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

2. BACKGROUND:

Overweight and obesity are one of the major public health challenges of the 21st century owing to their widespread prevalence and recognised impact on morbidity and mortality (1). Obesity has nearly doubled worldwide since 1980 (2) and this has implications for maternal health. In the UK, first trimester obesity increased more than two-fold between 1989 and 2007 from 7.6% to 15.6% (3). Overweight and obesity in pregnancy are associated with adverse health outcomes in mother and baby with increased risks such as gestational diabetes, pre-eclampsia, caesarean section, postpartum haemorrhage, stillbirth, increased offspring adiposity, and infant death (4,5). Furthermore, excessive gestational weight gain and postpartum weight retention are established predictors of long term obesity (4-7). Systematic review evidence (8-10) and NICE (National Institute for Health and Clinical Excellence) Public Health Guidance 27 (4) both highlight gaps in knowledge about effective and appropriate weight management interventions in women during the postpartum period.

Employing mobile technologies to change diet, weight and physical activity presents a promising and expanding area of behavioural research but one that has not, to date, been exploited extensively, or trialled in new mothers carrying excess weight (11-13). According to NICE Public Health Guidance 49 on Behaviour Change, there is a lack of primary research examining the effectiveness of individual behaviour change techniques (BCTs) (14). We propose a tailored SMS-delivered (short message service – i.e. a text message on a mobile) weight management intervention that will address NICE research recommendation 5.6: "*How effective and cost effective are behaviour change interventions delivered remotely (that is, by telephone, text message, phone and tablet apps or the internet)? How does this vary among behaviours and among people from different sociodemographic groups*." (Note: the word 'message' will be used throughout to denote an SMS text message).

The most up-to-date systematic review in the area, published in 2013 (10), examined interventions and trials where postpartum weight was a main outcome, and any combination of diet, physical activity and weight monitoring were intervention components. Interventions were delivered by a range of health professionals (nurses, fitness instructor, dietitian, trained counsellor, study assistant). No study used modern technologies such as mobile phones as an alternative to traditional face-to-face support; one study (15) used modern technology (online diet planner) as an adjunct to traditional face-to-face support. Seven out of the 11 included studies reported a decrease in postpartum weight retention (i.e. a decrease in the number of participants who did not return to their pre-pregnancy weight) and six of these interventions employed both diet and physical activity components. Shortcomings in study quality included lack of description of the randomisation process and lack of information on blinding of outcome assessment. Only two studies out of eleven were underpinned by theoretical frameworks and no study examined cost-effectiveness.

The intervention setting is a key consideration for postpartum weight management interventions. New mothers face challenges engaging in behaviour change interventions, owing to the many demands of motherhood and lifestyle restrictions that come with having a new baby. Interventions for overweight postpartum women delivered in community settings, using group approaches, have presented difficulties for new mothers at a challenging time, and have raised concerns about reach and retention, particularly for disadvantaged groups (10,16,17-19), creating a potential to increase health inequalities (20,21). For example, despite high initial motivation to enrol in the active mothers postpartum study (17), and even with the provision of group sessions multiple times per week and 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 (WL) in the general population (22), they may not be feasible for the postpartum period. This has led to the suggestion that a highly flexible and individualised approach to WL interventions is needed in the postpartum period, shifting away from structured community based programmes, to home-based or more adaptable 'anytime, anyplace' approaches such as those enabled by mobile

technologies (10,16-19). Furthermore, mobile health (mHealth) interventions have the ability to offer proportionate universalism, as recommended by Marmot (23) and NICE (14).

Future research must address the shortcomings noted in previous trials and carefully consider how to make weight management interventions an attractive and attainable proposition for women who are juggling multiple, competing demands in the postpartum period. Carefully designed, evidence and theory-based high-quality trials are needed to advance this field.

3. AIM AND OBJECTIVES:

Overall aim: To adapt and pilot test an evidence and theory-based tailored SMS-delivered intervention supporting overweight or obese (OW/OB) women's behaviour change for weight loss (WL) and weight loss maintenance (WLM) in the postpartum period.

Overall Objectives:

- To review BCTs used in txt2stop (24) and, through assimilation of relevant systematic review evidence, behaviour change theories and NICE guidance, build a logic model for an SMS-delivered weight management intervention in OW/OB postpartum women.
- To adapt the SMS intervention for use in the context of WL and WLM in OW/OB postpartum women.
- To develop an intervention manual, including a library of messages and recruitment materials and a protocol for a pilot trial of the SMS-delivered intervention.
- To conduct a pilot RCT to: test recruitment and randomisation strategies (including willingness to be randomised to active control; retention and attrition rates between groups); examine fidelity of implementation and acceptability of the intervention and control treatments; identify valid and PPI acceptable research instruments to be used in a full trial; provide variability data on the primary endpoints (WL and WLM) on which to base a formal power calculation for a definitive trial; and, to assess outcome data collection processes.
- To assess pilot data in relation to pre-defined stop/go criteria for a full trial.
- Based on the data from the pilot study and if proceeding to a full trial is warranted: to develop a protocol for a multicentre RCT (in line with TIDieR and SPIRIT guidance (25,26)), including a process manual and an analysis plan for secondary outcomes, to evaluate the effectiveness of a tailored SMS-delivered intervention for WL and WLM in OW/OB postpartum women.

4. RESEARCH DESIGN:

This project consists of two consecutive stages. ***Stage 1*** will adapt an existing and effective SMS-delivered intervention developed for smoking cessation (txt2stop) (24) to support OW/OB postpartum women to lose weight and maintain this WL. ***Stage 2*** will pilot the adapted intervention in a parallel group, single site randomised controlled trial (RCT). If pilot RCT stop/go criteria are met, a protocol for a large multi-centre RCT will be developed. This approach is consistent with the key steps of the 6SQUID framework for designing social interventions (27).

Stage 1 – Intervention adaptation and development of protocol for the pilot trial: An existing SMS-delivered intervention (txt2stop) proven to successfully support smoking cessation and implemented on a wide scale (28) will be adapted to support WL and WLM as described below. The existing SMS-delivered intervention, txt2stop, is an automated smoking cessation programme delivered via mobile phone text messaging (29). Over 31 weeks, a series of messages developed with the input of smokers and smoking cessation professionals is delivered to participants at a rate of five test messages a day for the first five weeks and then three a week for the next 26 weeks. The txt2stop messages include motivational and action focused BCTs. The messages are individualised according to an algorithm based on demographic and other information collected at study entry such as concerns about weight gain after quitting. Participants can also prompt instant messages to distract and support them during an episode of temptation by texting the word 'tempted'. Likewise, by texting a

pre-specified key word, such as 'crave'. participants receive a series of three messages that encourage them to continue with their behaviour change efforts. In addition, individuals can also request the mobile phone number of another individual who is also attempting behaviour change so they can text each other for support (29).

Intervention adaptation: This will be an iterative process conducted in conjunction with postpartum women and health professionals involved in their care in order to develop a woman-centred, tailored SMS-delivered intervention that facilitates a self-directed approach to behaviour change. The txt2stop approach will be adapted to support WL and WLM.

Update of literature to inform intervention adaptation: We will systematically examine relevant evidence and examine all systematic reviews which fulfil the following criteria: i) examined RCTs of behavioural interventions for weight management, ii) specified intervention content as BCTs using one of three relevant taxonomies (30-32); iii) linked BCTs to intervention effectiveness either narratively, using subgroup analysis in meta-analysis or meta-regression techniques. The information on effective BCTs for weight management gathered from these reviews will allow us to build an evidence-based logic model for an SMS-delivered weight management intervention in OW/OB postpartum women. While we are making no assumptions about what the suite of BCTs might include, we note that the majority of the BCTs used in txt2stop served to boost motivation and promote self-regulatory activities (33), which are key techniques relevant to successful diet and activity behaviour change and weight management (34-39). These will be supplemented by BCTs which have been found to facilitate behaviour change in weight management interventions and behaviour change and behavioural maintenance theory to ensure a coherent approach.

Intervention content: Intervention content and message development will be undertaken together with women who have had a baby in the last two years and health professionals involved in their care to test acceptability of messages, refine message content and tone, and define other aspects such as message frequency, timing and tailoring.

Stage 2 – Randomised controlled pilot trial: The pilot trial will be a parallel group RCT conducted at one site (Belfast). Eligibility: women from birth until 2 years postnatal, uniparous or multiparous, with postpartum BMI >25 kg/m^{2},.

The intervention group will receive the WL & WLM intervention; the control group will be an active control and will receive messages related to child health (child care and child development).

Data collection during the 12 month pilot intervention will take place at 3, 6, 9 and 12 months.

Baseline and outcome data will be collected via home visits, or at a research centre (i.e. the Centre for Public Health) if women prefer. Assessments at each visit will include collection of anthropometric measurements, blood pressure, questionnaires assessing target behaviours and theory-based potential mediators and moderators of behaviour change, and qualitative interviews to gather feedback on the intervention and its acceptability.

The randomisation will be carried out using the London School of Hygiene and Tropical Medicine's (LSHTM) secure remote web-based system which will link directly with the SMS database and will deliver the intervention or control content according to group allocation, phase of weight management (Phase 1 - WL or Phase 2 - WLM) and personalisation parameters. On reaching their target weight, or at the 6 month time point (when WL tends to plateau), women will move from Phase 1 (WL) to Phase 2 (WLM).

The researchers collecting outcome data will have no 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 and the fidelity of this will be examined as part of the process evaluation. Baseline assessments will be conducted before randomisation. To maximise completion of study assessments at each study time point, participants in both groups will be offered a small incentive to the value of £20 (likely to be a voucher but this will be determined by PPI) at each visit and on study exit (40).

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