Study Title: 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

Internal Reference Number / Short Title: Stay Active

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Funder: NIHR Oxford Biomedical Research Centre

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Declaration of Conflict of Interest(s): LM is supported by NIHR Oxford Biomedical Research Centre. LM is a part time employee of Sensyne Health plc.

Confidentiality Statement:

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

Protocol Signature Page

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

Protocol Date and Version Number: 23rd February 2021

The undersigned has read and understood the trial protocol detailed above and agrees to conduct the trial in compliance with the protocol.

L. Mackillop		Oxford University Hospitals NHS Foundation Trust	23rd February 2021
Principal Investigator (Please Print Name)	**Signature**	**Site Name or ID Number**	**Date**

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1. KEY CONTACTS

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2. LAY SUMMARY

Regular physical activity (PA) improves glycaemic control in women diagnosed with Gestational Diabetes Mellitus (GDM). In conjunction with other lifestyle interventions such as healthy eating and self-monitoring of blood glucose, PA is associated with a reduction in risk of babies being born large for gestational age, maternal post-natal depression and an increasing likelihood of women achieving postpartum weight goals. Behavioural change techniques (BCT), such as goal setting and planning, play an integral part in these interventions.

In this feasibility study, we aim to find out if a new smartphone application called 'Stay Active' can help motivate women to increase their activity levels during pregnancy. The application provides a link to the woman's midwife and gives encouragement and feedback on how they are doing against agreed targets.

This study will inform the development of the intervention and the future trial design leading to, subject to funding, a randomised controlled trial of the combined digital application "GDm-health Stay Active" versus GDm-Health™ (a CE marked patient app-to-clinician website) used alone, with the primary outcome being the difference in the change of PA levels from recruitment to the end of pregnancy, between groups, measured using a wrist worn accelerator.

3. SYNOPSIS

Study Title	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		
Internal Reference Number / Short Title	Stay Active		
Study Registration	ISRCTN Reference Number: 11366562		
Study Design	A feasibility study		
Study Participants	Women with gestational diabetes mellitus (GDM)		
Sample Size	60 participants		
Planned Study Period	Project start date: April 2021 Project End date: November 2022 Individual participation is for approximately 3 months during pregnancy until 6 weeks post-delivery – a maximum time of 6 months		
Planned Recruitment Period	April 2021 – March 2022		
	Objectives	**Outcome Measures**	**Timepoint(s)**
Primary	To evaluate how women with GDM interact, engage with and respond to a complex intervention known as *Stay Active* and to determine whether an RCT to assess the efficacy of this intervention, is feasible	Participant engagement with the intervention • Participant adherence to evaluation: Hours of wearing the wrist worn accelerometer; availability of data for outcome measures; attendance at follow-up sessions. • Acceptability: Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants. Fidelity of the intervention • Measuring change in mean and standard deviation of physical activity (measured as average daily minutes of Total PA (>40 mg) and, Moderate to Vigorous PA (≥ 93.2	Visit 2 and after 36 weeks gestation accelerometer Visit 1 and visit 3 acceptability questionnaire at day 0 and 36 weeks gestation After 36 weeks

		mg)) at recruitment and at 36-38 weeks pregnant using accelerometer data and using the validated pregnancy physical activity questionnaire (PPAQ) (Chasan-Taber L et la. 2004);) & the modified PA vital sign assessment (Coleman et al. 2012) and % goals achieved. • 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. Recruitment rates • Percentage of women with GDM who are eligible participants at the John Radcliffe Hospital. • Percentage of women who fulfil the eligibility criteria and who accept the invitation to participate. Retention rate • Proportion of women that completed the study (attended 6 week postnatal appointment)	Visit 2 motivational interview Visit 1, day 0 End of study
Secondary	1. Assessment of blood glucose control 2. Assessment of PA 3. Qualitative assessment of	1. 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	Visit 1 day 0 and Visit 3 at 36-38 weeks

	Participant's attitudes to Stay Active 4. Description of maternal outcomes 5. Description of neonatal outcomes 6. Assessment of health costs 7. Determine any refinements required of the intervention	and timing of measurements). 2. Attainment of information on physical activity time, intensity and frequency assessed from accelerometer data. 3. Participants attitudes to Stay Active (with 5 questions, pushed by the app), rating the usefulness of the following: • Motivational interviewing • Goal setting • Tracking your goals via the app • The automated motivational messages you receive • The personalised messages about your physical activity via the app 4. 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). 5. Neonatal outcomes (birth weight, neonatal hypoglycaemia, neonatal hyperbilirubinaemia, admission to SCBU for >24 hrs, shoulder dystocia).	Visit 2 & 36-38 weeks gestation 2 weeks after Visit 2 and at 36 weeks After delivery After delivery

		6. Health economic information such as number of clinic visits, time spent by clinical midwife delivering the intervention.	Entire duration of study
Intervention(s)	A multi-component lifestyle intervention for women with GDM known as *Stay Active*. This includes virtual face-to-face motivational interviewing and goal setting with an additional app-based behavioural re-enforcement. This includes goal recording, self-monitoring of activity levels, regular personalised feedback with motivational messaging and access to a region specific patient information centre including contact information on exercise classes in the area.		

4. ABBREVIATIONS

BCT	Behavioural Change Techniques
CI	Chief Investigator
CRF	Case Report Form
GP	General Practitioner
GCP	Good Clinical Practice
GDM	Gestational Diabetes Mellitus
HRA	Health Research Authority
ICF	Informed Consent Form
MI	Motivational Interviewing
MVPA	Moderate/Vigorous Physical Activity
NHS	National Health Service
OGTT	Oral Glucose Tolerance Test
PA	Physical Activity
PI	Principal Investigator
PIS	Participant Information Sheet
PPAQ	Pregnancy Physical Activity Questionnaire
RCT	Randomised Control Trial
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RES	Research Ethics Service
SOP	Standard Operating Procedure
T2DM	Type Two Diabetes Mellitus

5. BACKGROUND AND RATIONALE

Gestational diabetes mellitus (GDM) is defined as glucose intolerance first identified in pregnancy. The condition is an increasing problem among pregnant women worldwide with estimates of prevalence ranging from 1.7% to 20% dependent on diagnosis criteria and population characteristics (Chiefari et al. 2017).

Women with a diagnosis of GDM have an increased risk for pre-eclampsia, induction of labour, birth injuries, postpartum haemorrhage and caesarean section (NICE 2015). For the infant, there is an increased risk of macrosomia, birth injuries, neonatal hypoglycaemia and stillbirth (NICE 2015; Zhu, Zhang 2016). Furthermore, women with a history of GDM are at increased risk of T2DM and cardiovascular disease in later life. The cumulative incidence of women developing diabetes following GDM ranged from 2.6% to over 70% (Kim et al 2002). Offspring also have an increased risk of childhood obesity and T2DM.

Controlling blood glucose concentrations is fundamental to the management of GDM (RCOG 2011). Increasing levels of hyperglycaemia has been suggested as the mechanism for the increased risk of adverse maternal and infant outcomes (Lowe et al. 2012).

Treatment interventions for GDM include lifestyle intervention and pharmacological therapy. Lifestyle interventions (including as a minimum healthy eating, physical activity and self-monitoring of blood glucose concentrations) are the only interventions that have reported possible health improvements for maternal and fetal outcomes (Martis et al. 2018).

Physical activity/exercise interventions have been shown to improve glycaemic control and reduce insulin requirements (Cremona et al 2018; Hillyard 2018). However, often research based exercise interventions are challenging to translate into clinical practice. Time allocation, information and resources compete with other components of care and as a result, many inactive women with GDM are forgoing the benefits of physical activity. Integral to physical activity interventions are BCTs, particularly those that are person-centred addressing specific barriers and enablers. Therefore, we have integrated motivational interviewing (MI) into routine care within the existing clinic at The John Radcliffe Hospital for women at the time of GDM diagnosis. MI is a counselling approach developed in part by clinical psychologists William R. Miller and Stephen Rollnick. It is a directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence. Results from a small pilot study suggest this approach is effective at increasing self-reported activity levels (unpublished data).

Participating Trusts already use the NICE approved smartphone glucose monitoring application GDm-Health™ (Mackillop et al. 2014) for women with GDM. This is a monitoring and management system to record blood glucose measurements and deliver remote management with high levels of patient

engagement, compliance and usage (Hirst et al. 2015). GDm-Health allows women to record blood glucose measurements accurately, automatically uploading data to a secure server. Health care professionals access these measurements via a secure graphical web interface with alerts to allow prioritisation of women. There is a simple interface providing 2-way communication between women and health care professionals.

Whilst there is evidence that Apps may help to facilitate physical activity levels, there is limited success amongst pregnant women. However, it is clear that app-based interventions must be multi-component involving concepts such as goal setting, self-monitoring, performance feedback and motivational messages. (Schoeppe et al. 2016)

5.1. Aims

Purpose of the study

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* to determine whether an RCT to assess the efficacy of this intervention, is feasible.

A mixed methods approach will be used to assess process and effectiveness measures, test trial processes and procedures, resource use and management, aid sample size estimates for a future definitive trial, determine the most appropriate primary outcome measure and to inform modification and refinement of the *Stay Active* intervention.

This project evaluates a multi-component lifestyle intervention for women with GDM known as *Stay Active*. It builds on an existing clinic intervention of face-to-face motivational interviewing and goal setting with an additional app-based behavioural re-enforcement. This includes goal recording, self-monitoring of activity levels, regular personalised feedback with motivational messaging and access to a region specific patient information centre including contact information on exercise classes in the area. See appendix 4.

6. OBJECTIVES AND OUTCOME MEASURES

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 a complex intervention known as *Stay Active* and to determine whether an RCT to assess the efficacy of this intervention, is feasible.	Primary Outcomes: Participant engagement with the intervention • Participant adherence: Hours of wearing the wrist worn accelerometer; availability of data for outcome measures; attendance at follow-up sessions. • Acceptability: Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants. Fidelity of the intervention • Measuring change in mean and standard deviation of physical activity (measured as average daily minutes of Total PA (>40 mg) and, Moderate to Vigorous PA (≥ 93.2 mg)) at recruitment and at 36-38 weeks pregnant; the validated pregnancy physical activity questionnaire (PPAQ) (Chasan-Taber L et la. 2004); the modified PA vital sign assessment (Coleman et al. 2012) and % goals achieved. • 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. Recruitment rates • Percentage of women with GDM who are eligible participants at the John Radcliffe Hospital. • Percentage of women who fulfil the eligibility criteria and who accept the invitation to participate. Retention rate	Visit 2 and after 36 weeks gestation accelerometer Visit 1 and visit 3 acceptability questionnaire at day 0 and 36 weeks gestation After 36 weeks Visit 2 motivational interview At visit 1, day 0

	• Proportion of women that completed the study (attended 6 week postnatal appointment).	End of study
Secondary Objective 1. Assessment of blood glucose control 2. Assessment of PA 3. Qualitative assessment of Participant's attitudes to Stay Active 4. Description of maternal outcomes. 5. Description of neonatal outcomes. 6. Assessment of health costs 7. Determine any refinements required of the intervention.	1. 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). 2. Attainment of information on physical activity time, type, intensity and frequency assessed from accelerometer data. 3. Participants attitudes to Stay Active (with 5 questions, pushed by the app), rating the usefulness of the following: • Motivational interviewing • Goal setting • Tracking your goals via the app • The automated motivational messages you receive • The personalised messages about your physical activity via the app 4. 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). 5. Neonatal outcomes (birth weight, neonatal hypoglycaemia, neonatal hyperbilirubinaemia, admission to SCBU for >24 hrs, shoulder dystocia). 6. Health economic information such as number of clinic visits, time spent by clinical midwife delivering the intervention.	Visit 1 day 0 & Visit 3 at 36-38 weeks Visit 2 & 36-38 weeks gestation 2 weeks after Visit 2 and at 36 weeks After delivery After delivery Entire duration of study

7. STUDY DESIGN

Women who are found to have Gestational Diabetes (GDM) diagnosed by an abnormal response to either a 75g oral glucose tolerance test (using IADPSG or NICE thresholds), an HbA1c of 39 mmol/mol or above, a fasting plasma glucose of 5.6 mmol/L or above, or a random plasma glucose of 9 mmol/l or above (Royal College of Obstetricians & Gynaecologists (RCOG) Guidance for maternal medicine services in the evolving coronavirus (COVID 19) pandemic) taken as part of their routine clinical care, are invited to a specialist GDM clinic appointment. Women will not be eligible for the study until at least 20 completed weeks of pregnancy as the study is not investigating physical activity in early pregnancy. A patient information sheet will be given to all women invited to the clinic by a member of the clinical team. Following their hospital clinic appointment, a research midwife will talk them through the study procedure and give them the chance to ask any questions. If they consent to take part in the study, they will then be asked to complete questionnaires, including validated questionnaires for physical activity and they will be asked to wear a tri-axial accelerometer (GENEActiv, Active Insights Ltd, Kimbolton, UK) on their non-dominant wrist for at least seven consecutive days, during waking hours. This time frame was chosen as it has been shown that seven days were needed to estimate reliable measures of moderate to vigorous physical activities (MVPA) (da Silva et al. 2019). The participants GP will be informed about their participation in the study.

Participants will be provided with an A4 instruction sheet which includes general care instructions. Data will be collected at 100Hz, with minimum wear time criteria consisting of >4 days, >10 waking hours/day and including two weekend days.

We will ask participants to attend a virtual study visit (Visit 2) a week later. During this visit participants will receive a 20-minute motivational interview (MI) with a midwife during which they will agree a set of weekly exercise goals. The participant will be asked to wear the accelerometer for a further week after the MI (ie total of 2 weeks) and will be asked to post back the accelerometer using a pre-paid addressed envelope that will be given to the participant at visit 1.

The MI will take place remotely. All MI will be recorded for fidelity coding using a dictaphone. No patient identifiable data will be recorded and the audio-file will be labelled with a unique trial specific number only. Once each interview is finished, it will be downloaded onto a secure University of Oxford server and deleted from the portable device. Access to the anonymised audio-files will be by members of the study team directly involved in either recording or analysing the data. Please see appendix 3 for the purposed structure of the MI consultation.

The 'Stay Active' smartphone application will be downloaded and participants will be shown how to record their activities, review their physical activity goals and explore the resource centre. Participants will be

provided with feedback from a midwife or another member of the study team, every week by text message received via the Stay Active app. The midwife will review their physical activity goals every 1-2 weeks via the smartphone application. A routine follow-up appointment will be scheduled for around 36 weeks gestation at which the participant will be asked to complete the validated pregnancy physical activity questionnaire (PPAQ – appendix 6), the exercise vital sign assessment (EVS appendix 7) and the diabetes satisfaction questionnaire (OMDTSQ appendix 8). They will also be asked to wear the accelerometer for 1 week.

At their six-week postnatal appointment participants will be asked to undergo a fasting blood glucose measurement.

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 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), is associated with better compliance to wear protocols (Ellis et al 2015; Fairclough et al 2015) and has been shown to be acceptable to general and clinical populations in a range of study designs.

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 physical activity across the intervention period. Participants will be asked to wear the accelerometer on their left 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). The first specific outcome derived from the accelerometer data is the average daily accelerometer wear-time (in hours) 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 intervention related changes in physical activity 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 physical activity by intensity (as light, moderate and vigorous intensity) (Hildebrand et al 2014). The specific outcomes variables derived for descriptive analyses in this

study will be average daily minutes of total physical activity (any movement with a measured acceleration value of ≥ 40 mg) and average daily minutes of Moderate to Vigorous Physical Activity (MVPA) (≥ 93.2 mg). These physical activity variables are appropriate as: 1) both diabetes (Colberg et al 2016) and pregnancy (Mottola et al 2016) specific guidelines recommend 150 minutes per week of MVPA, and 2) there is growing recognition that physical activity of an intensity below moderate (i.e. any movement) is important for daily glycaemic control (Pulsford et al 2017). Observed changes in these variables from baseline through follow-up can be used to inform sample size calculations for a subsequent efficacy study.

PARTICIPANT IDENTIFICATION

7.1. Study Participants

The study will enrol women diagnosed with gestational diabetes mellitus (GDM).

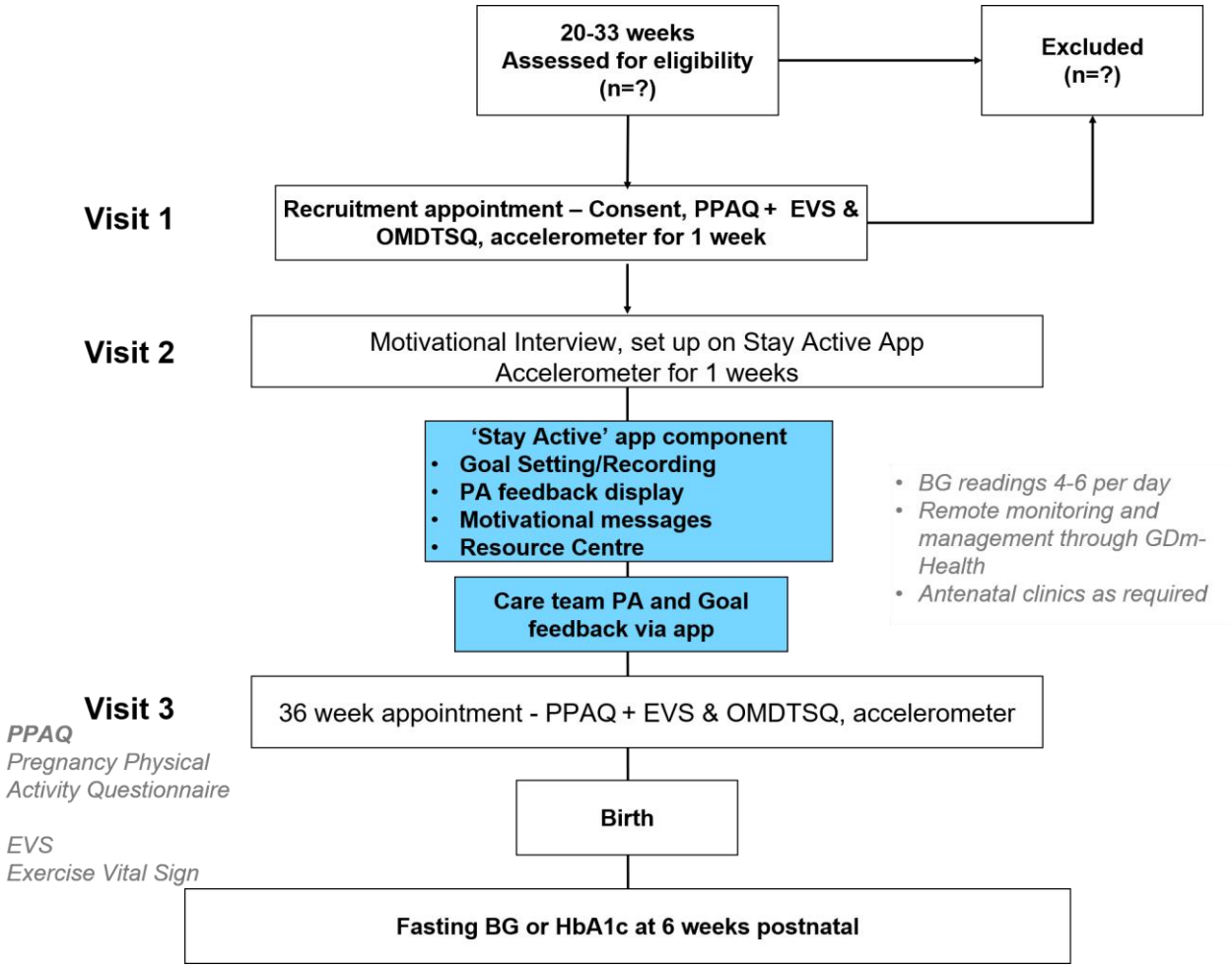
7.2. Inclusion Criteria

- 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 IADSPG or NICE, 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

7.3. Exclusion Criteria

- 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 (Mottola M et al, 2018) e.g. preterm rupture of membranes, limited mobility, haemodynamically significant heart disease, restrictive lung disease
- Unable to understand written or spoken English language

8. PROTOCOL PROCEDURES



8.1. Recruitment

All participants will be recruited from NHS maternity clinics at the John Radcliffe Hospital, Oxford.

8.2. Screening and Eligibility Assessment

Potential participants will be identified through abnormal glucose tolerance test results. This programme will be offered to all women with the risk factors below, in accordance with NICE guidelines:

- Previous macrosomic baby weighing 4.5kg or more
- Previous gestational diabetes
- Family history of diabetes (first-degree relative with diabetes)
- Family origin with a high prevalence of diabetes
- Booking BMI > 30kg/m2

The clinical care team will screen medical notes to identify individuals who are eligible to be approached. No exceptions will be made regarding eligibility, i.e. each participant must satisfy all approved inclusion and exclusion criteria in the protocol in order to be deemed eligible for participation in the study. This screening of the medical notes will occur on the day of the clinic.

8.3. Informed Consent

Once an individual has been deemed eligible for participation in the study a member of the clinical team will approach and provide them with a participant information sheet (PIS). If a woman wishes to participate, she will be introduced to a research midwife or member of the study team, who will discuss the study with her and answer any questions. If she is happy to participate she will be asked to sign the informed consent form (ICF). The participant must personally sign and date the latest approved version of the ICF before any study specific procedures are performed.

Written and verbal versions of the PIS and ICF will be presented to the participant detailing no less than; the exact nature of the study, what it will involve for the participant, the implications and constraints of the protocol, the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written informed consent will then be obtained by means of participant-dated signature and dated signature of the person who presented and obtained the informed consent. The person who obtained the consent will be suitably qualified and experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed ICF will be given to the participant. The original signed form will be retained at the study site, in the trial master file and a copy will be placed in the maternity notes.

8.4. Enrolment

This is not a randomised study and as there is no screening visit participants will be considered enrolled once they have given informed consent.

8.5. Blinding and Code-breaking

There is no blinding in the study and hence no code breaking procedure.

8.6. Description of Study Intervention(s), Comparators and Study Procedures (Clinical)

Current standard of care involves lifestyle advice regarding physical activity delivered by midwives and other healthcare professionals at routine antenatal visits. Women with GDM monitor their BG with GDm-health which does not have any specific component that facilitates PA. MI regarding PA is offered in the GDM clinic with follow-up via telephone after 2 weeks.

The intervention being tested is a multi-component lifestyle intervention for women with GDM known as *Stay Active*. It builds on an existing clinic intervention of face-to-face motivational interviewing and goal setting with an additional app-based behavioural re-enforcement. This includes goal recording, self-monitoring of activity levels, regular personalised feedback with motivational messaging and access to a region specific patient information centre including contact information on exercise classes in the area. See appendix 4.

8.7. Baseline Assessments

Following a hospital outpatient clinic appointment a research midwife will talk through the study procedure and give the chance to ask questions. After consent a questionnaire will be completed and an accelerometer fitted to wear for a week.

- At recruitment, NHS clinical care, weight, blood pressure, urine test, blood test. (Visit 1)
- Identify participants from clinic visit.
- Informed consent including eligibility checks
- Discuss study with potential participants
- Complete Pregnancy Physical Activity Questionnaire (PPAQ) (appendix 6)
- Complete the modified Exercise Vital Sign assessment (EVS) (see appendix 7)
- Complete the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants. (appendix 8)
- Wrist Accelerometer fitted (GENEActiv, Activ-insights Ltd, Kimbolton, UK) Participants will be provided with an A4 instruction sheet including general care instructions
- Participants will be given a prepaid envelope for the return of the accelerometer.

8.8. Subsequent Visits

Visit 2

Participants will be asked to attend a virtual meeting a week later at which time:

- Participants will be asked to continue wearing their accelerometer for a further week (total of 2 weeks)
- Participants will receive a 20-minute motivational interview with a midwife during which they will agree a set of weekly exercise goals. All Motivational interviews will be audio recorded (when consent is given to do this). 10% of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1) to assess the fidelity of sessions.
- The 'Stay Active' smartphone application will be downloaded and they will be shown how to record their activities, review their physical activity goals and explore the resource centre.

Between visit 2 and 3

- Participants will be provided with feedback from the midwife every week by text message received via the 'Stay Active' smartphone application.
- The midwife will review their physical activity goals via the app and will make contact via text message or telephone (depending on the most convenient method for the participant) with the participant on a weekly basis.
- 5 questions about the acceptability and usefulness of the intervention will be delivered as a push notification on the app, once during this time.

Visit 3

A routine follow up appointment will be scheduled for approximately 36 weeks, the following will be carried out:

- Participants will be asked to complete the PPAQ (Chasan-Taber L et al 2004)(appendix 6) and the Exercise vital sign (Coleman KJ et al 2012)assessment (appendix 7)
- Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants. (appendix 8)
- Participants will be asked to wear the wrist worn accelerometer for a further week.
- Participants will be given a prepaid envelope for the return of the accelerometer.
  5 questions about the acceptability and usefulness of the intervention will be delivered as a push notification on the app, once during this time.

6-12 weeks postnatal appointment

- Fasting blood glucose check or oral glucose tolerance test at 6wks postnatal or HbA1c after 12 weeks as per standard care and NICE guidance.

8.9. Early Discontinuation/Withdrawal of Participants

During the course of the study 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 AE
- Inability to comply with study procedures
- Participant decision

Data already collected with consent will be retained and used in the analysis. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator 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 in the CRF.

8.10. Definition of End of Study

The end of study is the point at which all the study data has been collected and queries resolved.

9. SAFETY REPORTING

9.1. Definition of Serious Adverse Events

A serious adverse event (SAE) is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. A causality assessment will be carried out by the PI, recorded in the CRF and reported as per 9.2.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

9.2. Reporting Procedures for Serious Adverse Events

SAEs occurring to a participant will be reported to the REC that gave a favourable opinion of the study where in the opinion of the CI the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 24 hours of the CI becoming aware of the event, using the HRA report of serious adverse event form (see HRA website).

10. STATISTICS AND 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 15. The measures that will be assessed are listed under a description of the visits (sections 8.7 and 8.8).

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.

10.1. Sample Size Determination

The study will run for 12 months. Individual participation is for approximately 3 months during pregnancy until 6 weeks post-delivery – a maximum time of 6 months. Recruitment will be 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 out target of 60 patients during this time.

11. DATA MANAGEMENT

The procedures for data management are outlined below. There is not a separate Data Management Plan for use in the study.

11.1. Source Data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence. Accelerometers measure movement acceleration only. They do not measure any location or other personal identifiable data and data files will be labelled using each participant's unique study ID only.

CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be kept in secured filing cabinets in buildings or locations with security passes. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

11.2. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

11.3. Data Recording and Record Keeping

All trial data will be entered on to paper CRFs

The participants will be identified by a unique trial specific number in any database. The name and any other identifying detail will NOT be included in any trial data electronic file.

The completed CRFs will be stored at the Nuffield Department of Women's and Reproductive Health (NDWRH), Women's Centre, John Radcliffe Hospital, Oxford in a locked filing cabinet in a locked room. The CRF data will be anonymised and transcribed onto an excel spreadsheet by the Lead Research Midwife and the Chief Investigator. The electronic data will be stored on password-protected computers on a secure server in The University of Oxford High Compliance System in the UK. Data from the CRFs will be analysed by the BRC statistician with access to the University of Oxford's secure server. Data from the accelerometers will be stored on a secure server at University of Exeter with the same unique trial specific

number but no other identifiers. This data will be accessed, extracted and analysed by Dr Richard Pulsford at the University of Exeter on a password protected computer within the University of Exeter. Once analysed both the raw and analysed data will be transferred securely to The University of Oxford High Compliance System, and all data on the University of Exeter's servers will be deleted. Dr Lucy Mackillop as study CI will take the role of data custodian. The MI will be recorded for fidelity coding using a dictaphone if the participant has consented to this. No patient identifiable data will be recorded and the audio-file will be labelled with a unique trial specific number only. Once each interview is finished, it will be downloaded onto a secure University of Oxford server and deleted from the portable device. Access to the anonymised audio-files will be by members of the study team directly involved in either recording or analysing the data.

Research documents with personal information, such as consent forms, and anonymised research documents, such as the CRFs and Questionnaires, will be held in a locked filing cabinet in NDWRH for 5 years after the end of the study. Electronic data including data from the Stay Active app and data collected from medical records, including blood test results (blood glucose and HbA1c), will be stored securely on the University of Oxford's server, for 5 years. Access to the research documents and electronic data will only be by members of the research study team – Lead Research Midwife, the Chief Investigator, the Statistician and Dr Richard Pulsford. The anonymised data may be shared with other researchers. These will mainly be local researchers, but ethically approved research projects requiring this data may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide. If participants agree to be contacted about future research, their consent form and details will be held securely separately from the study for as long as the participant agrees for the details to be held.

12. QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

12.1. Risk Assessment

No risk assessment will take place as this is a low risk study.

12.2. Study Monitoring

Not applicable.

12.3. Study Committees

There are no study committees as this is a feasibility study.

13. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements.

Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

14. SERIOUS BREACHES

A “serious breach” is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the C.I., the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

15. ETHICAL AND REGULATORY CONSIDERATIONS

15.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

15.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

15.3. Approvals

Following Sponsor approval the protocol, ICF and PIS will be submitted to an appropriate Research Ethics Committee (REC), HRA and host institutions for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

15.4. Other Ethical Considerations

Physical activity is associated with positive health benefits in pregnancy.
To reduce any potential risks, women will only be included in the study if they have no medical conditions that would make it unsafe for them to engage in a programme of moderate physical activity.
At the start of the intervention a detailed antenatal check will be carried out by a midwife.
The clinic visit may be longer than standard clinic appointments, but wherever possible we will try coincide research visit with standard care. Discussing exercise may be emotive but a midwife trained in MI will conduct the interviews and be aware of possible triggers.

Risks associated with wearing the accelerometers are minimal. There is a very small risk that the rubber wrist straps may cause some minor skin irritation in some participants, although this is very rare. If this does occur participants will be instructed to remove the device and to wash and dry the skin underneath. They will then be advised to either replace the accelerometer when the area feels comfortable enough to do so, or to contact study investigators and withdraw from the study.

15.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC, HRA (where required), host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties.

15.6. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

15.7. Expenses and Benefits

Parking expenses for all study visits will be reimbursed on production of valid car parking receipts.

16. FINANCE AND INSURANCE

16.1. Funding

The study is being supported by NIHR Oxford Biomedical Research Centre.

16.2. Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical research study as a result of negligence on the part of a member of the study team this liability cover would apply. Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

16.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

17. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge the study funders and authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

18. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the OUH vests in OUH. The protection and exploitation of any new IP is managed by the IP and Research Contracts Team at OUH unless it is generated in collaboration with Oxford University in which case this is led by the University's technology transfer office, Oxford University Innovations.

19. ARCHIVING

Following completion of the study data including identifiable data will be retained for a period of 5 years. This is to ensure that when the study is published and participants are contactable for dissemination of research findings. Study records including medical information, signed consent forms and anonymised scientific data will be stored in NDWRH. At the end of five years all study documentation will be disposed of as per guidance from the study sponsor and using an approved SOP. Dr. Lucy Mackillop as study CI will take the role of data custodian.

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21. APPENDIX 1 Motivational Interview structure and Fidelity testing

Motivational Interviewing (MI) is a particular BCT technique has been shown to be effective in helping persons change their lifestyle behaviours, such as physical activity and diet across different target populations. MI uses a "collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion. There are a variety of styles, however the technique used is one coached by the academy of health coaching. To focus on the four processes engaging, focus, evoking and planning using four main communications skills of using open questions, affirmations, reflecting and summarizing.

To ensure the standards and the format of MI sessions are consistent, prior to the study period, specialist midwives delivering the session will have:

1. Completed an introductory MI course with resource pack (from the academy of health coaching). The checklist for MI interviews is shown in appendix 2.
2. Completed supervised role play scenarios
3. During the motivational interview session, the midwife discusses physical activity with the woman following the structure shown in Table 1.
4. The 20 minute MI consultations will be audio recorded and the audiotapes will rated for treatment fidelity. Treatment fidelity is also called treatment integrity, is defined as the extent to which treatment is implemented as intended (Perepletchikova, 2011). Several instruments have been developed to measure fidelity to MI (Madson & Campbell, 2006). The Motivational Interviewing Treatment Integrity code (MITI) is the most widely used and the latest version is 4.2.1 . The MITI 4 (Moyers, Manuel & Ernst, 2010) is an open-source instrument available for download from the CASAA website (http://casaa.unm.edu/codinginst.html). It yields behaviour counts and global summary scores that allow the evaluation of treatment fidelity. It has four global summary scores (Cultivating Change talk, Softening Sustain Talk, Partnership, and Empathy), which are scored on a Likert-type scale from 1 (low) to 5 (high) and 10 behaviour counts: Questions, Simple Reflections, Complex Reflections, Persuade with Permission, Giving Information, Affirmations, Emphasize Autonomy, Seeking Collaboration (for example in negotiating an agenda or asking permission before giving information), persuade and confront. A sample of 10- 20% (TBC) of all the MI will be randomly chosen for fidelity assessment. The audio recording will be evaluated and coded by a trained rater.

22. APPENDIX 2: Motivational Interview structure

Motivational Interviewing (MI) is a particular BCT technique that has been shown to be effective in helping persons change their lifestyle behaviours, such as physical activity and diet across different target populations. MI uses a "collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion. There are a variety of styles, however the technique used is one coached by the academy of health coaching. To focus on the four processes engaging, focus, evoking and planning using four main communications skills of using open questions, affirmations, reflecting and summarizing.

During the motivational interview session, the midwife discusses physical activity with the woman following the structure shown in Table 1.

Table 1: Purposed Structure of motivational interview

Part	Details
1. Setting the scene	Establish empathy and rapport and 'goal congruence' from the start Manage some expectations of the consultation
2. Agreeing the agenda	Give the person a sense of control over the conversation and agreeing the main focus of the conversation
3. Exploring a typical day	Understanding of a particular aspect of the patient's life, where activity fit into the life, Demonstrates non-judgemental, person-centred listening skills. 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. Help them feel heard and understood
4. Exploring importance	Explore the importance of activity and their reasons for changing their activity levels Help the person give voice to, and better understand their own reasons for changing Elicit and develop change talk Strengthen the other persons readiness to change

5. Exploring and building confidence	Strengthen their self-efficacy for change. Elicit and develop change talk. Share with them what other people have found helpful when making the change e.g BM control (using ask-share-ask)
6. Looking forwards	Help the person imagine a better future for themselves Learn more about the persons hopes, plans and values Elicit and develop change talk
7. Exploring options	Generate a range of possible ways forward. 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. Make progress towards agreeing the way forwards.
8. The Key question	Help the person decide what to do next So, what's next for you?
9. Agreeing a plan	Help the person generate a plan for their future Help Evoke ideas Complete personal Goal setting tool
10. Two possible futures	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. Help the person better understand the risks of not changing and the benefits of changing, without you having to tell them 'Develop discrepancy' between their current behaviour and their desired future behaviour Learn more about the persons hopes, plans and values Build hope, elicit and develop change talk
11 Relapse Prevention	Agree about the need and timing of future conversations Agree about the medium and location of future conversations – face to face, telephone.

23. APPENDIX 3: 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
			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 crosschecked against a checklist of the core components.		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 a 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

24. APPENDIX 4: Description of Stay Active App

1. During the second half of the motivational interview consultation, women are invited to set weekly activity related goals on the Stay Active Application (APP) with the support of a trained midwife (figure 1).

2. Women can log (time of the activity) and tick off when an activity has been completed (figure 2&3)

Figure 1:

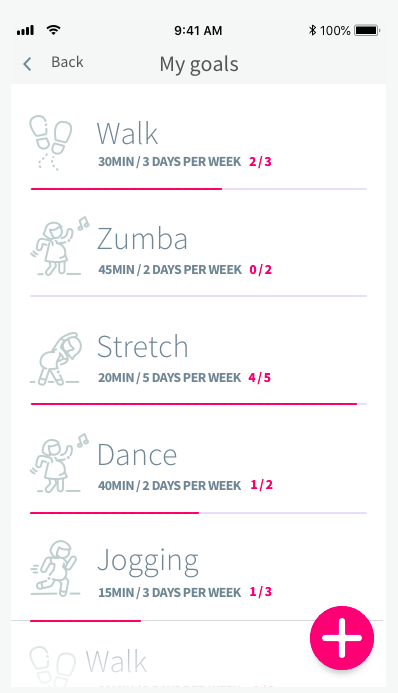


Figure 2:

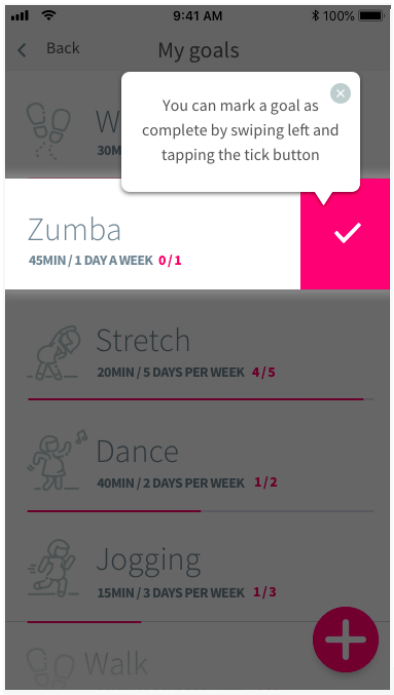
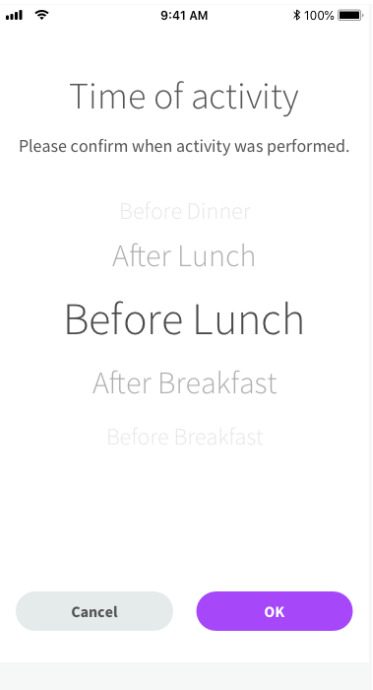
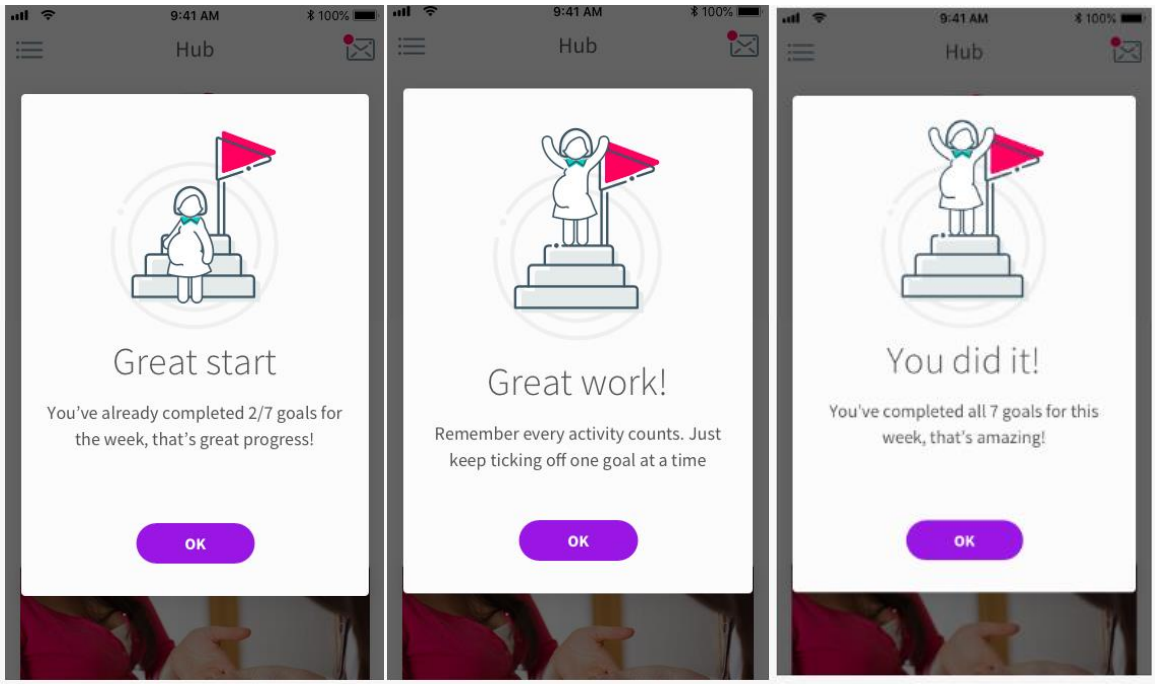


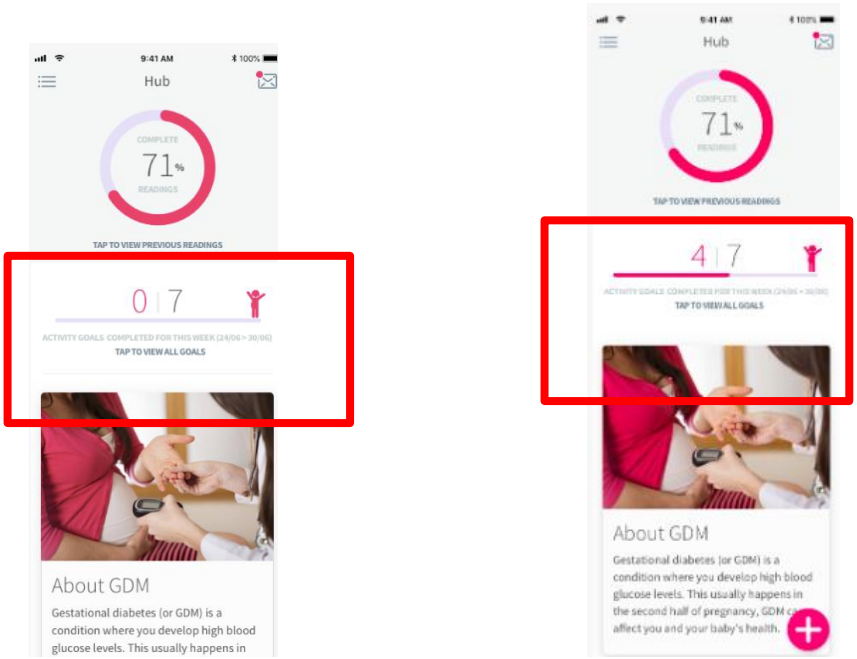
Figure 3:



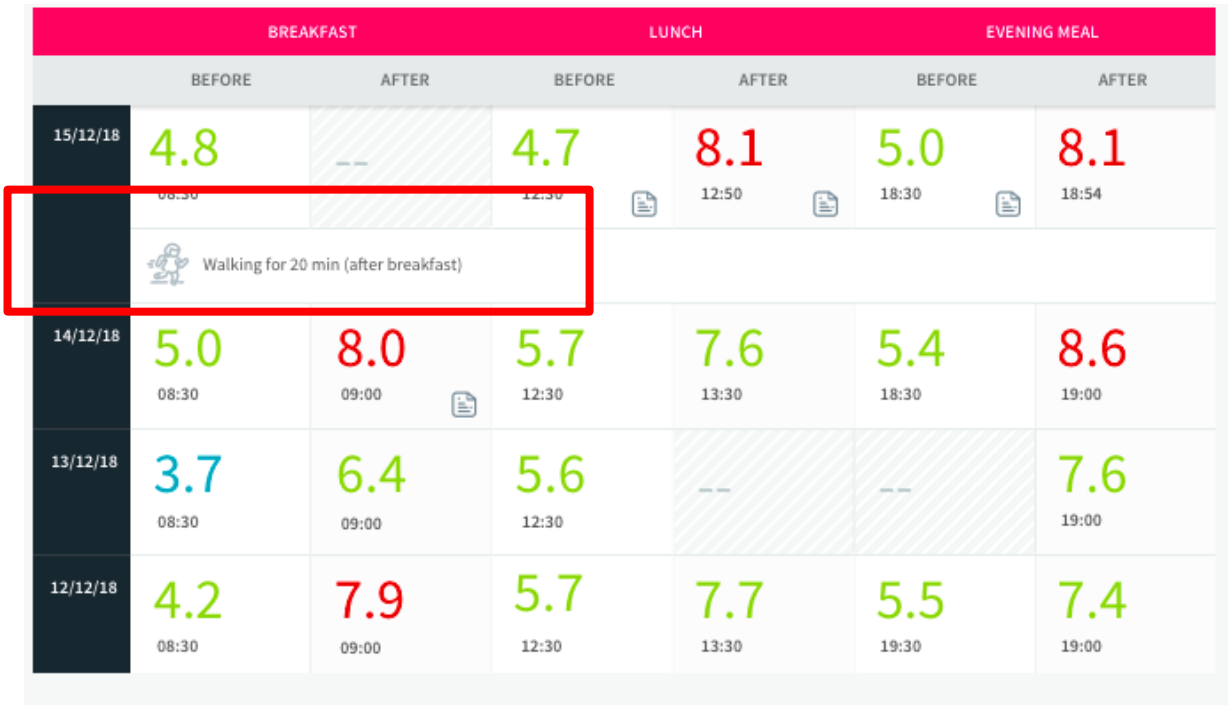
3. When a goal has been completed, they receive an automated promotional message depending on the stage of completion of their weekly goals (there are several versions)



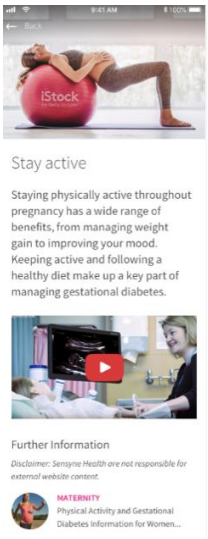
4. In the Hub section of the application, below the feedback wheel for glucose readings, there is a feedback bar related to show the progress of the weekly activity goals:



5. Women can view their activity in relation to the blood glucose control to help show the relationship.



6. There are information zones with links to specific GDM patient information leaflets, a promotional film, NHS activity finder and other useful resources/weblinks. Women can read and access this information in their own time.



7. Midwives can view their patient's activity progress, communicate by sending individualised feedback messages and adjust weekly goal setting remotely.

25. APPENDIX 5: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

26. APPENDIX 6: Pregnancy Physical Activity Questionnaire (PPAQ)

9364

Office Use Only - ID# ☐☐☐☐

UMASS

Pregnancy Physical Activity Questionnaire

Instructions:
Please use an ordinary No. 2 pencil. *Fill in the circles completely. The Question will be read by a machine so if you need to change your answer, erase the incorrect mark* ***completely.*** *If you have comments, please write them on the back of the questionnaire.*

Example: During this trimester, when you are NOT at work, how much time do you usually spend:

E1. **Taking care of an older adult**

If you take care of your mom for 2 hours each day, then your answer should look like this... →

- ○ None
- ○ Less than 1/2 hour per day
- ○ 1/2 to almost 1 hour per day
- ○ 1 to almost 2 hours per day
- ● 2 to almost 3 hours per day
- ○ 3 or more hours per day

It is very important you tell us about yourself honestly. There are no right or wrong answers. We just want to know about the things you are doing during this trimester.

1. Today's Date: ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year)
2. What was the first day of your last period? ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) ○ I don't know
3. When is your baby due? ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) ○ I don't know

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During this trimester, when you are NOT at work, how much time do you usually spend:

4. **Preparing meals (cook, set table, wash dishes)**
   - ○ None
   - ○ Less than 1/2 hour per day
   - ○ 1/2 to almost 1 hour per day
   - ○ 1 to almost 2 hours per day
   - ○ 2 to almost 3 hours per day
   - ○ 3 or more hours per day
5. **Dressing, bathing, feeding children while you are sitting**
   - ○ None
   - ○ Less than 1/2 hour per day
   - ○ 1/2 to almost 1 hour per day
   - ○ 1 to almost 2 hours per day
   - ○ 2 to almost 3 hours per day
   - ○ 3 or more hours per day

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During this trimester, when you are NOT at work, how much time do you usually spend:

6. **Dressing, bathing, feeding children while you are standing**
   - ○ None
   - ○ Less than 1/2 hour per day
   - ○ 1/2 to almost 1 hour per day
   - ○ 1 to almost 2 hours per day
   - ○ 2 to almost 3 hours per day
   - ○ 3 or more hours per day

7. **Playing with children while you are sitting or standing**
   - ○ None
   - ○ Less than 1/2 hour per day
   - ○ 1/2 to almost 1 hour per day
   - ○ 1 to almost 2 hours per day
   - ○ 2 to almost 3 hours per day
   - ○ 3 or more hours per day

8. **Playing with children while you are walking or running**
   - ○ None
   - ○ Less than 1/2 hour per day
   - ○ 1/2 to almost 1 hour per day
   - ○ 1 to almost 2 hours per day
   - ○ 2 to almost 3 hours per day
   - ○ 3 or more hours per day

9. **Carrying children**
   - ○ None
   - ○ Less than 1/2 hour per day
   - ○ 1/2 to almost 1 hour per day
   - ○ 1 to almost 2 hours per day
   - ○ 2 to almost 3 hours per day
   - ○ 3 or more hours per day

10. **Taking care of an older adult**
    - ○ None
    - ○ Less than 1/2 hour per day
    - ○ 1/2 to almost 1 hour per day
    - ○ 1 to almost 2 hours per day
    - ○ 2 to almost 3 hours per day
    - ○ 3 or more hours per day

11. **Sitting and using a computer or writing, while not at work**
    - ○ None
    - ○ Less than 1/2 hour per day
    - ○ 1/2 to almost 1 hour per day
    - ○ 1 to almost 2 hours per day
    - ○ 2 to almost 3 hours per day
    - ○ 3 or more hours per day

12. **Watching TV or a video**
    - ○ None
    - ○ Less than 1/2 hour per day
    - ○ 1/2 to almost 2 hours per day
    - ○ 2 to almost 4 hours per day
    - ○ 4 to almost 6 hours per day
    - ○ 6 or more hours per day

13. **Sitting and reading, talking, or on the phone, while not at work**
    - ○ None
    - ○ Less than 1/2 hour per day
    - ○ 1/2 to almost 2 hours per day
    - ○ 2 to almost 4 hours per day
    - ○ 4 to almost 6 hours per day
    - ○ 6 or more hours per day

14. **Playing with pets**
    - ○ None
    - ○ Less than 1/2 hour per day
    - ○ 1/2 to almost 1 hour per day
    - ○ 1 to almost 2 hours per day
    - ○ 2 to almost 3 hours per day
    - ○ 3 or more hours per day

15. **Light cleaning (make beds, laundry, iron, put things away)**
    - ○ None
    - ○ Less than 1/2 hour per day
    - ○ 1/2 to almost 1 hour per day
    - ○ 1 to almost 2 hours per day
    - ○ 2 to almost 3 hours per day
    - ○ 3 or more hours per day

16. **Shopping (for food, clothes, or other items)**
    - ○ None
    - ○ Less than 1/2 hour per day
    - ○ 1/2 to almost 1 hour per day
    - ○ 1 to almost 2 hours per day
    - ○ 2 to almost 3 hours per day
    - ○ 3 or more hours per day

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During this trimester, when you are NOT at work, how much time do you usually spend:

17. **Heavier cleaning (vacuum, mop, sweep, wash windows)**

- O None
- O Less than 1/2 hour per week
- O 1/2 to almost 1 hour per week
- O 1 to almost 2 hours per week
- O 2 to almost 3 hours per week
- O 3 or more hours per week

18. **Mowing lawn while on a riding mower**

- O None
- O Less than 1/2 hour per week
- O 1/2 to almost 1 hour per week
- O 1 to almost 2 hours per week
- O 2 to almost 3 hours per week
- O 3 or more hours per week

19. **Mowing lawn using a walking mower, raking, gardening**

- O None
- O Less than 1/2 hour per week
- O 1/2 to almost 1 hour per week
- O 1 to almost 2 hours per week
- O 2 to almost 3 hours per week
- O 3 or more hours per week

Going Places...

During this trimester, how much time do you usually spend:

20. **Walking slowly to go places (such as to the bus, work, visiting)** ***Not for fun or exercise***

- O None
- O Less than 1/2 hour per day
- O 1/2 to almost 1 hour per day
- O 1 to almost 2 hours per day
- O 2 to almost 3 hours per day
- O 3 or more hours per day

21. **Walking quickly to go places (such as to the bus, work, or school)** ***Not for fun or exercise***

- O None
- O Less than 1/2 hour per day
- O 1/2 to almost 1 hour per day
- O 1 to almost 2 hours per day
- O 2 to almost 3 hours per day
- O 3 or more hours per day

22. **Driving or riding in a car or bus**

- O None
- O Less than 1/2 hour per day
- O 1/2 to almost 1 hour per day
- O 1 to almost 2 hours per day
- O 2 to almost 3 hours per day
- O 3 or more hours per day

For Fun or Exercise...

During this trimester, how much time do you usually spend:

23. **Walking slowly for fun or exercise**

- O None
- O Less than 1/2 hour per week
- O 1/2 to almost 1 hour per week
- O 1 to almost 2 hours per week
- O 2 to almost 3 hours per week
- O 3 or more hours per week

24. **Walking more quickly for fun or exercise**

- O None
- O Less than 1/2 hour per week
- O 1/2 to almost 1 hour per week
- O 1 to almost 2 hours per week
- O 2 to almost 3 hours per week
- O 3 or more hours per week

25. **Walking quickly up hills for fun or exercise**

- O None
- O Less than 1/2 hour per week
- O 1/2 to almost 1 hour per week
- O 1 to almost 2 hours per week
- O 2 to almost 3 hours per week
- O 3 or more hours per week

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During this trimester, how much time do you usually spend:

26. **Jogging**
- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

27. **Prenatal exercise class**
- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

28. **Swimming**
- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

29. **Dancing**
- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

Doing other things for fun or exercise? Please tell us what they are.

30. _____ Name of Activity
- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

31. _____ Name of Activity
- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

Please fill out the next section if you work for wages, as a volunteer, or if you are a student. If you are a homemaker, out of work, or unable to work, you do not need to complete this last section.

At Work...

During this trimester, how much time do you usually spend:

32. **Sitting at working or in class**

- ○ None
- ○ Less than 1/2 hours per day
- ○ 1/2 to almost 2 hours per day
- ○ 2 to almost 4 hours per day
- ○ 4 to almost 6 hours per day
- ○ 6 or more hours per day

33. **Standing or slowly walking at work while carrying things (heavier than a 1 gallon milk jug)**
- ○ None
- ○ Less than 1/2 hour per day
- ○ 1/2 to almost 2 hours per day
- ○ 2 to almost 4 hours per day
- ○ 4 to almost 6 hours per day
- ○ 6 or more hours per day

34. **Standing or slowly walking at work not carrying anything**
- ○ None
- ○ Less than 1/2 hours per day
- ○ 1/2 to almost 2 hours per day
- ○ 2 to almost 4 hours per day
- ○ 4 to almost 6 hours per day
- ○ 6 or more hours per day

35. **Walking quickly at work while carrying things (heavier than a 1 gallon milk jug)**
- ○ None
- ○ Less than 1/2 hour per day
- ○ 1/2 to almost 2 hours per day
- ○ 2 to almost 4 hours per day
- ○ 4 to almost 6 hours per day
- ○ 6 or more hours per day

36. **Walking quickly at work not carrying anything**
- ○ None
- ○ Less than 1/2 hour per day
- ○ 1/2 to almost 2 hours per day
- ○ 2 to almost 4 hours per day
- ○ 4 to almost 6 hours per day
- ○ 6 or more hours per day

Thank You

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27. APPENDIX 7: Exercise Vital Sign assessment (EVS)

A modified version of the Exercise Vital Sign assessment (EVS) (Coleman et al 2012) will be used to evaluate baseline self-reported Physical Activity of moderate intensity or greater. We have modified the text slightly to include about pregnancy.

Please remember these questions are related to a week in the individual's life when they have been feeling well. For instance, if they have developed an acute illness or are pregnant and suffering morning sickness, it is related to a week prior to those symptoms when their health has been stable. The EVS consists of two questions.

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

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

28. APPENDIX 8: Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ)

Study ID.....

Oxford Maternity Diabetes Treatment Satisfaction Questionnaire

Please indicate your personal agreement with each of the following statements:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I find the equipment I use to check my blood sugars is convenient					
I feel the equipment I use to check my blood sugars is reliable					
My blood sugar monitoring fits in with my lifestyle					
The feedback I receive about my blood sugar level is useful					
I feel the system I use to calculate carbohydrate is convenient					
I feel the system I use to calculate carbohydrate reliable					
The feedback I receive about my carbohydrate intake is useful					
I feel the system I use to record my weight is convenient					
The feedback I receive about my weight is useful					

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I feel the system I use to measure my steps in convenient					
The feedback I receive about my steps is useful					

	Daily	Every 2-3 days	Every 4-5 days	Weekly	Only when necessary
How often would you have liked feedback?					

	Blood glucose levels	Carb intake	Physical activity (Steps)	Weight gain	None
Is there a particular area where you would have liked more feedback?					

Please use the box below for any further comments: