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

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6 7 8	2	of a complex physical activity intervention '+Stay Active' in women
9 10	3	with gestational diabetes mellitus: a non-randomised feasibility
11 12	4	study
13 14	5	
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25 Abstract

26 Introduction

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

33 Methods & analysis:

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

44 Primary outcomes will include recruitment and retention rates, fidelity and assessment of 45 participant engagement with the intervention. Secondary outcomes include assessment of 46 blood glucose control, self-reported and device determined assessment of PA, structured 47 feedback of participant's attitudes to +Stay Active and description of maternal outcomes and 48 neonatal outcomes.

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This study will provide key insights into this complex intervention regarding engagement in smartphone technology and wearing accelerometers. This data will inform the development of a randomised controlled trial with refinements to intervention implementation. **Ethics and dissemination** This study has received a favourable opinion from South Central - Hampshire B Research Ethics Committee; REC reference: 20/SC/0342. Findings will be disseminated through peer-reviewed journals, conferences and seminar presentations. Word Count (294) 300 **Keywords** Gestational diabetes Mellitus, Physical Activity, Smartphone Applications. Ziezoni

2 3 4 5	60	Strengthen and Weakness:
6 7	61	• The study will be the first to combine motivational interviewing with a bespoke, novel,
8 9	62	behavioural change designed smartphone application (Stay-Active) to support PA
10 11 12	63	activity levels in women with gestational diabetes.
12 13 14	64	
15 16	65	• Stay-Active aims to support women's PA levels with weekly goal setting, self-
17 18	66	monitoring, performance and personalised feedback with motivational messaging and
19 20 21	67	a specific resource centre. A unique feature of this application is the ability for the
22 23	68	clinicians to interact with the user.
24 25	69	
26 27 28	70	• This study will provide evidence on the feasibility and acceptability of this unique
29 30	71	complex intervention, combining motivational interviewing with a behaviourally
31 32	72	informed smartphone application to increase PA.
33 34 35	73	
36 37	74	• The feasibility study design is not powered to determine intervention efficacy or clinical
38 39	75	effectiveness
40 41	76	
42 43 44	70	
45 46	77	• This study will contribute to the future research agenda in this population including
47 48	78	helping to determine whether a randomised control trial (RCT) to evaluate this
49 50 51	79	intervention is feasible. This future RCT would explore the efficacy of intervention to
51 52 53	80	increase PA and evaluate the effect on clinical outcomes.
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58 59 60	82	
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83 Introduction

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

There is growing evidence supporting the benefits of PA amongst women with GDM. Metaanalyses 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).

105 We have shown how motivational interviewing (using several Behaviour Change Techniques106 (BCTs)) can increase PA in women with GDM. Motivational interviewing incorporated into

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

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

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

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

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

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

2		
5 4 5	145	Methods and Analysis
6 7	146	Aims
8 9 10	147	The purpose of the study is to evaluate how women with GDM interact, engage with and
10 11 12	148	respond to a complex intervention, known as +Stay Active. This will help determine whether
13 14	149	a randomised control trial (RCT) to evaluate this intervention is feasible. A future RCT would
15 16 17	150	explore the efficacy of intervention to increase PA and evaluate the effect on clinical outcomes
17 18 19	151	such has glycaemia control, medication usage and macrosomia.
20 21 22	152	
23 24	153	The +Stay Active intervention combines an initial PA motivational interview to encourage
25 26 27	154	women to recognise the value of PA in pregnancy and in the management of GDM. Women
28 29	155	are then supported by BCW designed multi-component smartphone application 'Stay-Active'.
30 31 32 33	156	Objectives
34 35	157	1. Assess the number of women at the Women's Centre, Oxford University Hospital
36 37	158	who are eligible to participate.
38 39 40	159	2. Determine recruitment and retention rate.
41 42	160	3. Assess fidelity of delivery of the motivational interviewing component by trained
43 44	161	research midwives.
45 46 47	162	4. Participant adherence: Hours of wearing a wrist worn accelerometer for tracking PA
47 48 49 50 51 52 53	163	levels; availability of data for outcome measures; attendance at follow-up sessions.
	164	5. Assessment of the variance in different measures of PA and how they change over
	165	gestation using: (i) accelerometer data; (ii) the validated pregnancy physical activity
54 55 56	166	questionnaire (PPAQ) (18), and (iii) percentage of goal achieved.
50 57 58	167	6. Explore the acceptability of the intervention to participants as assessed by the Oxford
59 60	168	Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ), structured

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

171 7. Determine any refinements required of the intervention.

172 Study Design

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

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

183 Setting & Study Participants:

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

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2 3 4 5 6	192	investigating PA in early pregnancy. Recruitment started for this trial in April 2021 and plans
	193	to be completed in April 2022.
7 8	194	
9 10 11	195	Patient and Public involvement:
12 13	196	The development of Stay-Active involved focus groups as part of patient and public
14 15 16	197	involvement (PPI) in line with Oxford University Hospital Trust's PPI Strategy and Policy(16).
16 17 18	198	AW (patient representative) provided input and oversight in the study protocol.
19 20	199	
21 22	200	Visit 1: Recruitment and baseline assessments
23 24 25	201	Women attending the GDM clinic who met the inclusion criteria (see table 2) will be identified
26 27	202	by the clinical team at their appointment and a patient information sheet will be provided.
28 29	203	Following their clinic appointment, a research midwife will talk them through the study
30 31 32	204	procedure, invite questions and sign a study consent form.
33 34	205	If they consent to take part in the study(consent form shown in supplemental material 4), to
35 36	206	determine baseline PA levels; they will be asked to:
37 38 39	207	1) Complete an online version of two validated questionnaires: PPAQ (18) and the exercise
40 41	208	vital sign assessment (EVS)(24).
42 43	209	2) Wear a tri-axial accelerometer (GENEActiv, Active Insights Ltd, Kimbolton, UK) on their
44 45 46	210	non-dominant wrist for at least seven consecutive days (worn day and night). This time
40 47 48	211	frame was chosen due to its reliability to estimate measures of moderate to vigorous
49 50 51 52	212	physical activity (MVPA) during pregnancy (25).
	213	
53 54 55	214	The participants' General Practitioner will be informed of their involvement in the study.
55 56 57	215	Participants will be provided with an A4 instruction sheet which includes general care
58 59 60	216	instructions. Data will be collected at 100Hz.

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 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 andom 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 GDM - Gestational Diabetes Mellitus RCOG - Royal College of Obstetries and Gynaecology OGTT - Oral Glucose Tolerance Test Intervention: Visit 2: Motivational interview & Smartphone Application download We will ask participants to attend a virtual study visit (Visit 2) one week later. During this vis participants will receive a 20-minute motivational interview with a trained research midw during which if appropriate they will agree a set of weekly exercise goals. A virtual study vis was chosen because of COVID-19 restrictions. The participant will be asked to wear to accelerometer for a further week after the motivational interview (i.e. total of 2 weeks) and w post back the accelerometer using a pre-paid addressed envelope that will be issued participant at visit 1.	Inclusion Criteria	Exclusion Criteria
 GDM not diagnosed by OGTT, HbA1C or fasting plasma glucose as defined by RCO 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 GDM – Gestational Diabetes Mellitus RCOG – Royal College of Obstetrics and Gynaecology OGTT - Oral Glucose Tolerance Test Intervention: Visit 2: Motivational interview & Smartphone Application download during which if appropriate they will agree a set of weekly exercise goals. A virtual study vi was chosen because of COVID-19 restrictions. The participant will be asked to wear the accelerometer using a pre-paid addressed envelope that will be issued participant at visit 1. 	Women who are more than 20 completed weeks	Multiple pregnancy
 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 	pregnant and less than 33 completed weeks pregnant	• GDM not diagnosed by OGTT, HbA1C or
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 (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 GDM - Gestational Diabetes Mellitus RCOG – Royal College of Obstetrics and Gynaecology OGTT - Oral Glucose Tolerance Test Intervention: Visit 2: Motivational interview & Smartphone Application download We will ask participants to attend a virtual study visit (Visit 2) one week later. During this visi participants will receive a 20-minute motivational interview with a trained research midw during which if appropriate they will agree a set of weekly exercise goals. A virtual study vi was chosen because of COVID-19 restrictions. The participant will be asked to wear taccelerometer for a further week after the motivational interview (i.e. total of 2 weeks) and w post back the accelerometer using a pre-paid addressed envelope that will be issued participant at visit 1. 	Abnormal Oral Glucose Tolerance Test	Guidance for maternal medicine services in the evolving coronavirus (COVID 19)
 An absolute contra-indication to physical activity as per 2019 Canadian guidelines (26)e.g. preterm rupture of membranes, limited mobility, haemodynamically significant heart diseas restrictive lung disease Aged between 18 and 45 years Willing and able to provide informed consent for participation in the study Have, and use, a smartphone GDM - Gestational Diabetes Mellitus RCOG - Royal College of Obstetries and Gynaecology OGTT - Oral Glucose Tolerance Test Mistri 2: Motivational interview & Smartphone Application download We will ask participants to attend a virtual study visit (Visit 2) one week later. During this vis participants will receive a 20-minute motivational interview with a trained research midw during which if appropriate they will agree a set of weekly exercise goals. A virtual study vi was chosen because of COVID-19 restrictions. The participant will be asked to wear the accelerometer for a further week after the motivational interview (i.e. total of 2 weeks) and w post back the accelerometer using a pre-paid addressed envelope that will be issued participant at visit 1. 	(OGTT) as defined by IADPSG, HbA1C,	pandemic.
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> The motivational interviewing will take place remotely via the secure NHS online platform 'Attend Anywhere' or by telephone depending on the woman's preference. All motivational interviews will be audio recorded using a dictaphone (where participants consent to this). No patient identifiable data will be recorded, and the audio-file will be labelled with a unique study specific number. Completed interviews will be downloaded onto a secure University of Oxford server and deleted from the portable device. The anonymised audio-files will be accessed only by the study team involved in either recording or analysing the data. The structure of the motivational interview consultation is shown in supplemental material 5). Ten percent of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1)(27) to assess the fidelity of the interview by an experienced coder. This sample size is in-line with practical recommendations(28). The interviews will be picked at random using a random number generator.

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

) 251

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

256 Interactions with participants & motivational support during study period

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

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260	Visit 3: Assessment & Completion of intervention
261	A follow-up appointment will be scheduled for 36 weeks' gestation at which the participant

will be asked to complete an online version of PPAQ (18), the exercise vital sign 262 263 assessment(24) and OMDTSQ (supplementary material 4). They will also be asked to wear the accelerometer for 1 week. Via the notification on Stay-Active participants will be prompted 264 to complete a feedback form on the intervention (a five-star scale rating will be used the 265 266 motivational interview, goal setting, tracking of goals, automated and personalised messages, also with an opportunity to provide written feedback). Access to the Stay-Active will terminate 267 268 1 week after the routine 36 weeks gestation follow up appointment.

269

Early Discontinuation/Withdrawal of Participants 270

271 A participant may choose to withdraw at any time. This may happen for several reasons, 272 including but not limited to:

- The occurrence of what the participant perceives as an intolerable adverse effect 273
- Inability to comply with study procedures 274
- Participant decision 275
- 276

Data already collected with consent will be retained and used in the analysis. In addition, the 277 278 lead Investigator (LM) may discontinue a participant from the study at any time if the considers 279 it necessary for any reason including, but not limited to:

280 Ineligibility (either arising during the study or retrospectively having been overlooked at screening) 281

- 282 Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements 283
- Clinical decision 284

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285	The type of withdrawal and reason for withdrawal will be recorded.
286	
287	Study Outcomes:
288	Primary Outcomes
289	The primary outcome will be the feasibility and acceptability of the intervention to inform a
290	decision on whether a randomised controlled trial is warranted and feasible. This will be
291	assessed against a set of predefined criteria related to i) participant engagement with the
292	intervention, ii) recruitment and iii) retention rates, iv) fidelity of the intervention. A traffic
293	light system will determine the progression to a definitive trial (figure 2). This system has been
294	suggested to be preferable to the stop/go pass/fail approach(30). The primary objective with
295	outcome measures and timepoints are shown in table 3 and figure 2.
296	

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1 2 3 297 4	Table 3: Objectives, outcome me	vright, inclusion:	
5 6	Objectives	Outcome Measures	Timepoint(s) of Evaluation of this Outcome Measure
7		Primary Objective	
8		Recruitment rates 8 8 7	
9 10 11 12	To evaluate how women with GDM interact, engage with and respond to <i>Stay Active</i> +	 Percentage of women with GDM who eligible participants at the Women Centre and the Women Centre and the Women Centre and the Women Centre and the Percentage of women who fulfil the eligibility criteria and who accept the invitation of the Percentage of women who fulfil the eligibility criteria and who accept the invitation of the Percentage of women who fulfil the eligibility criteria and who accept the invitation of the Percentage of women who fulfil the eligibility criteria and who accept the invitation of the Percentage of women who fulfil the eligibility criteria and who accept the invitation of the Percentage of women who fulfil the eligibility criteria and who accept the invitation of the Percentage of the P	At recruitment & at end of study period
13 14	and to determine whether an RCT to assess the efficacy of	Proportion of women that completed the study # Go	At end of the Study (36 weeks)
15 16 17 18 19 20 21	this intervention, is feasible.	 Participant engagement with the intervention Participant adherence: wrist worn accelerometer: number of days worn over 7 days period, average daily portion of wear of wearing the; availability of data for PA outcome measures. Attendance at follow-up sessions. Completion rates of Self-reported PA questionnaires 	At Visit 1& end of study period (36 weeks gestation)
22 23 24 25		Acceptability: • Completion of the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) by participants.	Visit 2 & end of study period (36 weeks gestation)
26 27 28 29 30 31 32		 Fidelity of the intervention All Motivational interviews will be audio recorded. 10% of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1) to assess the fidelity of sessions. Proportion of participants who set goals on Stay-Active Proportion of participants who recorded PA on Stay-Active 	Visit 2 End of study period (36 weeks gestation)
33 34		د جو Secondary Objectives بر المحافظ Secondary Objectives	
35 36 37 38 39 40 41		Agence Bibliograph	
42 43 44 45 46		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	16

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

300 Secondary outcomes include assessment of blood glucose measurements and control, 301 assessment of PA, qualitative assessment of participant's attitudes to +Stay Active, description 302 of maternal and neonatal outcomes, a description of additional health costs and any refinements 303 required of the intervention (table 3).

305 i) Assessment of Physical activity

Three methods for assessing PA will be used: Two self-reported questionnaires and one wristworn 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.

311

a) Self-Reported physical activity assessment:

312 Two self-reported questionnaire measuring PA (EVS & PPAQ) will be completed at baseline313 and visit 3 (36-week gestation).

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

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

- 2) On those days, how many minutes do you engage in activity at this level?
- Total weekly moderate aerobic activity can be calculated.

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

b) Device measured physical activity: Accelerometers & data

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

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

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

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370 Usage and Participant attitudes to +Stay Active

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

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

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

390 Assessment of blood glucose control and medication use

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

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1 2		
2 3 4	396	in the week that the accelerometer is worn), adjusted for number and timing of measurements).
5 6	397	The GDm-Health smartphone application records when medication for GDM is prescribed; for
7 8 9	398	all participants will record number and names and doses of medication at recruitment and at
10 11	399	week 36 gestation (visit 3).
12 13	400	
14 15	401	Description of maternal outcomes & neonatal outcomes
16	402	
17 18	403	After delivery the maternal outcomes and neonatal outcomes (listed in table 3) will be
19 20 21	404	extracted from the medical records.
21	405	
22	406	Assessment of health costs:
23	407	
25	108	Health economic information including number of additional visits contacts (both text
26	400	Treath economic mormation meruding number of additional visits, contacts (both text
27 28	409	message and telephone call) and time spent by research midwife delivering the intervention
29 30 31	410	will be recorded.
32 33	411	
34 35	412	Data Collection Procedure:
36 37 38	413	Both the self-reported questionnaire measures of PA (EVS & PPAQ) will be completed at
39 40	414	baseline and visit 3 (36-week gestation). The OMDTSQ will be completed at visit 2 and 3.
41 42	415	All questionnaires will be completed on Microsoft forms by participants through a secure
43 44 45	416	online link. The participants will be identified by a unique study specific number in any
46 47	417	database. The name and any other identifying detail will NOT be included in any study data
48 49 50	418	electronic file.
51 52 53	419	Statistics & Analysis
54 55	420	This is a single arm feasibility study. The results will consist of descriptive statistics for
56 57 58 59	421	assessments at the 3 visits - baseline, 36-38-week, endpoint, and for data collected from the

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422 postnatal visit. The statistics software package used will be Stata 14 and R. The measures that423 will be assessed are listed under a description of the visits.

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

428 Sample Size Determination

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

437 Discussion

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

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

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

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

- 476 Ethics and Dissemination:
 - 477 All procedures will be followed are in accordance with the Declaration of Helsinki.

478 This study has received a favourable opinion from South Central - Hampshire B Research
479 Ethics Committee; REC reference: 20/SC/0342. To facilitate the extra study visits, travel
480 expenses will be paid on presentation of a receipt. This study is registered
481 https://www.isrctn.com/ISRCTN11366562. The study protocol is pre-registered with ISRCTN
482 39136. Results will be disseminated through peer-reviewed journals, conferences and seminar
483 presentations.

2 3 4	484	Figure Legends:
5	485	Figure 1
7 8 9	486	This figure demonstrates a flow of the study design with participant visits and assessment over
10 11	487	the study period. All Women will receive standard clinic care during study which includes
12 13 14	488	remote blood glucose monitoring and management through GDm-health [™] smartphone
15 16	489	application.
17 18 10	490	
20 21	491	Figure 2
22 23	492	Figure 2 shows the primary outcomes and the predefined criteria. These are related to i)
24 25 26	493	participant engagement with the intervention, ii) recruitment and iii) retention rates, iv) fidelity
20 27 28	494	of the intervention. This traffic light system will determine the progression to a definitive trial.
29 30	495	
31 32 33	496	Authors' contributions
34 35	497	RS, LM, CR, MS contributed and helped with design of Stay-Active. RS, JH, MM, LM, SR
36 37	498	and YK drafted and wrote the manuscript. All authors revised the content of the article, and
38 39 40	499	approved the final version.
41 42	500	
43 44	501	Competing interests
45 46 47	502	LM, JH, MM, YK, RS, NW, JB are supported by the NIHR Oxford Biomedical Research
48 49	503	Centre. LM is a part-time employee of Sensyne Health plc. LT is a Non-Executive Director,
50 51	504	part-time employee and shareholder of Sensyne Health plc.
52 53 54	505	The remaining authors have no disclosures of interest and there are no other conflicts to
55 56	506	declare.
57 58	507	
60	508	Consent for publication

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In relation to supplemental file 1, informed consent for the publication of identifying images

in an online open-access publication was obtained from the individual shown in the exercise

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demonstration photographs.

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This research was supported by the National Institute for Health Research (NIHR) Oxford
Biomedical Research Centre (BRC). The views expressed are those of the authors and not
necessarily those of the NHS, the NIHR or the Department of Health.

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3	523	Reference
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7	526	World Health Organization (WHO) versus The International Association of Diabetes and
8	520	Program Study Croup (IADDSC) diagnostic criteria of gostational diabetes mollitus (CDM)
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BG – Blood Glucose

Figure 2: Primary Outcome Criteria			
Criteria	How it will be assessed?		Indications of success
Recruitment rate			Average recruitment rate of ≥3 participants per week.
≥3 participants enrolled per week	Mean rate of recruitment over the recruitment period	•	Average recruitment rate ≥2 but < 3 participants per week.
		:	Average recruitment rate <2 participants per month.
Participant engagement v	with the intervention		
	Proportion of participants		95% confidence intervals that do not include 47*
60% of participants engage with the intervention	60% of participantsassigned who wore the wristengage with theworn accelerometer for >10 hrsintorventiona day for >5 days from	•	95% confidence intervals that include 60 but also include 47*
	recruitment		95% confidence intervals that do no include 60 or 47*
Fidelity of the			
Intervention	Proportion of participants attended an MI meeting		95% confidence intervals that do not include 47*
	The audio recordings of the		
60% of the core elements of the intervention delivered as intended.	MI session will be coded using MITI	•	95% confidence intervals that include 60 but also include 47*
	Proportion of participants who set goals		
	Proportion of participants who recorded PA in the app	:	95% confidence intervals that do no include 60 or 47*

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	Retention rate			
		Proportion of all enrolled participants		95% confidence intervals that do not include 58*
0 1 2 3 4 5 6 7 8 9	70% of all enrolled participants attend the 36-38 week visit, compete a PPAQ and wear an accelerometer	Who attend the 36-38 week follow-up visit and complete PPAQ		95% confidence intervals that include 70 but also include 58*
		Proportion of participants assigned who wore the wrist worn accelerometer for >10 hrs a day for >5 days at 36-38 weeks		95% confidence intervals that do not include 70 or 58*
0 1 2 3	*Using formula p=estimate (percentage expected to be seen), q=1-p, n=sample size, SE= standard error			
- 4 5	SE= v((p*q)/n)			
6 7	95% CI= estimate ± 1.96*SE			
Therefore, 95% Cl= p ±1.96 * √((p * q)/n) Therefore, 95% Cl= p ±1.96 * √((p * q)/n)				
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Figure 1: Behaviour Change Techniques implemented in Stay-Active



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

		BMJ Open STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS BMJ Open STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS	Page
SPIRIT 2013 Chec Section/item	klist: Reco	Description	Addressed on
	No	to te	page number
Administrative inf	ormation	N Super Super Super Stran	
Title	1	Descriptive title identifying the study design, population, interventions, and, if apple the, trial acronym	1
rial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3 & 23
	2b	All items from the World Health Organization Trial Registration Data Set	23
Protocol version	3	Date and version identifier	
unding	4	Sources and types of financial, material, and other support	24
Roles and	5a	Names, affiliations, and roles of protocol contributors	_1
responsibilities	5b	Name and contact information for the trial sponsor	n/a
	5c	Role of study sponsor and funders, if any, in study design; collection, managemers, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	25
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee endpoint adjudication committee, data management team, and other individuals or groups over eeing the trial, if applicable (see Item 21a for data monitoring committee)	<u>n/a</u>
		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

Page	37 of 52		BMJ Open Cop - 20		
1 2	Introduction		yright, i		
3 4 5	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant	5-7	
6 7		6b	Explanation for choice of comparators	5-7	
8 9	Objectives	7	Specific objectives or hypotheses	8	
10 11 12 13 14	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factor single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, explored by)	9	
	Methods: Participa	nts, inte	erventions, and outcomes		
16 17 18	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of conditions where data will be collected. Reference to where list of study sites can be obtained	9-10	
19 20 21	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11 (table 2)	
22 23 24	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including hogy and when they will be administered	11-13	
25 26 27		11b	ح جَنَّ Criteria for discontinuing or modifying allocated interventions for a given trial parti∰paget (eg, drug dose change in response to harms, participant request, or improving/worsening diseas	13-14	
28 29 30 31		11c	Strategies to improve adherence to intervention protocols, and any procedures for the state of t	n/a	
32 33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a	
34 35 36 37 38	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), methed of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	<u>14-21 , figure 2</u> ,	, Table
39 40 41 42	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for _ participants. A schematic diagram is highly recommended (see Figure)	9, 10-13	
43 44 45 46			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml		2

			BMJ Open BMJ Open Cop 20		Page 38 of 52
1 2	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	22	
3 4 5 6 7	Recruitment	15	ୁର୍ଦ୍ଦୁ ଓ Strategies for achieving adequate participant enrolment to reach target sample size ର ଅଧି ଅଧି	22, 10	
	Methods: Assignm	ent of i	nterventions (for controlled trials)		
8 9	Allocation:		es reig		
10 11 12 13 14 15	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random name by the sequence), and list of any factors for stratification. To reduce predictability of a random sequence, details of the bound restriction (eg, blocking) should be provided in a separate document that is unavailable to the sequence participants or assign interventions	n/a	
16 17 18 19	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequerding any steps to conceal the sequence until in the sequence are assigned opaque, sealed envelopes), describing any steps to conceal the sequence until in the sequence until in the sequence are assigned of the sequence are ass	n/a	
20 21 22	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who was as sign participants to interventions	10	
23 24 25 26	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a	
20 27 28 29		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a	
30 31 32	Methods: Data coll				
32 33 34 35 36 37	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and additive formation. Reference to where data collection forms can be found, if not in the protocol	14-21	
38 39 40 41 42 42		18b	Plans to promote participant retention and complete follow-up, including list of any out complete follow-up, inclu	14-21	3
43 44 45			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml		U

Page 39 of 52			BMJ Open cp 2	
1 2 3 4	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21
5 6 7 8 9	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21
		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21
10 11 12 13		20c	Definition of analysis population relating to protocol non-adherence (eg, as randore is a analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21
14 15	Methods: Monitorir	ng	nload t and	
16 17 18 19 20 21	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and report for statement of whether it is independent from the sponsor and competing interests; and reference whether further details about its charter can be found, if not in the protocol. Alternatively, an explanation of whether it is needed	14-21
22 23 24		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
25 26 27	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13-14
28 29 30 31	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
32 33	Ethics and dissemi	ination	gies. 2025	
34 35 36	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	24
37 38 39 40 41 42	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility crueria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	24
43 44 45 46			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or autherised surrogates, and how (see Item 32)	10
3 4 5 6		26b	Additional consent provisions for collection and use of participant data and biological Specimens in ancillary studies, if applicable	n/a
7 8 9	Confidentiality	27	How personal information about potential and enrolled participants will be collected meaned, and maintained in order to protect confidentiality before, during, and after the trial	21
10 11 12	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall transford each study site	25
13 14 15	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contracted al agreements that limit such access for investigators	21
16 17 18	Ancillary and post- trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those the participation	n/a
19 20 21 22 23	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results data as s, or other data sharing arrangements), including any publication restrictions	24
24 25		31b	Authorship eligibility guidelines and any intended use of professional writers	25
26 27 28		31c	Plans, if any, for granting public access to the full protocol, participant-level datas at, and statistical code	n/a
29 30	Appendices		echn	
31 32 33	Informed consent materials	32	Model consent form and other related documentation given to participants and augo res	supplemental file 4
34 35 36	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a
37 38 39 40 41 42 43	*It is strongly recomm Amendments to the p " <u>Attribution-NonComm</u>	nended protoco <u>mercial</u>	that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarifica I should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Co -NoDerivs 3.0 Unported" license.	ation on the items. ommons
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7. I understand that any data that leave the research group will be fully anonymised so that I cannot be identified. I agree to take part in this study. 8. I agree to take part in this study. 9. I agree to comments being sent to me from the study team via the Stay Active app 10. I agree to data being extracted from the Stay Active app Image: Contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies. Yes Notacted about ethics approval. I understand this research may involve commercial organisations. 13. I agree to be audio recorded and for the use of anonymised quotes in research reports and publications. Yes Notacted approvention			
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research reports and publications.	13. I agree to be audio recorded and for the use of anonymised quotes in	Yes	No
	research reports and publications.		

Name of Participant	Date	Signature
		1
Name of Person taking Consent	Date	Signature

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

Consent Form Version/Date: V1.2 2nd October 2020 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 IRAS Project No:272096 Dr Lucy Mackillop REC Ref:20/SC/0342 Page:2 of 2

PIS and Consent Form Guidance, Form SP-01-m V3.0, 18 Jun 2018

For peer reviewed by the principal the principal termination of the period of the peri

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Supplemental material 5: Details regarding Existing Motivational interviewing intervention

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

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

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able 1: Structure of the Motiv	rational interview:	includir
Part	Details	Behaviour changes techniques:
1. Setting the scene & Agreeing the agenda	Establish empathy and rapport and 'goal congruence' from the start, (ii)Manage some expectations of the consultation (iii) Give the person a sense of control over the conversation and agreeing the main focus of the conversation	tember 2022. Down Enseignement Sur Ises related to text
2. Exploring a typical day	Understanding of a particular aspect of the patient's life, where activity fits into their lifestyle (ii)Demonstrates non-judgemental, person-centred listening skills. (iii) Listen for any 'change-talk' -indicating that the patient is thinking about change, wants to change, is able to change, has already started to make some changes, etc. (iv)Help them feel heard and understood	nloaded from http://bmjo perieur (ABES) . and data mining, Al trai
3. Exploring importance	(i)Explore the importance of activity and their reasons for changing their activity levels (ii)Help the person give voice to, and better understand their own reasons for changing (iii) Elicit and develop change talk (iv)Strengthen the other persons readiness to change	Prompt and gies .1 and similar on
4. Sharing information on benefits	Ask -Share-Ask information about benefits of physical activity specifically for GDM	Information ঞ্রীতার্দ্ধী Health Consequence 5.1 Credible souge জ়1
5. Sharing specific information/knowledge about activity	Ask -Share-Ask information about type, during and expectations about physical specifically for GDM, Address barriers about activity, discuss type, time, frequency	Information about Health Consequence 5.1 Instruction on how to perform behaviour 4.1 Credible source & 1
6. Exploring and building confidence	(i) Strengthen their self-efficacy for change.(ii) Elicit and develop change talk.(iii) Share with them what other	Prompts and cue

Page	46	of 52	
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		022-0625; yyright, in
	people have found helpful when making the change e.g. glucose control (using ask-share-ask)	Focus on past success 15.3
7. Sharing info about building confidence	Ask -Share-Ask information about increasing confidence to become more active (ii) Provide suggestions, increase readiness	Valued self-iden ty 13.4 Social comparison 6.2
9. The Key question	Help the person decide what to do next	Problem solv
10. Exploring options	(i)Generate a range of possible ways forward (ii)Build optimism and confidence that change is possible.	
	Share some of your experience and expertise about what might be helpful (ii) Make progress towards agreeing the way forwards.	loaded from erieur (ABES and data min
11. Agreeing a plan and goal setting	Help the person generate a plan for their future (ii)Help Evoke ideas (iii) Complete personal Goal setting tool	Goal setting delaviour) 1.1 Action planning d.4
12. Relapse prevention	Help the person explore how their life might be different if they did decide to (and were able to) change, compared to if they didn't. (ii) Help the person better understand the risks of not changing and the benefits of changing, without you having to tell them (iii) 'Develop discrepancy' between their current behaviour and their desired future behaviour (iv) Learn more about the persons hopes, plans and values (v)Build hope Elicit and develop change talk. (vi)Agree about the need and timing of future conversations (vii)Agree about the medium and location of future conversations –face to face, telephone	Comparative maging of future 9.3 and sout capability 15.1 Commitment 1.9 une 13, 2025 at Age
13. Support	Explaining the support offered.	Social Support 3
	For peer review only - http://bmjopen.bmj.com/site/about/g	guidelines.xhtml

BMJ Open The numbers in brackets related to the code for the behaviour Change Technique (BCT) as per the Behaviour Change Technique Taxonomy The numbers in brackets related to the code for the behaviour Change Technique (BCT) as per the Behaviour of the Behaviour Version 1.(4) The framework and content of the motivational interview (table 1) was developed with the support and assistance from the Academy for Health Coaching https://learn.academyforhealthcoaching.co.uk/

Mottola MF, Davenport MH, Ruchat SM, Davies GA, Poitras VJ, Gray CE, et al. 2019 Canadian additional for physical activity 2. throughout pregnancy. Br J Sports Med. 2018;52(21):1339-46.

Dipietro L, Evenson KR, Bloodgood B, Sprow K, Troiano RP, Piercy KL, et al. Benefits of Physical Activity during Pregnancy and 3. Postpartum: An Umbrella Review. Med Sci Sports Exerc. 2019;51(6):1292-302.

Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior clause technique taxonomy (v1) of 93 4. hierarchically clustered techniques: building an international consensus for the reporting of behavior chaffige interventions. Ann Behav Med. erien on 2013;46(1):81-95. Al training, and similar technologies //bmjopen.bmj.com/ on June 13, 2025 at Agence Bibliographique de

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

Please indicate your personal agreement with each of the following statements

* Required

1. Please enter your study participant number *

2. Visit 1 or 2 *

Visit 1(initial consultation)

) Visit 2 (approx 36 weeks)

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

- Strongly agree
- O Agree
- O Neutral
- O Disagree
- O Strongly disagree
- 🔘 N/a

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

\bigcirc s	Strongly Agree
\bigcirc μ	Agree
	Neutral
() [Disagree
\bigcirc s	Strongly disagree
	N/A
5. My t	blood sugar monitoring fits in with my lifestyle *
5. My b	blood sugar monitoring fits in with my lifestyle *
5. My b	blood sugar monitoring fits in with my lifestyle * Strongly Agree
5. My b	blood sugar monitoring fits in with my lifestyle * Strongly Agree Agree Neutral
5. My k	blood sugar monitoring fits in with my lifestyle * Strongly Agree Agree Neutral Disagree
5. My k	blood sugar monitoring fits in with my lifestyle * Strongly Agree Agree Neutral Disagree Strongly disagree
5. My b	blood sugar monitoring fits in with my lifestyle * Strongly Agree Agree Neutral Disagree Strongly disagree

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

Strongly Agree
Agree
Neutral
Disagree
Strongly disagree
N/a

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

Strongly agree
◯ Agree
O Neutral
O Disagree
Strongly disagree
○ N/A
8. I feel the system I use to calculate carbohydrate is reliable st
Strongly agree
⊖ Agree
O Neutral
Disagree
Strongly disagree
🔿 N/a
9. I feel the feedback I receive about my carbohydrate intake is useful st
Strongly agree
Agree
O Neutral
Disagree
○ N/A

BMJ Open

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

1	
1 2 3	Strongly agree
4 5	◯ Agree
6 7 8	O Neutral
9 10	O Disagree
12 13	Strongly disagree
14 15 16	○ N/A
17 18 19	
20 21 22	11. I feel the system I use to record my weight is useful st
23 24	Strongly agree
25 26 27	Agree
28 29	O Neutral
30 31 32	O Disagree
33 34 35	Strongly disagree
36 37	○ N/A
38 39 40	
40 41 42	12. I feel the system I use to measure my physical activity/exercise level is convenient *
43 44 45	
45 46 47	
48 49	⊖ Agree
50 51	O Neutral
52 53	Disagree
55 56	Strongly disagree
57 58	○ N/A
צכ	

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BMJ Open 13. I feel the feedback I receive about my physical activity/exercise levels is
Strongly agree
Agree
O Neutral
O Disagree
Strongly disagree
○ N/A
14. How often would you have liked feedback? *
O Daily
O Every 2-3 days
O Every 4-5 days
O Weekly
Only when necessary
○ N/A
15. Is there a particular area where you would have liked more feedback? *
O Blood glucose
Carbohydrate intake
O Physical Activity/Exercise

Weight gain

None

1 2 3 4 5 6 7	16. Please use box below for any further comments: Particular regarding the Stay-Active App (ease of use & recommendation to the others)
8 9 10 11 12 13 14 15 16 17	
18 19 20 21 22 23 24 25 26 27	
27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 9 60	This content is neither created nor endorsed by Microsoft. The data you submit will be sent to the form owner.

BMJ Open

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

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Manuscript ID	bmjopen-2022-062525.R1
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Date Submitted by the Author:	11-Aug-2022
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Secondary Subject Heading:	Sports and exercise medicine
Keywords:	Diabetes in pregnancy < DIABETES & ENDOCRINOLOGY, Information

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1	Study Protocol: Use of a smartphone application to support the
2	implementation of a complex physical activity intervention (+Stay
3	Active') in women with gestational diabetes mellitus: protocol for a
4	non-randomised feasibility study
5	
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25 Abstract

26 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.

33 Methods & analysis:

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

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5 6 7	50	Ethics and dissemination
8	51	The study has received a favourable opinion from South Central - Hampshire B Research
9 10 11	52	Ethics Committee; REC reference: 20/SC/0342. Written informed consent will be obtained
12 13	53	from all participants. Findings will be disseminated through peer-reviewed journals,
14 15	54	conferences and seminar presentations.
16 17	55	Trial registration: ISRCTN11366562.
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20	56	Word Count (296) 300
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24	57	Keywords Gestational diabetes Mellitus, Physical Activity, Smartphone Applications.
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3 4 5	58	Strengths and limitations of this study
6 7	59	• The study will combine motivational interviewing with a bespoke smartphone
8 9	60	application (Stay-Active) to support PA activity levels in women with gestational
10 11 12	61	diabetes.
12 13 14	62	• It will provide evidence on the feasibility and acceptability of this complex
15 16 17	63	intervention.
18 19 20 21	64	• The study design is not powered to determine intervention efficacy or clinical
21 22 23	65	effectiveness.
24 25 26	66	• Conclusions of this study will be limited due to the lack of a control group.
27 28	67	• Results from this study will inform whether a randomised control trial (RCT) to
29 30 31	68	evaluate this intervention is feasible.
32 33		
34 35	69	Introduction
36 37	70	Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance first
38 39 40	71	detected during pregnancy (1). GDM is associated with serious complications for both mother
40 41 42	72	and baby (2-4). Fundamental to the management of GDM is glycaemic control (5), with
43 44	73	increasing levels of blood glucose suggested as the mechanism for the increased risk of adverse
45 46 47	74	maternal and infant outcomes (6). Interventions for GDM include blood glucose (BG)
47 48 49	75	monitoring, lifestyle intervention and pharmacological therapy. Of the lifestyle interventions
50 51	76	dietetic modifications and physical activity are the only interventions that have reported
52 53 54	77	possible health improvements for maternal and fetal outcomes (7).

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

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

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

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

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

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

Resource Centre within Centre:

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

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

1 2 3 4 5	130		
6 7 8	131	Methods and Analysis	
9 10 11	132	Aims	
12 13	133	The purpose of the study is to evaluate how women with GDM interact, engage with and	
 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 	134	respond to a complex intervention, known as +Stay Active. This will help determine whether	
	135	a randomised control trial (RCT) to evaluate this intervention is feasible. A future RCT would	
	136	explore the efficacy of such an intervention to increase PA and evaluate the effect on clinical	
	137	outcomes such has glycaemia control, medication usage and macrosomia.	
	138		
	139	The +Stay Active intervention combines an initial PA motivational interview to encourage	
	140	women to recognise the value of PA in pregnancy and in the management of GDM. Women	
	141	are then supported by BCW designed multi-component smartphone app 'Stay-Active'.	
	142	Objectives	
37 38	143	1. Assess the number of women at the Women's Centre, Oxford University Hospital	
 39 40 41 42 43 44 45 46 47 48 	144	over a period who are eligible to participate	
	145	2. Determine recruitment and retention rate.	
	146	3. Assess fidelity of the motivational interviewing component by trained research	
	147	midwives.	
48 49 50	148	4. Participant adherence: Days and hours of wearing a wrist worn accelerometer for	
50 51 52 53 54 55 55	149	tracking PA levels; availability of data for outcome measures; attendance at follow-up	
	150	sessions.	
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151 5. Assessment of the variance in different measures of PA and how they change over
152 gestation using: (i) accelerometer data; (ii) the validated pregnancy physical activity
153 questionnaire (PPAQ) (18), and (iii) percentage of goals achieved.

- 6. Explore the acceptability of the intervention to participants as assessed by the Oxford
 Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ), structured
 questionnaire on participant's attitudes to +Stay Active and usage data from the
 smartphone app.
 - 158 7. Determine any refinements required of the intervention.
- 159 Study Design

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

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

0 170

O Setting & Study Participants:

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

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.75 International Association of Diabetes and Pregnancy Study Groups recommendations (21) to .76 RCOG guidance during the COVID-19 pandemic (22)and then from Jan 2022 to NICE thresholds for diagnosis (23). Women will not be eligible for the study until at least 20 .77 .78 completed weeks of pregnancy as the study is not investigating PA in early pregnancy. .79 Recruitment started for this trial in April 2021 and plans to be completed in April 2022.

.81 **Patient and Public involvement:**

The development of Stay-Active involved focus groups as part of Patient and Public .82 .83 involvement (PPI) in line with Oxford University Hospital Trust's PPI Strategy and Policy(16). AW (patient representative) provided input and oversight in the study protocol. .84

.86 Visit 1: Recruitment and baseline assessments

.87 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. .88 .89 Following their clinic appointment, a research midwife will talk through the study procedure,

.90 invite questions and ask participants to sign the consent form.

- 91 If they consent to take part in the study(consent form shown in supplemental material 4) to .92 determine baseline PA levels. They will be asked to:
- 1) Complete an online version of two validated questionnaires: PPAQ (18) and the exercise .93 .94 vital sign assessment (EVS)(24).
- 2) Wear a tri-axial accelerometer (GENEActiv, Active Insights Ltd, Kimbolton, UK) on their .95 non-dominant wrist for at least seven consecutive days (worn day and night). This time .96 .97 frame was chosen due to its reliability to estimate measures of moderate to vigorous physical activity (MVPA) during pregnancy (25). .98
- 60

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

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	Inclusion Criteria	Exclusion Criteria
	Women who are more than 20 completed weeks	Multiple pregnancy
	pregnant and less than 33 completed weeks pregnant	• GDM not diagnosed by OGTT, HbA1C or
	with a singleton pregnancy.	fasting plasma glucose as defined by RCOO
	 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 	 fasting plasma glucose as defined by RCOC Guidance for maternal medicine services in the evolving coronavirus (COVID 19) pandemic. An absolute contra-indication to physical activity as per 2019 Canadian guidelines(26)e.g. preterm rupture of membranes, limited mobility, haemodynamically significant heart disease restrictive lung disease Unable to understand written or spoken English
	• Have, and use, a smartphone	
206 207 208 209 210	RCOG – Royal College of Obstetrics and Gynaecology OGTT - Oral Glucose Tolerance Test	
211	Intervention:	
212	Visit 2: Motivational interview & Smartphone App download	
213	We will ask participants to attend a virtual study visit (Visit 2) one week later. During this visi	
214	participants will receive a 20-minute motivati	onal interview with a trained research midwi
215	during which if appropriate they will agree a set of weekly exercise goals. A virtual study vis	
216	was chosen because of COVID-19 restrictions. The participant will be asked to wear the	
217	accelerometer for a further week after the motivational interview (i.e. total of 2 weeks) and wi	
218	post back the accelerometer using a pre-paid addressed envelope that will be issued t	
219	participant at visit 1.	
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> The motivational interviewing will take place remotely via the secure NHS online platform 'Attend Anywhere' or by telephone depending on the woman's preference. All motivational interviews will be audio recorded using a dictaphone (where participants consent to this). No patient identifiable data will be recorded, and the audio-file will be labelled with a unique study specific number. Completed interviews will be downloaded onto a secure University of Oxford server and deleted from the portable device. The anonymised audio-files will be accessed only by the study team involved in either recording or analysing the data. The structure of the motivational interview consultation is shown in supplemental material 5). Ten percent of motivational interviews will be coded using the Motivational Interviewing Treatment Integrity Code (MITI 4.2.1)(27) to assess the fidelity of the interview by an experienced coder. This sample size is in-line with practical recommendations(28). The interviews will be picked at random using a random number generator.

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

) 237

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.

242 Interactions with participants & motivational support during study period

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

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3 4	246	Visit 3: Assessment & Completion of intervention
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	247	A follow-up appointment will be scheduled for 36 weeks' gestation at which the participant
	248	will be asked to complete an online version of PPAQ (18), the exercise vital sign
	249	assessment(24) and OMDTSQ (supplementary material 4). They will also be asked to wear
	250	the accelerometer for 1 week. Via the notification on Stay-Active, participants will be
	251	prompted to complete a feedback form on the intervention (a five-star scale rating will be used
	252	for the motivational interview, goal setting, tracking of goals, automated and personalised
	253	messages and an opportunity to provide written feedback). Access to the Stay-Active will
21 22	254	terminate 1 week after the routine 36 weeks gestation follow up appointment.
23 24 25	255	
23 26 27 28 29 30 31 32 33 34	256	Early Discontinuation/Withdrawal of Participants
	257	A participant may choose to withdraw at any time. This may happen for several reasons,
	258	including but not limited to:
	259	• The occurrence of what the participant perceives as an intolerable adverse effect
35 36	260	Inability to comply with study procedures.
37 38	261	Participant decision.
39 40 41	262	
41 42 43 44 45 46 47	263	Data with consent will be retained and used in the analysis. In addition, the lead investigator
	264	(LM) may discontinue a participant if it is considered necessary for any reason including, but
	265	not limited to:
48 49 50	266	• Ineligibility (either arising during the study or retrospectively having been overlooked
50 51 52 53 54 55 56	267	at screening).
	268	Significant protocol deviation.
	269	• Significant non-compliance with treatment regimen or study requirements.
58 59	270	Clinical decision.
60		

The nature and reason for the withdrawal will be recorded.
Study Outcomes:
Primary Outcomes
The primary outcomes will be the feasibility and acceptability of the intervention to inform a
decision on whether a randomised controlled trial is warranted and feasible. This will be
assessed against a set of predefined criteria (outlined in figure 2) related to i) participant
engagement with the intervention, ii) recruitment and iii) retention rates, iv) fidelity of the
intervention. A traffic light system will determine the progression to a definitive trial. This
system has been suggested to be preferable to the stop/go pass/fail approach(30). The primary
objective with outcome measures and timepoints are shown in table 3 and figure 2.
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	ght, in 52	
1. Assessment of PA	Attainment of information on physical activity time, type, intensity, and frequency assessed from baseline and subsequent visits i) Device specific (accelerometer) data: (Total PA average per measured day, moderate to vigorous PA and average Acceleration) ii) PPAQ – outcome: Energy expenditure iii) EVS – Weekly minutes of Moderate to Vigorous PA	At recruitment visit 2 and visit 3.
2.Usage and Participant attitudes to +Stay Active	 i) Stay-Active Usage: Average time spent on app per week Average time per session Frequency of app opened and duration per session Number of participant logging activity per week 	From visit 2 to participant completion
	ii) Participants attitudes to +Stay-Active (5 questions rating) on the usefulness of: Motivational interviewing, goal setting, tracking your goals via the app, automated and motivational messages, personalised messages and an open comments section.	Visit 3: 36 weeks gestation
3. Assessment of blood glucose control & medication prescribed	 i) Difference in glycaemic control measured as mean BG at recruitment and at 36-38 weeks (using BG taken in the week that the accelerometer is worn), adjusted for number and timing of measurements). ii) Participant's prescribed medication (generic name and dose) 	Recruitment & Visit 3 (36 weeks' gestation)
4. Description of maternal and Neonatal outcomes.	 i) Maternal outcomes (weight gain, pharmacological medication (initiation, timing and doses in relation to meals and BG readings), hypertensive disorders of pregnancy gestational hypertension and pre-eclampsia), gestation at delivery, mode of delivery). ii) Neonatal outcomes (birth weight, neonatal hypoglycaemia, neonatal hyperbilirubinaemia, admission to SCBU for >24 hrs, shoulder dystocia). 	Data gathered 6 weeks post delivery
5. Assessment of health costs	Number of additional visits, contacts made by research Midwife (both text message and telephone call) and time spent delivering intervention	Throughout study period
6 Determine any refinements required of the intervention.	Review and analysis of the primary and secondary outcome data	Following data analysis
	gence Bibliograph	
	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	17

285 Secondary Outcomes

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

291 i) Assessment of Physical activity

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

a) Self-Reported physical activity assessment:

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

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

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

- 2) On those days, how many minutes do you engage in activity at this level?
- Total weekly moderate aerobic activity can be calculated.

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

b) Device measured physical activity: Accelerometers & data

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

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

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

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Usage and Participant attitudes to +Stay Active

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

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

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

Assessment of blood glucose control and medication use

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

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384	(using BG taken in the week that the accelerometer is worn, adjusted for number and timing of
385	measurements). The GDm-Health smartphone app records when medication for GDM is
386	prescribed; for all participants number, name and doses of medication at recruitment and at
387	week 36 gestation (visit 3) will be recorded.
388	
389	Description of maternal outcomes & neonatal outcomes
390 391	After delivery the maternal outcomes and neonatal outcomes (listed in table 3) will be
392	extracted from the medical records.
393 394 205	Assessment of health costs:
395 396	Health economic information including number of additional visits, contacts (both text
397	message and telephone call) and time spent by research midwife delivering the intervention
398	will be recorded.
399	
400	Data Collection Procedure:
401	Both the self-reported questionnaire measures of PA (EVS & PPAQ) will be completed at
402	baseline and visit 3 (36-week gestation). The OMDTSQ will be completed at visit 2 and 3.
403	All questionnaires will be completed on Microsoft forms by participants through a secure
404	online link. The participants will be identified by a unique study specific number in any
405	database. The name and any other identifying detail will NOT be included in any study data.
400	
406	Statistics & Analysis
407	This is a single arm feasibility study. The results will consist of descriptive statistics for
408	assessments at the 3 visits - baseline, 36-38-week, endpoint, and for data collected from the
409	postnatal visit. The statistics software package used will be Stata 14 and R. The measures that
410	will be assessed are listed under a description of the visits.

Summary statistics will be calculated for all measures. Continuous variables will be reported

as means, standard deviations, maximum and minimum values. Binary variables will be

reported as counts. The number of missing values will be reported.

415 Sample Size Determination

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

423 Ethics and Dissemination:

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

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

Discussion

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

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

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

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

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

⁸ 473 Figure Legends:

1 474 **Figure 1**

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

2 3	479	
4 5		
6 7	480	Figure 2
8 9	481	Figure 2 shows the primary outcomes and the predefined criteria. These are related to i)
10 11	482	participant engagement with the intervention, ii) recruitment and iii) retention rates, iv) fidelity
12 13 14	483	of the intervention. This traffic light system will determine the progression to a definitive trial.
15 16	484	For this progression criteria the following formula was used to estimate the 95% CIs:
17 18	485	https://www.rds-london.nihr.ac.uk/resources/justify-sample-size-for-a-feasibility-study/.
19 20 21	486	Green represents a threshold above the desired rate of completion including 95% confidence
22 23	487	interval. Amber represents a threshold above the desired rate of completion but may cross 95%
24 25	488	CI and Red represents a threshold below the desired rate of completion including 95% CI.
26 27 28	489	
29 30	490	Supplementary material 1:
31 32	491	This figure includes a demonstration of a training exercise (wall press exercise). Please note
33 34 35	492	the person depicted is not patient and the photograph was taken with the participant's
36 37	493	knowledge and consent
38 39	494	
40 41 42	495	Authors' contributions
43 44	496	RS, LM, CR, MS contributed and helped with design of Stay-Active. RS, JH, MM, LM, NA,
45 46	497	JB, PB, PD, SJ, RP, CR, MS, LT, NW, AW and YK drafted and wrote the manuscript. All
47 48 49	498	authors revised the content of the article, and approved the final version.
50 51	499	
52 53	500	Competing interests
54 55 56	501	LM, JH, MM, YK, RS, NW, JB are supported by the NIHR Oxford Biomedical Research
57 58	502	Centre. LM is a part-time employee of EMIS Group plc. LT is a Non-Executive Director, part-
59 60	503	time employee and shareholder of Sensyne Health plc.

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1 2		
2 3 4	504	JH is funded by a UKRI Future Leaders fellowship.
5 6	505	The remaining authors have no disclosures of interest and there are no other conflicts to
/ 8 9	506	declare.
10 11	507	
12 13	508	Consent for publication
14 15 16	509	In relation to supplemental file 1, informed consent for the publication of identifying images
17 18	510	in an online open-access publication was obtained from the individual shown in the exercise
19 20	511	demonstration photographs.
21 22 23	512	
24 25	513	Funding
26 27	514	This research was supported by the National Institute for Health Research (NIHR) Oxford
28 29 20	515	Biomedical Research Centre (BRC). Grant number: N/A
31 32	516	
 33 34 35 36 37 38 39 40 41 	517	Acknowledgements:
	518	This research was supported by the National Institute for Health Research (NIHR) Oxford
	519	Biomedical Research Centre (BRC). The views expressed are those of the authors and not
	520	necessarily those of the NHS, the NIHR or the Department of Health.
42 43 44	521	
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3	523	Reference
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10	528	and their associated maternal and neonatal outcomes. Horm wol Biol Clin Investig.
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BG – Blood Glucose PA- Physical Activity

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PA- Physical Activity

Criteria Recruitment rate	How it will be assessed?	Indications of success		
Recruitment rate	HOW IL WIII DE ASSESSEU?			
Reclutinent late				
		Average recruitment rate of ≥3 participants per week.		
≥3 participants enrolled per week	Mean rate of recruitment over the recruitment period	Average recruitment rate ≥2 but < 3 participants per week.		
		Average recruitment rate <2 participants per month.		
Participant engagement w	vith the intervention			
	Proportion of participants assigned who wore the wrist	95% confidence intervals that do not include 47*		
60% of participants engage	worn accelerometer for >10 hrs a day for >5 days from recruitment	95% confidence intervals that include 60 but also include 47*		
with the intervention	Proportion of participants who set goals	95% confidence intervals that do not include 60 or 47*		
	who recorded PA in the app			
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	The audio recordings of the	95% confidence intervals that include 60 but also include 47*		
	coded using MITI	95% confidence intervals that do not include 60 or 47*		
Retention rate				
70% of all enrolled	Proportion of all enrolled participants Who attend the 36-38 week	95% confidence intervals that do not include 58*		
participants attend the 36- 38 week visit, compete a	follow-up visit and complete PPAQ Proportion of participants	95% confidence intervals that include 70 but also include 58*		
accelerometer	assigned who wore the wrist worn accelerometer for >10 hrs a day for >5 days at 36- 38 weeks	95% confidence intervals that do not include 70 or 58*		
*Using formula p	p=estimate (percentage exp	ected to be seen), q=1-p, n=sample size, SE=		
Standard Error SE= $V((p*q)/n)$.	e + 1 96*SF			
Therefore, 95% CI= p ±1.96 * V((p * q)/n)				

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Figure 1: Behaviour Change Techniques implemented in Stay-Active



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

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		STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS 102-06255 OP 28 5	
SPIRIT 2013 Checl	klist: Reco	ommended items to address in a clinical trial protocol and related documents*	
Section/item	ltem No	Description	Addressed on page number
Administrative inf	ormation	text and tex	
Title	1	Descriptive title identifying the study design, population, interventions, and, if apple and trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract & Ethics and Dissemination
	2b	All items from the World Health Organization Trial Registration Data Set	Ethics and Dissemination
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	Funding
Roles and	5a	Names, affiliations, and roles of protocol contributors	Title page
responsibilities	5b	Name and contact information for the trial sponsor	n/a
	5c	Role of study sponsor and funders, if any, in study design; collection, management, agalysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Funding
		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

			BMJ Open BMJ Open	P
1 2 3 4 5 6 7 8 9	Introduction	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee adjudication committee, data management team, and other individuals or groups over seeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
10 11 12 13	Background and rationale	6a	de to be the search question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each inter and be the second studies (published and unpublished) examining benefits and harms for each inter	Introduction
14 15 16 17 18		6b	Explanation for choice of comparators	Introduction & Method and analysis
19 20 21	Objectives	7	Specific objectives or hypotheses	Method and Analysis
22 23 24 25	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, face is single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, explored to realize the second structure is the second struc	Study design
26 27	Methods: Participa	ants, inte	erventions, and outcomes	
28 29 30 31 32 33 34 35 36 37 38 39 40 41 42	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study design
	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for and centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Study design (table 2)
	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Method and Analysis subsection intervention
43 44 45			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

Page	37 of 53		BMJ Open COLUMN COLUM COLUMN COLUMN COLUMN COLUMN COLUMN COLUMN COLUMN COLUMN COLUMN C	
1 2 3 4 5 6 7		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participatit (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Method and analysis - Early Discontinuation/Wi hdrawal of Participants
8 9 10 11		11c	Strategies to improve adherence to intervention protocols, and any procedures for وَلَقُهُمْ اللَّهُ المَّاتِ اللَّهُ اللَّهُ عَلَيْ اللَّهُ اللَّ	n/a
12 12		11d	Relevant concomitant care and interventions that are permitted or prohibited durine trial	ı/a
14 15 16 17 18	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement vare defined (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), needefined of aggregation (eg, systolic blood median, proportion), and time point for each outcome. Explanation of the clinical reference of chosen from efficacy and harm outcomes is strongly recommended	Study outcomes, igure 2, Table 3
19 20 21 22 23 24	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for I participants. A schematic diagram is highly recommended (see Figure)	Method and analysis visit description (figure 1)
25 26 27	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including sciences and statistical assumptions supporting any sample size calculations	Sample size determination
28 29 30 31 32 33 34 35 36	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size 13, 2025 at Agencial 14,	Sample size determination & /isit 1: Recruitment and paseline assessments
37 38	Methods: Assignme	ent of i	nterventions (for controlled trials)	
39 40 41 42	Allocation:		liographiqu	
43 44 45 46			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	3

			BMJ Open by co pen-20	Page 3				
1 2 3 4 5	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random refinitions), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to these who enrol participants or assign interventions	n/a				
6 7 8 9	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequertian tight numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until in المجية المعقية المعامية	n/a				
10 11 12 13 14 15 16 17	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will sign participants to interventions	Method and Analysis Visit 1: Recruitment and baseline assessments				
17 18 19 20	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a				
20 21 22 23 24		17b	If blinded, circumstances under which unblinding is permissible, and procedure for resealing a participant's allocated intervention during the trial	n/a				
24 25 26	Methods: Data collection, management, and analysis							
26 27 28 29 30 31	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, in the data and the processes to promote data quality (eg, duplicate measurements, training of asses or by and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and additional test and the study instruments (eg, questionnaires, laboratory tests) along with their reliability and additional test and the study instruments (eg, questionnaires, laboratory tests) along with their reliability and additional test and the study instruments (eg, questionnaires, laboratory tests) along with their reliability and additional test and	Method and analysis and study outcomes				
32 33 34 35 36		18b	Plans to promote participant retention and complete follow-up, including list of any our bound on the collected for participants who discontinue or deviate from intervention protocols	Method and anaylsis, subsection visits				
37 38 39 40 41	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of deta management procedures can be found, if not in the protocol	Outcomes -data collection procedure				
42 43 44 45			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	4				

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1 2	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Statistics & Analysis
3 4 5 6		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Statistics & Analysis
7 8 9 10 11		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomined analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Statistics & Analysis
12	Methods: Monitorir	ng	t Sup	
14 15 16 17 18 19	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and report a statement of whether it is independent from the sponsor and competing interests; and reference between further details about its charter can be found, if not in the protocol. Alternatively, an explanation of the protocol is not needed	method and analysis, Competing interests
20 21 22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
23 24 25 26 27	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneous ly peported adverse events and other unintended effects of trial interventions or trial conduct	Early Discontinuation/Wi thdrawal of Participants
28 29 30 31	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
32 33	Ethics and dissemi	ination	lies. 2025	
34 35 36 27	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics and Dissemination
37 38 39 40 41 42	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility creative eria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial regiseries, journals, regulators)	Ethics and dissemination
43 44 45 46			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	5

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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorities d surrogates, and	Ethics and
2 3 4				Dissemination:
4 5 6			ling for second	Visit 1:
7			or use use	Recruitment and baseline
o 9 10			s rela	assessments
10 11 12 13		26b	Additional consent provisions for collection and use of participant data and biolog	n/a
14	Confidentiality	27	How personal information about potential and enrolled participants will be collectant and maintained	
15 16 17			in order to protect confidentiality before, during, and after the trial	Data Collection Procedure
18 19 20	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall training deach study site	Competing interests
21 22	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contact all agreements that	
23 24 25			limit such access for investigators	Data Collection Procedure
25 26 27 28	Ancillary and post- trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those whose uffer harm from trial participation	n/a
29 30	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health are professionals,	Ethics and
31 32			sharing arrangements), including any publication restrictions	Dissemination
33 34		31b	Authorship eligibility guidelines and any intended use of professional writers	Authors'
35 36				contributions
37		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
38 39	Annendices			
40 41	Appendices		grap <u>p</u>	
42				
43 44			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	
45			-	

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1 2	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates supplemental file 4
3 4 5 6	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for gefetic or molecular n/a analysis in the current trial and for future use in ancillary studies, if applicable
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	*It is strongly recom Amendments to the " <u>Attribution-NonCor</u>	imendec protoco nmercial	t that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. I should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Configuration on the items. I-NoDerivs 3.0 Unported" license.
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								Dr I	Lucv Mac
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PIS and Consent Form Guidance, Form SP-01-m V3.0, 18 Jun 2018

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

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

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

 Consent Form
 Version/Date: V1.2 2nd October 2020

 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
 IRAS Project No:272096

 Dr Lucy Mackillop
 REC Ref:20/SC/0342
 Page:2 of 2

PIS and Consent Form Guidance, Form SP-01-m V3.0, 18 Jun 2018

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Supplemental material 5: Details regarding Existing Motivational interviewing intervention

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

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

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Table 1: Structure of the Motiv	ational interview:	cludir	
Part	Details	Benaviour changes techniques:	
1. Setting the scene & Agreeing the agenda	Establish empathy and rapport and 'goal congruence' from the start, (ii)Manage some expectations of the consultation (iii) Give the person a sense of control over the conversation and agreeing the main focus of the conversation	tember 2022. Dowi Enseignement Suj ses related to text	
2. Exploring a typical day	Understanding of a particular aspect of the patient's life, where activity fits into their lifestyle (ii)Demonstrates non-judgemental, person-centred listening skills. (iii) Listen for any 'change-talk' -indicating that the patient is thinking about change, wants to change, is able to change, has already started to make some changes, etc. (iv)Help them feel heard and understood	nloaded from http://bmjo perieur (ABES) . and data mining, Al trai	
3. Exploring importance	(i)Explore the importance of activity and their reasons for changing their activity levels (ii)Help the person give voice to, and better understand their own reasons for changing (iii) Elicit and develop change talk (iv)Strengthen the other persons readiness to change	Prompt and gives 1.1	
4. Sharing information on benefits	Ask -Share-Ask information about benefits of physical activity specifically for GDM	Information about Health Consequence 5.1 Credible souge 9.1	
5. Sharing specific information/knowledge about activity	Ask -Share-Ask information about type, during and expectations about physical specifically for GDM, Address barriers about activity, discuss type, time, frequency	Information about Health Consequence 5.1 Instruction on how to perform behaviour 4.1 Credible source & 1	
6. Exploring and building confidence	(i) Strengthen their self-efficacy for change.(ii) Elicit and develop change talk.(iii) Share with them what other	Prompts and cue	
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	people have found helpful when making the change e.g. glucose control (using ask-share-ask)	Focus on past success 15.3
7. Sharing info about building confidence	Ask -Share-Ask information about increasing confidence to become more active (ii) Provide suggestions, increase readiness	Valued self-identity 13.4 Social comparing 6.2
9. The Key question	Help the person decide what to do next	Problem solv
10. Exploring options	(i)Generate a range of possible ways forward (ii)Build optimism and confidence that change is possible.	
	Share some of your experience and expertise about what might be helpful (ii) Make progress towards agreeing the way forwards.	loaded from erieur (ABES
11. Agreeing a plan and goal setting	Help the person generate a plan for their future (ii)Help Evoke ideas (iii) Complete personal Goal setting tool	Goal setting deleviour) 1.1 Action planning d.4
12. Relapse prevention	Help the person explore how their life might be different if they did decide to (and were able to) change, compared to if they didn't. (ii) Help the person better understand the risks of not changing and the benefits of changing, without you having to tell them (iii) 'Develop discrepancy' between their current behaviour and their desired future behaviour (iv) Learn more about the persons hopes, plans and values (v)Build hope Elicit and develop change talk. (vi)Agree about the need and timing of future conversations (vii)Agree about the medium and location of future conversations –face to face, telephone	Comparative ging of future 9.3 and sign about capability 15.1 Commitment 1.9-une 13, 2025 at Age
13. Support	Explaining the support offered.	Social Support 3
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BMJ Open The numbers in brackets related to the code for the behaviour Change Technique (BCT) as per the Behaviour Change Technique Taxonomy The numbers in brackets related to the code for the behaviour Change Technique (BCT) as per the Behaviour of the Behaviour Version 1.(4) The framework and content of the motivational interview (table 1) was developed with the support and assistance from the Academy for Health Coaching https://learn.academyforhealthcoaching.co.uk/

Mottola MF, Davenport MH, Ruchat SM, Davies GA, Poitras VJ, Gray CE, et al. 2019 Canadian additional for physical activity 2. throughout pregnancy. Br J Sports Med. 2018;52(21):1339-46.

Dipietro L, Evenson KR, Bloodgood B, Sprow K, Troiano RP, Piercy KL, et al. Benefits of Physical Activity during Pregnancy and 3. Postpartum: An Umbrella Review. Med Sci Sports Exerc. 2019;51(6):1292-302.

Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior clause technique taxonomy (v1) of 93 4. hierarchically clustered techniques: building an international consensus for the reporting of behavior chaffige interventions. Ann Behav Med. erien on 2013;46(1):81-95. Al training, and similar technologies //bmjopen.bmj.com/ on June 13, 2025 at Agence Bibliographique de

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

Please indicate your personal agreement with each of the following statements

* Required

1. Please enter your study participant number *

2. Visit 1 or 2 *

Visit 1(initial consultation)

) Visit 2 (approx 36 weeks)

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

- Strongly agree
- Agree
- O Neutral
- O Disagree
- O Strongly disagree
- 🔵 N/a

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Strongly Agree
Agree
O Neutral
Disagree
Strongly disagree
○ N/A
5. My blood sugar monitoring fits in with my lifestyle $*$
Strongly Agree
◯ Agree
O Neutral
O Disagree
Strongly disagree
○ N/A
6. The feedback I receive about my blood sugar level is useful \ast
Strongly Agree
○ Agree
O Neutral
Disagree
O Strongly disagree
🔿 N/a

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

Strongly agree
O Agree
O Neutral
O Disagree
Strongly disagree
○ N/A
8. I feel the system I use to calculate carbohydrate is reliable st
Strongly agree
O Agree
O Neutral
O Disagree
Strongly disagree
◯ N/a
9. I feel the feedback I receive about my carbohydrate intake is useful *
Strongly agree
O Agree
O Neutral
O Disagree
Strongly disagree

🔿 N/A

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

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Strongly agree
○ Agree
O Neutral
O Disagree
Strongly disagree
○ N/A
11. I feel the system I use to record my weight is useful *
Strongly agree
O Agree
O Neutral
O Disagree
Strongly disagree
○ N/A
12. I feel the system I use to measure my physical activity/exercise level is convenient *
Strongly agree
O Agree
O Neutral
O Disagree
Strongly disagree

N/A
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2	Strongly agree
3	O saturgi, sgitt
4 5	
5	
7	
8	 Neutral
9	
10	 Disagree
11	
12	Strongly disagree
14	
15	○ N/A
16	
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18	
20	
21	14. How often would you have liked feedback? *
22	
23	
24	
25 26	
20	U Every 2-3 days
28	
29	 Every 4-5 days
30	
31	🔘 Weekly
32 33	
34	Only when necessary
35	
36	\bigcirc N/A
37	
38 30	
40	
41	
42	15. Is there a particular area where you would have liked more feedback? *
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44 15	
45 46	
47	Carle also dereta intella
48	
49	
50	 Physical Activity/Exercise
51	
52	🔘 Weight gain
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55	○ None
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58 59	
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16. Please use box below for any further comments: Particular regarding the Stay-Active App (ease of use & recommendation to the others) This content is neither created nor endorsed by Microsoft. The data you submit will be sent to the form owner. 📲 Microsoft Forms

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