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

Ralph Smith ,[1] Yvonne Kenworthy,[2] Nerys M Astbury ,[3] Jacqueline Birks ,[4] Paul Bateman,[3] Pamela Dyson,[5] Jane E Hirst,[6,7] Susan A Jebb,[3] Moscho Michalopoulou,[3] Richard Pulsford,[8] Cristian Roman,[9] Mauro Santos,[9] Lionel Tarassenko,[9] Nicola Wango,[7] Amy Wire,[10] Lucy H MacKillop [6,7]

To cite: Smith R, Kenworthy Y, Astbury NM, *et al*. 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. *BMJ Open* 2022;**12**:e062525. doi:10.1136/bmjopen-2022-062525

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-062525).

Received 03 March 2022
Accepted 30 August 2022

For numbered affiliations see end of article.

Correspondence to
Dr Ralph Smith;
ralph.smith@ouh.nhs.uk

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 and 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. These 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 number ISRCTN11366562.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study will combine motivational interviewing with a bespoke smartphone application (Stay-Active) to support physical 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 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 (BG) suggested as the mechanism for the increased risk of adverse maternal and infant outcomes.[6] Interventions for GDM include BG monitoring, lifestyle intervention and pharmacological therapy. Of the lifestyle interventions, dietetic modifications and physical activity (PA) 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 among 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 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 2 weeks.[13] Women were invited to a 20 min individual motivational interview with a trained healthcare professional focusing on being physically active during their pregnancy. A specific motivational interviewing framework was used including key microskills, 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 multicomponent 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 10 BCTs via an educational resource centre, with goal setting and action planning features, personalised performance feedback and individualised promotional messages (table 1 and online 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

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 min 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 10:00 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 (eg, written, verbal, visual) about health consequence.	See resource centre text below.

HCP, healthcare professionals; MI, motivational interview; PA, physical activity; SM, specialist midwife.

the combined interventions (Stay-Active+Motivational Interviewing consultation) in women with GDM.

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 National Health Service (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 controlled 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 multicomponent 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: (a) accelerometer data; (b) the validated pregnancy PA questionnaire (PPAQ),[18] and (c) 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 online supplemental material 2. A flow diagram demonstrates enrolment, allocation, follow-up and assessment process online supplemental material 3.

Setting and 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 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 Royal College of Obstetrics and Gynaecology guidance during the COVID-19 pandemic[22] and then from January 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] Amy Wire (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 online 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 triaxial 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

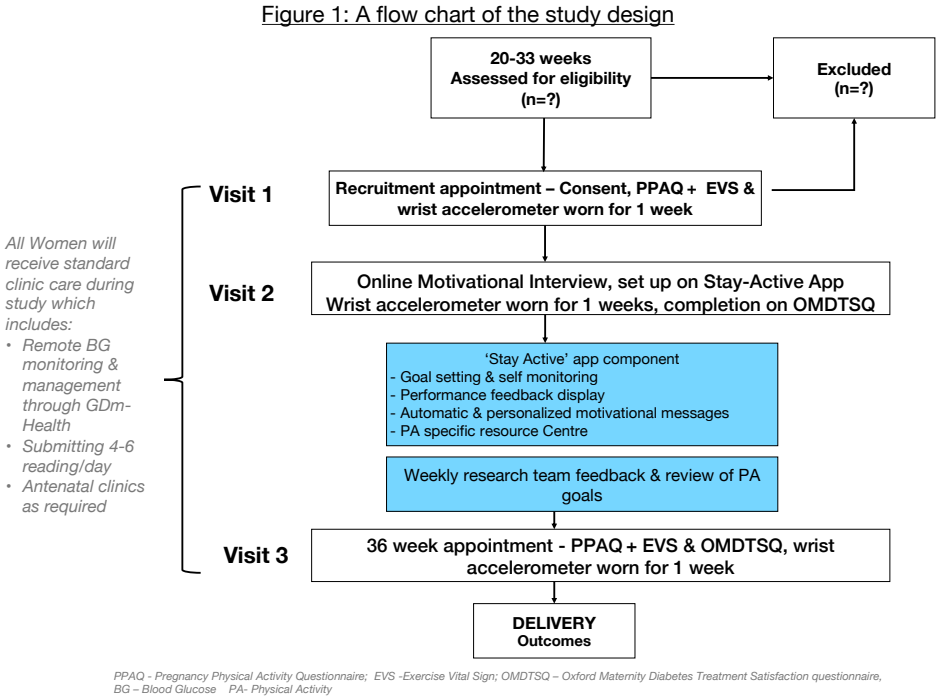

Figure 1 This figure demonstrates a flow chart of the study design with participant visits and assessment over the study period. All women will receive standard clinic care during the study which includes remote blood glucose monitoring and management through GDm-health smartphone application.

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 100 Hz.

INTERVENTION

Visit 2: motivational interview and smartphone app download

We will ask participants to attend a virtual study visit (visit 2) 1 week later. During this visit, participants will receive a 20-min 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 (ie, total of 2 weeks) and will post back the accelerometer using a prepaid 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

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,[34] for example, 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.

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 online supplemental material 5. Ten per cent of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (V.4.2.1)[26] to assess the fidelity of the interview by an experienced coder. This sample size is inline with practical recommendations.[27] The interviews will be picked at random using a random number generator.

Study participants are asked to complete the validated OMDTSQ[28] (online 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 and 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 and 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 EVS assessment[24] and OMDTSQ (online supplemental 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 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 RCT is warranted and feasible. This will be assessed against a set of predefined criteria (outlined in figure 2) related to (1) participant engagement with the intervention, (2) recruitment and (3) retention rates, (4) 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.[29] The primary objective with outcome measures and timepoints is shown in table 3 and figure 2.

Secondary outcomes

Secondary outcomes include assessment of BG 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).

Assessment of PA

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.

Self-reported PA assessment

Two self-reported questionnaire measuring PA (EVS and 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 phrasing 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 the MET to arrive at a measure

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 Proportion of participants who recorded PA in the app	95% confidence intervals that do not include 60 or 47*
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 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 58*
		95% confidence intervals that include 70 but also include 58*
		95% confidence intervals that do not include 70 or 58*

Figure 2 Primary outcome criteria. MITI, Motivational Interviewing Treatment Integrity Code; PA, physical activity; PPAQ, Pregnancy Physical Activity Questionnaire.

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 PA (like a brisk walk) lasting at least 10 min?
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 while 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 PA level. Data will be collected for a further study aiming to validate this tool among pregnant women.

Device measured PA: accelerometers and data

The GENEActiv is a triaxial accelerometer which can be worn continuously for long durations (up to 30 days) to provide precise estimates of PA. 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.[30 31] 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 PA.

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

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 and 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: Number of days worn over 7 days period, average daily wear, portion of wear; 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 and end of study period (36 weeks gestation)
	Acceptability: ▶ Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants.	Visit 2 and 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 ▶ Device specific (accelerometer) data: (total PA average per measured day, moderate to vigorous PA and average acceleration) ▶ PPAQ—outcome: energy expenditure ▶ 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 and 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 and 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 hours, 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

BG, blood glucose; EVS, exercise vital sign; GDM, gestational diabetes mellitus; PA, physical activity; PPAQ, pregnancy physical activity questionnaire; RCT, randomised controlled trial.

protocol and the feasibility of collecting sufficient data in a subsequent trial. Data will be collected at 100 Hz.

This study will also provide data regarding the interperson and intraperson 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, V.2.2, Active Insights). At the study's 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 PA variables by applying previously validated acceleration threshold values to define PA by intensity (as light, moderate and vigorous intensity).[32] The specific outcome 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 MVPA (≥ 93.2 mg). These PA variables are appropriate as: (1) both diabetes[33] and pregnancy[34] specific guidelines recommend 150 min per week of MVPA, and (2) there is growing recognition that PA of an intensity below moderate (ie, 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. Among the core functionalities, the participants can view their latest activity plan and record their PA 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 (eg, participant activity log, last synchronisation time of the app) is available in real time on the healthcare 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 BG control and medication use

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 and 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 and PPAQ) will be completed at baseline and visit 3 (36-week gestation). The OMDTSQ will be completed at visits 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.

This is a single-arm feasibility study. The results will consist of descriptive statistics for assessments at the three visits: baseline, 36–38 weeks, endpoint, and for data collected from the postnatal visit. The statistics software package used will be Stata V.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, SD, 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 six 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 preregistered 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 among women with GDM. Exercise interventions have been reported to significantly improve postprandial glycaemic control (mean difference –0.33 mmol/L) and lowered fasting BG (mean difference –0.31 mmol/L) when compared with standard care alone. Effects were found from both aerobic and resistance exercise programmes, if performed at a moderate intensity or greater, for 20–30 min, 3–4 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 BG 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 healthcare 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. Multicomponent 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 3 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 refocus 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.[28] 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 BG control.

This study will determine whether an 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.

Author affiliations
[1]Sport and Exercise Medicine, Rheumatology, Oxford University Hospitals NHS Foundation Trust, Oxford, UK
[2]Oxford Cardiovascular Clinical Research Facility, University of Oxford, Oxford, UK
[3]Nuffield Department of Primary Care Health Sciences, Univeristy of Oxford, Oxford, UK
[4]Centre for Statistics in Medicine, University of Oxford, Oxford, UK
[5]Oxford Centre for Diabetes, Endocrinology and Metabolism, University of Oxford, Oxford, UK
[6]Nuffield Department of Women's and Reproductive Health, University of Oxford, Oxford, UK
[7]Women Centre, Oxford University Hospitals NHS Foundation Trust, Oxford, UK
[8]College of Life and Environmental Sciences, University of Exeter, Exeter, UK
[9]Institute of Biomedical Engineering, Department of Engineering Science, University of Oxford, Oxford, UK
[10]Patient representative, Oxford University Hospitals NHS Foundation Trust, Oxford, UK

Acknowledgements This research was supported by the National Institute for Health Research Oxford Biomedical Research Centre.

Contributors RS, LHM, CR and MS contributed and helped with design of Stay-Active. All authors drafted and wrote the manuscript. All authors revised the content of the article, and approved the final version.

Funding This research was supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC). Grant number: N/A

Disclaimer The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing interests LHM, JEH, MM, YK, RS, NW and JB are supported by the NIHR Oxford Biomedical Research Centre. LHM is a part-time employee of EMIS Group plc. LT is a Non-Executive Director, part-time employee and shareholder of Sensyne Health plc. JEH is funded by a UKRI Future Leaders fellowship. The remaining authors have no disclosures of interest and there are no other conflicts to declare.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Ralph Smith http://orcid.org/0000-0003-0738-7626
Nerys M Astbury http://orcid.org/0000-0001-9301-7458
Jacqueline Birks http://orcid.org/0000-0002-8310-9911
Lucy H MacKillop http://orcid.org/0000-0002-1927-1594

REFERENCES

1 Basri NI, Mahdy ZA, Ahmad S, *et al*. The world Health organization (who) versus the International association of diabetes and pregnancy Study Group (IADPSG) diagnostic criteria of gestational diabetes mellitus (GDM) and their associated maternal and neonatal outcomes. *Horm Mol Biol Clin Investig* 2018;34. doi:10.1515/hmbci-2017-0077. [Epub ahead of print: 17 Feb 2018].
2 HAPO Study Cooperative Research Group, Metzger BE, Lowe LP, *et al*. Hyperglycemia and adverse pregnancy outcomes. *N Engl J Med* 2008;358:1991–2002.
3 Schneider S, Hoeft B, Freerksen N, *et al*. Neonatal complications and risk factors among women with gestational diabetes mellitus. *Acta Obstet Gynecol Scand* 2011;90:231–7.
4 Kim C, Newton KM, Knopp RH. Gestational diabetes and the incidence of type 2 diabetes: a systematic review. *Diabetes Care* 2002;25:1862–8.
5 Kim C. Gestational diabetes: risks, management, and treatment options. *Int J Womens Health* 2010;2:339–51.
6 Lowe LP, Metzger BE, Dyer AR, *et al*. Hyperglycemia and adverse pregnancy outcome (HAPO) study: associations of maternal A1c and glucose with pregnancy outcomes. *Diabetes Care* 2012;35:574–80.
7 Martis R, Crowther CA, Shepherd E, *et al*. Treatments for women with gestational diabetes mellitus: an overview of Cochrane systematic reviews. *Cochrane Database Syst Rev* 2018;8:CD012327.
8 Cremona A, O'Gorman C, Cotter A, *et al*. Effect of exercise modality on markers of insulin sensitivity and blood glucose control in pregnancies complicated with gestational diabetes mellitus: a systematic review. *Obes Sci Pract* 2018;4:455–67.
9 Harrison AL, Shields N, Taylor NF, *et al*. Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review. *J Physiother* 2016;62:188–96.
10 (NICE) TNifHaE. Gestational diabetes: risk assessment, testing, diagnosis and management update December 2020
11 Harrison AL, Taylor NF, Frawley HC, *et al*. Women with gestational diabetes mellitus want clear and practical messages from credible sources about physical activity during pregnancy: a qualitative study. *J Physiother* 2019;65:37–42.
12 Harrison AL, Taylor NF, Shields N, *et al*. Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review. *J Physiother* 2018;64:24–32.
13 Smith R, Ridout A, Livingstone A, *et al*. Motivational interviewing to increase physical activity in women with gestational diabetes. *Br J Midwifery* 2021;29:550–6.
14 Mackillop L, Hirst JE, Bartlett KJ, *et al*. Comparing the efficacy of a mobile Phone-Based blood glucose management system with standard clinic care in women with gestational diabetes: randomized controlled trial. *JMIR Mhealth Uhealth* 2018;6:e71.
15 Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
16 Smith R, Michalopoulou M, Reid H, *et al*. Applying the behaviour change wheel to develop a smartphone application 'stay-active' to increase physical activity in women with gestational diabetes. *BMC Pregnancy Childbirth* 2022;22.
17 Michie S, Richardson M, Johnston M, *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;46:81–95.
18 Chasan-Taber L, Schmidt MD, Roberts DE, *et al*. Development and validation of a pregnancy physical activity questionnaire. *Med Sci Sports Exerc* 2004;36:1750–60.
19 Eldridge SM, Lancaster GA, Campbell MJ, *et al*. Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. *PLoS One* 2016;11:e0150205.
20 Chan A-W, Tetzlaff JM, Altman DG, *et al*. Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
21 Metzger BE, Gabbe SG, Persson B, *et al*. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. *Diabetes Care* 2010;33:e98–82.
22 Relph S, Thangaratinam S. Maternal medicine in the COVID era. *Best Pract Res Clin Obstet Gynaecol* 2021;73:113–24.
23 Surveillance of diabetes in pregnancy: management from preconception to the postnatal period (NICE guideline NG3), 2018
24 Coleman KJ, Ngor E, Reynolds K, *et al*. Initial validation of an exercise "vital sign" in electronic medical records. *Med Sci Sports Exerc* 2012;44:2071–6.
25 da Silva SG, Evenson KR, Ekelund U, *et al*. How many days are needed to estimate wrist-worn accelerometry-assessed physical activity during the second trimester in pregnancy? *PLoS One* 2019;14:e0211442.
26 Moyers TB, Rowell LN, Manuel JK, *et al*. The motivational interviewing treatment integrity code (MITI 4): rationale, preliminary reliability and validity. *J Subst Abuse Treat* 2016;65:36–42.
27 Jelsma JGM, Mertens V-C, Forsberg L, *et al*. How to measure motivational interviewing fidelity in randomized controlled trials: practical recommendations. *Contemp Clin Trials* 2015;43:93–9.
28 Hirst JE, Mackillop L, Loerup L, *et al*. Acceptability and user satisfaction of a smartphone-based, interactive blood glucose management system in women with gestational diabetes mellitus. *J Diabetes Sci Technol* 2015;9:111–5.
29 Avery KNL, Williamson PR, Gamble C, *et al*. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open* 2017;7:e013537.
30 Ellis K, Kerr J, Godbole S, *et al*. Hip and wrist Accelerometer algorithms for free-living behavior classification. *Med Sci Sports Exerc* 2016;48:933–40.
31 Fairclough SJ, Noonan R, Rowlands AV, *et al*. Wear compliance and activity in children wearing Wrist- and Hip-Mounted Accelerometers. *Med Sci Sports Exerc* 2016;48:245–53.
32 Hildebrand M, VAN Hees VT, Hansen BH, *et al*. Age group comparability of raw accelerometer output from wrist- and hip-worn monitors. *Med Sci Sports Exerc* 2014;46:1816–24.
33 Colberg SR, Sigal RJ, Yardley JE, *et al*. Physical Activity/Exercise and diabetes: a position statement of the American diabetes association. *Diabetes Care* 2016;39:2065–79.
34 Mottola MF, Davenport MH, Ruchat S-M, *et al*. 2019 Canadian guideline for physical activity throughout pregnancy. *Br J Sports Med* 2018;52:1339–46.
35 Pulsford RM, Blackwell J, Hillsdon M, *et al*. Intermittent walking, but not standing, improves postprandial insulin and glucose relative to sustained sitting: a randomised cross-over study in inactive middle-aged men. *J Sci Med Sport* 2017;20:278–83.
36 Medbh H KC, Marlene S, MM H. Can physical activity and dietary interventions improve maternal and fetal outcomes in women with gestational diabetes mellitus?A systematic review and meta-analysis. *Evidence Based Midwifery* 2018;16:76–83.
37 Onaade O, Maples JM, Rand B, *et al*. Physical activity for blood glucose control in gestational diabetes mellitus: rationale and recommendations for translational behavioral interventions. *Clin Diabetes Endocrinol* 2021;7:7.
38 Schoeppe S, Alley S, Van Lippevelde W, *et al*. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. *Int J Behav Nutr Phys Act* 2016;13:127.
39 Fukuoka Y, Haskell W, Lin F, *et al*. Short- and long-term effects of a mobile phone APP in conjunction with brief In-Person counseling on physical activity among physically inactive women: the mPED randomized clinical trial. *JAMA Netw Open* 2019;2:e194281.
40 Lawson PJ, Flocke SA. Teachable moments for health behavior change: a concept analysis. *Patient Educ Couns* 2009;76:25–30.