing item on the TSC agenda).

As part of the outcome assessment, women complete the Edinburgh Postnatal Depression Scale (EPDS)[55]. EPDS is a screening questionnaire used to detect postnatal depression symptoms. It does not diagnose postnatal depression but, as per the guidance for the questionnaire, if a woman scores above nine, we will inform their GP and recommend follow-up and send a copy of the information to

woman. This procedure is covered in the consent process and detailed in the participant information sheet (PIS). Anecdotally, a few women in the pilot RCT reported receiving treatment for postnatal depression that they would not have sought themselves had it not been for their GP following up on the letter they received[3].

We have developed a signposting leaflet which will be given to all women during home visits and made available on the study website. It provides the name and contact details of relevant agencies and organisations that women can contact for support on a variety of issues, such as poor mental health, domestic violence and bereavement.

As home visits will be conducted by researchers, a lone working policy will be implemented at each site according to the relevant safety procedures of the institution. Researchers will receive training on all trial procedures from the Trial Manager before commencing recruitment.

With regard to safeguarding children and adults, all researchers will have undergone relevant security checks and the policies on safeguarding of children and adults from the Born in Bradford's Better Start cohort will be adapted for use across all the trial sites.

Restrictions to mitigate risk of COVID-19 transmission may be in place during the trial and the level of restriction may vary over time and by UK region. The trial will be conducted in-line with local Government guidance on COVID-19 restrictions and University policies on conducting research during COVID-19 in order to mitigate risk to researchers and participants. Site leads will ensure all necessary risk assessments, or other local paperwork required, is completed and reviewed on a regular basis throughout the pandemic.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Research question

Does a fully automated text message intervention support weight loss and maintenance of weight loss in women with overweight or obesity who have had a baby in the last two years?

3.2 Overall aim

To assess the effectiveness and cost-effectiveness of the Supporting MumS intervention for weight management in women with overweight or obesity who have had a baby in the last two years compared with an active control who receive messages about child health and development at 12 months.

3.3 Objectives

Stage 1: Trial set up and cultural adaptation of the text message library with PPI

1.To adapt the text message library to ensure broad acceptability across different ethnic groups and the four countries in the UK.

Stage 2: Multi-site RCT

2. To conduct a 2-arm parallel group RCT comparing weight change at 12 months for postpartum women with overweight or obesity who receive text messages about weight management or an active control.

3. To assess differences between groups in secondary outcomes.

4. To assess the prevalence and trajectories of PMH in women across the UK, particularly those from marginalised groups, including assessment of the mother-child relationship.

5. To assess the cost-effectiveness of the text message intervention.

6. To conduct a process evaluation to explore women's experiences of the intervention, the pathways through which the intervention effects are mediated and contextual factors affecting the outcomes or future implementation of the intervention, including the impact of PMH on intervention engagement and outcomes.

7. To seek permission for linkage to routine data for long term health outcomes (mum and youngest baby).

Stage 3: Long-term follow-up and implementation consultations (contingent upon TSC and NIHR assessment of clinically significant weight loss at 12 months)

8. To examine the long-term effect of the 12 month intervention at 24 months (i.e. 12 months after the intervention has ceased).

9. To conduct interviews with stakeholders to explore scale-up and implementation.

3.4 Endpoints/outcome measures

The outcome measures (as tested in the pilot study[3]) are summarised in Table 1.

3.4.1 Primary endpoint/outcome

Between group difference in weight change from baseline to 12 months (kg).

3.4.2 Secondary endpoints/outcomes

Proportion of women gaining a substantial amount of weight (>5kg) during the 12 and 24 month follow-up, change in waist circumference, change in dietary intake, change in physical activity and infant feeding practices.

3.4.3 Cost-effectiveness

Resource use and expenditure e.g. GP, hospitalisations, prescription and over the counter medicines, expenditure on lifestyle products, expenditure on lifestyle services, weekly cost of groceries (i.e. healthy eating may cost more), alcohol and smoking products; Health related quality of life - EQ-5D-5L (including visual analogue scale),[70] Capability wellbeing - ICECAP-A.[71]

3.4.4 Process evaluation

A process evaluation, informed by the Medical Research Council (MRC) guidance on process evaluation of complex interventions[72], will be conducted to explore participants experiences of the intervention with a view to understanding if, how and for whom the intervention works and what participants think the mechanisms of impact may be, as well as understanding contextual factors that may be important for implementation.

A Process Evaluation Analysis Plan will be prepared. Fidelity does not need to be assessed as the intervention is fully automated. Dose will be assessed based on whether women receive all text messages or use the 'Stop' function. Engagement with the intervention will be measured by assessing response to the two-way text messages (weekly weight reporting and 'Yes/No' questions). Reach will

be assessed from study records of trial recruitment across the five sites and examination of demographic characteristics of participants who withdraw or are lost to follow-up. Reason for withdrawal will be requested. Semi-structured interviews will be carried out at 6 months and 12 months with a purposive sample to explore the participants experiences of receiving the intervention and active control, how they feel the intervention 'worked' or did not work for them (mechanism of impact), and suggestions for implementation if the intervention was shown to be effective. Acceptability of intervention to a range of cultural groups will be assessed by participant rating of the text messages, qualitative interviews, recruitment, retention and engagement with the two-way text messages by site, ethnicity and socio-economic status (SES). If the intervention is shown to be effective at 12 months, stakeholder interviews will be conducted to explore factors relevant to implementation including possible facilitators and barriers to wider implementation as well as exploring women's longer-term use of the text messages in the 24 month questionnaire.

3.5 Exploratory endpoints/outcomes

As part of the process evaluation, a moderator (factors that influence response to intervention) and mediator (possible mechanisms that bring about behaviour change) analysis will be conducted based on outcome data shown in Table 1.

4 TRIAL DESIGN

A UK wide multi-site, parallel, two-arm, RCT, with embedded process evaluation and cost-effectiveness analysis, comparing weight change in women with overweight or obesity who have had a baby in the last two years and receive an automated text message weight loss intervention for 12 months, with an active control who receive messages about child health and development. The RCT will be monitored by an independent TSC.

There will be a qualitative sub-study of participant experiences at 6 and 12 months and, if effectiveness is demonstrated at 12 months, we will conduct a further follow-up at 24 months (i.e. up to 12 months post intervention) as well as interviews with stakeholders to inform implementation.

A traffic light system will be used to review study progression at the mid-point of the recruitment period with the following actions: proceed if >50% of target achieved; modify recruitment approach if 25-49% and consider stopping (discuss with funder and TSC) if <25% of target recruited.[2]

An independent TSC in conjunction with NIHR will decide if the study should progress to 24 month follow-up based on assessment of the 12 month primary outcome data and any other core outcome data required to make a fully informed decision at 12 months (end of intervention).

During Stage 1 (Months 0-6), PPI will help refine the library of text messages developed for the Supporting MumS pilot study for a UK wide audience to ensure messages are acceptable and culturally relevant to a range of ethnicities.

5 TRIAL SETTING

Five sites [Scotland, Northern Ireland, Wales, England (Bradford and London)] will recruit and follow-up participants. Outcome data will be collected at home visits as employed in the pilot study (91% of women opted for home visits in the pilot study and women indicated it facilitated their participation in the research) or women will also have the option of attending another venue of their choice such as a University building or community venue if they prefer. Intervention delivery is fully automated via the London School of Hygiene and Tropical Medicine's (LSHTM) text message platform managed by Prof Caroline Free (co-applicant and site lead for London).

6 PARTICIPANT ELIGIBILITY CRITERIA

As per NICE Postnatal care guideline NG194[1], this protocol uses the terms 'woman' or 'mother' throughout. These should be taken to include people who do not identify as women but are pregnant or have given birth. Similarly, where the term 'parents' is used, this should be taken to include anyone who has main responsibility for caring for a baby.

6.1 Inclusion criteria

- Women (as per NICE Postnatal care guideline NG194[1], for this trial, the term 'woman' is taken to include people who do not identify as women but are pregnant or have given birth)
- Aged > 18 years old
- BMI ≥25 kg/m^2
- Have had a baby within the last two years

6.2 Exclusion criteria

- Baby less than 6 weeks old
- No access to a mobile phone to receive personal messages
- Insufficient English to understand short written messages
- Currently pregnant
- Recent or planned bariatric surgery
- Eating disorder
- On a specialist diet and receiving dietetic care
- Taking part in another weight management research study currently, or in the last 3 months

7 TRIAL PROCEDURES

The trial procedures described below are based on our successful pilot RCT[3].

Government restrictions to mitigate risk of COVID-19 transmission may be in place during the trial and the level of restriction may vary over time and by UK region. The trial will be conducted in-line with local Government guidance on COVID-19 restrictions and University policies on conducting research during COVID-19 in order to mitigate risk to researchers and participants. Examples of measures that may be implemented include:

- Asking participants a number of COVID-19 screening questions before study visits as recommended by the NHS
- Using appropriate PPE and hand sanitiser
- Minimising face-to-face contact e.g. measuring waist circumference standing behind or to the side of the participant rather than face-to-face
- Maintaining a suitable distance from the participant
- Sanitising equipment before and after use with a participant

- Ventilating rooms where visits take place
- Following local contact-tracing protocols should either the researcher or participant experience COVID-19 symptoms or test positive for the virus after a face-to-face visit.

Site PIs will ensure any COVID-19 risk assessments required by their institution have been conducted and implemented to protect participants and researchers.

Trial assessments would be modified based on COVID-19 restrictions as detailed in section 7 of the protocol.

This trial is being conducted in all four countries in the UK and it is possible that different sites will be operating under different levels of COVID-19 restrictions and these are likely to change over time; for example mask wearing is still required in NI currently but has not been required in England for some time. The restrictions in place and measures to comply with these restrictions and mitigate risk of COVID-19 will be recorded by sites.

7.1 Recruitment

The recruitment strategy has been designed to reach women at a range of postpartum time points as per our inclusion criteria above.

Recruitment will target disadvantaged areas and a range of ethnic groups, facilitated by study sites which represent each country in the UK and will enhance generalisation of the findings of the trial.

The sites in England (Bradford and London) will specifically target recruitment of South Asian and Black communities, as they represent the second and third largest ethnic groups in the UK, with White being the largest.

As in the pilot study[3] we will use a range of community based recruitment approaches but this will also be extended to employ recruitment methods that make use of the routine contacts women have with healthcare professionals during the immediate and extended postpartum period.

7.1.1 Participant identification

Community based recruitment including social media

Our target is to recruit 75% of the total sample (approx. 125 out of 170 women at each site) using this approach, as this is likely to be a useful way of recruiting hard to reach groups who may not engage with or respond to recruitment via health services. We successfully recruited 100 postpartum women in five months for the Supporting MumS pilot RCT using these approaches[3].

Community groups aimed at mothers of young children will be identified in each region, for example mother and toddler groups in churches, breastfeeding support groups, ‘rhythm and rhyme’ type groups within community libraries and family centres. With relevant permissions, researchers will visit the group to talk about the study and disseminate flyers (small version of study poster), business cards and study posters for display in relevant areas and via social media. Where it is not feasible for the researcher to conduct a face-to-face group visit, posters, flyers, business cards and social media content will be sent to the group facilitators. Study promotion materials including posters, pop-up banners (larger version of study poster), flyers and business cards will also be placed in community spaces such as libraries, pharmacies, shopping centres, leisure centres and health hubs. We will use a trial webpage and social media to further promote recruitment to the study including, for example, targeted Facebook newsfeeds to disseminate the study poster to women aged between 18 and 45 years and living within approximately a 40 kilometres radius of each site (this radius will be expanded if necessary to boost recruitment) and Facebook pages/websites/newsletters of community and parenting organisations. The study promotion

materials will provide information about the study along with contact details of the research team so women interested can make contact with the research team via telephone, email or website (or scanning a QR (quick response) code that takes them directly to an MS Form to complete their contact details with data stored on QUB secure data systems). Through our previous and ongoing research the co-applicants have established contacts with a range of community networks that can help to facilitate this recruitment.

As the study employs an active control to encourage retention, the purpose of the study will be advertised as testing two new text message services: messages about child, health and development or messages about weight management. This aims to minimise women's preference for one group over another. The PIS clearly describes that women have a 50:50 chance of being assigned to receive messages about child health and development or messages about weight management thus preserving participant autonomy. This approach proved to be acceptable in the pilot study.

In Bradford, the study will be hosted by the Born in Bradford (BiB) team. The principal recruitment method will be through an existing birth cohort study (Born in Bradford's Better Start (BiBBS)) which currently recruits approximately 650 pregnant women per year from three wards of Bradford: the majority of this area falls into the most deprived 10% of areas in England. The area is also very ethnically diverse, with residents of Pakistani heritage forming the largest ethnic group (48.6%) and a White British population of 24.8%. Women who have joined the cohort who have consented to receive information about other potentially-relevant studies, will be given information about the study in pregnancy and again postpartum (REC Reference: 15/YH/0455, Yorkshire & The Humber – Bradford Leeds REC). This will be through bespoke mail outs and telephone contacts from the research team. The study will also be advertised more widely through the BiB social media platforms and newsletters that reach more than 15,000 families in the local area. The BiB programme also have excellent links with local maternity services, Health Visiting teams and early years services. These links will prove invaluable in promoting the study and ensuring good recruitment and retention to the study.

Recruitment in London will focus on South East London; the top four boroughs of London with the highest total Black population are Lambeth, Southwark, Lewisham and Croydon.

Our recruitment of women from different ethnic groups will follow the best practice framework on how to improve the participation of minority ethnic groups in health and social care research[73]. We will link with community champions in order to explore how best to liaise with community, voluntary and faith-based organisations for the purposes of recruiting women. We have conducted PPI to ensure the study recruitment materials are culturally appropriate.

Routine contacts women have with healthcare professionals during the immediate and extended postpartum period - GP Practices and Early Years Health Services (target about 25% of total sample, approx. 45 women per site – NI, Scotland, Wales, London)

Recruitment will be extended to the GP practice setting for the full trial to make use of the routine contacts women have with healthcare professionals during the immediate and extended postpartum period, as this would be an important avenue for scale-up and implementation of the intervention and also allows targeted recruitment of practices that serve patients from more disadvantaged areas. Women will attend their GP for a 6-8 week postnatal check-up and, if they want to commence contraception, weight will be recorded at this time; the postnatal check-up is recommended by NICE[18] as a key opportunity to discuss weight with women. Women also attend GP surgeries for 'baby clinics' and the childhood immunisation programme at 2, 3, 4 months and 1 year. GP surgeries will be provided with flyers for dissemination at these contact points by surgery staff and a sample text message will be provided to GPs that may be sent to women identified as potentially eligible for the study, and will include research team contact details. Where possible, or desired by the practice, researchers will attend practices. GP practices will also have records of women who have had a baby in the last two years and will have a BMI recorded at the time of referral to the antenatal clinic, and also possibly at the 6-8 week postnatal check-up or if they have co-morbidities e.g. diabetes or gestational diabetes, hypertension.

A search template based on the study eligibility criteria (women who have had a baby in the last 2 years & BMI > 25 kg/m^2, if recorded) will be produced to be applied to GP databases to identify women who may be potentially eligible for the trial and letters will then be sent on GP practice headed paper. Letters *will not* be sent to women whose babies have died or where the GP records indicate another reason why it would not be suitable to send the letter such as complex social issues; this will be at the discretion of the practice clinical team. Response rates to recent letter based approaches in primary care by the NI Primary Care Research Network varied from 10-50% between practices and was 10% in another recent NIHR-funded text message intervention for men in Scotland (Game of Stones).[74]

Primary care research networks in England, Scotland, Wales and Northern Ireland will work with approximately six GP practices serving more disadvantaged areas in each country to identify potentially eligible women and send trial invitation letters.

The invitation letters on GP headed paper will include the study flyer with research team contact details and a pre-paid opt-in card to indicate whether they are interested in receiving further information about the study, and will be sent to eligible lists using Docmail or regular mail.

Participating practices will also be asked to display/make available other trial recruitment materials e.g. posters in waiting areas, business cards that can be left in waiting area or handed over at the end of an appointment with the GP or practice nurse or other primary care contact.

Women will also be signposted to the SMS study via other routine contacts with health professionals such as health visitors, postnatal gestational diabetes clinics and family planning clinics.

Should recruitment be slower than expected, researchers will attend waiting areas (with relevant permissions) during baby immunisation clinics to give out flyers and discuss the study with women; this would not happen in a real-world implementation scenario and so would only be used as a reserve recruitment strategy.

7.1.2 Screening

Women who are potentially interested in taking part in the trial will return the opt-in card included with GP letters or will make contact with the research team via telephone, email or website (or scanning a QR code that takes them directly to an MS Form that allows them to complete their contact details and is stored on QUB secure data systems).

The researchers at each site will contact women who are interested in the study and will provide them with a PIS, privacy notice and copy of the consent form to read either by email if they are happy to share this information or by post. The researchers will make contact with women again after at least 48 hours to discuss the study procedures in more detail and answer any questions the women may have. Following this, women will be asked if they are interested in taking part and, if willing, will be screened by telephone and a screening number will be allocated to the woman. Screening will be guided by, and documented in, a study screening sheet and will be recorded on the NICTU database by the researchers at each site. Women will be asked to self-report their weight and height over the telephone at screening but both will be measured by researchers at the baseline visit to confirm eligibility before written informed consent is obtained and baseline data is collected.

Anonymised information on participants who are not randomised will be collated for Consolidated Standards of Reporting Trials (CONSORT) reporting and for reporting the generalisability of the results[75]:

- age
- gender
- ethnicity

- the reason not eligible for trial participation, or if they are eligible but declined
- where they heard about the study
- Country of residence

Those who do not meet the screening criteria at time of screening may be eligible for rescreening if it is the case that they come forward for screening when their baby is less than 6 weeks old. In this situation, the researcher will ask the woman if they want to be contacted again after their 6 weeks postpartum date and if they do, the researcher will keep a record of their telephone and/or email for rescreening purposes. The researcher will make contact with the woman to arrange rescreening. If a first attempt at contact is unsuccessful, no more than two further attempts to contact will be made.

7.1.3 Payment

Home visits will be the primary approach to data collection but women will also have the option of attending another venue of their choice such as a University building or community venue if they prefer. In the pilot study, 91% of women opted for home visits in the pilot study and women indicated it facilitated their participation in the research. For women who wish to attend a research centre for data collection, receipted travel expenses or mileage will be reimbursed. Women will receive a £25 voucher at each data collection point (0, 6, 12 and 24 months; total £100) in recognition of time taken to complete study assessment.

7.2 Consent

All research staff with delegated responsibility to collect informed consent will be trained and competent to do so according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

Written informed consent will be obtained from women at the baseline visit before any data has been collected. At the baseline visit women will be given the opportunity to ask any further questions they have about the study and the researcher will affirm they want to proceed. Women will be told at each stage that they have the right to refuse participation without giving a reason. Once consented, the participant will also be aware that they have the right to withdraw at any time from the trial without giving a reason. Participants will be made aware in the PIS and consent form that their data up to the point of withdrawal will be used.

Should COVID-19 restrictions preclude collection of written consent, the consent form will be made available online for completion via the Qualtrics platform (privacy notice can be viewed here - https://www.qualtrics.com/privacy-statement/). Baseline data collection will not take place until consent has been provided.

As this is a text-message delivered intervention, women who have insufficient English to understand short written messages will be excluded from the trial.

An audio version of the PIS and privacy notice will be made available on the study website.

To comply with the Welsh Language Act 1993, the PIS and Consent Forms must be translated into Welsh or provided bilingually where this is requested by a participant at a research site.

7.3 The randomisation scheme

Participants will be block randomised and randomisation will be stratified by site. The randomisation sequence will be developed in STATA (using ralloc[76]) by a statistician who is independent of the study team. The randomisation will be implemented via the LSHTM secure remote web-based system which

will link directly with the text message database and will deliver the intervention or control content according to the random allocation sequence. After obtaining informed consent and collection of baseline data, the researcher will register the participant on the LSHTM text message database. Participants will become aware of their group allocation when they start to receive the messages. The researchers collecting outcome data will not have access to this randomisation system and will be blind to treatment group. Participants will be requested not to talk to the researcher about the study or their group allocation, which worked well in the pilot RCT[3].

7.3.1 Method of implementing the randomisation/allocation sequence

The randomisation allocation sequence generated by the independent statistician will be sent directly to the SMS platform manager at LSHTM. The sequence will be implemented via the LSHTM secure remote web-based system which will link directly with the text message database and will deliver the intervention or control content to individual trial participants according to the random allocation sequence.

After obtaining informed consent and collection of baseline data, the researcher will register the participant on the LSHTM text message database inputting first name, telephone number and recruitment site. Participants will become aware of their group allocation when they start to receive the messages. The researchers collecting outcome data *will not have access to* this randomisation system and will be blind to treatment group. Participants will be requested not to talk to the researcher about the study or their group allocation, which worked well in the pilot RCT[3].

7.4 Blinding

Participants will become aware of their group allocation when they start to receive the messages. The researchers collecting outcome data will not have access to the randomisation system and will be blind to treatment group. Participants will be requested not to talk to the researcher about the study or their group allocation, which worked well in the pilot RCT[3]. All statistical analyses will be conducted blinded to group allocation until analyses of the 12 month data point are complete.

7.5 Emergency Unblinding

Given the nature of the intervention, emergency unblinding will not be required.

7.6 Baseline data

Baseline data will be collected after consent is obtained and prior to randomisation. Only information directly relevant to the objectives and outcome measures detailed in the protocol will be collected and these are summarised in Table 1.

All researchers will undergo training in the relevant data collection processes and will follow SOPs to standardise data collection across sites.

Table 1: Measurement of SMS study outcomes

Outcome collected	Measure used	Time point (month)			
		0	6	12	24
Anthropometric measures and Demographics*					
Height (m)	-	✓			
Body weight (kg) (primary endpoint)	-	✓	✓	✓	✓
Waist circumference (cm)	-	✓	✓	✓	✓
Demographic characteristics**	Study-specific questions	✓			
Acceptability outcomes					
Satisfaction with SMS messages¥	Study-specific questions		✓	✓	
Acceptability of intervention, active control and study methods¥	Study-specific questions			✓	
Longer-term use of text messages¥	Study-specific questions				✓
Qualitative interviews	-		✓	✓	
Interviews with stakeholders	-				✓
Economic evaluation - Within trial health and social care cost data¥					
Health service resources use	Questions on health resource usage	✓	✓	✓	✓
Medication usage	Questions on over-the-counter medications	✓	✓	✓	✓
Healthy lifestyle-related costs	Questions on personal expenditure	✓	✓	✓	✓
Exercise-related costs	Questions on costs of exercise	✓	✓	✓	✓
Food and drink costs	Questions on weekly cost of groceries, alcohol and smoking products	✓	✓	✓	✓
Change of employment status	Study-specific questions	✓	✓	✓	✓
Health-related quality of life	EQ-5D-5L[70]	✓	✓	✓	✓
Capability well-being	ICEpop CAPability measure Adults (ICECAP-A)[71]	✓	✓	✓	✓
Secondary outcome measures¥					
Dietary intake	Fat and fibre barometer[77]	✓	✓	✓	✓
Sugar intake	Study-specific questions	✓	✓	✓	✓
Alcohol consumption	Study-specific questions	✓	✓	✓	✓
Physical activity	International Physical Activity Questionnaire (IPAQ) - Short form[78]	✓	✓	✓	✓
Infant feeding	Infant feeding survey[79]	✓	✓	✓	✓
Moderators of intervention effect¥					
Mental health – depression	Edinburgh Postnatal Depression Scale (EPDS)[55]	✓	✓	✓	✓
Mental health - anxiety	Generalised Anxiety Disorder (GAD-7)[56]	✓	✓	✓	✓
Mother and child relationship	Me and My Baby (MaMB)/Me and My Child (MaMC)[58] and Mothers Object Relations Scale (MORS-Baby/Child)[59]	✓	✓	✓	✓
Sleep	Pittsburgh Sleep Quality Index[80]	✓	✓	✓	✓
Confidence/importance/desire for weight loss and maintenance	Study-specific questions	✓	✓	✓	✓
Mediators of intervention effect¥					
Intention and self-efficacy for diet and physical activity	Health Action Process Approach (HAPA) including action and coping planning and self-efficacy [81,88]	✓	✓	✓	✓
Habit behaviour	Self-report behavioural automaticity index[83]	✓	✓	✓	✓
Self-regulation of eating behaviour	Self-regulation of eating behaviour questionnaire[84]	✓	✓	✓	✓
Weight self-monitoring	Study-specific questions	✓	✓	✓	✓
Diet and exercise monitoring	Study-specific questions	✓	✓	✓	✓
Goal-setting for diet and exercise	Study-specific questions	✓	✓	✓	✓
Weight loss motivation	Motivation for weight loss scale[85]	✓	✓	✓	✓

Taking part in other weight loss programme	Study-specific questions	✓	✓	✓	✓
Social support	Social support for eating & exercise[86] plus general social support (BiB study-specific questions)	✓	✓	✓	✓
Self-esteem	Rosenberg Self-Esteem Scale[87]	✓	✓	✓	✓

*Recorded in case report form (CRF)

**Date of birth, where they heard about the study, NHS number, ethnicity, income, employment, education, relationship status, weeks postpartum at study entry, parity, medical information (disability status, medication use), infant feeding, weight history, smoking status, alcohol intake, technology usage

¥Recorded in questionnaire booklet

7.7 Trial assessments

Trial assessments are based on our successful pilot RCT[3] and are summarised in Table 2. Assessments will take place at baseline (start of intervention), 6 months, 12 months (end of intervention period and 24 months (12 months after intervention stops) unless otherwise indicated.

Researchers will visit women in their homes (or another venue of their choice such as a University building or community venue if they prefer) for collection of outcome measures. The home visits are important to overcome previous issues with follow-up in postpartum trials and proved to be successful in our pilot study[3]; 91% of study assessments in the pilot were home visits and women commented in qualitative interviews that the home visits enabled their participation in the research at this busy stage of their lives and removed barriers to participating e.g. childcare.

Anthropometric data will be collected using standardised protocols and calibrated scales. To maximise data completeness for weight at 12 months (primary endpoint) and 24 months, when attempts to arrange a face-to-face visit with a researcher have been unsuccessful, participants will be asked to provide a self-reported weight via email, text or phone. Such data will be clearly labelled as self-reported rather than researcher-measured in the CRF and considered in the analysis as described in the Statistical Analysis Plan (section 10.3).

Hard copy questionnaires worked well in the pilot trial but women will also have the option of completing the questionnaires online using a user friendly tool called Qualtrics. Either way, questionnaires can be completed by women in one sitting or in smaller blocks of time according to their personal circumstances which was valued by women in the pilot RCT[3]. Researchers will provide assistance with completion of questionnaires if required for less literate participants either at the visit or via telephone (method of completion – hard copy/online via Qualtrics/with researcher (in-person or via telephone) will be noted in study CRF). In the pilot RCT[3], women felt that the questionnaire booklet was clear and easy to complete, taking between 20 to 30 minutes.

As per the pilot study, to maximise completion of study assessments at each study time point, all participants (intervention and control group) will be offered a voucher as a token of appreciation for the measurement time commitment at each assessment point (£25 per data assessment point 0, 6, 12 and 24 months; £100 maximum over 24 months). Women will be sent the voucher once questionnaires are returned/completed, as per the pilot study.

Qualitative data collection will be in the form of telephone interviews for women and stakeholders as described in section 7.9 below.

Should restrictions relating to COVID-19 be in place, these approaches will be modified as shown in Table 2 below.

Table 2: Overview of researcher administered measures collected at the baseline and follow-up study visits along with possible modifications related to COVID-19 restrictions

	Time point (months)				Place of assessment without COVID-19 restrictions	Possible modification depending on level of COVID-19 restrictions
	0	6	12	24		
Height (m)	✓				At home visit*	Doorstep visit** rather than entering the home or self-report
Weight (kg) (primary outcome)	✓	✓	✓	✓	At home visit*	Doorstep visit** rather than entering the home or, if no contact permitted, provide Bluetooth scales and video call via safe online platform supported by participating institutions such as MS Teams.
Waist circumference (cm)	✓	✓	✓	✓	At home visit*	Doorstep visit** rather than entering the home or, if no contact permitted, provide flexible measuring tape and instructions for self-report
Demographic questionnaire	✓				At home visit*	Via telephone with researcher
Questionnaire booklet	✓	✓	✓	✓	At home visit* after measurements taken, hard copy of questionnaire left for completion and return by post (postage paid)	Post hard copy of questionnaire for completion and return by post (postage paid)
					Online - qualtrics	No modification needed
					Via telephone with researcher	No modification needed
Telephone interview		✓	✓		Telephone	No modification needed

*Or women will have the option of attending another venue of their choice such as a University building or community venue if they prefer

**Or women will have the option of attending another venue of their choice such as a University building or community venue if they prefer and permissible based on COVID-19 restrictions

7.8 Long term follow-up assessments

Written informed consent will be obtained from all participants at baseline. This will include a request to consent to future data linkage to routinely collected health records for long term health outcomes for

participants and their youngest baby (at the time of signing up to the study). This long-term linkage to routine data is not part of the timeline of the current study.

We will also seek permission to agree to being contacted at a later date and invited to take part in future studies of a similar nature on the understanding that this is only agreeing to receive information and does not place the individual under any obligation to take part in any future studies of a similar nature.

7.9 Qualitative assessments

Qualitative research will be undertaken to assess participants' views as part of the trial process evaluation and to inform implementation. These will take place at 6 as well as 12 months in order to explore how the intervention is being received across the four countries and with a more ethnically diverse sample and to explore reasons for non-response (i.e. not engaging with the interactive text messages, not losing weight or not completing trial outcome assessments).

Interviews with women: At baseline, women will be asked to provide optional consent to be invited for a telephone interview at 6 and 12 months. For women who agree to be contacted and are happy to participate, we will confirm their consent at the start of the interview to the interview being audio-recorded and to the use of anonymised quotations in publications. The opt-in semi-structured telephone interviews will be conducted with a sample of approximately 50 women at each time point by a researcher who will not have had any prior contact with participants. Participants will be purposively sampled according to study site, randomised group (equal numbers of intervention and control), stage postpartum, parity, ethnicity, SES, engagement with the two-way text messages (intervention group), PMH (as measured in the baseline questionnaires) and weight loss; to gather a range of views in relation to participants' experiences. Building on the pilot work which focused on views within a Northern Ireland context, the interview sampling will aim to achieve ethnic, geographic and socio-demographic diversity. We will also aim to gather some brief information where possible from women who stop the messages or withdraw from the study for a reason other than pregnancy by asking them to provide a reason at the time they withdraw via telephone or via text message (e.g. "Thank you for letting us know you no longer wish to take part in the Supporting MumS study. We will stop the messages, delete your personal information and you will receive no further communication from us. It would be very helpful if you could please tell us the reason you no longer wish to continue by replying to this message. Thank you, the Supporting MumS team."). This will help us to establish their views of the messages they received and reasons for discontinuing.

Interviews at 6 and 12 months will explore women's views of the text messages they received and contextual factors related to engagement with messages related to weight loss (6 month interviews) and weight loss maintenance (12 month interviews), including barriers and facilitators of behaviour change and what elements were considered helpful/unhelpful. We will explore perceived benefits and unintended consequences of the intervention on health or wellbeing, including gathering participants' views in relation to the theoretical mediators of change as well as the interaction between PMH and intervention engagement/outcomes. Discussions about PMH will be explored to understand support received in the past and further support needed, to inform future service provision. We will gather participants' suggestions for further refinement of the intervention for implementation purposes. Interview guides will be informed by the underlying theoretical basis for the intervention, the pilot study interview guide, the CICI (context and implementation of complex interventions) Framework for implementation[88] and the New South Wales Ministry of Health Public Health Research and Practice (PHRP) guide to scaling up population health interventions[89].

For women who would prefer to conduct the interviews in a language other than English because they feel they would be better able to fully express their views, a translator will be used.

We will use an iterative process for data collection and analysis whereby findings from early interviews will be incorporated as topics to explore in subsequent interviews. Interviews will continue until it is

determined that 'information power' has been achieved[90]. Telephone interviews will be audio-recorded, transcribed verbatim (using pseudonyms) and checked by the researcher. We will employ thematic analysis techniques[91] which seek to identify and classify the content of qualitative data, to explore patterns and differences across accounts and allowing for the discovery of unexpected concepts in participants' accounts, with the aim of providing explanatory conclusions clustered around themes. The transcripts will be coded then collated into themes and sub-themes according to conceptual similarity of codes. Agreement on concepts and coding will be sought between members of the research team throughout the analysis process to ensure reliability. A proportion of the data (20%) will be coded by two different team members to check for inter-coder reliability. Thematic analysis will be supported by qualitative analysis software (NVivo).

Stakeholder interviews: If the intervention is shown to be effective at 12 months, stakeholder interviews will be conducted to explore factors relevant to implementation including possible facilitators and barriers to wider implementation and scale-up and any further work that is needed to develop a coherent implementation model. The interview guide will be informed by the CICI Framework for implementation[88] and the New South Wales Ministry of Health PHRP guide to scaling up population health interventions[89]. Stakeholders will be identified from research team and TSC networks and we will target stakeholders from across the four UK countries.

We will follow triangulation protocols[92-94] to combine quantitative and qualitative findings at the interpretation stage in order to inform the trial process evaluation and implementation strategies.

7.10 Withdrawal criteria

As part of the informed consent process, women will be assured that they retain the right to withdraw consent for participation in any aspect of the trial at any time and do not have to give a reason for doing so.

If participants are willing to provide a reason for their withdrawal, it will be documented in the CRF. We will ask women who stop the messages or withdraw from the study for a reason other than pregnancy about this at the time they withdraw via telephone or via text message (e.g. "Thank you for letting us know you no longer wish to take part in the Supporting MumS study. We will stop the messages, delete your personal information and you will receive no further communication from us. It would be very helpful if you could please tell us the reason you no longer wish to continue by replying to this message. Thank you, the Supporting MumS team."). This will help us to establish their views of the messages they received and reasons for discontinuing.

Participants can text 'STOP' at any time to stop receiving the text messages. In this case, participants who stop the text messages will still be contacted for follow-up assessments and so will remain in the study.

Participants will be classified as withdrawn from the study and so 'discontinued intervention' on the trial flow chart (section vi) if:

- They request withdrawal from the study
- They become pregnant - If a participant becomes pregnant during the trial they will not be able to continue and so will not continue with study assessments but will contribute data prior to their pregnancy date including data from the SMS platform. Participants who become pregnant will be given the option of continuing to receive the text messages for their own information as they may be useful to them after pregnancy on the understanding that the content of the Supporting MumS text messages has not been designed specifically for pregnant women. They will be advised that they should follow dietary and physical activity guidance for pregnancy, such as that provided by the NHS, and consult their general practitioner if they have any concerns or queries. This decision will be recorded on the SMS study pregnancy form and logged in the CRF.

Participants will be classified as lost to follow-up if:

- They are contacted for follow-up but do not attend study visits or provide any follow-up data

Any data collected up to the point of withdrawal will be retained for analysis unless the participant specifically requests otherwise.

A trial withdrawal form is included in the CRF and will be completed for any participant who withdraws.

Participants who withdraw or become pregnant will not be replaced unless the loss to follow-up or pregnancy rate by the 6 month time point exceeds the level observed in the pilot RCT[3]; a pregnancy rate of 15% (as observed in the pilot RCT) and a loss to follow-up rate of 15% (12% loss to follow-up was experienced in the pilot RCT) has been factored into the sample size calculation. The Trial Manager will collate and report this data at PMT meetings and a course of action would be discussed and agreed with the TSC to address this should the need arise.

7.11 End of trial

The end of follow-up will be the last data collection point of the last participant in the trial.

The end of the trial is the end of the funding period.

The end of the trial will be reported to the Sponsor and REC within 90 days by submitting a 'Declaration of the end of study form', or 15 days if the trial is terminated prematurely. If terminated prematurely, the Investigators will inform participants. A summary report of the trial will be provided to the Sponsor and REC within one year of the end of the trial. The status of the trial will be updated on the clinical trials register and the end of study declaration and all related correspondence will be retained in the Trial Master File (TMF).

8 DESCRIPTION OF INTERVENTION AND CONTROL

8.1 Control

An active control, as used successfully in the txt2stop trial,[95] was developed for the pilot RCT[3]. Previous weight loss trials with postpartum women have been compromised by high levels of attrition in general, and by differential attrition.[14,42,96] For example, the WeighWell feasibility study[42] which employed a 'usual care' control group demonstrated differential attrition rates between the intervention and control groups in a postpartum weight loss intervention with women from areas of social disadvantage in the UK. Providing an active control offers an opportunity to create equipoise and enhance satisfaction with randomisation. In the pilot RCT[3], although many women in the active control group indicated an initial preference for the intervention group, satisfaction with the active control was high and similar to those reported for the intervention: 80-90% of participants were either 'very satisfied' or 'mostly satisfied' at 3, 6 9 and 12 month follow-up, and less than 3% (one participant) reported being 'mostly dissatisfied' or 'very dissatisfied' with the active control messages. Receiving text messages related to child health and development was perceived as beneficial and participants said that they would recommend the active control to other mothers. A few participants in the active control group, who initially signed up to the study with an interest in receiving weight management advice, had a change in attitude as a result of how beneficial they were finding the receipt of text messages related to child health and development. The use of the active control is likely to have contributed to the high participant retention noted during the pilot RCT[3] (retention at 12 months = 86% intervention, 91% control group) and will be used in this trial. As for the intervention messages, the active control messages were developed by the study team with PPI input (see final report[3]). The messages relate to general child care and development and the content was consistent with evidence based information provided by the NHS Start4life information service for parents[97] and includes a play idea/activity each week and information on specific milestones,

home safety, separation anxiety and similar topics. The active control does not mention the target behaviours and does not contain the active ingredients of the intervention (diet and physical activity content and embedded BCTs related to weight loss). There is no bi-directional functionality for the active control messages. Given the study inclusion criteria, the active control messages were developed for mothers with babies from six weeks of age or older (women have to be at least six weeks postpartum to enrol in the study) up to 36 months of age (as women can opt in at any stage up to 24 months postpartum). Women will receive three messages each week for the 12 month intervention period and messages correspond to the age of their baby, i.e. if their baby is six months old when they enrol, they start receiving messages corresponding to this age. The duration of the trial (2 years) means a wait-list approach would not have been a viable alternative. The control group will be offered the opportunity to receive a summary of the intervention text messages on completion of the trial, if they desire.

8.2 Intervention

The intervention group will receive an automated text message intervention about weight loss and maintenance of weight loss for 12 months – full details of the development of the intervention are given in our NIHR final report[3]. The evidence and theory-based intervention consists of a library of text messages focused on diet and physical activity with embedded BCTs known to be positively associated with weight management. Fully automated messages include uni- and bi-directional messages and interactive features as described in brief below (according to the Template for Intervention Description and Replication; TIDieR[98])

8.2.1 Why: Rationale, theory and goal of elements essential to the intervention

The intervention is based on the Health Action Process Approach (HAPA)[99] and a systematic review of over 100 behavioural theories which synthesised theoretical explanations for maintenance of behaviour change.[100] Overall, the intervention was designed to encourage a self-guided approach to lifestyle behaviour change and weight management as supported by the literature.[101-105] In-line with existing evidence, the intervention focused on dietary intake as well as physical activity to address energy balance with BCTs supported by an evidence base and specifically linked to the relevant phases and psychological processes of behaviour change embedded within the text messages alongside specific consideration of barriers for this group (full details can be found in the final report[3]). The messages aimed to adopt a friendly accessible tone including humour to encourage engagement; provide information, advice, practical tips and signpost to external resources; provide encouragement and motivation, discourage guilt and encourage self-reflection. A core library of text messages was created with additional components:

(i) Messages addressing other weight-related behaviours (smoking and breastfeeding): In addition to the core text messages, women can also opt-in when they register for the intervention to receive messages related to weight management when breastfeeding (n=10) or trying to stop smoking (n=15). The text messages were created to alleviate participant fears or concerns in relation to weight management whilst breastfeeding and to address vulnerabilities around weight gain during smoking cessation.
(ii) A weekly text message asking women to report weight (n=50)
(iii) Bi-directional messages (encourage engagement, self-monitoring, prevent relapses and allow provision of feedback.) – “Yes/No” questions which trigger an automated response to the participant based on their reply as do trigger words designed to address barriers, deal with slip-ups and prevent relapses. Women can text trigger words (‘slip-up’; ‘crave; ‘bad day’ or ‘tired’) at any time and will receive a reply from a bank of messages. During months 7-12, when the focus shifts to maintenance strategies, the weekly message reminding women to weigh themselves asks them to text back their weight and ‘up’ or ‘down’ or ‘same’ in relation to how they did last week which triggers an automated

response. Automated responses for these bi-directional messages are sent from a bank of messages that is uploaded to the text message platform; responses are not individually scripted or tailored.

8.2.2 What (materials and procedures): Physical or informational materials used in intervention delivery

The intervention consists of 353 core messages, i.e. messages that are delivered by the system to all intervention group participants. The number of messages sent during the first six months starts at a rate of 14-15 per week and is tapered to 9-10 per week. Fewer messages, 4-5 per week, are sent in the weight loss maintenance phase (months 7-12) as the emphasis in this phase is on reinforcing self-regulation techniques developed during the first six months of the intervention, focusing more on maintenance relevant strategies such as relapse prevention and dealing with slip-ups.

Timing of text messages: Participants choose the time of day they prefer to get messages and also what time of day they want to be kept message free e.g. 7pm to 7am. Messages are programmed to arrive at different times to avoid predictability. The message asking participants to weigh themselves is always sent on the same day of the week.
Social support: Social support is facilitated throughout the intervention using a buddy system (as used previously in txt2stop)[95] where a participant can nominate a friend or family member to receive the same messages they are receiving and so be in a better position to provide support to them. Participants are sent the instructions on how to do this within the messages and can request a friend/ family buddy at any stage and reminders of this facility are sent throughout the intervention period. Messages are also sent to participants to tell them about the value that support can play in weight loss success.

8.2.3 Who provided/Intervention provider

Intervention costs will be provided by the Northern Ireland Public Health Agency. The intervention will be completely automated using LSHTM's existing text message platform as used in our pilot study. The intervention package is designed so that the text message library can be readily delivered by other text message providers to facilitate future roll out by the NHS or public services.

8.2.4 How - mode of delivery

The exchange of messages with participants will be via a secure server at the LSHTM.

8.2.5 Where intervention will occur – setting

The intervention will occur anyplace, anytime.

8.2.6 When and how much (period of time, number of sessions, schedule, duration, intensity of dose)

The number of messages sent varies throughout the 12 month intervention: months 1 and 2: 14-15/week; months 3 and 4: 9-10/week; months 5 and 6: 9-10/week; months 7 to 12: 4-5/week. Participants can text the word STOP at any time if they no longer want to receive the messages (in that event they would still continue in the study unless they also formally withdrew from the study assessments); or they can text the word PAUSE if they want to pause the messages for a period of time.

9 ADVERSE EVENTS

Reporting and managing adverse events will be conducted in accordance with the Sponsor's SOP.

9.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom the intervention has been delivered, including occurrences which are not necessarily caused by or related to the intervention.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • requires medical or surgical intervention in order to prevent permanent damage or impairment of a body function. Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

This is a low risk lifestyle change intervention designed to support weight loss. Given the nature of the intervention, adverse events related to weight management are well known and will not be collected in this trial.

Serious adverse events will be recorded and reported in accordance with the Good Clinical Practice (GCP) guidelines and the Sponsor's SOP on 'Reporting and Managing Research Related Adverse Events'.

9.2 Operational definitions for SAEs

- A SAE is defined as detailed in 9.1 above.
- SAEs will be recorded by researchers at each site within the CRF from the time a participant consents to join the study until the end of the 12 month intervention period (up to one month after).
- Hospitalisations for treatment planned prior to randomisation and routine hospitalisation for elective treatment will **not** be considered or recorded or reported. Complications occurring during such hospitalisation will also not be considered, recorded or reported.
- Any death that occurs during the trial is very unlikely to be related, but all cause of deaths will be documented and relatedness determined. All deaths will be reported immediately to the site team

so that no further correspondence is sent to the participant and the messages will be stopped.

9.3 Detecting, recording and reporting of AEs/SAEs

There are no expected SAEs given the very low risk nature of the intervention. Participants will be monitored for SAEs from the time of consent until one month after they have finished receiving the 12 month intervention.

At each contact with a participant during the intervention delivery period (6 and12 month follow-up visits), the researcher will ask a general open question about the occurrence of SAEs. Participants will also be advised to report the occurrence of SAEs to the researcher anytime outside of the follow-up visits. Any information disclosed will be recorded in the CRF and entered into the NICTU database within 72 hours (3 days) of the event being identified.

If any event is reported, the researcher will inform the site PI directly within 24 hours of collection. The site PI will review the reported event and make an evaluation of severity, causality and expectedness (as per the criteria below) and will record this assessment within the CRF. If deemed to be related and unexpected, the site PI will inform the CI or medically qualified delegate who will review the event information within 72 hours (3 days) of the PI assessment.

SAEs categorised as related and unexpected by the PI and CI will be reported to Sponsor by the CI or Trial Manager within 24 hours of the CI (or medically qualified delegate) confirmation. The CI will report any related and unexpected SAEs to the REC using the relevant safety report form within 15 days of the event being identified.

The CI for all QUB sponsored studies is responsible for ensuring that SAEs are reported to the Sponsor, to the REC, or to other relevant organisations.

All SAEs that have occurred during the preceding 12 months will be included in the annual report to the REC.

SAEs will be reported at meetings of the PMT and TSC under participant safety which will be a standing item on the agenda.

Severity	• Mild: An event that is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities. • Moderate: An event that is sufficiently discomforting to interfere with normal everyday activities. • Severe: An event that prevents normal everyday activities.
Causality	• Related: An event that resulted from administration of any of the research procedures • Unrelated: An event that is not considered to be related to any of the research procedures
Expectedness	• Unexpected – The type of event is not listed in the protocol as an expected occurrence • Expected – The type of event that is listed in the protocol as an expected occurrence

10 STATISTICS AND DATA ANALYSIS

A Statistical Analysis Plan, Health Economics Analysis Plan and Process Evaluation Analysis Plan will be written and approved by the Project Management Team and Trial Steering Committee prior to analysis. Trial results will be reported in accordance with the CONSORT guidelines[75].

10.1 Sample size calculation

In the pilot RCT[3], between baseline and 12 months, the intervention group lost on average 1.75 kg whereas the active control group gained 0.19 kg [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)]. Based on pilot RCT[3] data from the active control group for mean weight change from baseline to 12 months (SD of the change from baseline to 12 months of 7.5 kg), 594 completing participants (297 participants in each group) gives the study over 90% power to detect a statistically significant difference of 2kg, at the 5% level, in the mean weight change from baseline, between the intervention and active control groups. This mean difference of 2 kg is accepted as being associated with metabolic health benefits and is frequently used to power weight loss studies[106].

In the pilot RCT[3] a pregnancy rate of 15% was observed. In a more ethnically diverse sample it is anticipated the pregnancy rate could be higher, for example, in the BiBBS cohort, 22% of the South Asian population have a second pregnancy within two years.

Therefore, accounting for a loss to follow-up rate of 15% (12% loss to follow-up was experienced in the pilot RCT[3]) and pregnancy rate, in order to have 119 participants completing at each site (594 participants in total), the following will be recruited at each site:

NI, Scotland and Wales: 15% Pregnancy rate + 15% loss to follow-up = recruit 170 women to have 119 completing;

Bradford and London: 22% Pregnancy rate + 15% loss to follow-up = recruit 189 women to have 119 completing.

The proposed total sample size for this multi-site full RCT therefore would be 444 participants in each of the intervention and active control groups, with a total sample size of 888 women.

10.2 Planned recruitment rate

The recruitment period for the trial is based on the rate of recruitment in the pilot RCT[3]. The trial aims to recruit 888 women over a 12 month period at a rate of approximately 74 women per month, with NI, Scotland and Wales sites aiming to recruit 170 women across the recruitment period, and Bradford and London aiming to recruit 189 women.

10.3 Statistical analysis plan

A statistical analysis plan will be prepared, aligned with best practice[107].

10.3.1 Summary of baseline data and flow of participants

Flow of participants through the trial will be summarised in a Consort flow diagram (http://www.consort-statement.org/).[75]

Tables of baseline characteristics (variables will be specified in the SAP) by group will be presented, including summary statistics for continuous variables and frequencies for categorical variables. These tables will be repeated including only individuals who contribute to the primary analysis[108].

10.3.2 Primary outcome analysis

In the primary analysis, weight (in kg) at 12 months will be compared, on an intention to treat basis, between the intervention and control group, using analysis of covariance to adjust for weight at baseline[109] and additionally adjusting for site, recruitment method (community vs GP) and ethnicity. The adjusted difference in mean between the intervention and control group, and corresponding 95% CIs and P-value, will be reported. A complete-case approach will be used for the primary analysis as based upon the pilot for we anticipate only around 10% will have missing weight data at baseline or 12 months. Sensitivity analysis will be conducted to 1) include participant self-reported weight (only where researcher-measured weight is not available) to assess the impact on the primary outcome analysis and 2) using last observation carried forward, using multiple imputation to impute missing outcome values and using δ-based methods[110] to explore the impact of worse or better outcomes in the individuals with missing data.

An independent TSC will assess the primary outcome at 12 months and discuss with NIHR if clinically significant weight loss has been achieved in order to determine progression to stage 3. A further analysis will be conducted at 24 months, if the trial proceeds to 24 months and the primary analysis at 12 months is convincing, despite the sequential nature of this comparison we do not intend to change the significance level because this test is a secondary analysis.

All testing will be done at the two-sided 5% significance level. All analysis will be conducted using STATA software (Statcorp, USA). All statistical analyses will be conducted blinded to group allocation until analyses of the 12 month data point are complete.

10.3.3 Secondary outcome analysis

Similar analyses will be conducted for secondary continuous outcomes and for secondary analyses of outcomes at other time points. Secondary analysis of binary outcomes will be conducted using logistic regression to compare the intervention and control group whilst adjusting for site, recruitment method and ethnicity. Adjusted odds ratios and 95% CIs, and corresponding P-values will be reported. The interpretation of these secondary analyses will be considered exploratory and hence the P-values will not be altered for multiple testing. The focus of all secondary analysis will be on estimating the between groups with 95% confidence intervals rather than hypothesis testing.

10.4 Subgroup analyses

To understand if there are differential effects of the intervention,[111] subgroup analyses will be conducted stratifying by pre-specified variables including site, SES, ethnicity, recruitment method, weeks postpartum (at study entry), BMI (at study entry), parity, mental health and sleep duration/quality. Interaction tests will be conducted, separately, by including interaction terms within analysis of covariance regression models[75]. The significance level for subgroup analyses will not be reduced but will be interpreted cautiously and, as recommended, all subgroup analyses mentioned above will be reported.[112]

10.5 Adjusted analysis

As described above the primary analysis will be an adjusted analysis. Specifically, weight (in kg) at 12 months will be compared, between the intervention and control group, using analysis of covariance to adjust for weight at baseline[109] and additionally adjusting for site, recruitment method (community vs GP) and ethnicity.

10.6 Interim analysis and criteria for the premature termination of the trial

As this is a very low risk lifestyle behaviour change intervention, a DMC will not be convened and there will be no interim analysis. No evidence of harm has been reported in text message studies for other health behaviours or in our pilot RCT [3]. Data on adverse events, as detailed in section 9 of the protocol, will be reported to the TSC. Participant safety will be a standing item on the TSC agenda.

10.7 Participant population

The primary analysis of weight (in kg) at 12 months will be compared between the intervention and control group on an intention to treat basis (i.e. all participants, as randomised). In this primary analysis all participants randomised who provided a weight measurement at baseline and 12 months will be included regardless of whether or not they engaged with the text messages. This intention to treat analysis could be impacted by missing data but we anticipate, from the pilot study, only around 10% of participants will have missing weight data at baseline or 12 months and, if so, the primary analysis will be based upon a complete case. A number of sensitivity analyses will be conducted subject to different assumptions concerning the missing data as described below. A separate analysis will be conducted comparing the primary outcome in individuals who engaged with the two-way texts with those who did not engage, restricted to the intervention group

10.8 Procedure(s) to account for missing or spurious data

A complete-case approach will be used for the primary analysis as based upon the pilot for we anticipate only around 10% will have missing weight data at baseline or 12 months. Sensitivity analysis will be conducted to 1) include participant self-reported weight (only where researcher-measured weight is not available) to assess the impact on the primary outcome analysis and 2) using last observation carried forward, using multiple imputation to impute missing outcome values and using δ-based methods (using a range of δ values, including 10%, 25% and 50% of the observed change in all participants)[110] to explore the impact of worse or better outcomes in the individuals with missing data.

10.9 Other statistical considerations.

If criteria are not met for progression to Stage 3 (24 month follow-up and interviews with stakeholders), any 24 month follow-up data that has been collected (as some participants may already have completed 24 month follow-up) will be analysed.

Any deviations from the original Statistical Analysis Plan will be described and justified in trial outputs.

In line with the MRC guidance on process evaluation[72] and based on the underlying theoretical models (i.e. HAPA and the maintenance model) mediation analysis will examine the casual assumptions underlying the intervention effects.

10.10 Economic evaluation

The within trial economic evaluation will build directly on the methods and instruments successfully used in the pilot economic evaluation including the identification, measurement and valuation of resource use and expenditure and quality of life/capability wellbeing. Resource use measured will include: GP visits, hospitalisations, prescription and over the counter medicines, expenditure on lifestyle products and services, weekly cost of groceries, alcohol and smoking products. Health economic outcomes will include health related quality of life captured using the EQ-5D-5L[70] instrument, including visual analogue scale (www.euroqol.org) and capability wellbeing measured ICECAP-A[71] In line with the UK's NICE guidance for public health economic evaluations[111] the economic evaluation will be conducted from a UK NHS and personal social services perspective with the addition of a societal perspective applied to capture broader impacts. Within the direct costs to the health care system, the costs for implementation of the intervention and any follow-up service use costs will be included. These health and personal perspectives will be assessed to investigate a broader impact of the intervention, including direct cost to participants and indirect costs. Both costs and health outcomes will be discounted at the same annual rate of 1.5% for the reference case, as recommended by NICE public health methods guidelines. The assessment of cost and outcomes in economic evaluation will be conducted at baseline, 6, 12 and 24 months. The economic analysis will use a 'multi-pronged' approach. The total and mean per-participant costs for the intervention and control group will be calculated (incorporating the costs of implementing and delivery of the intervention). Incorporation of the development costs will be included within a sensitivity analysis. Regression analysis will be used to control for differences in participant characteristics, socio-demographic circumstances and baseline health (EQ-5D-5L). This will allow for identification of skewed data and the estimation of the average cost per participant and the average quality-adjusted life year (QALY) achieved (intervention and control group). A cost-utility analysis (CUA) will report cost per QALY gained over the 24-month period using the area under the curve (AUC) approach.[112] Results will be presented on the cost effectiveness plane (to clearly illustrate differences in costs and effects between different interventions) and 95% CIs for the incremental cost-effectiveness ratio (ICER) will be determined.[113] Joint uncertainty in costs and outcomes will be represented using a cost-effectiveness acceptability curve (CEAC) to present the probability of SMS intervention being cost effective for given prevailing UK ceiling thresholds for costs per QALY gained.[114] A cost-effectiveness analysis (CEA) will align with the primary outcome measure of the main trial, by examining differences in weight and BMI and total costs between the intervention and control group, the incremental cost per weight gain averted will be calculated. The mean costs and effects for each arm of the intervention will be calculated and presented along with the incremental costs and effects between arms (including 95% CIs).

The within trial economic analysis will be carried out for 24 months follow up and will form the primary analysis. However, as this short time horizon may be insufficient to capture the total costs and benefits related to the intervention and only if differences in quality of life or capability wellbeing are identified the results will be extrapolated to a lifetime horizon using modelling methods (including the possibility of adapting currently existing models).

11 DATA COLLECTION AND MANAGEMENT

Only data required by the protocol will be collected.

11.1 Data collection tools and source document identification

The source documents are as follows:

- Contact details form – detailing contact details for each participant including participant study ID and preferred mode of contact, to be kept separate from all other study documentation.

- the CRF (case report form) hard copy which records measurement data at each time point as well as other study visit data completed by the researcher including – date, time and location of visit, if a letter to GP is required in relation to EPDS, baseline demographics (see Table 1) and participant measurements (height, weight, waist circumference), mode of completion of trial questionnaire (hard copy/online via Qualtrics/with researcher (in-person or via telephone), serious adverse events, any notes regarding questionnaire completion, date CRF data entered into trial database and by who, and end of trial/early withdrawal form (and reason for withdrawal if known).
- the trial questionnaire which can be completed either in hard copy or electronically on Qualtrics. The source document will either be the hard copy or the Qualtrics record depending on mode of completion. Qualtrics survey software is stored on EU based servers and is compliant with EU GDPR. When all data has been collected, it will be exported by the researcher into password-protected files stored on a computer which is password protected and backed up daily. When all analysis has been completed and checked by the research team, the data will be permanently deleted from Qualtrics.
- to assess engagement with the two-way text messages - replies to the text messages downloaded from the London School of Hygiene and Tropical Medicine text message platform.

To maximise completeness of data, researchers will contact participants (telephone/ email/ text message) to arrange visits, to remind participants about study visits, to attempt to collect self-reported weight from participants who are unable to complete study visits at 12 and 24 months, to follow-up on any questionnaires that have not been returned and to follow-up on any missing data within the questionnaire when it is returned. The data collection tools are summarised in Table 2.

The consent form and contact details collected from women at baseline will be securely stored separate from all other data (questionnaires and case report forms) in locked filing cabinets in locked offices in buildings that have keypad access and are alarmed outside normal working hours. Electronic or digital copies of this information will be held on password protected files held on secure servers that are routinely backed up and require username and password and/or multi-factor authentication to access.

The data captured by the study questionnaires and case report forms (CRF) will be entered and stored in a database that is built and managed by the Northern Ireland Clinical Trials Unit (NICTU). Only designated research team members will have password-protected access. Should women wish to complete the questionnaire online this will be done using the Qualtrics platform which will be set-up and managed by the Trial Manager at QUB. If any questionnaire data is collected offline in the field on encrypted portable devices such as tablets or laptops, it will be uploaded to the Qualtrics secure server within 24 hours of collection. CRF data will be entered into the NICTU trial database by researchers at each site. At the end of the trial, hard copies of CRFs will be archived by sites. Hard copy trial questionnaires will be scanned at the collection site and originals will be posted in batches to the NICTU for data entry.

Scanned source documents will be retained in password protected electronic files stored on secure servers that are routinely backed up and require username and password and/or multi-factor authentication to access.

The NICTU will retain original hard copies of all source documents they receive for data entry in locked filing cabinets in locked offices in keypad entry buildings that are alarmed outside of normal working hours and these will be archived and retained at the end of the trial in accordance with the Sponsors requirements.

Electronic source files from Qualtrics will be downloaded weekly by the Trial Manager and stored securely to be merged with the NICTU secure trial database by the Trial Statistician, Professor Chris Cardwell, QUB.

Data from qualitative interviews will be anonymised by removing any information which could potentially identify the participant. Only interview transcribers who are approved by the sites and meet confidential data handling requirements will be used. Each participant will have a unique participant study ID. The interview recordings, transcriptions and NVivo database will be password protected and encrypted and stored securely as for other files. When transcripts have been prepared and checked for accuracy, the recordings will be deleted.

Any file transfer between sites and QUB will be done via the QUB Dropoff file transfer facility. QUB Dropbox ensures all files transferred across the network are securely encrypted. Retrieval of a drop-off by a recipient can only be done by the recipient entering the drop-off's Claim ID and Passcode. The Passcode is not stored on Dropoff and cannot be recovered if lost. No one can access the files without it. All files uploaded and temporarily stored on Dropoff are held on equipment owned and operated at the University's own Data Centre. All data is subject to the Data Protection regulations and laws of the University and the country. Dropoff is in no way a "cloud" service. Everything is stored (even temporarily) on equipment directly owned by the University, and managed by its own IT staff. All access to data is very tightly and strictly controlled by the University. All accesses to data on Dropoff are logged and can be easily checked if you are ever concerned that a 3rd party might have gained access to your data. Furthermore, uploaded data is only held on Dropoff for a maximum of 14 days, after which time it is automatically deleted. There is no "undelete" facility available. No backups are taken of the uploaded data (it is only a transitory stopping point), so no uploaded data ever moves off Dropoff itself onto other equipment or media such as backup tapes. After an uploaded file has been deleted, there is no way of recovering the file.

11.2 Data management

Following the entry of participant data into the study database, the data will be processed as per the study specific Data Management Plan (DMP). Data queries will be generated electronically for site staff to clarify data or provide missing information. The designated site staff will be required to respond to these queries. All queries will be responded to or resolved within the study database and amended in the study database.

11.3 Access to Data

Direct access to all trial records and source documents will be granted to authorised representatives from the Sponsor (or delegate), representatives of the REC, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections in-line with participant consent.

Only members of the research team employed on the study will have access to the personal/sensitive data of participants. Trial data will only be shared with those responsible for the healthcare of the participants such as their GP for the purposes of informing the GP about an EPDS greater than nine.

At the end of the trial, the Trial Manager, trial statistician and health economist will have access to the anonymised dataset to permit analysis.

The Chief Investigator will manage access rights to the trial data set in collaboration with the sponsor. Any transfer of data to other institutions will be governed by a Data Access Agreement and will be in the form of an anonymised dataset.

11.4 Archiving

Study documentation will be kept for 10 years after end of trial/publication of data in-line with requirements of the sponsor. Archiving will be authorised by the Sponsor following submission of the end of trial report. Destruction of essential documents will require authorisation from the Sponsor.

Personal data (e.g. name and address, or any data from which a participant might be identified) will not be kept for longer than is required for the purpose for which it has been acquired. Destruction of archived documents will require authorisation from the Sponsor and CI.

At the end of the trial, each site will send original source documentation (hard copy or electronic) along with consent forms and contact details for individuals who have provided consent to be contacted about future related studies to QUB for archive.

Sites will be responsible for archiving general site files accumulated during the day-to-day operation of the trial.

12 MONITORING, AUDIT & INSPECTION

Direct access to all trial records and source documents will be granted to authorised representatives from the Sponsor (or delegate), representatives of the REC, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections in-line with participant consent.

The study will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research.

Sites will assist the sponsor in monitoring the trial as required, for example, hosting site visits, providing information for remote monitoring, or putting procedures in place to monitor the trial internally.

The TSC will be informed of the main findings of any monitoring, audit or inspection of the trial.

13 ETHICAL AND REGULATORY CONSIDERATIONS

The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions, the UK Policy Framework for Health and Social Care, the UK Data Protection Act 2018, the General Data Protection Regulation (GDPR), the UK Data Protection Act 2018 (DPA) and the principles of GCP. QUB will act as sponsor for the study and has in place comprehensive SOPs, both for the approval and monitoring of research.

13.1 Research Ethics Committee (REC) review & reports

Before the start of the trial, ethical review and approval will be sought from a REC for the trial protocol, informed consent forms and all other relevant documents including trial advertisements and recruitment materials. The trial will only commence recruitment once the REC grants a favourable opinion for the trial.

Substantial amendments that require review by REC will not be implemented until REC approval is obtained. Amendments that also need R&D approval will not be implemented at sites until such approval is obtained.

All correspondence with the REC will be retained in the TMF. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended

It is the Chief Investigator's responsibility to produce the annual reports as required. The Chief Investigator will notify the REC of the end of the trial. If the trial is ended prematurely, the Chief

Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

13.2 Peer review

This trial has undergone independent, expert peer-review as part of the NIHR PHR funding process. It has also been reviewed and approved by the QUB Research Governance, Ethics and Integrity Manager, on behalf of the Sponsor (QUB).

13.3 Public and Patient Involvement

Design of the research: PPI was an integral component of the pilot trial (full details can be found in the final report[3]), contributing to the development of the text message library and shaping the trial in a number of ways. The trial methods were chosen based on research with women showing they find it challenging to attend study appointments; home visits were therefore used and highly valued by women in the pilot study. Women chose the study name, reviewed all the pilot study materials (information sheets, consent forms, posters) and tested the questionnaires for the pilot study. The preparatory work for this trial included developing and pilot testing a library of text messages designed to support weight loss after having a baby, The development of the text message library involved extensive PPI involvement via mother and baby/toddler groups as well as recruitment of three women who had recently had a baby as PPI representatives who were paid for their time and input, according to the INVOLVE principles (https://www.invo.org.uk/). Since the PPI representatives had each recently had a baby, they provided input and feedback either at mother and baby groups or via phone or email as this was easiest for them to fit in with their lives as new mothers. The message development process involved writing an initial collection of 30 text messages and then testing these to get initial thoughts from PPI on the tone, length, style, content, inclusion of links, use of 'emojis' and, importantly, to get an instant reaction from women if they felt any messages were unsuitable. Taking into account this feedback, messages for the first 12 weeks were then drafted and again the PPI representatives reviewed the first 12 weeks of the weight loss messages (n=146) for tone, length, clarity and acceptability by completing a response for each message: 'like it', 'it's ok', 'don't like it' and 'other comments/ suggestions'. The feedback was collated by study researchers and messages for the first 12 weeks were further refined. This writing and review process was repeated in stages, developing a few months messages at a time until the full library was completed and all messages had been PPI approved.

The library of text messages from the pilot study will undergo further PPI. To ensure messages are acceptable and culturally relevant for women from a range of backgrounds and ethnicities across the UK. We will follow guidance from a tool kit of adaptation approaches as a framework for policymakers, practitioners and researchers delivering behaviour change interventions to ethnically diverse, underserved populations in the United Kingdom.[115] Key considerations when adapting for religion and culture will be liaising with ethnically appropriate informal networks such as community groups, lay workers or health educators and religious networks. Message adaptation will reflect the target population's language use (usage, concepts and vocabulary) and social and cultural values and incorporate preferences of the target population with regard to lifestyle behaviours including foods, recipes, and consideration of social contexts such as church meals, religious food restrictions, situations at social gatherings. The messages will aim to maintain the cultural significance of food, avoid the use of stigmatising language and consider cultural norms around body aesthetics.

The control group in this study is an active control who receives messages about child health and development. As for the weight loss messages, for the pilot study, PPI feedback was sought on a small bank of drafted active control messages. Based on the initial PPI comments on the active control messages, the full library (consisting of messages related to child health and development for infants

aged six weeks to 36 months) was generated by the study team and sent for further PPI feedback, repeating until all messages had been reviewed and approved.

Conduct of the research: The PPI work will be led by the trial lead and Trial Manager in conjunction with the site leads. All PPI will be conducted and reimbursed according to the principles of involve.

We have conducted PPI in Bradford, London and Scotland to ensure the study recruitment materials and approaches are suitable for women across the UK. Our recruitment of women from different ethnic groups will follow the best practice framework on how to improve the participation of Black Asian and Minority Ethnic (BAME) groups in health and social care research (https://centreforbmehealth.org.uk/resources/toolkits/). We will link with community champions in order to explore how best to liaise with community, voluntary and faith-based organisations for the purposes of recruiting women.

Study management and decision-making: We have PPI representation on our Project Management Team and independent Trial Steering Committee who will contribute to decision making throughout the trial. We will also carry out additional PPI on an ad hoc basis throughout the trial if required, for example if trial recruitment materials needed to be adapted during the recruitment phase.

Dissemination: Our PPI representatives will help shape the dissemination plan (see section 14) and help to develop dissemination materials to ensure communication of findings to postpartum women from all walks of life.

13.4 Regulatory Compliance

The trial will not commence until a Favourable REC opinion has been provided.

The Chief Investigator and site leads will ensure that appropriate approvals from participating organisations such as R&D approvals at NHS sites are in place before recruiting via these routes.

13.5 Protocol compliance

All researchers will undergo training on all trial processes and SOPs including the collection of informed consent to ensure the protocol is understood and implemented consistently across sites. There will be no prospective, planned deviations or waivers to the protocol. If an accidental deviation from the protocol should occur it will be documented on the relevant forms and reported immediately to the CI and sponsor. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

13.6 Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct, in-line with the Sponsor’s SOP on ‘Matters of Non-compliance with Study Protocol’.

13.7 Data protection and patient confidentiality

All data will be collected, stored and disseminated in accordance with the QUB Research Management Policy (February, 2015), as well as in line with GDPR and the UK Data Protection Act (2018). All trial

investigators and researchers working on the study must be compliant with these regulations with regards to the collection, storage, processing and disclosure of participant's personal and sensitive information. Detailed descriptions of the study data processing have been documented in a Data Privacy Impact Assessment and in the Privacy Notice given to participants. Data access will be limited to only individuals necessary for quality control, audit and analysis.

We will ensure that participant confidentiality is maintained throughout the study. When a participant consents to join the trial, they will be allocated a unique participant study ID which will be used to pseudonymise sensitive personal data collected in CRFs, questionnaires and interview transcripts, with the key held by the site teams in password protected files. Electronic data will be stored on password protected computers in locked offices in buildings that are alarmed outside of normal working hours. Paper based data will be stored in locked cupboards in locked offices in buildings that have keypad entry and are alarmed outside of normal working hours. Identifiable information (e.g. consent forms and contact details) will be stored separately from clinical and sensitive data (e.g. questionnaires). Participants will not be identifiable from any published report from the study.

Participants who consent to take part in study interviews will provide information which will be recorded using a digital recorder. Audio files will be downloaded to password protected systems, named according to the participant's unique study ID and transferred securely via secure encrypted file transfer to a QUB approved transcription service. The transcription service provider will be required to sign a confidentiality agreement. Audio files will be transcribed verbatim and transferred back to QUB via the secure Dropoff facility. They will be stored on password protected computer systems as for all other electronic data. When transcripts are received, they will be checked for accuracy against the audio recordings and any potentially identifiable information with the transcript such as names will be removed. Audio recordings will be destroyed when it has been satisfied that the transcript is an accurate written record of the interview.

A minimal amount of information will be entered into the text messages delivery system (hosted by the London School of Hygiene and Tropical Medicine) to allow delivery of text messages according to randomised group (i.e. intervention messages or active control messages). This information will include: first name (for welcome message), mobile phone number, participant study ID.

NICTU database - Participants will be identified using a unique participant study ID in the NICTU database. Trial researchers at each site will have secure password access to the NICTU trial database to allow entry of CRF data.

Data collected from those women who are interested in taking part in the study but then decline to provide their consent or are identified as ineligible, will be shredded and disposed of as confidential waste.

Data for consenting participants will be stored, as described above, for 10 years until the research has been completed and after final publication of study results. Documents that contain personal data will then be shredded and disposed of as confidential waste.

Written informed consent will be obtained from all participants at baseline. This will include a request to consent to future data linkage to routinely collected health records for long term health outcomes for participants and their youngest baby (at the time of signing up to the study).

We will also seek permission to agree to being contacted at a later date about: a follow-up to this study; and/or to receive information about future studies of a similar nature.

These are optional parts of the consent process. If women do provide consent we will store a minimum amount of personal data to permit the above activities including contact details and NHS number (if provided). The CI will conduct periodic reviews (every 5 years) to ensure that the data retention remains necessary.

Data from qualitative interviews will be anonymised by removing any information which could potentially identify the participant. Only interview transcribers who are approved by the sites and meet confidential data handling requirements will be used. Each participant will have a unique participant study ID. The interview recordings, transcriptions and NVivo database will be password protected and encrypted and stored securely as for other files. When transcripts have been prepared and checked for accuracy, the recordings will be deleted.

Data transmitted to sponsors and co-investigators will contain participant study ID but will not contain any personal identifiers such as name, address, date of birth or NHS number.

13.8 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

The CI, PIs, grant co-applicants, trial staff and TSC will disclose any competing interests that might influence trial design, conduct, or reporting such as:

- ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial
- commercial ties requiring disclosure include, but are not restricted to, any pharmaceutical, behaviour modification, and/or technology company
- any non-commercial potential conflicts e.g. professional collaborations that may impact on academic promotion.

This information will be collected by the Trial Manager and recorded in the TMF.

Competing interests will be reported in all publications and in the final report.

13.9 Indemnity

Trial insurance is provided by the Sponsor. A statement regarding indemnity for negligent and non-negligent harm is included in the PIS.

13.10 Amendments

The Chief Investigator will be responsible for the decision to amend the protocol. Substantial and non-substantial amendments will be discussed with the Project Management Team and Sponsor.

All protocol amendments will be undertaken in accordance with the regulatory requirements. Substantial changes to the protocol will require REC, and, where applicable, NHS R&D approval prior to implementation.

The CI will be responsible for communicating substantive changes to relevant stakeholders (e.g. REC, funder, trial registries, R&D, regulatory agencies).

The amendment history will be tracked in the protocol (page 2). The most recent protocol version will be provided to all trial staff, the PMT and TSC.

13.11 Access to the final trial dataset

At the end of the trial, the Trial Manager, Trial Statistician and Health Economist will have access to the full dataset to permit analysis. Following publications addressing the trial objectives, there may be scope to conduct additional analyses on the data collected. In such instances, formal requests for data will

need to be made in writing to the CI, who will discuss this with the Sponsor. The study will comply with the good practice principles for sharing individual participant data from publicly funded trials and data sharing will be undertaken in accordance with the required regulatory requirements. In the event of publications arising from such analyses, those responsible will need to provide the CI with a copy of any intended manuscript for approval prior to submission.

14 DISSEMINATION POLICY

14.1 Dissemination policy

A range of outputs relevant for different audiences are anticipated: NIHR final report; peer reviewed publications; conference presentations for academic audiences; policy briefings for Government, public health bodies and those responsible for developing clinical and public health guidelines (NICE and SIGN); research summaries for non-academic audiences including the media; a draft scaling up plan to aid implementation work with service commissioners, the trial dataset, with the potential addition of long-term data linkage to health outcomes; two automated text message interventions (weight management messages and child health and development messages); a library of text messages for the intervention and active control that can be used immediately or further adapted for different audiences. Ownership of the data is governed by a collaboration agreement signed by all grant holders. At the end of the trial, data will be analysed and tabulated; a final report for NIHR and peer reviewed publications will be prepared in-line with the Consort guidelines and checklist. The final report will be available from the NIHR Journals library. Peer reviewed publications will be published in open access form meaning they are freely and permanently available online for anyone, anywhere to read.

In line with NIHR guidance a dissemination plan will be developed during the first year of the trial, and will be refreshed yearly thereafter through: our PPI work, connections made during recruitment, via the co-applicants networks, advice from the TSC and discussions with stakeholders in stage 3 of the trial. The audiences will include women who took part in the study, postpartum women throughout the UK, health care professionals, service commissioners, academics, the Government and public health bodies. Dissemination will use a range of methods such as online, social media and print media and will make use of established networks in each country as well as nationally relevant events and relevant UKPRP networks.

Importantly, the findings of the research will also be shared with study participants. In the exit questionnaire at 12 months, we will ask participants how they would like to be informed about the research findings with some options (not an exhaustive list) being – a written summary, a YouTube video, a webinar, all of the above or alternative suggestions gained through PPI. This will direct how we communicate the findings. We will communicate the finding to our participants in advance of, or simultaneously with, any media releases associated with the trial.

14.2 Authorship eligibility guidelines

QUB Guidelines on authorship and publication[116] will be followed which supports an approach based on the 'Vancouver Guidelines' (ICMJE Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, 2013) with authorship credit based on all four of the following criteria being met: (i) Substantial contributions to conception and design, or acquisition of data, or analysis of interpretation of data; (ii) Drafting the article or revising it critically for important intellectual content; (iii) Final approval of the version to be published; (iv) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The above criteria are not intended to be used to deny authorship to those who deserve credit and individuals who meet the first criterion should have the opportunity to participate in the review, drafting and final approval of the article or manuscript. It should

be noted that the acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. The practices of honorary/gift authorship or ghost authorship are unacceptable.

All published material will contain an acknowledgement of funding and appropriate disclaimer as per the NIHR website.

The Chief Investigator or Trial Manager will submit an output notification of any research output at the time of submission or at least 28 days before the publication date, whichever is earlier.

A final report will be prepared in-line with the Consort guidelines[75] and checklist and the requirements of the funder with authorship following the eligibility guidelines detailed above. The final report will be freely available from the NIHR Journals library.

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