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Stay Active: a smartphone application to support the delivery of a physical activity intervention in women with gestational diabetes

Submission date
07/12/2020

Recruitment status
No longer recruiting

Registration date
11/02/2021

Overall study status
Completed

Last Edited
11/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus (GDM) is high blood sugar (glucose) that develops during pregnancy and usually disappears after giving birth. It can happen at any stage of pregnancy but is more common in the second or third trimester. It happens when the body cannot produce enough insulin – a hormone that helps control blood sugar levels – to meet the extra needs in pregnancy.
Regular physical activity (PA) improves blood sugar control in women diagnosed with gestational diabetes. 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 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.

Who can participate?
Women who are more than 24 and less than 33 completed weeks pregnant with a singleton pregnancy who have been diagnose with gestational diabetes mellitus.

What does the study involve?
The women will be asked to wear an accelerometer on their wrist to record their activity for 2 weeks. After a week they will take part in a motivational interview remotely with a midwife in which they will agree a weekly set of exercise goals. They will be asked to download the Stay Active app and shown how to record their activities, review their physical activity goals and explore the resource centre. They 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 where the participant will be asked wear the accelerometer for a further week. At their six week postnatal appointment they will be asked to undergo a fasting blood glucose measurement.

What are the possible benefits and risks of participating?
Physical activity is associated with positive health benefits in pregnancy. Carrying out moderate intensity exercise during pregnancy may improve control of blood glucose levels in women with GDM and potentially, lead to better outcomes for mother and baby.
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. If they do take part in the study, any suggested activity will be in keeping with that currently recommended for women with GDM

Where is the study run from?
Oxford University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2020 to December 2024

Who is funding the study?
NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
Dr Lucy Mackillop, lucy.mackillop@wrh.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
272096

Study information

Scientific 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

Acronym
Stay Active

Study objectives
Gestational diabetes mellitus (GDM) is defined as glucose intolerance first identified in pregnancy. The condition is an increasing problem among pregnant women worldwide. 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. Controlling blood glucose concentrations is fundamental to the management of GDM. 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. 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. Participating Trusts already use the NICE approved smartphone glucose monitoring application GDm-HealthTM (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)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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2020, South Central - Hampshire B Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)20 7104 8057; hampshireb.rec@hra.nhs.uk), ref: 20/SC/0342

Primary study design
Interventional

Study design

Single-centre feasibility study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Physical activity in women with gestational diabetes mellitus (GDM)

Interventions
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.

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 (i.e. total of 2 weeks) and will be asked to post back the accelerometer. 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), the exercise vital sign assessment (EVS) and the diabetes satisfaction questionnaire (OMDTSQ). 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.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 15/08/2022:
The feasibility and acceptability of the intervention to inform a decision on whether a randomised controlled trial is warranted:
1. Recruitment rates measured as a percentage of women with GDM who are eligible for the study at first contact with potential recruit:
1.1. The percentage of eligible participants at the Gestational Diabetes Clinic, Women Centre, John Radcliffe Hospital
1.2. The percentage of women who fulfil the eligibility criteria and accept the invitation to participate
2. Retention rate measured by assessing the proportion of women that completed the study at visit 3 - 36 week gestation (number)
3. Participant engagement with the intervention measured using:
3.1. Participant adherence rates to wrist-worn accelerometer at baseline visit and at baseline and visit 3 between 36 and 38 weeks pregnant (number of days worn over 7 days period,

average daily wear, portion of wear (hours); availability of data for Physical Activity (PA) outcome measures)
3.2. Attendance rate at follow-up sessions
3.3. Completion rates of self-reported PA questionnaires (both at baseline and follow-up visit 3)
3.4. Proportion of participants who set goals on Stay-Active (%) during the study period
3.5. Proportion of participants who recorded PA on Stay-Active (%) during the study period
4. Acceptability of the interview with Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants at baseline and between 36 and 38 weeks pregnant.
5. Fidelity of the motivational interviewing component of the intervention measured in 10% of participants' MI interviews one week after study enrolment
5.1. Whether all Motivational Interviews are audio recorded
5.2. 10% of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1) to assess the fidelity of sessions

Previous primary outcome measures:
1. Participant adherence measured by hours of wearing the wrist-worn accelerometer (hours) for first week after baseline appointment, for the week after first MI session and for one week between 36 and 38 weeks pregnant.
2. Acceptability measured using Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) at baseline and between 36 and 38 weeks pregnant
3. Physical activity measured by average daily minutes of Total PA (>40 mg) and Moderate to Vigorous PA (≥ 93.2 mg) using the acceleromter at recruitment and at 36-38 weeks pregnant
4. Recruitment rates measured as a percentage of women with GDM who are eligible for the study at first contact with potential recruit

Key secondary outcome(s)

Current secondary outcome measures as of 15/08/2022:
1. Physical activity (PA) levels assessed using information on physical activity time, type, intensity, and frequency assessed from baseline and follow-up visits:
1.1. Device-specific (accelerometer) data: Total PA average per measured day in moderate to vigorous (defined as any movement with a measured acceleration value ≥93.2 mg). PA and average accelerations in g (the standard SI unit of acceleration)
1.2. Pregnancy Physical Activity Questionnaire (PPAQ) – outcome: Energy expenditure (units measure of average weekly energy expenditure (MET-h·week-1) in both moderate (activities >3. 0 and <6.0 METs) and vigorous activity (activity >6.0 METs)
1.3. Exercise Vital Sign – total weekly minutes of Moderate to Vigorous PA
2. Usage and participant attitudes to +Stay Active:
2.1. Stay-Active usage during the study period from enrolment and activation of the App to completion:
2.1.1. Average time spent on app per week (seconds and minutes)
2.1.2. Average time per session (seconds and minutes)
2.1.3. Frequency of app opened and duration per session (seconds)
2.1.4. Number of participants logging activity per week
2.2. 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 at approximately 36 weeks pregnant
3. Blood glucose control and medication prescribed assessed using:
3.1. Difference in glycaemic control measured as mean blood glucose (mmol/L) at recruitment and at 36-38 weeks (using blood glucose taken in the week that the accelerometer is worn), adjusted for number and timing of measurements

3.2. Participant's prescribed medication (generic name and dose) from enrolment to end of the study
4. Maternal and neonatal outcomes measured using collected from medical records within 6 weeks after birth
4.1. Maternal outcomes (weight gain (kg), pharmacological medication (initiation, timing and doses in relation to meals and blood glucose readings), hypertensive disorders of pregnancy (gestational hypertension and pre-eclampsia), gestation at delivery (weeks), mode of delivery
4.2. Neonatal outcomes (birth weight (grams), neonatal hypoglycaemia (number of cases requiring IV glucose treatment for hypoglycaemia), neonatal hyperbilirubinaemia (number of cases requiring phototherapy), admission to SCBU for >24 h (number of cases), shoulder dystocia (number of cases)
5. Health costs: number of additional visits, contacts made by research midwife (both text message and telephone call) and time spent delivering the intervention (minutes) measured using collected from medical records and study SOP during the study period

Previous secondary outcome measures:
1. Blood glucose (BG) measured using a blood glucose monitor weekly from baseline until birth
2. Information on physical activity time, type, intensity and frequency assessed from accelerometer data throughout the study
3. Participants attitudes to Stay Active (with 5 questions, pushed by the app) measured 2 weeks after visit 2 and 36-38 week gestation, rating the usefulness of:
3.1. Motivational interviewing
3.2. Goal setting
3.3. Tracking your goals via the app
3.4. The automated motivational messages you receive
3.5. The personalised messages about your physical activity via the app
4. Maternal outcomes measured using patient records after birth:
4.1. Weight (kg) at baseline and at birth
4.2. Pharmacological medication (initiation, timing and doses in relation to meals and BG readings) throughout gestation
4.3. Hypertensive disorders of pregnancy (gestational hypertension and pre-eclampsia) throughout gestation
4.4. Gestation at delivery (weeks)
4.5. Mode of delivery
5. Neonatal outcomes measured using patient records after birth:
5.1. Birth weight (kg)
5.2. Neonatal hypoglycaemia (yes/no)
5.3. Neonatal hyperbilirubinaemia (yes/no)
5.4. Admission to SCBU for >24 hrs
5.5. Shoulder dystocia (yes/no)
6. Health economic information measured using patient records after birth:
6.1. Number of clinic visits throughout gestation
6.2. Time spent by clinical midwife delivering the intervention (minutes)

Completion date
31/12/2024

Eligibility

Key inclusion criteria

Current inclusion criteria as of 15/08/2022:
1. Women who are more than 20 completed weeks pregnant and less than 33 completed weeks pregnant with a singleton pregnancy
2. 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.
3. Using GDm-Health to monitor their blood glucose
4. Aged between 18 and 45 years
5. Willing and able to provide informed consent for participation in the study
6. Have, and use, a smartphone

Previous inclusion criteria:
1. Women who are more than 24 completed weeks pregnant and less than 33 completed weeks pregnant with a singleton pregnancy
2. 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.
3. Using GDm-Health to monitor their blood glucose
4. Aged between 18 and 45 years
5. Willing and able to provide informed consent for participation in the study
6. Have, and use, a smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
67

Key exclusion criteria
1. Multiple pregnancy
2. 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
3. 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
4 Unable to understand written or spoken English language

Date of first enrolment
01/04/2021

Date of final enrolment
30/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
As the data collected during this study will contain potentially identifiable and sensitive information, they will not be made available in a public repository. De-identified (anonymised) individual participant data that underlie the results reported in this article will be made available, with requests accepted immediately after publication, for proposals that set out to achieve aims specified in a methodologically and scientifically sound protocol that is approved by Oxford University Hospital Foundation Trust Research and Development where costs of providing access to the data are covered, where requests are compliant with the legal permissions and data security requirements are met.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2024	20/05/2024	Yes	No
Protocol article		28/09/2022	29/09/2022	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 1.7	10/01/2022	28/09/2022	No	No