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Randomised controlled trial to test whether text message reminders sent to women with previous gestational diabetes helps improve testing for type 2 diabetes

Submission date
07/09/2022

Recruitment status
Not yet recruiting

Registration date
10/10/2022

Overall study status
Ongoing

Last Edited
31/03/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
We normally test new interventions to improve health using randomised controlled trials (RCTs). These divide people into two groups, one gets the intervention and the other does not. We compare the health effects between the two groups to see if the intervention worked. Finding and including patients is usually 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 for everyone.

Data-driven trials are RCTs within electronic medical records. This simplifies methods by automatically finding and inviting suitable patients, checking they have given their consent to take part, then randomly dividing them into two groups and giving one group the intervention. We can also reduce the burden of taking part for both patients and health workers by using data recorded in usual clinical practice to find out whether the intervention works.

We want to show we can answer clinical questions that benefit patients by running a data-driven RCT. We have found a current health problem: a lack of testing for diabetes in women who developed diabetes during pregnancy. Each year, 30,000 UK women develop diabetes during pregnancy (we call this gestational diabetes mellitus or GDM for short). It is common in ethnic minority women. Often GDM goes away after giving birth but women who had GDM are more likely to develop diabetes in the next few years. Therefore, women are advised to have yearly diabetes tests to find out and manage diabetes early before problems occur. But many women are not tested yearly so we need ways to help more get tested.

Who can participate?
Women with a previous diagnosis of gestational diabetes who have not had a test for type 2 diabetes in the past 12 months and have previously been sent a test message from their GP practice will be entered into the study. Women with a previous diagnosis of type 1 or 2 diabetes, or pregnant in the past 12 months will be excluded.

What does the study involve?
Women who are assigned to the intervention group will be sent a text message reminding them to be tested for type 2 diabetes. There will also be a link to an animation that details what the test will involve and the purpose of the test.

What are the possible benefits and risks of participating?
The wording of the text message and the animation will be produced following consultation with lay people, health professionals and researchers to make sure the information it contains is accurate, and the tone is non-coercive. We do not anticipate any risks that may harm women who take part in the trial.

Where is the study run from?
The study is run from the Institute of Applied Health Research at the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
September 2022 to December 2026.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Francesca Crowe
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
297067

Protocol serial number
IRAS 297067

Study information

Scientific Title
impRoving testing for cardiometabolic diseases in women with previous gestational diabetes mellitus: an exemplar study on implementation and evaluation of a novel dAta-DrIven rANdomised clinical Trial platform in primary care (RADIANT)

Acronym
RADIANT

Study objectives
We aim to conduct a data-driven randomised controlled trial (RCT) to demonstrate the capacity of NHS data to answer an important clinical question that benefits patients. We will test this by developing an SMS and animation intervention for women with previous GDM to assess whether it increases testing for T2DM and cardiometabolic disease risk factors in primary care compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/05/2024, South Central - Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048 088; hampshireb.rec@hra.nhs.uk), ref: 24/SC/0069

Study design
Multicentre randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Testing for type 2 diabetes in women with previous gestational diabetes

Interventions
Randomisation will be done using the randomise function within Outcomes Manager (computer software that is used in GP practices). Randomisation will be stratified by practice. The GP will not be aware of the upcoming allocation and this randomisation process can only occur once for each participating practice.

Intervention: women will be sent a text message and link to an animation explaining what the procedure is for testing for type 2 diabetes
Control: women will receive the usual care as per the National Institute of Health and Care Excellence (NICE) guidelines

The text message will only be sent to each of the women in the intervention group on one occasion (at randomisation). The researchers will follow women up for 3 months post-randomisation to assess whether they have a test for type 2 diabetes.

Intervention Type
Behavioural

Primary outcome(s)
Blood test for type 2 diabetes (glycosylated haemoglobin (HbA1c), fasting blood glucose or a 2-hour oral glucose tolerance test) in their primary care records 3 months after randomisation

Key secondary outcome(s))
Measurement of blood pressure, body mass index or blood lipids (total, LDL and HDL cholesterol) in primary care records 3 months after randomisation

Completion date
01/12/2026

Eligibility

Key inclusion criteria
Women with a previous diagnosis of gestational diabetes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Previous diagnosis of type 1 or 2 diabetes
2. A test of glycaemia in the past 12 months (fasting blood glucose, glycosylated haemoglobin (HbA1c) or oral glucose tolerance test),
3. Pregnant in the past 12 months.
4. GP considers them unsuitable for the RCT on clinical or social grounds

Date of first enrolment
01/05/2026

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University of Birmingham
Prichatts Road
Edgbaston
Birmingham
England
B15 2TT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data collected for this trial will come from routinely collected health care data that is available in THe Health Improvement Network (THIN) database. Anonymised data will be available upon application to the Scientific Review Committee of THIN.

IPD sharing plan summary
Available on request