Full/long title of the study

Improving testing for cardiometabolic diseases in those with previous gestational diabetes mellitus: randomised clinical trial in primary care (RADIANT)

Short study title/acronym

Reminders to improve testing for type 2 diabetes in those with previous gestational diabetes: a randomised controlled trial

Protocol version number and date

Version 1.0 13th October 2023
Version 2.0 16th July 2024
Version 3.0 2nd March 2026

Research reference numbers

IRAS Number	297067
Sponsor reference number	RG_22-138
ISRCTN number	13791687
REC reference number	24/SC/0069

This protocol has regard for the HRA guidance

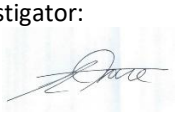
Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to adhere to the signed University of Birmingham's Sponsorship CI declaration.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the

Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:  Date: 13/10/2023

Name: (please print): Francesca Crowe

Sponsor statement:

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

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Key study contacts

Chief Investigator: Francesca Crowe (F.Crowe@bham.ac.uk, M: +44 773345 0666) and

Study Co-ordinator: Francesca Crowe

Sponsor: University of Birmingham
Study coordinator – Francesca Crowe
Co-investigators Krishnarajah Nirantharakumar, Shamil Haroon, Jenny Cooper

Joint-sponsor(s)/co-sponsor(s)

Funder(s): National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB)

Key Protocol Contributors: Francesca Crowe, Karla Hemming, Ngawai Moss, Krish Nirantharakumar

Committees

Study management committee

Chair:
University of Birmingham
Francesca Crowe
Krish Nirantharakumar,
Krishna Gokhale
Shamil Haroon
Jenny Cooper
Our Health Partnership
Clair Huckerby
Anushree Choudhary

Medical Oversight (if applicable) Not applicable

Study summary

Study Title: impRoving testing for cardiometabolic diseases in those with previous gestational diabetes mellitus: a randomised clinical trial in primary care (RADIANT)

Internal ref. no. (or short title) Reminders to improve testing for type 2 diabetes in those with previous gestational diabetes: a randomised controlled trial

Study Design: Randomised controlled trial

Study Participants: Women age 18-50 years with a previous diagnosis of gestational diabetes who have not been tested for type 2 diabetes in the past 12 months.

Planned Size of recruitment target (if applicable): ~200 targeted for recruitment

Follow up duration (if applicable): 3 months

Planned Study Period: 6 months

Research Question/Aim(s): Does a SMS and animation intervention reminder sent to women with previous gestational diabetes mellitus (GDM) increase testing for type 2 diabetes mellitus (T2DM) and cardiometabolic disease risk factors in primary care compared to usual care?

Funding and support in kind

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
National Institute for Health Research (NIHR)	**Financial support (£370,000)**

Role of study sponsor and funder

The funder has no role in the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. They do not control the final decision regarding any aspects of the study; however, the NIHR will review manuscripts prior to dissemination to ensure they meet the funder's policies.

Roles and responsibilities of study management committees/groups and individuals

Protocol contributors

The sponsor (the University of Birmingham) will ensure the following:

1. Ensuring reporting safety information to the CI, delegate, or independent clinical reviewer for the ongoing assessment of the risk/benefit according to the Study Monitoring Plan.

Women with lived experience of gestational diabetes and members of the public have been and continue to be involved and have contributed to this study. They were central in developing the animation that forms part of the intervention. They have inputted to aspects of the lay summary and the dissemination plan. They helped us shape how women with previous GDM and the public are embedded into the study.

KEY WORDS:
electronic health records; gestational diabetes; randomised controlled trials; reminder systems; type 2 diabetes mellitus

Study flow chart

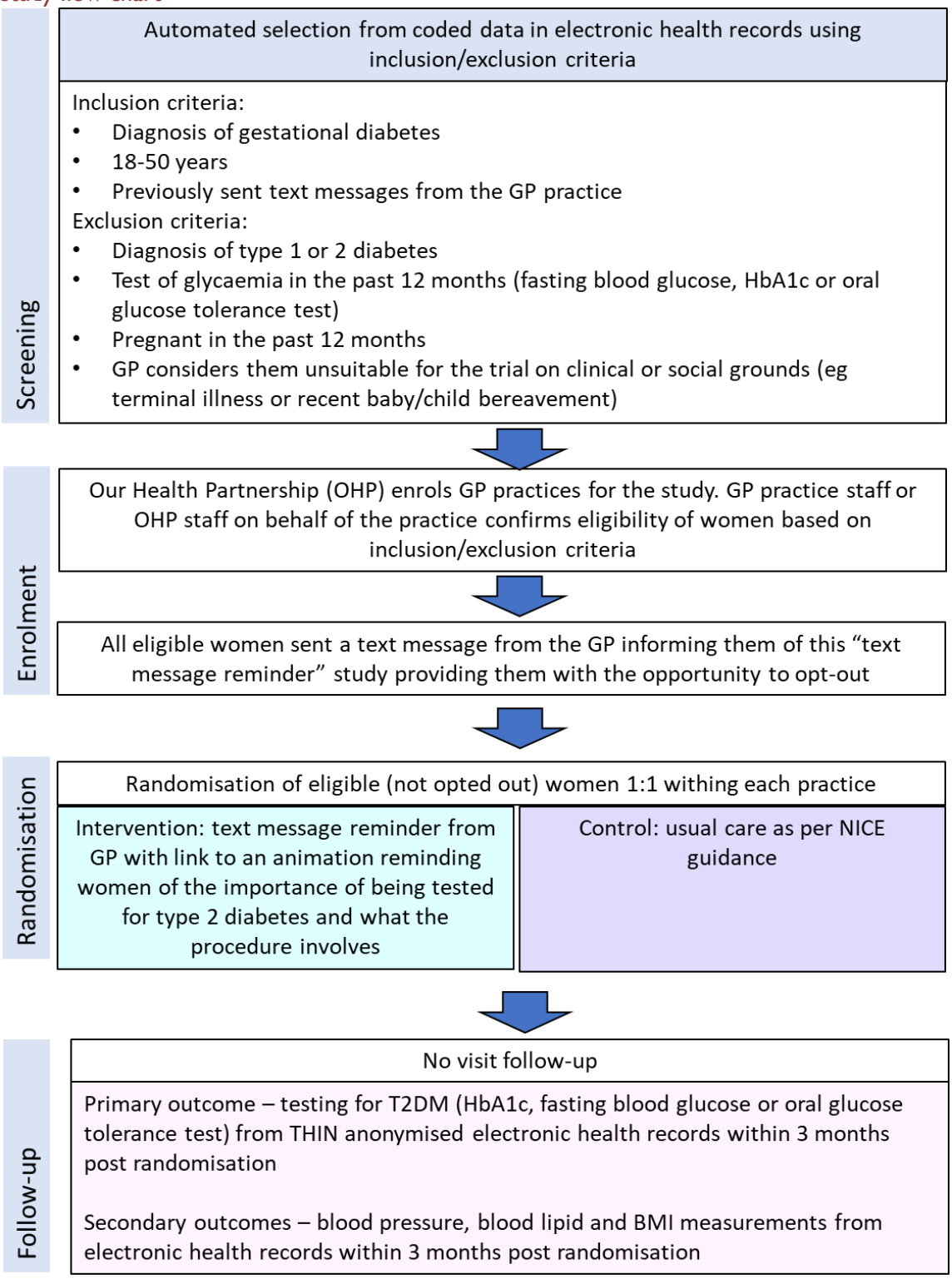

Figure 1. Study flow chart of the RADIANT randomised controlled trial of text message reminders to women with previous gestational diabetes

Abbreviations: GP, general practitioner, HbA1c, glycosylated haemoglobin; NICE, National Institute for Health and Care Excellence; T2DM, type 2 diabetes mellitus;

Study protocol

1. Background

Each year, 30,000 UK women develop diabetes during pregnancy (we call this gestational diabetes mellitus or GDM). The average number of pregnancies affected is about 4% in white British and 24% in British Asian women (1). GDM usually goes away after giving birth but women who had it are more likely to develop type 2 diabetes in the next few years. Moreover, women with GDM have at least double the risk of high blood pressure (hypertension), heart disease and non-alcoholic fatty liver disease (2–5). Because of this, women are advised to have yearly diabetes tests (fasting blood glucose or glycosylated haemoglobin – HbA1c) to find out and manage diabetes early before problems occur. Data from primary care records shows approximately 60% of women with GDM in the UK are tested for T2DM in the first year after giving birth (postpartum) but this declines rapidly to 36% at 2-3 years postpartum despite their risk of cardiometabolic disease (diabetes and heart disease) increasing over time (2). Therefore, cost-effective strategies to increase annual testing for cardiometabolic disease in women with a history of GDM are essential and need to be evaluated in randomised controlled trials (RCT).

Reminders sent to those with previous GDM may help improve testing for type 2 diabetes. Evidence from a Cochrane systematic review showed that postal reminders to those with previous GDM, their clinician or both substantially increased the uptake of testing for T2DM in the first year postpartum (6). Another systematic review which included observational studies suggested that telephone, email and letter reminders to women and their healthcare provider helped increase postpartum testing (7). Sending letter reminders is expensive and time-consuming. A large proportion of GP surgeries use short message service (SMS) to send text messages patients to remind them about appointments booked and SMS has been instrumental in rolling out the COVID-19 vaccine by the NHS (8). Whilst a single RCT of postpartum SMS reminders did not show a significant difference in testing attendance among women with previous GDM at six months postpartum in Australia, attendance in both groups were above 75%; and confidence intervals were wide and included the possibility of important improvements (9). To date, all trials have focused on reminders to test sent in the first year after delivery, which we already know is high (2) but there are a paucity of trials assessing whether reminders work to improve longer-term annual testing.

A recent systematic review of qualitative studies synthesised facilitators and barriers for those with previous GDM attending postpartum blood glucose testing. They made recommendations and highlighted behaviour change techniques to improve testing. One recommendation made with a high degree of confidence included educating women of the purpose of testing and how the procedure for testing works (10).

Finding and including participants in clinical trials is mainly done manually and few of those who are suitable actually take part. This makes RCTs time-consuming, and it is hard to know if the intervention will work in everyone. Data-enabled trials are RCTs that are conducted using electronic medical records. This can simplify methods by screening finding and inviting suitable participants, checking they have given their consent to take part, then randomly splitting them into two groups and giving them the intervention. We can also reduce the burden of taking part for both participants and health workers by using data recorded in usual clinical practice to find out whether the intervention works.

2. Rationale

Results from trials in the UK show SMS are effective at improving screening for cervical (11) and breast cancer (12). Given that more than 96% of people under the age of 55 years own a smartphone (13), SMS could be a cost-effective intervention to improve annual testing for T2DM and risk factors for cardiometabolic disease by encouraging those with previous GDM to book a test with their GP. Moreover, we can embed a link to a short animation educating women about their future risk of cardiometabolic disease, why it is important to be tested every year, and how the procedure for testing works (10).

A data-enabled RCT will allow for efficient selection of eligible patients, randomisation, and data collection. Moreover, this type of trial will provide evidence on effectiveness of the intervention in routine clinical practice making it widely generalisable and easier to scale-up (14). It will capitalise on the investments already made by the NHS into data and IT systems by using relevant clinical outcomes that are already captured within routine health care data and address an unmet need in those with previous GDM.

This trial will focus on only one strategy (sending SMS reminders to women) to help improve testing for cardiometabolic diseases. Other aspects such as recall system for postpartum testing from primary or secondary care will be the subject of other studies and are beyond the scope of the RADIANT study.

3. Theoretical framework

The theories that underpin aspects of this study are based on previous research of sending text message reminders to women that increased attendance at breast and cervical cancer screening programmes (11,12). The animation will fill some gaps that were highlighted in previous research where there was a need to educate women of the importance of annual testing of T2DM, and cardiometabolic disease risk factors and the procedures involved in testing for type 2 diabetes (10).

The animation will also draw upon some of the theoretical frameworks of behavioural economics to help encourage behaviour change. Some aspects we aim to incorporate include:

- Behavioural analysis of components of the animation using the Behaviour Change Wheel (BCW) (14)
- Risk attitudes (ie risk taking and risk perceptions) to help construct appropriate wording in the SMS, to motivate women to click on the message link to obtain more information.
- The type of messaging in the animation that will motivate women (eg messages about self, messages about significant others in their lives including family and friends);
- Format of such messaging (eg positively versus negatively framed); and,
- Timing of SMS delivery (eg time of the day which is most suitable).

Table 1. Behavioural analysis of components of the animation using the Behaviour Change Wheel (BCW)*

Target Behaviour	Barriers to the target behaviour	Animation component	Target construct (BCW)	Intervention function (BCW)	Behaviour change technique (BCT) (using 93 BCT taxonomy v1)
Understanding purpose of testing	Lack of information and consistency in advice about the need to test for type 2 diabetes	Show risk of type 2 diabetes and heart disease is higher but lifestyle options to help (diet and physical activity)	Reflective Motivation	Education	Inform of health consequences
Remembering to be tested annually	No reminder from GP about testing	Booking an appointment around the time of your baby's birthday.	Opportunity	Education	Prompts/cues
Attending the appointment	Lack of support to look after baby/child to attend the appointment	Bringing baby/child to the appointment	Opportunity	Education	Prompts/cues
Understanding procedure for testing	Long appointments and hassle of fasting before the blood test	Show women going in for the appointment with no need to fast or stay for long	Reflective Motivation	Education	Demonstration of the behaviour
Understanding purpose of testing	Lack of information and consistency in advice about the need to test for type 2 diabetes	Finding out their risk of type 2 diabetes, having BMI and blood pressure measured (and doing little more physical activity with baby)	Reflective Motivation	Education	Inform of health consequences

*From Michie *et al* (2011) (15)

4. Research question/aims

4.1. Objectives

Randomised controlled trial
To determine whether the SMS and animation sent to women with previous GDM increases the number of women tested for T2DM (plasma fasting glucose, glycosylated haemoglobin (HbA1c) or oral glucose tolerance test (OGTT)) and cardiometabolic disease risk factors (measurement of blood pressure, body mass index (BMI) or blood lipids) at three months post randomisation compared to usual care.

4.2. Outcome

Randomised controlled trial
Primary outcome – test for type 2 diabetes (fasting blood glucose, HbA1c) in primary care within 3 months after randomisation
Secondary outcomes – measurement of weight or BMI, blood pressure measurement, blood cholesterol measurement within 3 months the intervention

5. Study design and methods of data collection and data analysis

Using the eligibility criteria, the GP or Our Health Partnership (OHP) on behalf of the GP will select women with previous GDM, previously sent text messages by GP practice who have not been tested for type 2 diabetes in the past 12 months. We will exclude women who are previously diagnosed with type 1 or 2 diabetes, who have been tested for type 2 diabetes in the past 12 months, pregnant in the past 12 months and GP considers women who are unsuitable for the trial on clinical or social grounds (eg terminal illness with < 1 year to live, recent pregnancy loss or baby/child bereavement).

Data collected in electronic health records is covered under the NHS national opt-out so that patients who do not want their data used for purposes beyond their direct care that is, for research and planning can opt-out. These women will not be selected as being eligible for the RADIANT study.

Once practices have given permission to take part in the trial, each practice (or OHP on behalf of the practice) will run the eligibility algorithm. Once this list has been generated either the GP practice staff within each practice or OHP (if the practice wants OHP to conduct the screening on their behalf) will view the women's details. They will review their medical history to ensure they meet the eligibility criteria.
Randomisation
The study design of the trial is a randomised controlled trial. Stratified by GP practice, women will be randomised 1:1 to the intervention (receive the text message and link to the animation) or the control (usual care as per National Institute of Health and Care Excellence (NICE) guidelines) using the randomise function within Microsoft Excel. This function randomly assigns "0" (control) or "1" (intervention) to the list of women who are eligible for the trial.

Blinding

Blinding of women is not possible as they will receive a text message (intervention) or they will not (control group). Part of the intervention is to make women aware of the recommendation for testing for type 2 diabetes. GPs will know which women has been allocated to the intervention. As the outcome (a record of blood glucose testing) is measured objectively and results from the blood test are returned to the records electronically it is unlikely to be affected by lack of blinding (15).

Text message
The template for the SMS will be entered onto and sent through Accurx or similar software by the practice. Women will be sent a text message informing them they are part of a research study and if they do not want their data contributing to this research, they can opt out of the study. The proposed wording of the opt-out text message is shown in Box 1.

Two weeks after this text message is sent, all women who have not opted out will be randomised (1:1) stratified by practice to the intervention text message with a link to the animation or control group (usual care, no text message). Details of this text message intervention are shown in Box 2. Upon sending the text message through Accurx (or similar) text messaging software, the GP practice (or OHP on behalf of the practice) will record one extra variable within the electronic health record each woman who are randomised (combination of study ID and group allocation) and this variable will be available in the anonymised data extracted from the healthcare records. Women allocated to the intervention group will be sent the text message reminder with a link to the animation.

Box 1. Proposed wording for the text message sent to all eligible women allowing them the opportunity to opt out of the study.

Dear *First Name Last Name*,

The University of Birmingham is conducting a research study on sending a text message reminder (RADIANT trial). If you do not want your data contributing to this research, please call your GP practice on the number below and let them know.

Thanks, *Name of Practice Manager*
GP practice Name
GP practice telephone number

Box 2. Proposed wording for the text message reminder that will be sent to women randomised to the intervention.

Dear *First Name/Title Last Name*,

You are due your annual diabetes health check. Please book an appointment with the nurse.

You can find more information on this test here: *https://www.youtube.com/watch?v=zXV1J3py-vs*

Thanks, *Name of Practice Manager*
GP practice Name

The animation contains information on the following:

- The importance of being tested for type 2 diabetes every year

- The procedures involved in testing for type 2 diabetes
- Motivational drivers for women to be regularly testing

The storyboard and accompanying script (Box 3) for the animation were developed and from this the animation can be found here.

Box 3. Script for the animation reminding women of the importance of having an annual test.

Woman 1 – I had high blood sugar levels when I was pregnant and was told I had gestational diabetes.

Woman 1 – It went away after I had my baby. But having gestational diabetes means I am more likely to get type 2 diabetes and heart disease in the future. If I have a higher risk, I can get support to make changes to my activity and diet to help prevent them.

Woman 1 – Every year I have a blood test at my GPs to measure my blood sugar levels.

Woman 2 – I learnt that there is no need to fast before the test.

Woman 3 – An easy way for me to remember to get tested every year is to make an appointment around the time of my baby's birthday!

Woman 2 – While I'm at the GPs I also get my blood pressure checked.

Woman 1 – Getting checked was important for me and my family because if I am healthy then I can be there for them.

Woman 1 – Contact your GP and book your annual diabetes health check now.

The only data that will be recorded for this trial are a code that will be entered into patient's electronic health records after women have been randomised and the text message intervention has been sent by Accurx (or similar) software. No other data will be collected specifically for this study as only data that is available in routinely collected records will be used. The electronic healthcare records held at GP practices include certain sociodemographic in the anonymised patient records. These include variables such as ethnicity, year of birth, smoking status (never, former and current), measurements such as body mass index (BMI) and previous measures of glycosylated haemoglobin, diagnoses of other health conditions and prescriptions which are all date stamped variables.

Three months after the intervention has been delivered, the GP practices taking part will securely transfer anonymised minimal dataset for the women who were part of the study to the University of Birmingham This data will include the **primary outcome** – a record of a measurement of fasting blood glucose, HbA1c or OGTT within three months post-randomisation and **secondary outcomes** – a record of a measurement of blood pressure, BMI, and blood lipids within three months post-randomisation.

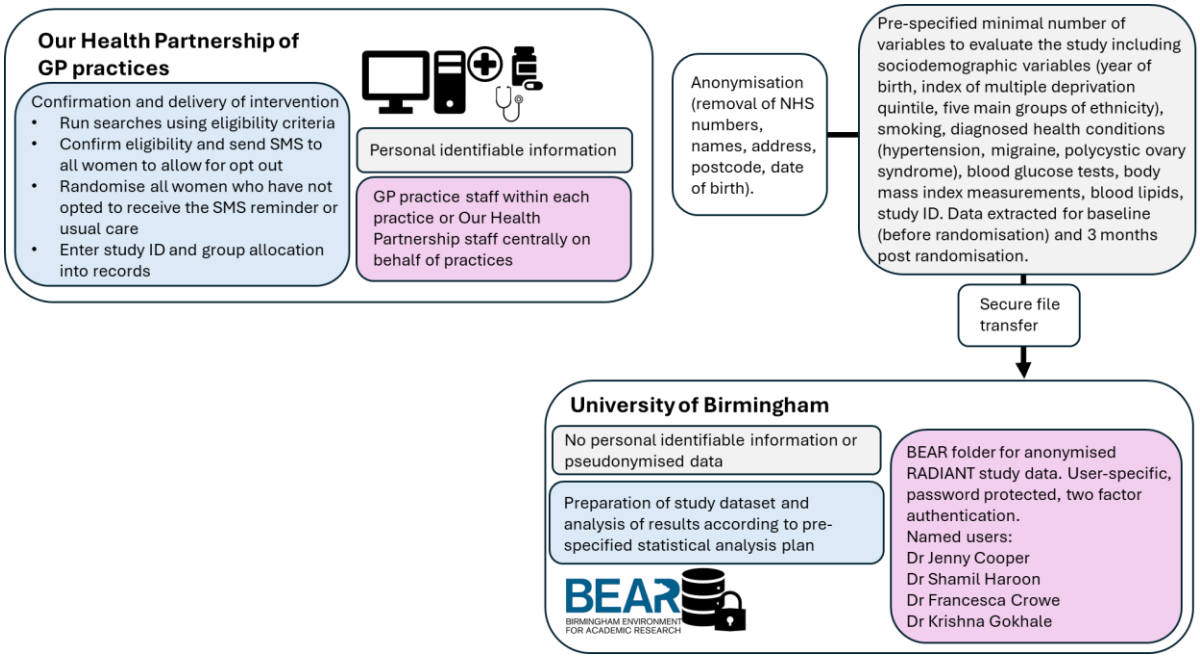

Figure 2. RADIANT randomised controlled trial of text message intervention data flow from practices to University of Birmingham

A full analysis plan will be derived before the study commences. A flow diagram will be produced to describe the patient flow through each stage of the study (16). We will describe the characteristics of the participants between study arms. Categorical data will be summarised by frequencies and percentages. Continuous data will be using mean and standard deviation if deemed to be normally distributed and median and interquartile range if data appear skewed. Tests of statistical significance between the intervention and control arms will not be undertaken.

All analysis will be by intention-to-treat, analysing women according to the randomised allocation irrespective of the allocation received. For the primary outcome, where no record of a test for T2DM is recorded it will be assumed it was not measured, as is appropriate with the nature of this outcome. We will estimate effect sizes (with 95% confidence intervals: CI) using relative risks and risk differences. Primary analysis will adjust for variables used in the randomization (stratified by GP practice). A secondary covariate adjusted analysis will adjust for a set of pre-specified set of important prognostic factors that include age, ethnicity (white, black, Asian, mixed, and other), index of multiple deprivation (quintiles; 1 being the least deprived and 5 being the most deprived), and presence of long-term health conditions hypertension, heart disease, depression and anxiety (yes or no).

All adjusted estimates of relative risks and risk differences will be estimated using generalised linear (mixed) models with a binomial distribution and log or log link as appropriate. In the case of non-convergence of the binomial model with a log-link, a Poisson model with robust standard errors will be fitted. If the binomial model with the identity link does not converge then only a relative risk will be reported. If neither the log or identity link converge, we will use the logistic link and report odds ratios.

We will report interaction tests for investigations of subgroup effects, as well as a small number of pre-specified subgroup specific estimates of treatment effects. These will include age (<30, 30-39, ≥40 years), and ethnicity (white, black, Asian, mixed, and other).

No interim analysis will be conducted on outcomes, but a plan will be derived to monitor quality and accuracy of data throughout.

Before the data is securely transferred from the GP practices, data will be anonymised where any personal identifiable information will be removed. This includes variables such as NHS number, names, address, and date of birth. Data will be stored on the University's secure server – Birmingham Environments for academic research (BEAR) HPC (High Performance Computing) and Cloud infrastructure. BEAR provides a controlled infrastructure for storing, accessing, and analysing sensitive health data and provides secure virtual machines (VMs) to store and process research data. Only the principal investigators and named people involved in the RADIANT trial at the University will have access to the data via password protected and two-factor authentication.

Data will be archived as per the University of Birmingham's data storage policy and retained for up to 10 years on BEAR Archive.

6. Study setting

Randomised controlled trial

This study is a randomised controlled trial of text messaging reminders using routinely collected data for the outcomes and the study participants are not required to attend any visits specifically for this trial. The main study site will be the GP practices where checks for eligibility, randomisation and sending the text message will take place. If women decide to book an appointment for a test for type 2 diabetes then this will most likely take place at the GP practice.

This trial will be a multicentre study involving GP practices that are part of Our Health Partnership within the West Midlands. There are currently 30 GP practices who are part of Our Health Partnership, but we anticipate that there will be around 10 to 20 GP practices taking part in this trial.

Final eligibility checks will be performed by a member of the GP practice (eg practice manager, practice nurse or GP) or by OHP on behalf of practices.

7. Participant recruitment

7.1. Eligibility Criteria

GP practices will screen using their clinical judgement to identify any reason that a woman should not participate, for example if she has been diagnosed with a terminal illness (a prognosis of less than 12 months).

7.1.1. Inclusion criteria

- Diagnosis of gestational diabetes
- 18 to 50 years
- Previously sent text messages from the GP practice

7.1.2. Exclusion criteria

- Diagnosis of type 1 or 2 diabetes

- Test of glycaemia in the past 12 months (fasting blood glucose, HbA1c or oral glucose tolerance test)
- Pregnant in the past 12 months
- GP considers them unsuitable for the trial on clinical or social grounds (e.g. terminal illness, recent pregnancy loss, baby/child bereavement).

7.2. Recruitment target

Randomised control trial

There are approximately 30 practices that are part of OHP that includes around 600 women with previous gestational diabetes. We anticipate that around 10 of these practices will take part in the trial representing ~200 women.

7.2.1. Size of recruitment target

Our target recruitment is 200 women. The estimated prevalence of testing in the control group is informed by our previous research where annual testing for T2D 2-3 years postpartum was 36% (5) and therefore, over 3 months, testing in is ~10%. Previous research where SMS reminders have been sent have shown an increase in testing by five percentage points. Testing for T2DM and cardiometabolic disease risk factors are less invasive than screening for breast and cervical cancer and with the addition of an animation, we estimate that testing in the SMS group might be up to 15 percentage points higher and is realistic and clinically worthwhile. Allowing for 80% power at 5% significance the total sample size requirement is estimated to be 200 women across both the intervention and control groups.

7.2.2. Recruitment technique

After GP practices have given their written permission to take part in the study, the list of eligible women will be made available for individual practices or centrally via OHP for practices giving their permission for OHP to complete this on their behalf. A GP staff member or OHP on behalf of the practice will check the list of eligible women based on the inclusion criteria and confirm eligibility prior to sending out a text message for the option to opt out of the study.

Women who opt out will be removed from the list of eligible women (**Figure 1**). Using this technique will maintain patient confidentiality; only the patients' GPs will have access to patient identifiable information, the University of Birmingham will not hold any patient identifiers.

7.3. Recruitment

7.3.1. Participant identification

Randomised controlled trial

The searches will either be carried out independently by each GP practice or centrally by OHP on behalf of practices. A GP/OHP staff member will run the searches using the inclusion and exclusion

criteria and the list of women will be made available. Only staff employed within the OHP will access the patient records in order to confirm that potential participants are eligible to take part in the trial. They will then check whether they meet the inclusion criteria and the GP practice or OHP will send the a text message via Accurx to all women who meet the inclusion criteria informing them that there is a study of text message reminders that is being undertaken in the practice that will provide information that tells women how they can opt out of taking part (Box 1).

7.3.2. Consent

Randomised controlled study

Each GP practice will be provided with information on the study and their written permission for participation in the trial sought to randomise eligible women registered in the practice. If GP practices would like Our Health Partnership to complete the screening and sending of text messages on their behalf, further permission from the GP practices to share this information centrally will be sought.

For informed consent from individual women, we will seek opt-out consent. Seeking opt-out consent from women is possible because of the following justifications:

1. There is minimal research-related risk to the women.
2. Informing women that the research is to increase uptake of blood glucose testing is likely to affect their behaviour and hence the study's internal validity.
3. There is substantial social and public value from conducting the trial.
4. All data for the study is being collected as part of routine care and we do not require additional data or contact with the women to collect this data.
5. Women who have already opted out from receiving text messages from their GP practice will not be eligible for the trial.
6. Women who have opted out of having their anonymised healthcare records shared with trusted third-parties will not be eligible for the trial.

Furthermore, there are no additional investigations or follow up appointments involved with participating in the study other than those randomised to the intervention may be more likely to receive tests for type 2 diabetes, but these are already recommended as part of routine care.

One of the requirements for opt-out consent is that all women must be notified and informed of the study. This is to ensure the preservation of trust in research. In order to notify women that there is research taking place, each GP practice will first send a text message to all women eligible to be randomised from the practice (**Figure 1**). This will inform women that that there is a health research study on text message reminders and if they do not want their data to be contributed to the study they can opt out. The proposed wording for this message is shown in **Box 1.**

Women can opt out by giving the GP surgery a call and asking them to be removed from the study. We will allow for women to opt out of the study for up to two weeks. This will not affect the internal validity of the results, because randomisation will take part after women have opted-out. It may decrease the sample size but others who have used a similar approach have reported only a small number opting out (less than 5%) (11). At the same time, this will also inform us of the mobile numbers of women that are incorrect or inactive. These women will also be removed from the study before randomisation takes place.

8. Safety reporting

We will follow the guidance on safety reporting outlined on the Health Research Authority (HRA) website (17) and the sponsor's safety reporting procedures. As this is a non-CTIMP randomised trial, only reports of Serious Adverse Events (SAEs) that are:

- related to the study (that is, they resulted from sending the text message or watching the animation) and
- unexpected (ie that is, we have not listed them in this protocol as an expected occurrence)

Will be notified to the REC using the Non-CTIMP safety report to REC form within 15 days of the Chief Investigator becoming aware of them in accordance with the sponsors safety event reporting procedures.

9. Ethical and regulatory considerations

9.1. Assessment and management of risk

Randomised controlled trial

There is minimal risk being posed to participants who will be sent a text message with a link to an animation, reminding them of the importance of annual testing for type 2 diabetes. While we aim to present non-distressing material in the animation, participants may feel worried by hearing that they have a greater risk of developing type 2 diabetes and heart disease. We have mitigated against this in the animation by also stating that they can be offered support to help reduce their risk of developing these conditions.

9.2. Research Ethics Committee (REC) and other Regulatory review & reports

Regulatory Review & Compliance

Amendments

Ethical approval will be sought from NHS REC. The study application will include a copy of this protocol, completed IRAS form and all relevant documents. The REC will be notified of any changes to the study dates or approved documents.

We expect minimum, if any, changes to the methods outlined in this protocol and to the drafted documents. However, in the event of any changes made through discussion with the research team (and if necessary, the trial steering group and PPI group), the CI will be responsible for amending the protocol and deciding whether an amendment is substantial or non-substantial. The key protocol contributor will communicate any agreed changes to the relevant stakeholders. We will keep a log of any protocol changes along with each protocol (the version labelled clearly) within our team's shared network.

Prior to applying for ethical approval from NHS REC, we will seek approval from our sponsor's (University of Birmingham) research governance team. They will be sent a copy of this protocol, completed IRAS form and all relevant documents mentioned above.

Recruitment for the study will not commence until ethical approval has been provided by NHS REC and our sponsor's research governance team.

9.3. Peer review

The study was peer-reviewed and approved for funding by the National Institute of Health Research (NIHR) 202826.

9.4. Patient & Public Involvement

Members of the public and women with previous GDM have been involved in helping to develop this research from its inception. Two lay co-applicants have advised us throughout the development of our research and grant proposal. We altered what was included in our overall project, so it was more relevant to the needs of women with previous GDM. This included the idea of including a link to an animation that will be provided with the text message reminder. Our lay co-applicants are also helping to co-ordinate the public and patient involvement (PPI) activities that will take place during the course of this research. We have recruited a PPI advisory group made up of a further four members all of whom have lived experience gestational diabetes who are involved with this research. They have co-developed the content and the script for the animation.

Our PPI co-applicants helped us shape how PPI will be structured and embedded into the research and they have been involved with the following activities:

- Helping to set up the PPI advisory group
- Input to this ethics application and IRAS form including reviewing sections to ensure that they the application was suitable for a lay audience, that all aspects related to participation in the research were acceptable, and the public and patient work is suitable.
- Involved in regular work package meetings

Our PPI advisory group also advises on the reports and will help disseminate the findings from this research.

9.5. Protocol compliance

The study principal investigators along with the study coordinator will ensure protocol and GCP compliance by adhering to GCP standards and applicable regulations. Any accidental deviation will be documented according to guidelines from REC and sponsor (University of Birmingham).

Any deviation from the protocol or principals of GCP that is likely to affect the safety, rights of study participants and/or data reliability and integrity will be deemed as serious and will be reportable to the REC and study sponsor in accordance with the sponsor's procedures for reporting serious breaches.

9.6. Data protection and patient confidentiality

All data used in this study will be anonymised. No identifiable patient information will be accessed or stored by the research team. The University of Birmingham will not hold any additional information that could be used to identify patients. Data will be obtained from routinely collected healthcare records and processed in accordance with the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018.

All anonymised data will be stored and analysed within the Birmingham Environment for Academic research (BEAR) HPC (High Performance Computing) and Cloud infrastructure. BEAR provides a controlled infrastructure for storing, accessing, and analysing sensitive health data and provides secure virtual machines (VMs) to store and process research data.

Access to the data will be restricted to authorised study team members who have completed the required information governance and data security training. All outputs will be subject to disclosure control to ensure that no individual can be identified.

Permission to use patients anonymised data for research purposes is provided via the NHS opt-out. NHS national opt-out so that patients who do not want their data used for purposes beyond their direct care that is, for research and planning can opt-out. Their data will not be available in the electronic healthcare database and they will not be selected as being eligible for the RADIANT study. The study will comply with all relevant ethical and legal requirements, including approvals from the appropriate research ethics committee and data governance bodies.

9.7. Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage. This includes for harm to participants arising from the management, design or conduct of the research. No provision has been made for indemnity in the event of a claim for “non-negligent” harm.

This study requires no equipment and therefore no arrangements will be made for insurance and/or indemnity to meet the legal liability arising in relation to equipment.

The NHS has a duty of care to its patients, in the event of clinical negligence being proven, compensation will be available via the NHS indemnity.

9.8. End of study and archiving

Data will be stored for 10 years after the end of the study at the University of Birmingham and then securely destroyed. The University of Birmingham is the data controller/data custodian for the study.

9.9. Access to the final study dataset

Only the Co-PIs, the study analyst and the software engineer/health data scientist will have access to the anonymised data containing the study results within BEAR.

The University of Birmingham will not make the study dataset available publicly. However, for those people who take part in the trial, someone from the participating GP practice will document in the electronic health record whether they are taking part in the trial were sent the text message intervention. This data will be available in the anonymised health records in a similar way that other codes are available after the appropriate research governance and/or ethics are in place to access them. Definitions will be provided in a SNOMED CT code dictionary.

10. Dissemination policy

10.1. Dissemination policy

The University of Birmingham will own the data arising from the study. The data will be kept securely on the University's servers for 10 years and then securely destroyed, as per the University's policy. Within one month following completion of the study, a final study report will be delivered to the funder (NIHR). The final study report will be peer-reviewed and circulated to relevant stakeholders within the Department of Health and Social Care and its partners. A summary of the final report will be made publicly available by the NIHR.

The funder will not have a role in the analysis, interpretation of results or writing of the manuscripts for this study, nor will they be involved in the decision to submit for publication. However, all publications must acknowledge the funder and provide the unique award identifier. The funder expects the findings to be published in peer-reviewed open-access journals of which we will adhere to.

10.2. Authorship eligibility guidelines and any intended use of professional writers

We will follow the International Committee of Medical Journal Editors in determining authorship for any publication or materials presented at conferences. This will include members of the research team that contributed to the conception or design of the study or acquisition, analysis or interpretation of the data and drafted or revised the written content and approved the final version for publication and agreed to be accountable for all aspects of the work. Specific parts of the work that each author was responsible for will also be detailed in any peer-reviewed publication.

The final study reports will include all named collaborators within our funding application along with additional members of the team that worked on the report and substantially contributed to the conception or design of the study or acquisition, analysis or interpretation of the data.

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12. Appendices

12.1. Appendix 1- Required documentation

12.2. Appendix 2 – Schedule of Procedures

Schedule of Procedures: Non-clinical interventions and clinical procedures that will be received by participants as part of the research protocol.

Intervention/procedure	1	2	3	4
Receiving text message	1	0	1 min	GP practice will send a text message to the intervention and control group
Testing type 2 diabetes & CVD risk factors	1	1	10 min	Practice nurse will take blood sample and measure and record blood pressure and weight at the GP practice.

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.

2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?

3. Average time taken per intervention/procedure (minutes, hours or days)

4. Details of who will conduct the intervention/procedure, and where it will take place.

12.3. Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2	26 July 2024	Francesca Crowe	1) correction to the name of the organisation of two of the people in the data monitoring committee. 2) changes to the number of Read codes (codes used in GP practices that use a specific software called Vision software) that will be added to the women's electronic health records to include more than one; 3) changes to the data flow diagram (Figure 4) where GP practices do not de-anonymise women as they are legally allowed to hold personal information about their patients; 4) a change in the text to reflect the change in the data flow diagram that patients will not be de-anonymised by the GP practices.
2	3		Francesca Crowe	**Recruitment and Setting** Original: Network of general practices using Vision software (including Scotland and Wales).

				Revised: Smaller number of practices within Our Health Partnership in Birmingham (approximately 10-20 practices). Reason: Vision software is being phased out in key regions, reducing eligible practices and compromising recruitment and generalisability. No semi-quantitative interviews with GP staff or patients. **Impact on Participants** No additional burden or negative impact. Intervention remains unchanged and low risk. No direct contact with participants; opt-out consent to share data will be used. Data will continue to be drawn from routinely collected administrative health records, anonymised before transfer to the University of Birmingham.