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Study Protocol: Use of a smartphone application to support delivery of a complex physical activity intervention '+*Stay Active*' in women with gestational diabetes mellitus: a non-randomised feasibility study

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Abstract

Introduction

Physical activity (PA) interventions have a promising role in the management of gestational diabetes mellitus (GDM). Digital technologies can support and promote PA remotely and at scale. This protocol describes a study designed to determine the feasibility and acceptability of a complex intervention; known as +Stay active. +Stay Active combines motivational interviewing with a bespoke behaviour change informed smartphone application (Stay-Active) to support PA levels in women with gestational diabetes.

Methods & analysis:

This is a non-randomised feasibility study using a mixed methods approach. Participants will be recruited from the GDM antenatal clinic at the Women Centre, John Radcliffe Hospital, Oxford. Following baseline assessments (visit 1) including self-reported and device determined PA assessment (wearing a wrist accelerometer), women will be invited to participate in an online motivational interview, then download and use the Stay-Active app (Android or iOS) (visit 2). Stay-Active aims to support women's PA levels with weekly goal setting, self-monitoring, performance and personalised feedback with motivational messaging and a specific resource centre. Women will have access to the Stay-Active until 36 weeks' gestation, whereby engagement and PA levels will be reassessed (visit 3).

Primary outcomes will include recruitment and retention rates, fidelity and assessment of participant engagement with the intervention. Secondary outcomes include assessment of blood glucose control, self-reported and device determined assessment of PA, structured feedback of participant's attitudes to +Stay Active and description of maternal outcomes and neonatal outcomes.

This study will provide key insights into this complex intervention regarding engagement in smartphone technology and wearing accelerometers. This data will inform the development of a randomised controlled trial with refinements to intervention implementation.

Ethics and dissemination

This study has received a favourable opinion from South Central - Hampshire B Research Ethics Committee; REC reference: 20/SC/0342. Findings will be disseminated through peer-reviewed journals, conferences and seminar presentations.

Word Count (294) 300

Keywords Gestational diabetes Mellitus, Physical Activity, Smartphone Applications.

Strengthen and Weakness:

- The study will be the first to combine motivational interviewing with a bespoke, novel, behavioural change designed smartphone application (Stay-Active) to support PA activity levels in women with gestational diabetes.

- Stay-Active aims to support women's PA levels with weekly goal setting, self-monitoring, performance and personalised feedback with motivational messaging and a specific resource centre. A unique feature of this application is the ability for the clinicians to interact with the user.

- This study will provide evidence on the feasibility and acceptability of this unique complex intervention, combining motivational interviewing with a behaviourally informed smartphone application to increase PA.

- The feasibility study design is not powered to determine intervention efficacy or clinical effectiveness

- This study will contribute to the future research agenda in this population including helping to determine whether a randomised control trial (RCT) to evaluate this intervention is feasible. This future RCT would explore the efficacy of intervention to increase PA and evaluate the effect on clinical outcomes.

Introduction

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance first detected during pregnancy (1). GDM is associated with serious complications for both mother and baby (2-4). Fundamental to the management of GDM is glycaemic control (5), with increasing levels of blood glucose suggested as the mechanism for the increased risk of adverse maternal and infant outcomes (6). Treatment interventions for GDM include blood glucose (BG) monitoring, lifestyle intervention and pharmacological therapy. Of the lifestyle interventions dietetic modifications and physical activity are the only interventions that have reported possible health improvements for maternal and fetal outcomes (7).

There is growing evidence supporting the benefits of PA amongst women with GDM. Meta-analyses of interventions to increase PA among pregnant women, have shown improvements in glycaemic control and reduced insulin requirements (8, 9). Guidance on the clinical management of GDM, from the National Institute for Health and Care Excellence (NICE), recommends healthcare professionals advise women with GDM to exercise regularly (10). Qualitative reports have found that women with GDM would prefer clear, simple and specific PA messages with flexible options(11).

Fundamental to the success of PA interventions is a sound theoretical basis with the incorporation of appropriate Behaviour Change Techniques (BCTs), particularly those that are person-centred, addressing specific barriers and enablers (12).

We have shown how motivational interviewing (using several Behaviour Change Techniques (BCTs)) can increase PA in women with GDM. Motivational interviewing incorporated into

the routine clinical care for 64 women with GDM, found a significant increase in self-reported PA levels after two weeks(13). Women were invited to a 20-minute individual motivational interview with trained health care professional focusing on being physically active during their pregnancy. A specific motivational interviewing framework was used including key micro-skills, individual goal setting, activity planning and specific information about the benefits and types of suggested PA. While motivational interviewing has been shown be effective and may provide the initial catalyst for behaviour change, the challenge of supporting women to maintain this change remains.

Digital technologies provide an opportunity to support and promote PA remotely and are already used for remote management of glycaemic control in women with GDM (14). A smartphone application 'Stay-Active', further referred to as 'the app', has been designed to enhance and support the existing motivational interviewing intervention. This multi-component application was designed following a systematic approach using the Behaviour Change Wheel (BCW)(15). The development process was informed by current evidence, focus groups and input from key stakeholders (16). The final design of Stay-Active delivers ten BCTs via an educational resource centre, with goal setting and action planning features, personalised performance feedback and individualised promotional messages (table 1 and supplemental material 1 show the integration of BCTs within Stay-Active). A unique feature of this application is the ability for the clinicians to interact with the user. Clinician can review the users recorded PA remotely and then directly send users specific tailored messages via the application to support and maintain PA. This protocol outlines a study (+Stay Active) to determine the feasibility and acceptability of the combined interventions (Stay-Active + Motivational Interviewing consultation) in women with GDM.

Table 1: The Selected Behaviour Change Techniques with descriptions and Stay-Active Function

Behaviour Change Technique	BCT description	Stay-Active (Smartphone Application) function
Goal setting [1.1]	set or agree a goal defined in terms of behaviour to be achieved	Specific goal setting function. Users can set personalised weekly goals. They can review & record goals directly onto the application, update & can access them at any time. Weekly goals are integrated into the performance feedback wheel.
Action planning [1.4]	prompt detailed planning of performance of the behaviour must include at least one of the context, frequency, duration and intensity	Users are encouraged to set personalised weekly goals with a specialist midwife at the end of MI. Users can set personalised weekly goals on the application. Examples include a brisk walk for 20 minutes x3/week or attending a yoga class
Review behaviour goals. [1.5]	review behaviour goals (s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement	SM's can view how the women progress in real time. SM's can contact women via the message centre if they have not logged or registered activity. The midwives will provide support over the phone or via the message centre on a weekly basis
Self- monitoring of behaviour [2.3]	Establish a method for a person to monitor and record their behaviour(s)as part of a behaviour change strategy	Users can record their PA on Stay-Active with tracking of their completed goals on the performance feedback wheel.
Instruction to perform the behaviour [4.1]	advice or agree on how to perform behaviour	See resource centre text below
Credible source [9.1]	present verbal or visual communication from a credible source in favour of or against the behaviour	See resource centre text below
Written persuasion about capabilities [15.1]	inform the person that they can successfully perform the wanted behaviour	See resource centre text below
Prompts and cues [7.1]	introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour	Users receive motivational messages about PA at 10am every day via the smartphone notification system
Feedback on behaviour [2.2]	monitor and provide informative or evaluative feedback on performance of the behaviour	HCPs can view and monitor their user's activity progress and communicate feedback by individualised text messages.
Information about health Consequence [5.1]	provide information (e.g. written,verbal, visual) about health consequence	See Resource centre text below

SM – Specialist Midwife MI – Motivational interview PA- Physical Activity

Resource Centre within Centre:

Specific resources with Stay-Active including a healthcare provider approved leaflet on GDM and PA addressing and explaining specific benefit of PA, an infographic on the benefits and types of PA, examples with explanations of suggested home-based workouts/exercise, a short educational film on the benefits and key messages about PA in pregnancy, an embedded search function for local NHS recommended pregnancy specific PA classes, and links to two credible PA resources

[Bracketed numbers] referred to The Behaviour Change Technique Taxonomy (v1) (17)

Methods and Analysis

Aims

The purpose of the study is to evaluate how women with GDM interact, engage with and respond to a complex intervention, known as +Stay Active. This will help determine whether a randomised control trial (RCT) to evaluate this intervention is feasible. A future RCT would explore the efficacy of intervention to increase PA and evaluate the effect on clinical outcomes such has glycaemia control, medication usage and macrosomia.

The +Stay Active intervention combines an initial PA motivational interview to encourage women to recognise the value of PA in pregnancy and in the management of GDM. Women are then supported by BCW designed multi-component smartphone application 'Stay-Active'.

Objectives

1. Assess the number of women at the Women's Centre, Oxford University Hospital who are eligible to participate.
2. Determine recruitment and retention rate.
3. Assess fidelity of delivery of the motivational interviewing component by trained research midwives.
4. Participant adherence: Hours of wearing a wrist worn accelerometer for tracking PA levels; availability of data for outcome measures; attendance at follow-up sessions.
5. Assessment of the variance in different measures of PA and how they change over gestation using: (i) accelerometer data; (ii) the validated pregnancy physical activity questionnaire (PPAQ) (18), and (iii) percentage of goal achieved.
6. Explore the acceptability of the intervention to participants as assessed by the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ), structured

questionnaire on participant's attitudes to +Stay Active and usage data from the smartphone application.

7. Determine any refinements required of the intervention.

Study Design

This feasibility study is a non-randomised trial. All participants will receive the intervention. A mixed methods approach will be used to assess process and effectiveness measures, test trial procedures, resource use, determine the most appropriate primary outcome measure and aid sample size estimates for a future definitive trial. This will inform modification and refinement of the +Stay Active intervention. Figure 1 a flow chart of the study designs, visits, and assessments.

The feasibility study will be in line with the guidance proposed (19) and reported using the Standard Protocol Items: Recommendations for Interventional Trials reporting template(20) and checklist can be found in supplemental material 2. A Flow diagram demonstrates enrolment, allocation, follow up and assessment process (supplemental material 3).

Setting & Study Participants:

All participants will be recruited from NHS maternity clinics at the Women's Centre, Oxford University Hospitals NHS Foundation Trust. The study will enrol women with a confirmed diagnosed with Gestational Diabetes Mellitus (GDM) as defined by the standard of care screening test in this NHS hospital at the time of recruitment. During recruitment this changed from International Association of Diabetes and Pregnancy Study Groups recommendations (21) to RCOG guidance during the COVID-19 pandemic (22), during the COVID-19 pandemic, and from Jan 2022, to NICE thresholds for diagnosis (23). Women will not be eligible for the study until at least 20 completed weeks of pregnancy as the study is not

investigating PA in early pregnancy. Recruitment started for this trial in April 2021 and plans to be completed in April 2022.

Patient and Public involvement:

The development of Stay-Active involved focus groups as part of patient and public involvement (PPI) in line with Oxford University Hospital Trust's PPI Strategy and Policy(16). AW (patient representative) provided input and oversight in the study protocol.

Visit 1: Recruitment and baseline assessments

Women attending the GDM clinic who met the inclusion criteria (see table 2) will be identified by the clinical team at their appointment and a patient information sheet will be provided. Following their clinic appointment, a research midwife will talk them through the study procedure, invite questions and sign a study consent form.

If they consent to take part in the study(consent form shown in supplemental material 4), to determine baseline PA levels; they will be asked to:

1) Complete an online version of two validated questionnaires: PPAQ (18) and the exercise vital sign assessment (EVS)(24).
2) Wear a tri-axial accelerometer (GENEActiv, Active Insights Ltd, Kimbolton, UK) on their non-dominant wrist for at least seven consecutive days (worn day and night). This time frame was chosen due to its reliability to estimate measures of moderate to vigorous physical activity (MVPA) during pregnancy (25).

The participants' General Practitioner will be informed of their involvement in the study. Participants will be provided with an A4 instruction sheet which includes general care instructions. Data will be collected at 100Hz.

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Table 2: Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Women who are more than 20 completed weeks pregnant and less than 33 completed weeks pregnant with a singleton pregnancy • Abnormal Oral Glucose Tolerance Test (OGTT) as defined by IADPSG, HbA1C , fasting plasma glucose or random blood glucose as defined by RCOG Guidance for maternal medicine services in the evolving coronavirus (COVID 19) pandemic. • Using GDm-Health to monitor their blood glucose • Aged between 18 and 45 years • Willing and able to provide informed consent for participation in the study • Have, and use, a smartphone	• Multiple pregnancy • GDM not diagnosed by OGTT, HbA1C or fasting plasma glucose as defined by RCOG Guidance for maternal medicine services in the evolving coronavirus (COVID 19) pandemic. • An absolute contra-indication to physical activity as per 2019 Canadian guidelines(26)e.g. preterm rupture of membranes, limited mobility, haemodynamically significant heart disease, restrictive lung disease • Unable to understand written or spoken English language

GDM – Gestational Diabetes Mellitus
RCOG – Royal College of Obstetrics and Gynaecology
OGTT - Oral Glucose Tolerance Test

Intervention:

Visit 2: Motivational interview & Smartphone Application download

We will ask participants to attend a virtual study visit (Visit 2) one week later. During this visit, participants will receive a 20-minute motivational interview with a trained research midwife during which if appropriate they will agree a set of weekly exercise goals. A virtual study visit was chosen because of COVID-19 restrictions. The participant will be asked to wear the accelerometer for a further week after the motivational interview (i.e. total of 2 weeks) and will post back the accelerometer using a pre-paid addressed envelope that will be issued to participant at visit 1.

The motivational interviewing will take place remotely via the secure NHS online platform 'Attend Anywhere' or by telephone depending on the woman's preference. All motivational interviews will be audio recorded using a dictaphone (where participants consent to this). No patient identifiable data will be recorded, and the audio-file will be labelled with a unique study specific number. Completed interviews will be downloaded onto a secure University of Oxford server and deleted from the portable device. The anonymised audio-files will be accessed only by the study team involved in either recording or analysing the data. The structure of the motivational interview consultation is shown in supplemental material 5). Ten percent of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1)(27) to assess the fidelity of the interview by an experienced coder. This sample size is in-line with practical recommendations(28).The interviews will be picked at random using a random number generator.

Study participants are asked to complete the validated Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ)(29) (supplemental material 6) after the motivational interview.

During the second half of the motivational interview, participants will be encouraged to download the 'Stay-Active' smartphone application and shown the main features: recording their activities, reviewing their PA goals, and exploring the resource centre.

Interactions with participants & motivational support during study period

Participants will receive a weekly telephone call from the research team to review and adjust their activity goals. Participants will be provided with individual motivational feedback messages from research team at least weekly by text message via the Stay-Active.

Visit 3: Assessment & Completion of intervention

A follow-up appointment will be scheduled for 36 weeks' gestation at which the participant will be asked to complete an online version of PPAQ (18), the exercise vital sign assessment(24) and OMDTSQ (supplementary material 4). They will also be asked to wear the accelerometer for 1 week. Via the notification on Stay-Active participants will be prompted to complete a feedback form on the intervention (a five-star scale rating will be used the motivational interview, goal setting, tracking of goals, automated and personalised messages, also with an opportunity to provide written feedback). Access to the Stay-Active will terminate 1 week after the routine 36 weeks gestation follow up appointment.

Early Discontinuation/Withdrawal of Participants

A participant may choose to withdraw at any time. This may happen for several reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable adverse effect
- Inability to comply with study procedures
- Participant decision

Data already collected with consent will be retained and used in the analysis. In addition, the lead Investigator (LM) may discontinue a participant from the study at any time if the considers it necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- Clinical decision

The type of withdrawal and reason for withdrawal will be recorded.

Study Outcomes:

Primary Outcomes

The primary outcome will be the feasibility and acceptability of the intervention to inform a decision on whether a randomised controlled trial is warranted and feasible. This will be assessed against a set of predefined criteria related to i) participant engagement with the intervention, ii) recruitment and iii) retention rates, iv) fidelity of the intervention. A traffic light system will determine the progression to a definitive trial (figure 2). This system has been suggested to be preferable to the stop/go pass/fail approach(30). The primary objective with outcome measures and timepoints are shown in table 3 and figure 2.

297 Table 3: Objectives, outcome measures and timepoint of evaluation:

Objectives	Outcome Measures	Timepoint(s) of Evaluation of this Outcome Measure
Primary Objective		
To evaluate how women with GDM interact, engage with and respond to *Stay Active+* and to determine whether an RCT to assess the efficacy of this intervention, is feasible.	Recruitment rates • Percentage of women with GDM who eligible participants at the Women Centre at John Radcliffe Hospital. • Percentage of women who fulfil the eligibility criteria and who accept the invitation to participate	At recruitment & at end of study period
	Retention rate • Proportion of women that completed the study	At end of the Study (36 weeks)
	Participant engagement with the intervention • Participant adherence: • wrist worn accelerometer: number of days worn over 7 days period, average daily proportion of wear of wearing the; availability of data for PA outcome measures. • Attendance at follow-up sessions. • Completion rates of Self-reported PA questionnaires	At Visit 1& end of study period (36 weeks gestation)
	Acceptability: • Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants.	Visit 2 & end of study period (36 weeks gestation)
	Fidelity of the intervention • All Motivational interviews will be audio recorded. • 10% of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1) to assess the fidelity of sessions. • Proportion of participants who set goals on Stay-Active • Proportion of participants who recorded PA on Stay-Active	Visit 2 End of study period (36 weeks gestation)
Secondary Objectives		

1. Assessment of PA	Attainment of information on physical activity time, type, intensity, and frequency assessed from baseline and subsequent visits i) Device specific (accelerometer) data: (Total PA average per measured day, moderate to vigorous PA and average Acceleration) ii) PPAQ – outcome: Energy expenditure iii) EVS – Weekly minutes of Moderate to Vigorous PA	At recruitment visit 2 and visit 3.
2.Usage and Participant attitudes to +Stay Active	i) Stay-Active Usage: • average time spent on app per week • Average time per session • frequency of app opened and duration per session • Number of participant logging activity per week ii) Participants attitudes to Stay-Active (5 questions rating the usefulness of the following: Motivational interviewing, Goal setting, Tracking your goals via the app, The automated motivational messages, The personalised messages about your physical activity via the app and an open comments section	From visit 2 to participant completion Visit 3: At 36 weeks gestation
3. Assessment of blood glucose control & medication prescribed	i) Difference in glycaemic control measured as mean BG at recruitment and at 36-38 weeks (using BG taken in the week that the accelerometer is worn), adjusted for number and timing of measurements). ii) Participant's medication prescribed total number & generic name and dose	Recruitment & Visit 3 (36 weeks' gestation)
4. Description of maternal and Neonatal outcomes.	i) Maternal outcomes (weight gain, pharmacological medication (initiation, timing and doses in relation to meals and BG readings), hypertensive disorders of pregnancy (gestational hypertension and pre-eclampsia), gestation at delivery, mode of delivery). ii) Neonatal outcomes (birth weight, neonatal hypoglycaemia, neonatal hyperbilirubinaemia, admission to SCBU for >24 hrs, shoulder dystocia).	Data gathered 6 weeks post delivery
5. Assessment of health costs	Number of Additional visits, Contacts made by research Midwife (both text message and telephone call) and time spent delivering intervention	Throughout study period
6 Determine any refinements required of the intervention.	Review and analysis of the primary and secondary outcome data	Following data analysis

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Secondary Outcomes

Secondary outcomes include assessment of blood glucose measurements and control, assessment of PA, qualitative assessment of participant's attitudes to +Stay Active, description of maternal and neonatal outcomes, a description of additional health costs and any refinements required of the intervention (table 3).

i) Assessment of Physical activity

Three methods for assessing PA will be used: Two self-reported questionnaires and one wrist-worn accelerometer. All have different strengths and limitations. Both the PPAQ and the wrist worn accelerometer are validated measures in this population. An evaluation of the feasibility, acceptability and quality of data gathered by each method will be undertaken. This will inform the method to be used in future studies.

a) Self-Reported physical activity assessment:

Two self-reported questionnaire measuring PA (EVS & PPAQ) will be completed at baseline and visit 3 (36-week gestation).

The PPAQ is self-administered. Participants are asked to select the category that best approximates the amount of time spent in 32 activities including household/caregiving, occupational, sports/exercise, and inactivity during the current trimester. Following completion, the duration of time spent in each activity is multiplied by its intensity to arrive at a measure of average weekly energy expenditure (MET-h·week-1) attributable to each activity.

EVS is self-administered and consists of two questions. The introductory texts of the EVS has been modified to be specific to pregnancy.

1) On average, how many days per week do you engage in moderate intensity or greater physical activity (like a brisk walk) lasting at least 10 minutes?

2) On those days, how many minutes do you engage in activity at this level?

Total weekly moderate aerobic activity can be calculated.

Both self-reported measures have been chosen because whilst PPAQ has been specifically designed and validated for pregnant women(18), it takes time to complete and is not entirely practical for the clinical setting. The EVS has been validated as a self-reported PA outcome measure(24), but to date has not been specifically validated for pregnant women. EVS is a simple, practical, and time-efficient tool to use for clinical staff. It is already integrated in the hospital's electronic patient record system; it automatically calculates and documents a weekly physical activity level. Data will be collected for a further study aiming to validate this tool amongst pregnant women.

b) Device measured physical activity: Accelerometers & data

The GENEActiv is a triaxial accelerometer which can be worn continuously for long durations (up to 30 days) to provide precise estimates of physical activity. The device can be worn on multiple different bodily locations: hip, thigh, waist and wrist. However, wearing the device at the wrist has been found to provide robust PA estimates (at least equal to hip/waist worn devices) and is associated with better compliance to wear protocols and acceptable to clinical populations (31, 32). The GENEActiv accelerometer objectively measures and stores movement acceleration in g (the standard SI unit of acceleration) for offline analysis, thereby allowing a range of data processing techniques to be applied post data-collection to derive estimates of physical activity.

This study will examine the feasibility of using the GENEActiv accelerometer to assess changes in PA across the intervention period. Participants will be asked to wear the accelerometer on their non-dominant wrist continuously for 7 consecutive days at baseline (following visit 1), the week following motivational interviewing (visit 2) and at 36 weeks (following visit 3). Average daily accelerometer wear-time (in hours) can be calculated from which we can infer the acceptability of the measurement protocol and the feasibility of collecting sufficient data in a subsequent trial.

This study will also provide data regarding the inter and intra-person variation in PA, and the change in PA across gestation to inform a subsequent trial. At the end of each measurement period, the raw accelerometer output data will be uploaded securely using the GENEActiv software (GENEActiv, version 2.2, Active Insights Ltd). These raw data files will then be processed using the validated 'GGIR' script in the R environment (http://cran.r-project.org) to derive a series of standardised physical activity variables by applying previously validated acceleration threshold values to define PA by intensity (as light, moderate and vigorous intensity) (33). The specific outcomes variables derived for descriptive analyses in this study will be average daily minutes of total PA (any movement with a measured acceleration value of ≥ 40 mg) and average daily minutes of Moderate to Vigorous PA (MVPA) (≥ 93.2 mg). These PA variables are appropriate as: 1) both diabetes (34) and pregnancy (26) specific guidelines recommend 150 minutes per week of MVPA, and 2) there is growing recognition that PA of an intensity below moderate (i.e. any movement) is important for daily glycaemic control(35). Observed changes in these variables from baseline through follow-up can be used to inform sample size calculations for a subsequent efficacy study.

Usage and Participant attitudes to +Stay Active

The Stay-Active app-based platform is available on Android and iOS mobile operating systems. Amongst the core functionalities, the participants can view their latest activity plan and record their physical activity sessions. The App also measures the sequence of actions and time taken that participant perform to access various sections of the App (user flow). If an active internet connectivity is available on the phone, or once it is restored, all the information is synchronised with the secure Stay-Active server, hosted in the Oxford University Hospitals NHS Trust network.

The compliance information (e.g. participant activity log, last synchronisation time of the App) is available in real-time on the health-care professional interface, hosted in the above mentioned secure NHS server, which also allows nurse researchers to register new participants, create and manage their activity plan, review the participants registered activities in real-time, and send SMS messages directly to the participants. To contribute to an assessment of engagement; the following information will be evaluated: average time spent on app per week, frequency of app opened and duration of each session.

At 36 weeks; via a feature on Stay-Active; study participants will complete the star rating questionnaire outlined in visit 3.

Assessment of blood glucose control and medication use

Blood glucose (BG) values during the periods of accelerometer (recruitment and 36 weeks) will be extracted from the participant medical records. All participants will be recording their BGs using the GDm-health™ smartphone application which is a standard of care. Difference in glycaemic control measured as mean BG at recruitment and at 36-38 weeks (using BG taken

in the week that the accelerometer is worn), adjusted for number and timing of measurements). The GDm-Health smartphone application records when medication for GDM is prescribed; for all participants will record number and names and doses of medication at recruitment and at week 36 gestation (visit 3).

Description of maternal outcomes & neonatal outcomes

After delivery the maternal outcomes and neonatal outcomes (listed in table 3) will be extracted from the medical records.

Assessment of health costs:

Health economic information including number of additional visits, contacts (both text message and telephone call) and time spent by research midwife delivering the intervention will be recorded.

Data Collection Procedure:

Both the self-reported questionnaire measures of PA (EVS & PPAQ) will be completed at baseline and visit 3 (36-week gestation). The OMDTSQ will be completed at visit 2 and 3. All questionnaires will be completed on Microsoft forms by participants through a secure online link. The participants will be identified by a unique study specific number in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

Statistics & Analysis

This is a single arm feasibility study. The results will consist of descriptive statistics for assessments at the 3 visits - baseline, 36–38-week, endpoint, and for data collected from the

postnatal visit. The statistics software package used will be Stata 14 and R. The measures that will be assessed are listed under a description of the visits.

Summary statistics will be calculated for all measures. Continuous variables will be reported as means, standard deviations, maximum and minimum values. Binary variables will be reported as counts. The number of missing values will be reported.

Sample Size Determination

The sample size determination is pragmatic and based on this fixed period of recruitment and likely recruitment rates. Individual participation is for approximately 3 months during pregnancy. Recruitment will be initially for 6 months. During this time, it is estimated that 6 new patients will attend the GDM clinic per week. Informed by recruitment to TREAT-GDM (ClinicalTrials.gov NCT01916694), we expect 50% to agree to participate in this study; therefore 78 over a 6-month period. Estimating a 20% drop out rate; this would allow us to reach our pragmatic target of 60 patients during this time.

Discussion

We describe the protocol for a study to assess the feasibility and acceptability of this unique complex intervention combining motivational interviewing with a behaviourally informed smartphone application to increase PA.

There is growing evidence supporting the benefits of PA amongst women with GDM. Harrison et al meta-analysis reported that exercise interventions significantly improved postprandial glycaemic control (mean difference –0.33 mmol/L) and lowered fasting blood glucose (mean difference–0.31mmol/L) when compared with standard care alone. Effects were found from both aerobic and resistance exercise programs, if performed at a moderate intensity or greater, for 20 to 30 minutes, three to four times per week(9). A separate analysis of 12 studies (2 resistance training, 8 aerobic exercise, 2 combination resistance/aerobic) found requirements of insulin therapy, dosage, and latency to administration were improved in the exercise groups. Both aerobic, resistance or combination were effective at improving blood glucose control in patients with GDM(8). Hillyard et al meta-analysis of dietary and PA intervention including 21 RCT (n=1613), of which 7 were PA interventions, reported PA reduced insulin use by 47%(36).

However, most exercise interventions are supervised exercise and well resourced; potentially being difficult to translate into the health care setting. Integration of health coaching and evidence based behavioural strategies (goal setting, monitor and feedback) has been suggested to provide the most appropriate tools for translation of this evidence into clinical practice(37). +Stay Active integrates these key principles.

Digital technologies provide a potential to remotely support PA at scale. App-based interventions have been shown to be effective for increasing PA. Multi-component interventions appear to be more effective than standalone interventions (38). Promising results from a randomised trial, that used a similar approach to +Stay Active, found the combination of a mobile phone app and brief counselling increased objectively measured PA over three months in physically inactive non-pregnant women (39). A key aspect is the timing of our intervention, building on a potential 'teachable moment'(40) following a diagnosis of GDM where there is opportunity for women to re-focus on PA with the health of the baby and glycaemic control being strong motivators. There is already a commercially available CE-marked smartphone glucose management application GDm-Health (14) embedded within the clinical pathway for women with GDM at the study site, which has previously shown high levels of patient engagement, compliance and usage (29). If +Stay Active is feasible and acceptable, it could provide additional functionality to applications such as GDm-Health, improving usability and accessibility allowing users to observe the direct impact of PA of their blood glucose control. Furthermore, if this complex intervention is effective, it could be adaptable for other cohorts of pregnant women including pre-eclampsia and other risk conditions.

Ethics and Dissemination:

All procedures will be followed are in accordance with the Declaration of Helsinki.

This study has received a favourable opinion from South Central - Hampshire B Research Ethics Committee; REC reference: 20/SC/0342. To facilitate the extra study visits, travel expenses will be paid on presentation of a receipt. This study is registered https://www.isrctn.com/ISRCTN11366562. The study protocol is pre-registered with ISRCTN 39136. Results will be disseminated through peer-reviewed journals, conferences and seminar presentations.

Figure Legends:

Figure 1

This figure demonstrates a flow of the study design with participant visits and assessment over the study period. All Women will receive standard clinic care during study which includes remote blood glucose monitoring and management through GDm-health™ smartphone application.

Figure 2

Figure 2 shows the primary outcomes and the predefined criteria. These are related to i) participant engagement with the intervention, ii) recruitment and iii) retention rates, iv) fidelity of the intervention. This traffic light system will determine the progression to a definitive trial.

Authors' contributions

RS, LM, CR, MS contributed and helped with design of Stay-Active. RS, JH, MM, LM, SR and YK drafted and wrote the manuscript. All authors revised the content of the article, and approved the final version.

Competing interests

LM, JH, MM, YK, RS, NW, JB are supported by the NIHR Oxford Biomedical Research Centre. LM is a part-time employee of Sensyne Health plc. LT is a Non-Executive Director, part-time employee and shareholder of Sensyne Health plc.

The remaining authors have no disclosures of interest and there are no other conflicts to declare.

Consent for publication

In relation to supplemental file 1, informed consent for the publication of identifying images in an online open-access publication was obtained from the individual shown in the exercise demonstration photographs.

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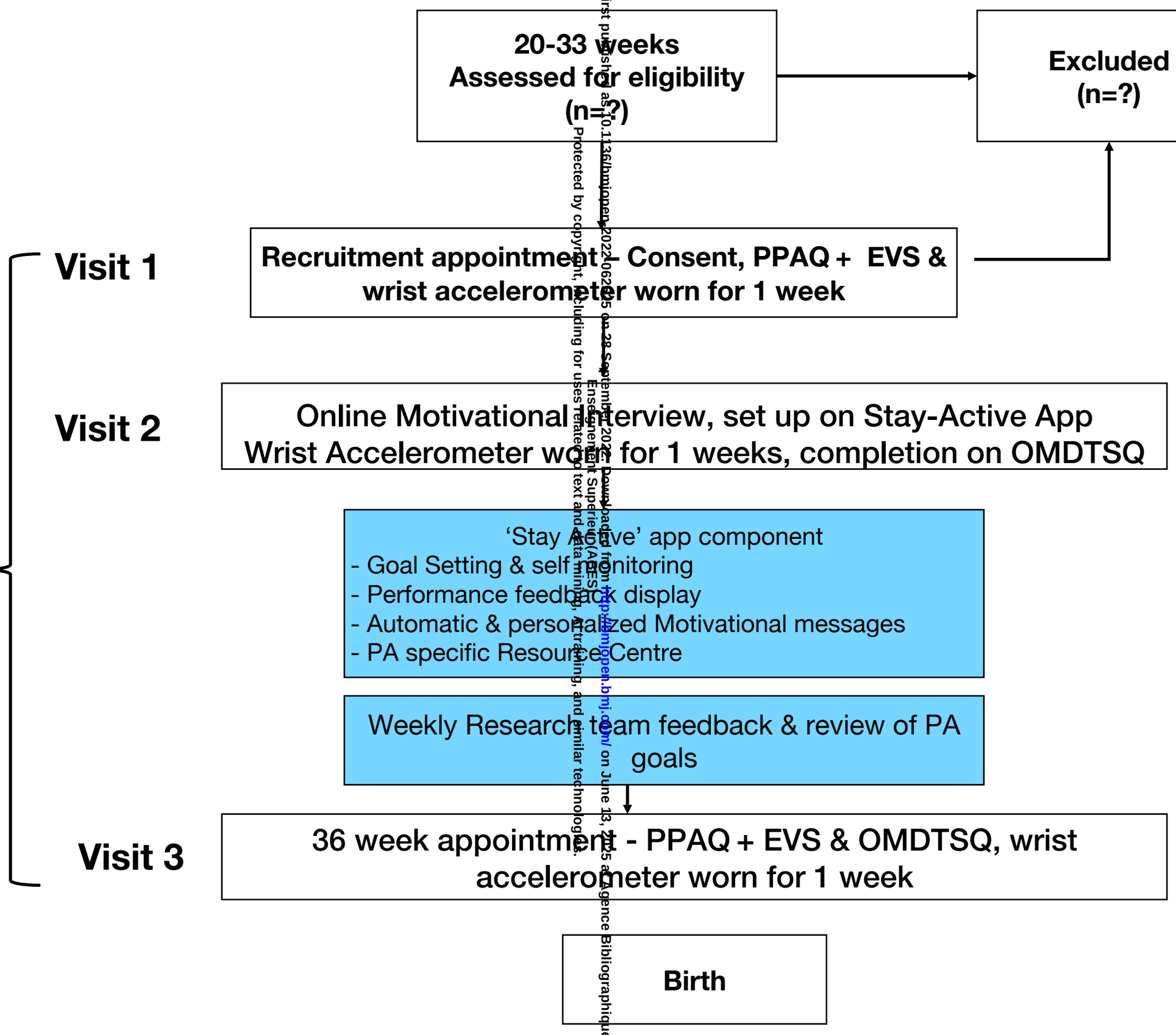
Figure 1: A flow chart of the study design



PPAQ - Pregnancy Physical Activity Questionnaire; EVS -Exercise Vital Sign; OMDTSQ – Oxford Maternity Diabetes Treatment Satisfaction questionnaire, BG – Blood Glucose

Figure 2: Primary Outcome Criteria

Criteria	How it will be assessed?		Indications of success
Recruitment rate			
			Average recruitment rate of ≥3 participants per week.
≥3 participants enrolled per week	Mean rate of recruitment over the recruitment period		Average recruitment rate ≥2 but < 3 participants per week.
			Average recruitment rate <2 participants per month.
Participant engagement with the intervention			
			95% confidence intervals that do not include 47*
60% of participants engage with the intervention	Proportion of participants assigned who wore the wrist worn accelerometer for >10 hrs a day for >5 days from recruitment		95% confidence intervals that include 60 but also include 47*
			95% confidence intervals that do not include 60 or 47*
Fidelity of the intervention			
	Proportion of participants attended an MI meeting		95% confidence intervals that do not include 47*
60% of the core elements of the intervention delivered as intended.	The audio recordings of the MI session will be coded using MITI		95% confidence intervals that include 60 but also include 47*
	Proportion of participants who set goals		
	Proportion of participants who recorded PA in the app		95% confidence intervals that do not include 60 or 47*

Retention rate			
70% of all enrolled participants attend the 36-38 week visit, compete a PPAQ and wear an accelerometer	Proportion of all enrolled participants		95% confidence intervals that do not include 58*
	Who attend the 36-38 week follow-up visit and complete PPAQ		95% confidence intervals that include 70 but also include 58*
	Proportion of participants assigned who wore the wrist worn accelerometer for >10 hrs a day for >5 days at 36-38 weeks		95% confidence intervals that do not include 70 or 58*

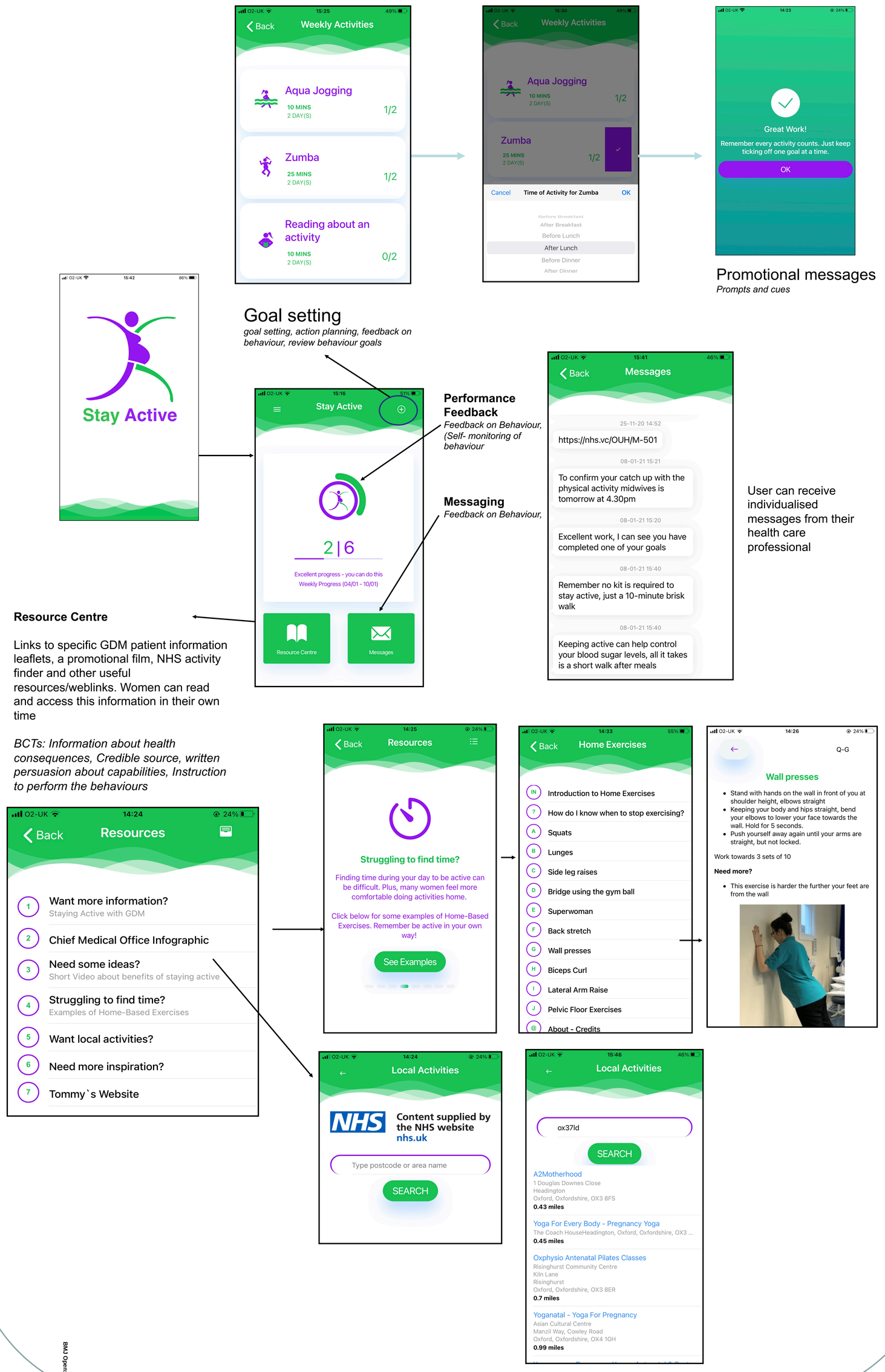
*Using formula p=estimate (percentage expected to be seen), q=1-p, n=sample size, SE= standard error

SE= √((p*q)/n)

95% CI= estimate ± 1.96*SE

Therefore, 95% CI= p ±1.96 * √((p * q)/n)

Figure 1: Behaviour Change Techniques implemented in Stay-Active



GDM – gestational diabetes Mellitus BCT – Behaviour change techniques NHS – National Health Service

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3 & 23
	2b	All items from the World Health Organization Trial Registration Data Set	23
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	n/a
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	25
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-7
	6b	Explanation for choice of comparators	5-7
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9-10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11 (table 2)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13-14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14-21 , figure 2, Table 3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9, 10-13

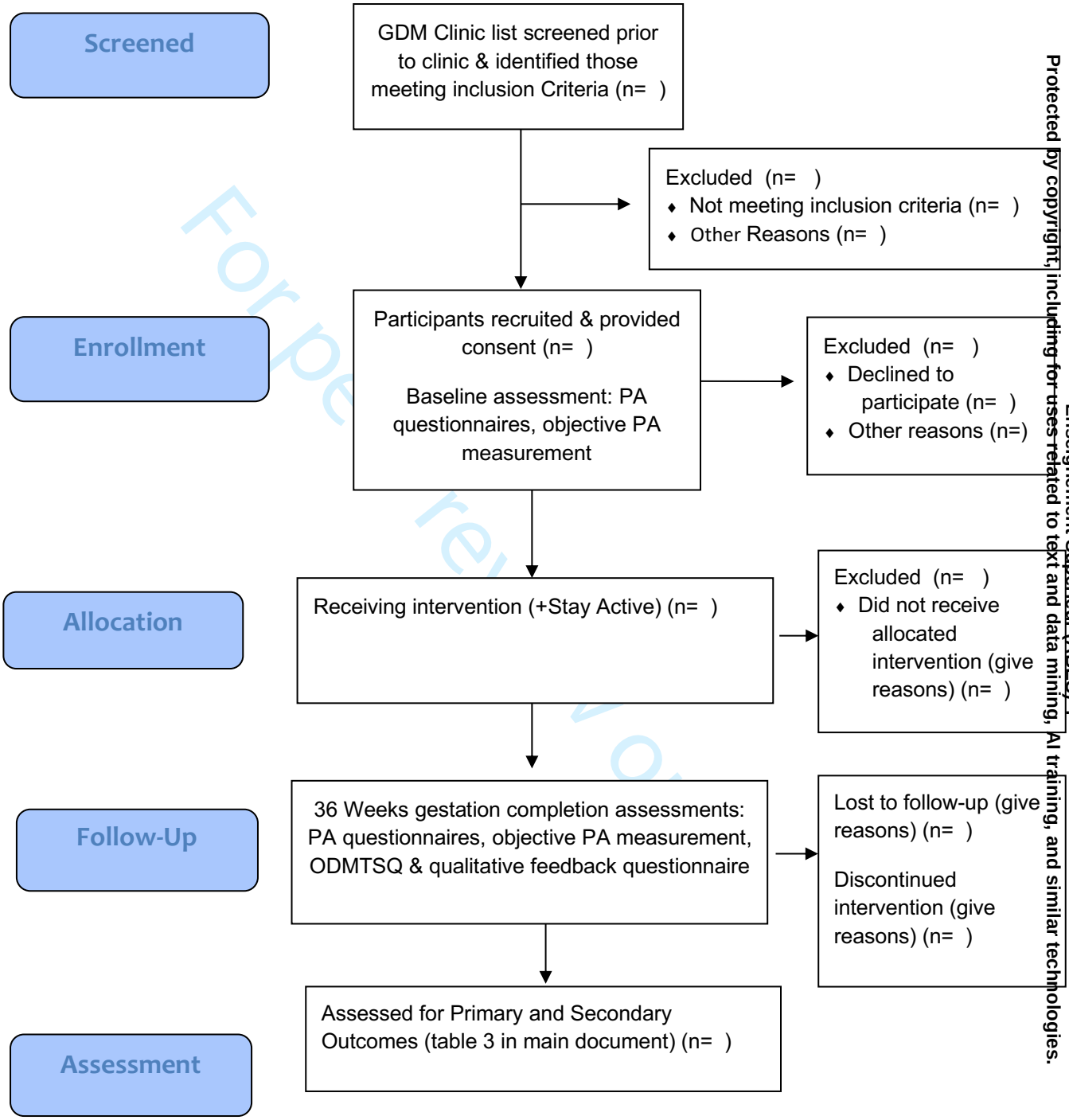
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	22
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	22, 10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-21
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-21

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14-21
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13-14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	24
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	24

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	24
	31b	Authorship eligibility guidelines and any intended use of professional writers	25
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	supplemental file 4
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Supplemental material 3: Flow diagram of enrollment, allocation, follow-up and assessment



PA – Physical Activity **OMDTSQ** – Oxford Maternity Diabetes Treatment Satisfaction questionnaire

Oxford University Hospitals
NHS Foundation Trust

Dr Lucy Mackillop

lucy.mackillop@ouh.nhs.uk

Tel: 01865 851165

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM

A feasibility study to evaluate the use of a smartphone application to support delivery of a physical activity complex intervention 'Stay Active' in women with gestational diabetes mellitus

Name of Researcher:

If you agree, please initial box

1. I confirm that I have read the information sheet dated 2nd October 2020 (version 1.2) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities and from the NHS Trust(s), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree to provide data as part of my involvement in this study and I understand I will not gain any direct personal or financial benefit from it. If a commercial product were developed as a result of this study, I will not profit financially from such a product.	
5. I agree to my GP being informed of my participation in this study	
6. I agree to the study team contacting me via telephone during the study period	

7. I understand that any data that leave the research group will be fully anonymised so that I cannot be identified.		
8. I agree to take part in this study.		
9. I agree to comments being sent to me from the study team via the Stay Active app		
10. I agree to data being extracted from the Stay Active app		
Optional:		
11. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes	No
12. I agree for my anonymised data to be used in future research, here or abroad, which has ethics approval. I understand this research may involve commercial organisations.	Yes	No
13. I agree to be audio recorded and for the use of anonymised quotes in research reports and publications.	Yes	No

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

**1copy for participant; 1 copy for researcher site file; 1 (original) to be kept in maternity notes* (if participant is a patient).

Supplemental material 5:

Details regarding Existing Motivational interviewing intervention

Women attending the clinic are invited to engage in a 20-minute individual motivational interview on PA, in addition to their routine care appointments. Most women attending their first clinic appointment are in the third trimester at approximately 28 weeks' gestation. The motivational interview consultation takes place at their initial hospital appointment following a diagnosis of GDM. It is delivered by a trained healthcare professional (HCP). Each HCP delivering the motivational interview had completed a certificated two-day training course and eight hours of supervised training. The interview is delivered using a framework, where motivational interviewing micro skills (open-ended questions, affirmations, reflections and summaries) are used in all sessions to progress participants through the processes of change (engagement, focusing, evocation, and planning)(1). It includes person-centred goal setting and activity planning if deemed appropriate for that stage of the interview. Specific information about the benefits and types of suggested PA is discussed. Table 1 outlines the structure of the motivational interviewing delivered and the BCTs used.

Results from a published quality improvement project demonstrated encouraging results (awaiting reference). Self-reported PA levels increased significantly at two-week follow-up, with a mean increase of 75 minutes/week in PA levels and more than half (56%) of the women increasing their activity to meet the PA guidelines(2, 3). The Stay-Active app will seek to build on this initial PA behaviour change supporting women to help maintain their activity levels.

Table 1: Structure of the Motivational interview:

Part	Details	Behaviour changes techniques:
1. Setting the scene & Agreeing the agenda	Establish empathy and rapport and 'goal congruence' from the start, (ii)Manage some expectations of the consultation (iii) Give the person a sense of control over the conversation and agreeing the main focus of the conversation	
2. Exploring a typical day	Understanding of a particular aspect of the patient's life, where activity fits into their lifestyle (ii)Demonstrates non-judgemental, person-centred listening skills. (iii) Listen for any 'change-talk' -indicating that the patient is thinking about change, wants to change, is able to change, has already started to make some changes, etc. (iv)Help them feel heard and understood	
3. Exploring importance	(i)Explore the importance of activity and their reasons for changing their activity levels (ii)Help the person give voice to, and better understand their own reasons for changing (iii) Elicit and develop change talk (iv)Strengthen the other persons readiness to change	Prompt and cues 7.1
4. Sharing information on benefits	Ask -Share-Ask information about benefits of physical activity specifically for GDM	Information about Health Consequence 5.1 Credible source 5.1
5. Sharing specific information/knowledge about activity	Ask -Share-Ask information about type, during and expectations about physical specifically for GDM, Address barriers about activity, discuss type, time, frequency	Information about Health Consequence 5.1 Instruction on how to perform behaviour 4.1 Credible source 5.1
6. Exploring and building confidence	(i) Strengthen their self-efficacy for change.(ii) Elicit and develop change talk.(iii) Share with them what other	Prompts and cues 7.1

	people have found helpful when making the change e.g. glucose control (using ask-share-ask)	Focus on past success 15.3
7. Sharing info about building confidence	Ask -Share-Ask information about increasing confidence to become more active (ii) Provide suggestions, increase readiness	Valued self-identity 13.4 Social comparison 6.2
9. The Key question	Help the person decide what to do next	Problem solving 2.2
10. Exploring options	(i)Generate a range of possible ways forward (ii)Build optimism and confidence that change is possible. Encourage autonomy and personal decision making. Share some of your experience and expertise about what might be helpful (ii) Make progress towards agreeing the way forwards.	Social support 3.3
11. Agreeing a plan and goal setting	Help the person generate a plan for their future (ii)Help Evoke ideas (iii) Complete personal Goal setting tool	Goal setting (behaviour) 1.1 Action planning 1.4
12. Relapse prevention	Help the person explore how their life might be different if they did decide to (and were able to) change, compared to if they didn't. (ii) Help the person better understand the risks of not changing and the benefits of changing, without you having to tell them (iii) 'Develop discrepancy' between their current behaviour and their desired future behaviour (iv) Learn more about the persons hopes, plans and values (v)Build hope Elicit and develop change talk. (vi)Agree about the need and timing of future conversations (vii)Agree about the medium and location of future conversations –face to face, telephone	Comparative imagining of future 9.3 Verbal persuasion about capability 15.1 Commitment 1.9
13. Support	Explaining the support offered.	Social Support 3.1

The numbers in brackets related to the code for the behaviour Change Technique (BCT) as per the Behaviour Change Technique Taxonomy Version 1.(4)

'The framework and content of the motivational interview (table 1) was developed with the support and assistance from the Academy for Health Coaching https://learn.academyforhealthcoaching.co.uk/

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Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (GDM Health & Stay active)

Please indicate your personal agreement with each of the following statements

* Required

1. Please enter your study participant number *

2. Visit 1 or 2 *

- ◯ Visit 1(initial consultation)
- ◯ Visit 2 (approx 36 weeks)

3. I find the equipment I use to check my blood sugars is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/a

4. I feel the equipment I use to check my blood sugars is reliable *

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

5. My blood sugar monitoring fits in with my lifestyle *

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

6. The feedback I receive about my blood sugar level is useful *

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/a

7. I feel the system I use to calculate carbohydrate is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

8. I feel the system I use to calculate carbohydrate is reliable *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/a

9. I feel the feedback I receive about my carbohydrate intake is useful *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

10. I feel the system I use to record my weight is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

11. I feel the system I use to record my weight is useful *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

12. I feel the system I use to measure my physical activity/exercise level is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

13. I feel the feedback I receive about my physical activity/exercise levels is useful *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

14. How often would you have liked feedback? *

- ◯ Daily
- ◯ Every 2-3 days
- ◯ Every 4-5 days
- ◯ Weekly
- ◯ Only when necessary
- ◯ N/A

15. Is there a particular area where you would have liked more feedback? *

- ◯ Blood glucose
- ◯ Carbohydrate intake
- ◯ Physical Activity/Exercise
- ◯ Weight gain
- ◯ None

16. Please use box below for any further comments: Particular regarding the Stay-Active App (ease of use & recommendation to the others)

BMJ Open

Study Protocol: Use of a smartphone application to support the implementation of a complex physical activity intervention (+Stay Active') in women with gestational diabetes mellitus: protocol for a non-randomised feasibility study

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Secondary Subject Heading:	Sports and exercise medicine
Keywords:	Diabetes in pregnancy < DIABETES & ENDOCRINOLOGY, Information

	technology < BIOTECHNOLOGY & BIOINFORMATICS, Maternal medicine < OBSTETRICS, PUBLIC HEALTH

Study Protocol: Use of a smartphone application to support the implementation of a complex physical activity intervention (+*Stay Active'*) in women with gestational diabetes mellitus: protocol for a non-randomised feasibility study

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Abstract

Introduction

Physical activity (PA) interventions have a promising role in the management of gestational diabetes mellitus (GDM). Digital technologies can support PA at scale and remotely. The protocol describes a study designed to determine the feasibility and acceptability of a complex intervention; known as +Stay active. +Stay Active combines motivational interviewing with a bespoke behaviour change informed smartphone application (Stay-Active) to augment PA levels in women with GDM.

Methods & analysis:

This is a non-randomised feasibility study using a mixed methods approach. Participants will be recruited from the GDM antenatal clinic at the Women Centre, John Radcliffe Hospital, Oxford. Following baseline assessments (visit 1) including self-reported and device determined PA assessment (wearing a wrist accelerometer), women will be invited to participate in an online motivational interview, then download and use the Stay-Active app (Android or iOS) (visit 2). Women will have access to Stay-Active until 36 weeks gestation, when engagement and PA levels will be reassessed (visit 3). The target sample size is 60 women. Primary outcomes are recruitment and retention rates, compliance and assessment of participant engagement and acceptability with the intervention. Secondary outcomes are assessment of blood glucose control, self-reported and device determined assessment of PA, usage and structured feedback of participant's attitudes to +Stay Active, assessment of health costs and description of maternal and neonatal outcomes. This study will provide key insights into this complex intervention regarding engagement in smartphone technology and the wearing of accelerometers. This data will inform the development of a randomised controlled trial with refinements to intervention implementation.

Ethics and dissemination

The study has received a favourable opinion from South Central - Hampshire B Research Ethics Committee; REC reference: 20/SC/0342. Written informed consent will be obtained from all participants. Findings will be disseminated through peer-reviewed journals, conferences and seminar presentations.

Trial registration: ISRCTN11366562.

Word Count (296) 300

Keywords Gestational diabetes Mellitus, Physical Activity, Smartphone Applications.

Strengths and limitations of this study

- The study will combine motivational interviewing with a bespoke smartphone application (Stay-Active) to support PA activity levels in women with gestational diabetes.
- It will provide evidence on the feasibility and acceptability of this complex intervention.
- The study design is not powered to determine intervention efficacy or clinical effectiveness.
- Conclusions of this study will be limited due to the lack of a control group.
- Results from this study will inform whether a randomised control trial (RCT) to evaluate this intervention is feasible.

Introduction

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance first detected during pregnancy (1). GDM is associated with serious complications for both mother and baby (2-4). Fundamental to the management of GDM is glycaemic control (5), with increasing levels of blood glucose suggested as the mechanism for the increased risk of adverse maternal and infant outcomes (6). Interventions for GDM include blood glucose (BG) monitoring, lifestyle intervention and pharmacological therapy. Of the lifestyle interventions dietetic modifications and physical activity are the only interventions that have reported possible health improvements for maternal and fetal outcomes (7).

There is growing evidence supporting the benefits of PA amongst women with GDM. Meta-analyses of interventions to increase PA among pregnant women, have shown improvements in glycaemic control and reduced insulin requirements (8, 9). Guidance on the clinical management of GDM, from the National Institute for Health and Care Excellence (NICE), recommends healthcare professionals advise women with GDM to exercise regularly (10). Qualitative reports have found that women with GDM would prefer clear, simple and specific PA messages with flexible options(11).

Fundamental to the success of PA interventions is a sound theoretical basis with the incorporation of appropriate Behaviour Change Techniques (BCTs), particularly those that are person-centred, addressing specific barriers and enablers (12).

We have shown how motivational interviewing (using several Behaviour Change Techniques (BCTs)) can increase PA in women with GDM. Motivational interviewing incorporated into the routine clinical care for 64 women with GDM, found a significant increase in self-reported PA levels after two weeks(13). Women were invited to a 20-minute individual motivational interview with a trained health care professional focusing on being physically active during their pregnancy. A specific motivational interviewing framework was used including key micro-skills, individual goal setting, activity planning and specific information about the benefits and types of suggested PA. While motivational interviewing has been shown to be effective and may provide the initial catalyst for behaviour change, the challenge of supporting women to maintain this change remains.

Digital technologies are used for remote management of glycaemic control in women with GDM (14) and provide an opportunity to support and promote PA remotely. A smartphone application 'Stay-Active', referred to as the 'app', has been designed to enhance and support the existing motivational interviewing intervention. This multi-component application was designed following a systematic approach using the Behaviour Change Wheel (BCW)(15). The development process was informed by current evidence, focus groups and input from key stakeholders(16). The final design of Stay-Active delivers ten BCTs via an educational resource centre, with goal setting and action planning features, personalised performance feedback and individualised promotional messages (table 1 and supplemental material 1 show the integration of BCTs within Stay-Active). A unique feature of this app is the clinicians ability to interact with the user. Clinicians can review recorded PA remotely and directly send users specific tailored messages via the app to support and maintain PA. This protocol outlines a study (+Stay Active) to determine the feasibility and acceptability of the combined interventions (Stay-Active + Motivational Interviewing consultation) in women with GDM.

Table 1: The Selected Behaviour Change Techniques with descriptions and Stay-Active Function

Behaviour Change Technique	BCT description	Stay-Active (Smartphone App) function
Goal setting [1.1]	Set or agree a goal defined in terms of behaviour to be achieved.	Specific goal setting function. Users can set personalised weekly goals. They can review and record goals directly onto the app, update and can access them at any time. Weekly goals are integrated into the performance feedback wheel.
Action planning [1.4]	Prompt detailed planning of performance of the behaviour (must include at least one of the following context, frequency, duration and intensity).	Users are encouraged to set personalised weekly goals with a specialist midwife at the end of MI. Users can set personalised weekly goals on the app. Examples include a brisk walk for 20 minutes x3/week or attending a yoga class.
Review behaviour goals. [1.5]	Review behaviour goals(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement.	SM's can view how the women progress in real time. SM's can contact women via the message centre if they have not logged or registered activity. The midwives will provide support over the phone or via the message centre weekly.
Self- monitoring of behaviour [2.3]	Establish a method for a person to monitor and record their behaviour(s)as part of a behaviour change strategy.	Users can record their PA on Stay-Active and tracking their completed goals on the performance feedback wheel.
Instruction to perform the behaviour [4.1]	Advice or agree on how to perform behaviour.	See resource centre text below.
Credible source [9.1]	Present verbal or visual communication from a credible source in favour of or against the behaviour.	See resource centre text below.
Written persuasion about capabilities [15.1]	Inform the person that they can successfully perform the wanted behaviour.	See resource centre text below.
Prompts and cues [7.1]	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour.	Users receive motivational messages about PA at 10am every day via the smartphone notification system.
Feedback on behaviour [2.2]	Monitor and provide informative or evaluative feedback on performance of the behaviour.	HCPs can view and monitor their user's activity progress and communicate feedback by individualised text messages.
Information about health Consequence [5.1]	Provide information (e.g. written, verbal, visual) about health consequence.	See resource centre text below.

SM – Specialist Midwife MI – Motivational interview PA- Physical Activity HCP – Healthcare professionals

Resource Centre within Centre:

Specific resources with Stay-Active including a healthcare provider approved leaflet on GDM and PA addressing and explaining specific benefit of PA, an infographic on the benefits and types of PA, examples with explanations of suggested home-based workouts/exercise, a short educational film on the benefits and key messages about PA in pregnancy, an embedded search function for local NHS recommended pregnancy specific PA classes, and links to two credible PA resources

[Bracketed numbers] referred to The Behaviour Change Technique Taxonomy (v1) (17)

Methods and Analysis

Aims

The purpose of the study is to evaluate how women with GDM interact, engage with and respond to a complex intervention, known as +Stay Active. This will help determine whether a randomised control trial (RCT) to evaluate this intervention is feasible. A future RCT would explore the efficacy of such an intervention to increase PA and evaluate the effect on clinical outcomes such has glycaemia control, medication usage and macrosomia.

The +Stay Active intervention combines an initial PA motivational interview to encourage women to recognise the value of PA in pregnancy and in the management of GDM. Women are then supported by BCW designed multi-component smartphone app 'Stay-Active'.

Objectives

1. Assess the number of women at the Women's Centre, Oxford University Hospital over a period who are eligible to participate
2. Determine recruitment and retention rate.
3. Assess fidelity of the motivational interviewing component by trained research midwives.
4. Participant adherence: Days and hours of wearing a wrist worn accelerometer for tracking PA levels; availability of data for outcome measures; attendance at follow-up sessions.

5. Assessment of the variance in different measures of PA and how they change over gestation using: (i) accelerometer data; (ii) the validated pregnancy physical activity questionnaire (PPAQ) (18), and (iii) percentage of goals achieved.
6. Explore the acceptability of the intervention to participants as assessed by the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ), structured questionnaire on participant's attitudes to +Stay Active and usage data from the smartphone app.
7. Determine any refinements required of the intervention.

Study Design

This feasibility study is a non-randomised trial. All participants will receive the intervention. A mixed methods approach will be used to assess process and effectiveness of the measures, test trial procedures, resource use, determine the most appropriate primary outcome measure and aid sample size estimates for a future definitive trial. This will inform modification and refinement of the +Stay Active intervention. Figure 1 illustrates a flow chart of the study designs, visits, and assessments.

The feasibility study will be in line with the guidance proposed(19) and reported using the Standard Protocol Items: Recommendations for Interventional Trials reporting template(20) and checklist can be found in supplemental material 2. A Flow diagram demonstrates enrolment, allocation, follow up and assessment process (supplemental material 3).

Setting & Study Participants:

All participants will be recruited from NHS maternity clinics at the Women's Centre, Oxford University Hospitals NHS Foundation Trust. The study will enrol women with a confirmed diagnosed of Gestational Diabetes Mellitus (GDM) as defined by the standard of care screening test in this NHS hospital at the time of recruitment. During recruitment this changed from

International Association of Diabetes and Pregnancy Study Groups recommendations (21) to RCOG guidance during the COVID-19 pandemic (22)and then from Jan 2022 to NICE thresholds for diagnosis (23). Women will not be eligible for the study until at least 20 completed weeks of pregnancy as the study is not investigating PA in early pregnancy. Recruitment started for this trial in April 2021 and plans to be completed in April 2022.

Patient and Public involvement:

The development of Stay-Active involved focus groups as part of Patient and Public involvement (PPI) in line with Oxford University Hospital Trust's PPI Strategy and Policy(16). AW (patient representative) provided input and oversight in the study protocol.

Visit 1: Recruitment and baseline assessments

Women attending the GDM clinic who met the inclusion criteria (see table 2) will be identified by the clinical team at their appointment and a patient information sheet will be provided. Following their clinic appointment, a research midwife will talk through the study procedure, invite questions and ask participants to sign the consent form.

If they consent to take part in the study(consent form shown in supplemental material 4) to determine baseline PA levels. They will be asked to:

1) Complete an online version of two validated questionnaires: PPAQ (18) and the exercise vital sign assessment (EVS)(24).
2) Wear a tri-axial accelerometer (GENEActiv, Active Insights Ltd, Kimbolton, UK) on their non-dominant wrist for at least seven consecutive days (worn day and night). This time frame was chosen due to its reliability to estimate measures of moderate to vigorous physical activity (MVPA) during pregnancy (25).

The participants' General Practitioner will be informed of their involvement in the study. Participants will be provided with an A4 instruction sheet which includes general care instructions. Data will be collected at 100Hz.

Table 2: Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Women who are more than 20 completed weeks pregnant and less than 33 completed weeks pregnant with a singleton pregnancy. • Abnormal Oral Glucose Tolerance Test (OGTT) as defined by IADPSG, HbA1C, fasting plasma glucose or random blood glucose as defined by RCOG Guidance for maternal medicine services in the evolving coronavirus (COVID 19) pandemic. • Using GDm-Health to monitor their blood glucose • Aged between 18 and 45 years • Willing and able to provide informed consent for participation in the study • Have, and use, a smartphone	• Multiple pregnancy • GDM not diagnosed by OGTT, HbA1C or fasting plasma glucose as defined by RCOG Guidance for maternal medicine services in the evolving coronavirus (COVID 19) pandemic. • An absolute contra-indication to physical activity as per 2019 Canadian guidelines(26)e.g. preterm rupture of membranes, limited mobility, haemodynamically significant heart disease, restrictive lung disease • Unable to understand written or spoken English

GDM – Gestational Diabetes Mellitus
RCOG – Royal College of Obstetrics and Gynaecology
OGTT - Oral Glucose Tolerance Test

Intervention:

Visit 2: Motivational interview & Smartphone App download

We will ask participants to attend a virtual study visit (Visit 2) one week later. During this visit, participants will receive a 20-minute motivational interview with a trained research midwife during which if appropriate they will agree a set of weekly exercise goals. A virtual study visit was chosen because of COVID-19 restrictions. The participant will be asked to wear the accelerometer for a further week after the motivational interview (i.e. total of 2 weeks) and will post back the accelerometer using a pre-paid addressed envelope that will be issued to participant at visit 1.

The motivational interviewing will take place remotely via the secure NHS online platform 'Attend Anywhere' or by telephone depending on the woman's preference. All motivational interviews will be audio recorded using a dictaphone (where participants consent to this). No patient identifiable data will be recorded, and the audio-file will be labelled with a unique study specific number. Completed interviews will be downloaded onto a secure University of Oxford server and deleted from the portable device. The anonymised audio-files will be accessed only by the study team involved in either recording or analysing the data. The structure of the motivational interview consultation is shown in supplemental material 5). Ten percent of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1)(27) to assess the fidelity of the interview by an experienced coder. This sample size is in-line with practical recommendations(28).The interviews will be picked at random using a random number generator.

Study participants are asked to complete the validated Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ)(29) (supplemental material 6) after the motivational interview.

During the second half of the motivational interview, participants will be encouraged to download the 'Stay-Active' smartphone app and shown the main features: recording their activities, reviewing their PA goals, and exploring the resource centre.

Interactions with participants & motivational support during study period

Participants will receive a weekly telephone call from the research team to review and adjust their activity goals. Participants will be provided with individual motivational feedback messages from the research team at least weekly by text message via the Stay-Active.

Visit 3: Assessment & Completion of intervention

A follow-up appointment will be scheduled for 36 weeks' gestation at which the participant will be asked to complete an online version of PPAQ (18), the exercise vital sign assessment(24) and OMDTSQ (supplementary material 4). They will also be asked to wear the accelerometer for 1 week. Via the notification on Stay-Active, participants will be prompted to complete a feedback form on the intervention (a five-star scale rating will be used for the motivational interview, goal setting, tracking of goals, automated and personalised messages and an opportunity to provide written feedback). Access to the Stay-Active will terminate 1 week after the routine 36 weeks gestation follow up appointment.

Early Discontinuation/Withdrawal of Participants

A participant may choose to withdraw at any time. This may happen for several reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable adverse effect
- Inability to comply with study procedures.
- Participant decision.

Data with consent will be retained and used in the analysis. In addition, the lead investigator (LM) may discontinue a participant if it is considered necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening).
- Significant protocol deviation.
- Significant non-compliance with treatment regimen or study requirements.
- Clinical decision.

The nature and reason for the withdrawal will be recorded.

Study Outcomes:

Primary Outcomes

The primary outcomes will be the feasibility and acceptability of the intervention to inform a decision on whether a randomised controlled trial is warranted and feasible. This will be assessed against a set of predefined criteria (outlined in figure 2) related to i) participant engagement with the intervention, ii) recruitment and iii) retention rates, iv) fidelity of the intervention. A traffic light system will determine the progression to a definitive trial. This system has been suggested to be preferable to the stop/go pass/fail approach(30). The primary objective with outcome measures and timepoints are shown in table 3 and figure 2.

283 Table 3: Objectives, outcome measures and timepoint of evaluation:

Objectives	Outcome Measures	Timepoint(s) of Evaluation of Outcome Measure
Primary Objective		
To evaluate how women with GDM interact, engage with and respond to *Stay Active+* and to determine whether an RCT to assess the efficacy of this intervention is feasible.	Recruitment rates • Percentage of eligible participants at the Gestational Diabetes Clinic, Women Centre, John Radcliffe Hospital. • Percentage of women who fulfil the eligibility criteria and accept the invitation to participate	Recruitment & at end of study period
	Retention rate • Proportion of women that completed the study	At end of the study (36 weeks)
	Participant engagement with the intervention • Participant adherence rates to wrist worn accelerometer: o Number of days worn over 7 days period, average daily wear, portion of week availability of data for PA outcome measures. • Attendance rate at follow-up sessions. • Completion rates of self-reported PA questionnaires. • Proportion of participants who set goals on Stay-Active. • Proportion of participants who recorded PA on Stay-Active.	At visit 1& end of study period (36 weeks gestation)
	Acceptability: • Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants.	Visit 2 & end of study period (36 weeks gestation)
	Fidelity of the intervention • All Motivational Interviews will be audio recorded. • 10% of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1) to assess the fidelity of sessions.	Visit 2 End of study period (36 weeks gestation)
Secondary Objectives		

1. Assessment of PA	Attainment of information on physical activity time, type, intensity, and frequency assessed from baseline and subsequent visits i) Device specific (accelerometer) data: (Total PA average per measured day, moderate to vigorous PA and average Acceleration) ii) PPAQ – outcome: Energy expenditure iii) EVS – Weekly minutes of Moderate to Vigorous PA	At recruitment visit 2 and visit 3.
2.Usage and Participant attitudes to +Stay Active	i) Stay-Active Usage: • Average time spent on app per week • Average time per session • Frequency of app opened and duration per session • Number of participant logging activity per week ii) Participants attitudes to +Stay-Active (5 questions rating) on the usefulness of: Motivational interviewing, goal setting, tracking your goals via the app, automated motivational messages, personalised messages and an open comments section.	From visit 2 to participant completion Visit 3: 36 weeks gestation
3. Assessment of blood glucose control & medication prescribed	i) Difference in glycaemic control measured as mean BG at recruitment and at 36-38 weeks (using BG taken in the week that the accelerometer is worn), adjusted for number and timing of measurements). ii) Participant's prescribed medication (generic name and dose)	Recruitment & Visit 3 (36 weeks' gestation)
4. Description of maternal and Neonatal outcomes.	i) Maternal outcomes (weight gain, pharmacological medication (initiation, timing and doses in relation to meals and BG readings), hypertensive disorders of pregnancy (gestational hypertension and pre-eclampsia), gestation at delivery, mode of delivery). ii) Neonatal outcomes (birth weight, neonatal hypoglycaemia, neonatal hyperbilirubinaemia, admission to SCBU for >24 hrs, shoulder dystocia).	Data gathered 6 weeks post delivery
5. Assessment of health costs	Number of additional visits, contacts made by research Midwife (both text message and telephone call) and time spent delivering intervention	Throughout study period
6 Determine any refinements required of the intervention.	Review and analysis of the primary and secondary outcome data	Following data analysis

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Secondary Outcomes

Secondary outcomes include assessment of blood glucose measurements and control, assessment of PA, qualitative assessment of participant's attitudes to +Stay Active, description of maternal and neonatal outcomes, a description of additional health costs and any refinements required of the intervention (table 3).

i) Assessment of Physical activity

Three methods for assessing PA will be used: Two self-reported questionnaires and one wrist-worn accelerometer. All have different strengths and limitations. Both the PPAQ and the wrist worn accelerometer are validated measures in this population. An evaluation of the feasibility, acceptability and quality of data gathered by each method will be undertaken. This will inform the method to be used in future studies.

a) Self-Reported physical activity assessment:

Two self-reported questionnaire measuring PA (EVS & PPAQ) will be completed at baseline and visit 3 (36-week gestation).

The PPAQ is self-administered. Participants are asked to select the category that best approximates the amount of time spent in 32 activities including household/caregiving, occupational, sports/exercise, and inactivity during the current trimester. Minor adaptations to the phasing of two PPAQ questions were made to make them more appropriate more relevant to a UK population. Following completion, the duration of time spent in each activity is multiplied by its intensity to arrive at a measure of average weekly energy expenditure (MET-h·week-1) attributable to each activity.

EVS is self-administered and consists of two questions. The introductory texts of the EVS has been modified to be specific to pregnancy.

1) On average, how many days per week do you engage in moderate intensity or greater physical activity (like a brisk walk) lasting at least 10 minutes?

2) On those days, how many minutes do you engage in activity at this level?

Total weekly moderate aerobic activity can be calculated.

Both self-reported measures have been chosen because whilst PPAQ has been specifically designed and validated for pregnant women(18), it takes time to complete and is not entirely practical for the clinical setting. The EVS has been validated as a self-reported PA outcome measure(24), but to date has not been specifically validated for pregnant women. EVS is a simple, practical, and time-efficient tool for clinical staff. It is already integrated in the hospital's electronic patient record system; it automatically calculates and documents a weekly physical activity level. Data will be collected for a further study aiming to validate this tool amongst pregnant women.

b) Device measured physical activity: Accelerometers & data

The GENEActiv is a triaxial accelerometer which can be worn continuously for long durations (up to 30 days) to provide precise estimates of physical activity. The device can be worn on multiple different bodily locations: hip, thigh, waist and wrist. The device worn on the non-dominant wrist has been found to provide robust PA estimates (at least equal to hip/waist worn devices) and is associated with better compliance to wear protocols and acceptable to clinical populations (31, 32). The GENEActiv accelerometer objectively measures and stores movement acceleration in g (the standard SI unit of acceleration) for offline analysis, thereby allowing a range of data processing techniques to be applied post data-collection to derive estimates of physical activity.

This study will examine the feasibility of using the GENEActiv accelerometer to assess changes in PA across the intervention period. Participants will be asked to wear the accelerometer on their non-dominant wrist continuously for 7 consecutive days at baseline (following visit 1), the week following motivational interviewing (visit 2) and at 36 weeks (following visit 3). Average daily accelerometer wear-time (in hours) can be calculated from which we can infer the acceptability of the measurement protocol and the feasibility of collecting sufficient data in a subsequent trial. Data will be collected at 100Hz.

This study will also provide data regarding the inter and intra-person variation in PA, and the change in PA across gestation to inform a subsequent trial. At the end of each measurement period, the raw accelerometer output data will be uploaded securely using the GENEActiv software (GENEActiv, version 2.2, Active Insights Ltd). At the studies completion, these raw data files will then be processed using the validated 'GGIR' script in the R environment (http://cran.r-project.org) to derive a series of standardised physical activity variables by applying previously validated acceleration threshold values to define PA by intensity (as light, moderate and vigorous intensity) (33). The specific outcomes variables derived for descriptive analyses in this study will be average daily minutes of total PA (any movement with a measured acceleration value of ≥ 40 mg) and average daily minutes of moderate to vigorous PA (MVPA) (≥ 93.2 mg). These PA variables are appropriate as: 1) both diabetes (34) and pregnancy (26) specific guidelines recommend 150 minutes per week of MVPA, and 2) there is growing recognition that PA of an intensity below moderate (i.e. any movement) is also important for daily glycaemic control(35). Observed changes in these variables from baseline through follow-up can be used to inform sample size calculations for a subsequent efficacy study.

Usage and Participant attitudes to +Stay Active

The Stay-Active app-based platform is available on Android and iOS mobile operating systems. Amongst the core functionalities, the participants can view their latest activity plan and record their physical activity sessions. The App also measures the sequence of actions and time taken for participants to access various sections of the App (user flow). If an active internet connectivity is available on the phone, or once it is restored, all the information is synchronised with the secure Stay-Active server, hosted in the Oxford University Hospitals NHS Trust network.

The compliance information (e.g. participant activity log, last synchronisation time of the app) is available in real-time on the health-care professional interface, hosted in the above mentioned secure NHS server. This will allow researchers to register new participants, create and manage their activity plan, review the participants registered activities in real-time, and send SMS messages directly to the participants. To contribute to an assessment of engagement; average time spent on app per week, frequency of app opened, and duration of each session will be evaluated.

At 36 weeks; via a feature on Stay-Active; study participants will complete the star rating questionnaire outlined in visit 3.

Assessment of blood glucose control and medication use

Blood glucose (BG) values during the periods of accelerometer (recruitment and 36 weeks) will be extracted from the participant medical records. All participants will be recording their BGs using the GDm-health™ smartphone app which is a standard of care. The difference in glycaemic control measured as mean BG at recruitment and at 36-38 weeks will be assessed

(using BG taken in the week that the accelerometer is worn, adjusted for number and timing of measurements). The GDm-Health smartphone app records when medication for GDM is prescribed; for all participants number, name and doses of medication at recruitment and at week 36 gestation (visit 3) will be recorded.

Description of maternal outcomes & neonatal outcomes

After delivery the maternal outcomes and neonatal outcomes (listed in table 3) will be extracted from the medical records.

Assessment of health costs:

Health economic information including number of additional visits, contacts (both text message and telephone call) and time spent by research midwife delivering the intervention will be recorded.

Data Collection Procedure:

Both the self-reported questionnaire measures of PA (EVS & PPAQ) will be completed at baseline and visit 3 (36-week gestation). The OMDTSQ will be completed at visit 2 and 3. All questionnaires will be completed on Microsoft forms by participants through a secure online link. The participants will be identified by a unique study specific number in any database. The name and any other identifying detail will NOT be included in any study data.

Statistics & Analysis

This is a single arm feasibility study. The results will consist of descriptive statistics for assessments at the 3 visits - baseline, 36–38-week, endpoint, and for data collected from the postnatal visit. The statistics software package used will be Stata 14 and R. The measures that will be assessed are listed under a description of the visits.

Summary statistics will be calculated for all measures. Continuous variables will be reported as means, standard deviations, maximum and minimum values. Binary variables will be reported as counts. The number of missing values will be reported.

Sample Size Determination

The sample size determination is pragmatic and based on this fixed period of recruitment and likely recruitment rates. Individual participation is for approximately 3 months during pregnancy. Recruitment will be initially for 6 months. During this time, it is estimated that 6 new patients will attend the GDM clinic per week. Informed by recruitment to TREAT-GDM (ClinicalTrials.gov NCT01916694), we expect 50% to agree to participate in this study; therefore 78 over a 6-month period. Estimating a 20% drop out rate; this would allow us to reach our pragmatic target of 60 patients during this time.

Ethics and Dissemination:

All procedures will be followed are in accordance with the Declaration of Helsinki.

This study has received a favourable opinion from South Central - Hampshire B Research Ethics Committee; REC reference: 20/SC/0342. Written informed consent will be obtained from all participants. To facilitate the extra study visits, travel expenses will be paid on presentation of a receipt. This study is registered https://www.isrctn.com/ISRCTN11366562. The study protocol is pre-registered with ISRCTN 39136. Results will be disseminated through peer-reviewed journals, conferences and seminar presentations.

Discussion

We describe the protocol for a study to assess the feasibility and acceptability of an intervention combining motivational interviewing with a smartphone application to increase PA.

There is growing evidence supporting the benefits of PA amongst women with GDM. Exercise interventions have been reported to significantly improve postprandial glycaemic control (mean difference –0.33 mmol/L) and lowered fasting blood glucose (mean difference–0.31mmol/L) when compared with standard care alone. Effects were found from both aerobic and resistance exercise programs, if performed at a moderate intensity or greater, for 20 to 30 minutes, three to four times per week(9). A separate analysis of 12 studies (2 resistance training, 8 aerobic exercise, 2 combination resistance/aerobic) found requirements of insulin therapy, dosage, and latency to administration were improved in the exercise groups. Both aerobic, resistance or combination were effective at improving blood glucose control in patients with GDM(8). Hillyard et al meta-analysis of dietary and PA intervention including 21 RCT (n=1613), of which 7 were PA interventions, reported PA reduced insulin use by 47%(36).

However, most exercise interventions are supervised exercise and well resourced; potentially being difficult to translate into the health care setting. Integration of health coaching and evidence based behavioural strategies (goal setting, monitor and feedback) has been suggested to provide the most appropriate tools for translation of this evidence into clinical practice(37). +Stay Active integrates these key principles and has a unique ability for the clinicians to interact with the user.

Digital technologies provide a potential to remotely support PA at scale. App-based interventions have been shown to be effective for increasing PA. Multi-component interventions appear to be more effective than standalone interventions (38). Promising results from a randomised trial, that used a similar approach to +Stay Active, found the combination of a mobile phone app and brief counselling increased objectively measured PA over three months in physically inactive non-pregnant women (39). A key aspect is the timing of our intervention, building on a potential 'teachable moment'(40) following a diagnosis of GDM where there is an opportunity for women to re-focus on PA with the health of the baby and glycaemic control being strong motivators. There is already a commercially available CE-marked smartphone glucose management application GDm-Health (14) embedded within the clinical pathway for women with GDM at the study site, which has previously shown high levels of patient engagement, compliance and usage (29). If +Stay Active is feasible and acceptable, it could provide additional functionality to applications such as GDm-Health, improving usability and accessibility, allowing users to observe the direct impact of PA on their blood glucose control.

This study will determine whether a RCT to evaluate this intervention is feasible. A future RCT would explore the efficacy of intervention to increase PA and evaluate the effect on clinical outcomes. Furthermore, it could be adaptable for other cohorts of pregnant women including pre-eclampsia and other risk conditions.

Figure Legends:

Figure 1

This figure demonstrates a flow chart of the study design with participant visits and assessment over the study period. All women will receive standard clinic care during the study which includes remote blood glucose monitoring and management through GDm-health™ smartphone application.

Figure 2

Figure 2 shows the primary outcomes and the predefined criteria. These are related to i) participant engagement with the intervention, ii) recruitment and iii) retention rates, iv) fidelity of the intervention. This traffic light system will determine the progression to a definitive trial. For this progression criteria the following formula was used to estimate the 95% CIs: https://www.rds-london.nihr.ac.uk/resources/justify-sample-size-for-a-feasibility-study/. Green represents a threshold above the desired rate of completion including 95% confidence interval. Amber represents a threshold above the desired rate of completion but may cross 95% CI and Red represents a threshold below the desired rate of completion including 95% CI.

Supplementary material 1:

This figure includes a demonstration of a training exercise (wall press exercise). Please note the person depicted is not patient and the photograph was taken with the participant's knowledge and consent

Authors' contributions

RS, LM, CR, MS contributed and helped with design of Stay-Active. RS, JH, MM, LM, NA, JB, PB, PD, SJ, RP, CR, MS, LT, NW, AW and YK drafted and wrote the manuscript. All authors revised the content of the article, and approved the final version.

Competing interests

LM, JH, MM, YK, RS, NW, JB are supported by the NIHR Oxford Biomedical Research Centre. LM is a part-time employee of EMIS Group plc. LT is a Non-Executive Director, part-time employee and shareholder of Sensyne Health plc.

JH is funded by a UKRI Future Leaders fellowship.

The remaining authors have no disclosures of interest and there are no other conflicts to declare.

Consent for publication

In relation to supplemental file 1, informed consent for the publication of identifying images in an online open-access publication was obtained from the individual shown in the exercise demonstration photographs.

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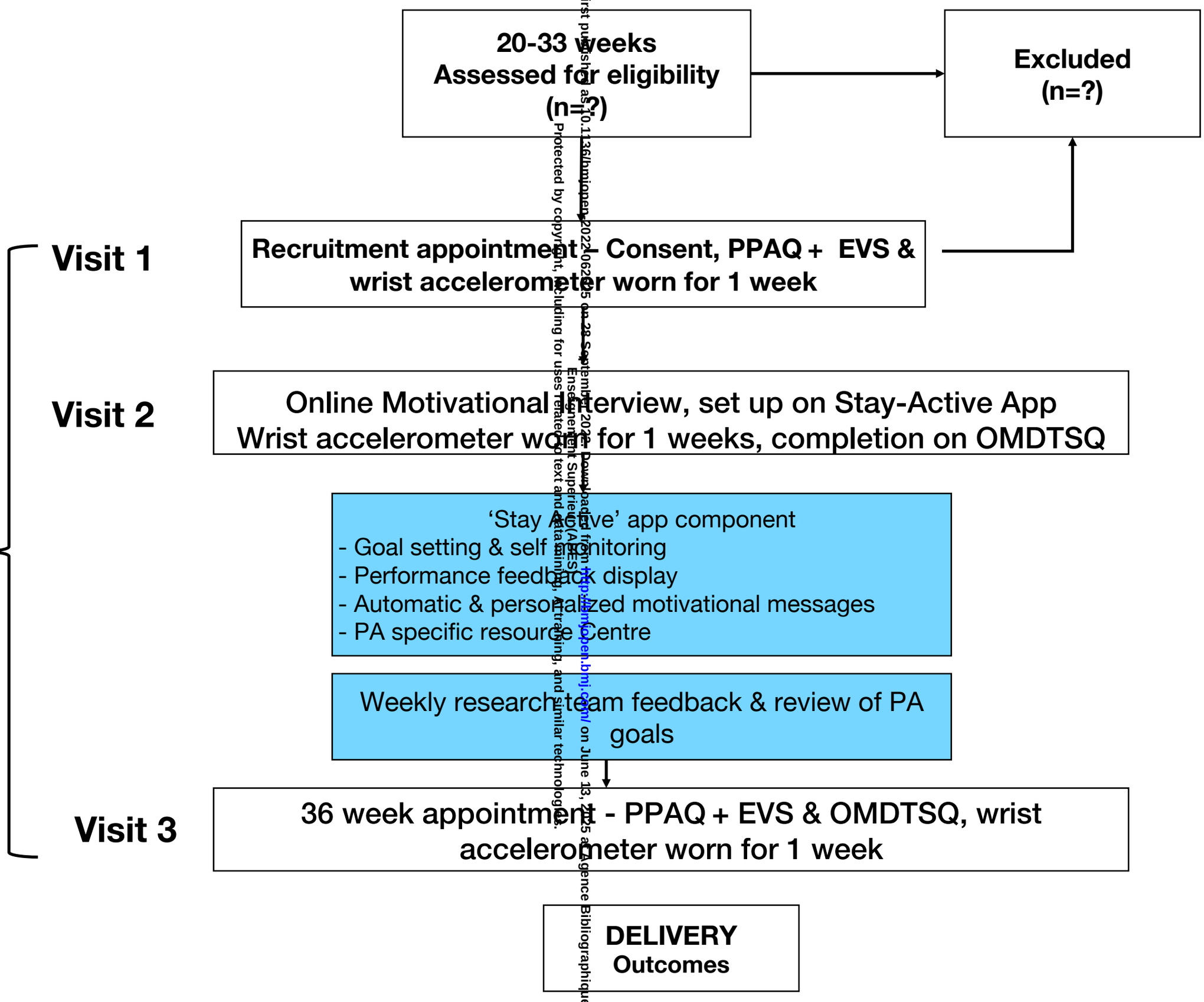
Figure 1: A flow chart of the study design



PPAQ - Pregnancy Physical Activity Questionnaire; EVS -Exercise Vital Sign; OMDTSQ – Oxford Maternity Diabetes Treatment Satisfaction questionnaire, BG – Blood Glucose PA- Physical Activity

Figure 2: Primary Outcome Criteria

Criteria	How it will be assessed?		Indications of success
Recruitment rate			
≥3 participants enrolled per week	Mean rate of recruitment over the recruitment period		Average recruitment rate of ≥3 participants per week.
			Average recruitment rate ≥2 but < 3 participants per week.
			Average recruitment rate <2 participants per month.
Participant engagement with the intervention			
60% of participants engage with the intervention	Proportion of participants assigned who wore the wrist worn accelerometer for >10 hrs a day for >5 days from recruitment		95% confidence intervals that do not include 47*
			95% confidence intervals that include 60 but also include 47*
	Proportion of participants who set goals		95% confidence intervals that do not include 60 or 47*
	Proportion of participants who recorded PA in the app		
Fidelity of the intervention			
60% of the core elements of the intervention delivered as intended.	Proportion of participants attended an MI meeting		95% confidence intervals that do not include 47*
	The audio recordings of the MI session will be coded using MITI		95% confidence intervals that include 60 but also include 47*
			95% confidence intervals that do not include 60 or 47*
Retention rate			
70% of all enrolled participants attend the 36-38 week visit, compete a PPAQ and wear an accelerometer	Proportion of all enrolled participants Who attend the 36-38 week follow-up visit and complete PPAQ		95% confidence intervals that do not include 58*
			95% confidence intervals that include 70 but also include 58*
	Proportion of participants assigned who wore the wrist worn accelerometer for >10 hrs a day for >5 days at 36-38 weeks		95% confidence intervals that do not include 70 or 58*

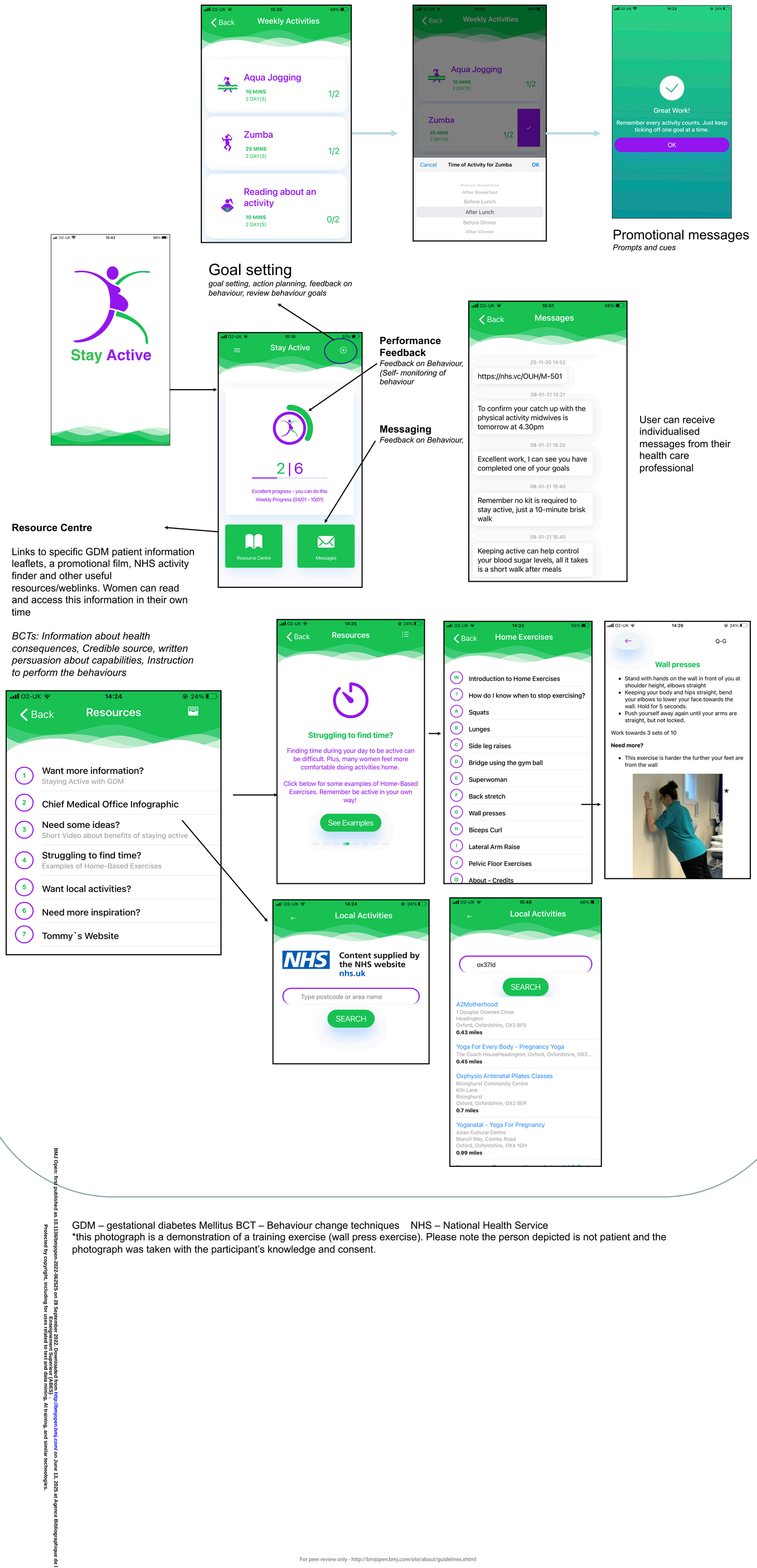
*Using formula p=estimate (percentage expected to be seen), q=1-p, n=sample size, SE= standard error

SE= √((p*q)/n).

95% CI= estimate ± 1.96*SE

Therefore, 95% CI= p ±1.96 * √((p * q)/n)

Figure 1: Behaviour Change Techniques implemented in Stay-Active



GDM – gestational diabetes Mellitus BCT – Behaviour change techniques NHS – National Health Service
*this photograph is a demonstration of a training exercise (wall press exercise). Please note the person depicted is not patient and the photograph was taken with the participant's knowledge and consent.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract & Ethics and Dissemination:
	2b	All items from the World Health Organization Trial Registration Data Set	Ethics and Dissemination
Protocol version	3	Date and version identifier	_____
Funding	4	Sources and types of financial, material, and other support	Funding
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page
	5b	Name and contact information for the trial sponsor	n/a
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Funding

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Introduction
	6b	Explanation for choice of comparators	Introduction & Method and analysis
Objectives	7	Specific objectives or hypotheses	Method and Analysis
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Study design
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study design
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Study design (table 2)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Method and Analysis subsection intervention

	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Method and analysis - Early Discontinuation/Withdrawal of Participants
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Study outcomes, figure 2, Table 3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Method and analysis visit description (figure 1)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size determination
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Sample size determination & Visit 1: Recruitment and baseline assessments

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Method and Analysis Visit 1: Recruitment and baseline assessments
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Method and analysis and study outcomes
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Method and anaylsis, subsection visits
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Outcomes -data collection procedure

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Statistics & Analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Statistics & Analysis
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Statistics & Analysis
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	method and analysis, Competing interests
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Early Discontinuation/Withdrawal of Participants
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics and Dissemination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Ethics and dissemination

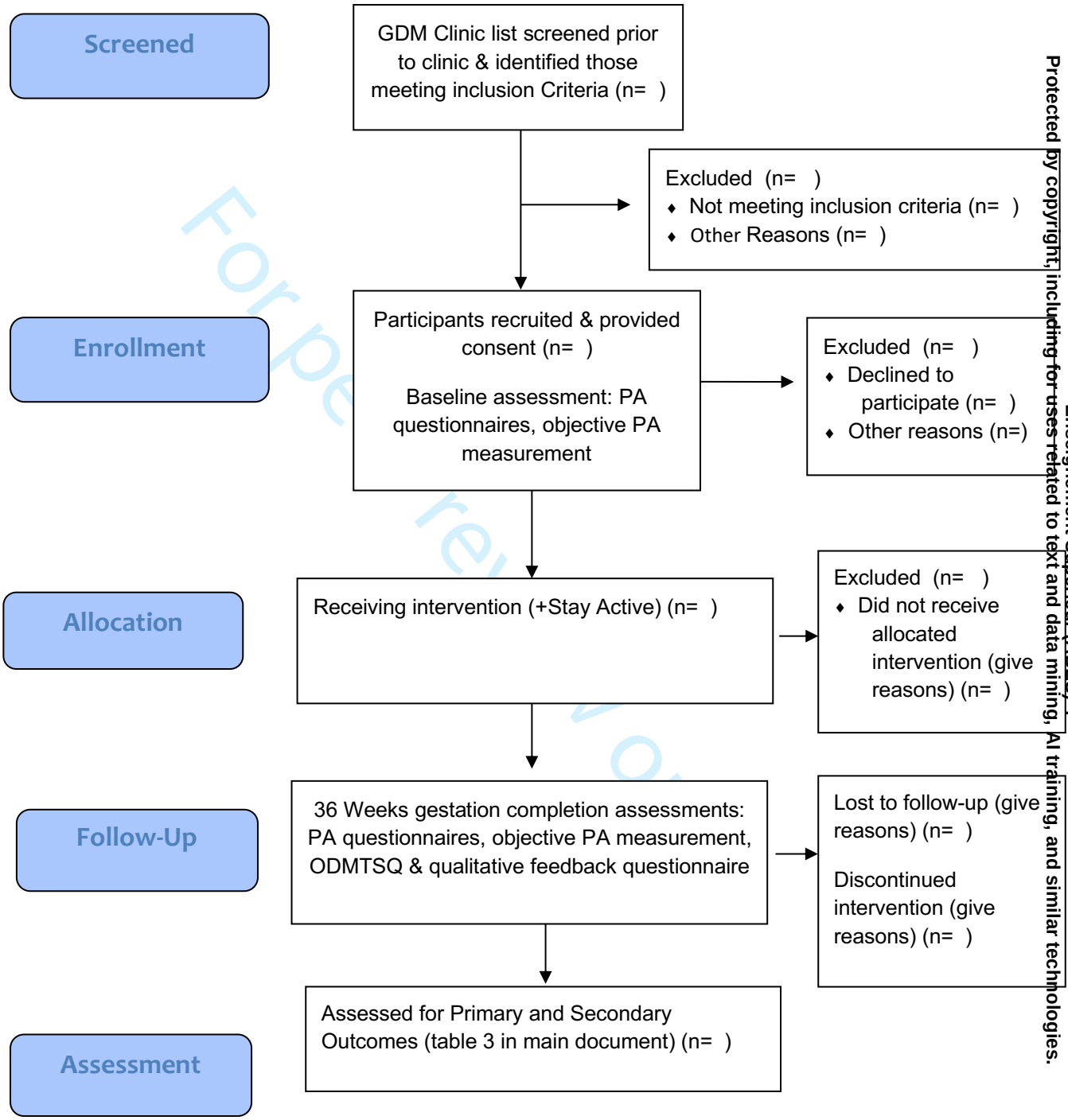
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Ethics and Dissemination: Visit 1: Recruitment and baseline assessments
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Data Collection Procedure
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Competing interests
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Data Collection Procedure
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Ethics and Dissemination
	31b	Authorship eligibility guidelines and any intended use of professional writers	Authors' contributions
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	supplemental file 4
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Supplemental material 3: Flow diagram of enrollment, allocation, follow-up and assessment



PA – Physical Activity **OMDTSQ** – Oxford Maternity Diabetes Treatment Satisfaction questionnaire

Oxford University Hospitals
NHS Foundation Trust

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Tel: 01865 851165

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM

A feasibility study to evaluate the use of a smartphone application to support delivery of a physical activity complex intervention 'Stay Active' in women with gestational diabetes mellitus

Name of Researcher:

If you agree, please initial box

1. I confirm that I have read the information sheet dated 2nd October 2020 (version 1.2) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities and from the NHS Trust(s), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree to provide data as part of my involvement in this study and I understand I will not gain any direct personal or financial benefit from it. If a commercial product were developed as a result of this study, I will not profit financially from such a product.	
5. I agree to my GP being informed of my participation in this study	
6. I agree to the study team contacting me via telephone during the study period	

7. I understand that any data that leave the research group will be fully anonymised so that I cannot be identified.		
8. I agree to take part in this study.		
9. I agree to comments being sent to me from the study team via the Stay Active app		
10. I agree to data being extracted from the Stay Active app		
Optional:		
11. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes	No
12. I agree for my anonymised data to be used in future research, here or abroad, which has ethics approval. I understand this research may involve commercial organisations.	Yes	No
13. I agree to be audio recorded and for the use of anonymised quotes in research reports and publications.	Yes	No

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

**1copy for participant; 1 copy for researcher site file; 1 (original) to be kept in maternity notes* (if participant is a patient).

Supplemental material 5:

Details regarding Existing Motivational interviewing intervention

Women attending the clinic are invited to engage in a 20-minute individual motivational interview on PA, in addition to their routine care appointments. Most women attending their first clinic appointment are in the third trimester at approximately 28 weeks' gestation. The motivational interview consultation takes place at their initial hospital appointment following a diagnosis of GDM. It is delivered by a trained healthcare professional (HCP). Each HCP delivering the motivational interview had completed a certificated two-day training course and eight hours of supervised training. The interview is delivered using a framework, where motivational interviewing micro skills (open-ended questions, affirmations, reflections and summaries) are used in all sessions to progress participants through the processes of change (engagement, focusing, evocation, and planning)(1). It includes person-centred goal setting and activity planning if deemed appropriate for that stage of the interview. Specific information about the benefits and types of suggested PA is discussed. Table 1 outlines the structure of the motivational interviewing delivered and the BCTs used.

Results from a published quality improvement project demonstrated encouraging results (awaiting reference). Self-reported PA levels increased significantly at two-week follow-up, with a mean increase of 75 minutes/week in PA levels and more than half (56%) of the women increasing their activity to meet the PA guidelines(2, 3). The Stay-Active app will seek to build on this initial PA behaviour change supporting women to help maintain their activity levels.

Table 1: Structure of the Motivational interview:

Part	Details	Behaviour changes techniques:
1. Setting the scene & Agreeing the agenda	Establish empathy and rapport and 'goal congruence' from the start, (ii)Manage some expectations of the consultation (iii) Give the person a sense of control over the conversation and agreeing the main focus of the conversation	
2. Exploring a typical day	Understanding of a particular aspect of the patient's life, where activity fits into their lifestyle (ii)Demonstrates non-judgemental, person-centred listening skills. (iii) Listen for any 'change-talk' -indicating that the patient is thinking about change, wants to change, is able to change, has already started to make some changes, etc. (iv)Help them feel heard and understood	
3. Exploring importance	(i)Explore the importance of activity and their reasons for changing their activity levels (ii)Help the person give voice to, and better understand their own reasons for changing (iii) Elicit and develop change talk (iv)Strengthen the other persons readiness to change	Prompt and cues 7.1
4. Sharing information on benefits	Ask -Share-Ask information about benefits of physical activity specifically for GDM	Information about Health Consequence 5.1 Credible source 5.1
5. Sharing specific information/knowledge about activity	Ask -Share-Ask information about type, during and expectations about physical specifically for GDM, Address barriers about activity, discuss type, time, frequency	Information about Health Consequence 5.1 Instruction on how to perform behaviour 4.1 Credible source 5.1
6. Exploring and building confidence	(i) Strengthen their self-efficacy for change.(ii) Elicit and develop change talk.(iii) Share with them what other	Prompts and cues 7.1

	people have found helpful when making the change e.g. glucose control (using ask-share-ask)	Focus on past success 15.3
7. Sharing info about building confidence	Ask -Share-Ask information about increasing confidence to become more active (ii) Provide suggestions, increase readiness	Valued self-identity 13.4 Social comparison 6.2
9. The Key question	Help the person decide what to do next	Problem solving 2.2
10. Exploring options	(i)Generate a range of possible ways forward (ii)Build optimism and confidence that change is possible. Encourage autonomy and personal decision making. Share some of your experience and expertise about what might be helpful (ii) Make progress towards agreeing the way forwards.	Social support 3.5
11. Agreeing a plan and goal setting	Help the person generate a plan for their future (ii)Help Evoke ideas (iii) Complete personal Goal setting tool	Goal setting (behaviour) 1.1 Action planning 1.4
12. Relapse prevention	Help the person explore how their life might be different if they did decide to (and were able to) change, compared to if they didn't. (ii) Help the person better understand the risks of not changing and the benefits of changing, without you having to tell them (iii) 'Develop discrepancy' between their current behaviour and their desired future behaviour (iv) Learn more about the persons hopes, plans and values (v)Build hope Elicit and develop change talk. (vi)Agree about the need and timing of future conversations (vii)Agree about the medium and location of future conversations –face to face, telephone	Comparative imagining of future 9.3 Verbal persuasion about capability 15.1 Commitment 1.9
13. Support	Explaining the support offered.	Social Support 3.1

The numbers in brackets related to the code for the behaviour Change Technique (BCT) as per the Behaviour Change Technique Taxonomy Version 1.(4)

'The framework and content of the motivational interview (table 1) was developed with the support and assistance from the Academy for Health Coaching https://learn.academyforhealthcoaching.co.uk/

1. Miller WR, Rollnick S. Motivational interviewing : helping people change. 3rd ed. ed. New York, N.Y.: Guilford Press; 2013.
2. Mottola MF, Davenport MH, Ruchat SM, Davies GA, Poitras VJ, Gray CE, et al. 2019 Canadian guideline for physical activity throughout pregnancy. Br J Sports Med. 2018;52(21):1339-46.
3. Dipietro L, Evenson KR, Bloodgood B, Sprow K, Troiano RP, Piercy KL, et al. Benefits of Physical Activity during Pregnancy and Postpartum: An Umbrella Review. Med Sci Sports Exerc. 2019;51(6):1292-302.
4. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013;46(1):81-95.

Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (GDM Health & Stay active)

Please indicate your personal agreement with each of the following statements

* Required

1. Please enter your study participant number *

2. Visit 1 or 2 *

- ◯ Visit 1(initial consultation)
- ◯ Visit 2 (approx 36 weeks)

3. I find the equipment I use to check my blood sugars is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/a

4. I feel the equipment I use to check my blood sugars is reliable *

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

5. My blood sugar monitoring fits in with my lifestyle *

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

6. The feedback I receive about my blood sugar level is useful *

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/a

7. I feel the system I use to calculate carbohydrate is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

8. I feel the system I use to calculate carbohydrate is reliable *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/a

9. I feel the feedback I receive about my carbohydrate intake is useful *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

10. I feel the system I use to record my weight is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

11. I feel the system I use to record my weight is useful *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

12. I feel the system I use to measure my physical activity/exercise level is convenient *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

13. I feel the feedback I receive about my physical activity/exercise levels is useful *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree
- ◯ N/A

14. How often would you have liked feedback? *

- ◯ Daily
- ◯ Every 2-3 days
- ◯ Every 4-5 days
- ◯ Weekly
- ◯ Only when necessary
- ◯ N/A

15. Is there a particular area where you would have liked more feedback? *

- ◯ Blood glucose
- ◯ Carbohydrate intake
- ◯ Physical Activity/Exercise
- ◯ Weight gain
- ◯ None

16. Please use box below for any further comments: Particular regarding the Stay-Active App (ease of use & recommendation to the others)