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Reduced-carbohydrate intervention to prevent gestational diabetes

Submission date
12/02/2021

Recruitment status
No longer recruiting

Registration date
01/03/2021

Overall study status
Completed

Last Edited
21/05/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
This study aims to test if it is possible to deliver a dietary programme designed to reduce the risk that women who are pregnant will develop gestational diabetes (GDM). GDM is a condition that develops usually during the second or third trimester of pregnancy, in which women's blood glucose levels are high. It can lead to health complications for the mother and the baby during pregnancy and later in life. Carrying or gaining too much weight during pregnancy, increases the chances of developing GDM. Effective ways to help women who are at increased risk of GDM to control their weight and blood glucose levels early in pregnancy are needed. GDM is usually diagnosed in the third trimester of pregnancy. By that time, many women have already gained too much weight and their babies have been exposed to high blood glucose levels. Effective ways to help limit weight gain and control blood glucose levels in women at risk of GDM, and that can be used early in pregnancy, are needed. What we eat affects our weight and blood glucose levels. Carbohydrates are the main source of energy (calories) and eating carbohydrates leads to rise in blood glucose. The researchers have therefore developed a new dietary programme to help women starting pregnancy with too much weight, to moderately reduce, but not cut out, the amount of carbohydrate that they eat, while maintaining a balanced diet. This small study will test if it is possible to deliver the new programme alongside routine appointments and how well women can follow this advice until delivery (approximately 6 months). The researchers will monitor the impact of the programme on some markers in the blood, and explore its effect on weight gain and other health outcomes throughout pregnancy. If the programme is feasible and well-liked, they will run a bigger study aiming to help prevent GDM.

Who can participate?
Women with a Body Mass Index score of 30 or more, a risk factor for GDM, who are less than 20 weeks pregnant.

What does the study involve?
Women who are interested in taking part will be asked to attend two research study visits (individual sessions) at the hospital with the study team. One visit will happen before they are 20 weeks pregnant, and the other visit will happen around 24-28 weeks of pregnancy. This second visit replaces a visit that they would be required to attend even if they were not taking part in

the study. Each visit will be scheduled in the morning and will last for about 2 hours.
Women will be asked to arrive at these appointments after an overnight fast. This means they should not eat or drink anything (apart from water) from the night before the visit. They should also avoid smoking, vaping, using nicotine replacement therapy and chewing sugar gum since the previous night.
At the first study visit (before 20 weeks of pregnancy), the researcher will go through the participant information sheet and women will have the opportunity to ask any questions about the study. Women that are happy to take part, will be asked to sign a consent form and will be given a copy to keep. With their consent, the researchers will complete the following procedures:
To test how well the body handles the ingestion of sugar the researchers will collect a small blood sample and then ask the participant to drink a special sugar drink. They will collect further small blood samples after 1 and 2 hours.
Whist participants are waiting, the researchers will measure their height, weight and blood pressure, and ask them to fill in questionnaires about themselves, including their usual diet and quality of life.
Participants will also be allocated to one of the study groups. Two-thirds of participants will be assigned to the RECORD diet group, who will be guided to moderately reduce their carbohydrate intake, whilst the other participants will be assigned to the control group, who will continue to receive the usual care and support given to women who are pregnant. Having a control group helps us test if the intervention is more beneficial compared to the usual dietary advice. Group allocation is entirely down to chance and will be decided by a computer programme. Participants cannot choose which group they are in and they won't be able to change group allocation once they have been allocated.
Women assigned to the RECORD diet group will be asked to follow the dietary advice and recommendations to the best of their ability until the delivery of their baby. During the first study visit, they will be advised to moderately reduce, but not cut out, the amount of carbohydrate in their diet. They will receive a booklet, meal and recipe ideas and other materials to help them follow the dietary advice. The researchers will arrange another six brief sessions to support them through the diet plan, at a convenient time, when they are around 16, 18, 20, 24-28, 32 and 36 weeks pregnant. These sessions will be by telephone, except the one at 24-28 weeks, which is on the same day as their second study visit and can be either on the telephone or face-to-face. All support sessions will take a maximum of 15 minutes. The researchers will ask their permission to audio-record the face-to-face and telephone sessions. Participants in this group will also be asked to monitor their weight once a week and send the measurements to the study team. The researchers can lend weighing scales to those women who don't own a set.
Women assigned to the control group will continue to receive any dietary advice that is given as part of the routine pregnancy care.
Everyone taking part will be asked to measure their blood glucose and ketone levels at home twice a week for the duration of the study, using a monitor the researchers will provide. They can log their measurements into a mobile phone/tablet/iPad application or text them to the study team. The study team and members of the clinical care team will have access to these readings. Taking part in this study will not affect any other treatment participants may be receiving.
During the follow-up appointment at 24-28 weeks of pregnancy, the researchers will repeat the procedures conducted at the first study visit. The OGTT conducted at this visit will determine whether participants have developed GDM. Women would usually have this same test at this time at the hospital or their GP practice, even if they were not taking part in the study. To avoid having the same test twice, the test will replace the test they would usually have and the researchers will share the results with their clinical care team.
If the results of this second OGTT indicate that a woman has developed GDM, they will have the same access to medical care and any necessary medications, regardless of their study group allocation. Everyone will be offered routine care dietary advice for GDM, which is similar to that

the researchers are testing in this study. Therefore, if diagnosed women are in the intervention group, they can continue following the RECORD moderately reduced-carbohydrate programme, and weigh themselves weekly until delivery.
After the follow-up visit, participants in the RECORD diet group may be asked if they would be willing to have an in-depth discussion on the phone with a member of the study team about their experiences of the intervention. This is entirely optional. The researchers will provide them with more details during their follow-up visit.
With participants' consent, the researchers will access their medical records after the delivery of their baby. This will enable us to compare health outcomes of the mothers and newborns between the two study groups.

What are the possible benefits and risks of participating?
Women randomised to the RECORD diet group will receive detailed advice, support and guidance on their diet early in pregnancy. In addition, the knowledge gained in this study may help to plan a bigger study which may help in the future other women who are pregnant, to control their weight gain and blood glucose levels with diet alone, and to possibly reduce their risk of developing GDM.
Severely restricting carbohydrate intake may lead to increased ketone levels, compounds that are produced when glucose – which mainly comes from carbohydrate foods – is not available to the body. It is not expected that the RECORD programme will lead to increased ketones because it has been designed to provide adequate amount of carbohydrate which is the same as advised in routine care if women are diagnosed with GDM. The only difference is that the researchers ask participants to follow this advice earlier in pregnancy and in a more structured way. In addition, no evidence is available to determine any effect of the diet on the unborn child. The researchers will provide all with a device to monitor both their blood glucose and ketone levels as an extra check. They will also ask participants to measure their blood glucose and ketones if they are unwell and contact their clinical care team for advice if required.
All participants will be asked to fast overnight before each study visit. Some people can feel lightheaded or unwell if they don't eat for long periods of time. Once the researchers have finished the tests, they will provide participants with a light breakfast before they leave the hospital. Participants will be asked to provide small blood samples and as with any blood sample, there is a possibility of stinging and a risk that they develop some bruising around the area, which should go away in a few days. Some people may feel faint while the sample is taken, but all blood samples will be taken by health care professionals who are trained and experienced in these procedures. Finally, all measures against COVID-19 will be taken during the study visits as per Government guidance.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
March 2020 to December 2022

Who is funding the study?
1. Medical Research Council (UK)
2. National Institute for Health Research Oxford Biomedical Research Centre (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
279623

Central Portfolio Management System (CPMS)
47778

Study information

Scientific Title
REduced-Carbohydrate intervention for managing Obesity and Reduction of gestational Diabetes (RECORD): a feasibility study

Acronym
RECORD

Study objectives
The hypothesis is that compared to usual care, an intervention involving dietary and behavioural consultation, simple rules, and structured written dietary information, will support women to adhere to a moderately reduced-carbohydrate dietary programme, during the second and third trimester of pregnancy, that will help them to limit the amount of weight they gain and improve their blood glucose control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2021, South Central – Oxford B (Whitefriars, Level 3, Block B, Bristol Research Ethics Committee Centre, BS1 2NT, UK; +44 (0)207 104 8235; +44 (0)207 104 8270; oxfordb.rec@hra.nhs.uk), REC ref: 20/SC/0442

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Screening, Prevention, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Active Monitoring

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
Recruitment and consent

Previous:
Research midwives will screen the medical records of women who are pregnant and due for their first scan appointment at the hospital, to identify women who fulfil the obesity inclusion criteria (BMI ≥30 kg/m²). A research midwife will approach women who fulfil this criterion while they are waiting for their first scan appointment in the waiting area of the hospital, will inform them that they are eligible for our study, and will provide them with a flyer summarising the aims and content of the study. Women who are interested to hear more about the study will have the opportunity to talk to a research midwife or the main researcher after their scan appointment, given that their pregnancy is determined viable. After discussing the study and asking questions, women interested to take part will be booked for a first study visit and will

take home all the recruitment material to think and decide if they would like to take part. During the first study visit, full eligibility will be confirmed and informed consent will be sought.

Current as of 16/03/2021:
Research midwives will provide a flyer summarising the study to all women attending their first scan appointment at the hospital. After reading the flyer, women who are interested in the study will have the option if they wish to speak either before or after their appointment about it, to a research midwife or a member of the research team, who will be available and present in the ultrasound waiting area. The research midwife or member of the research team will explain the study purpose and procedures to those women who express interest in the study and will provide the participant information sheet and study flowchart. All women will be given as much time as they wish to decide if they would like to take part. A broad eligibility check will be performed in women who are interested in the study, by asking them to self-report. Interested women who seem eligible at this initial stage will be booked in for a first study visit where full eligibility will be confirmed and informed consent will be sought. Approach, screening, discussion about the study and provision of recruitment materials will not be performed if the pregnancy is determined non-viable, or there are serious problems identified during the scan.

Intervention development
The reduced-carbohydrate behavioural dietary programme was developed using a person-based approach. This involved reviewing the literature and scoping systematic reviews, reviewing study protocols and qualitative data of similar interventions, and consulting a diabetes-specialist dietitian, two obstetricians, a research midwife and a patient representative. A Patient and Public Involvement activity with women affected by GDM currently or in the past, helped to shape the ideas for this research, and to determine the questions the researchers are trying to answer and the type of dietary information to provide.

Study design
The researchers will conduct a feasibility randomised two-arm parallel-group trial to test if it is possible to deliver this new dietary programme as part of routine antenatal appointments to help attenuate gestational weight gain and improve blood glucose control in women with obesity who are pregnant and at increased risk of developing GDM.

Randomisation and blinding
Two-thirds of participants will be allocated to the intervention diet group, who will receive advice on how to follow a moderately-reduced carbohydrate diet until the delivery of their baby. One-third of the participants will be allocated to the control group who will continue receiving any dietary advice provided to women during pregnancy in routine practice. Due to the nature of the study, it will not be possible to blind the participants, the research team, the person delivering the intervention, the research midwife and the clinical care team.

Study visits
Each participant will be enrolled in the study for approximately 6 months (from baseline until giving birth which varies from person to person). All participants will attend a total of two study visits, one at the beginning of the study, before 20 weeks of pregnancy (baseline), and one when they are 24-28 weeks pregnant (follow-up). The same assessments will be completed during both visits. These include: an Oral Glucose Tolerance Test, height, weight, blood pressure measurements, and questionnaires about diet and quality of life.

The initial intervention session will be delivered during the baseline study visit. Following that visit, participants in the intervention group will be invited to complete six further brief sessions on the phone, one of which can be also face-to-face if preferred as it coincides with the second

study visit. These support sessions will be arranged at around 16, 18, 20, 24-28 (can also be face-to-face if preferred), 32 and 36 weeks of pregnancy, which means around 2, 4, 8, 16 (can also be face-to-face if preferred), 20 and 24 weeks after the baseline study visit respectively, for review of their progress, reinforcement of the intervention, provision of support and troubleshooting.

Intervention content:
The core principles of the dietary intervention are based on the '3 Rs' and include:
1. Advice to Refrain from free sugars, i.e. avoid sweets, cakes, juices, sugary drinks, juices, honey and syrups, but maintain the intake of whole fruit and dairy.
2. Advice to Reduce the amount of starchy carbohydrates. E.g. eat smaller portions of pasta, rice, bread, potatoes.
3. Advice to Replace i.e. swap the refined starchy carbohydrates for wholegrain unrefined varieties (e.g. replace white pasta/bread/rice with wholegrain pasta/bread/rice), and sugary foods and drinks with lower-carb and low/no-sugar varieties.

Apart from consultation, women in the intervention group will be provided with structured written dietary information and resources to help with self-monitoring and behaviour change. As part of the intervention, participants in this group will be asked to monitor their weight once a week at home and send the measurements to the study team.

Blood glucose and ketone monitoring
All participants will be provided with a meter to measure their blood glucose and ketone levels at home twice a week. The readings will be transferred either automatically via Bluetooth or entered manually into an application connected to the meter or simply sent via SMS from the participants to the research team. The research team will be able to log on to the app and monitor the readings or just view the readings via the SMS sent from the participants. This will help us track the progress and distribution of glucose and ketone levels throughout pregnancy and compare the two groups. It will also provide the opportunity for an extra check for the participants because if the research team spots any abnormalities in the readings, they can escalate this to obstetricians from the hospital who are also members of the research team and will advise the participants if necessary.

Participants will also be asked that if they feel unwell and this persists even after following steps to feel better such as resting and being well-hydrated, or if they are concerned about any symptoms, they should measure their blood glucose and ketones before contacting their clinical care team for advice, as well as still log or send the readings to the research team.

If participants develop GDM, their clinical care team may ask them to monitor their blood glucose more often during the day and on more days of the week.

GDM diagnosis:
If abnormal glucose levels are detected during the baseline study visit, it will be assumed that women either have undiagnosed diabetes or GDM. They will be discontinued as ineligible but their clinical care team will be informed so that they can receive treatment.

If a GDM diagnosis is confirmed at 24-28 weeks' gestation (follow-up visit), women in the usual care group will be offered routine care dietary advice. Women in the intervention group, will be advised to continue following the moderately reduced-carbohydrate programme and weigh themselves weekly until delivery. The routine dietary advice after GDM diagnosis is similar to that in our intervention, so they will still have the option to receive the routine advice if they

wish. All women, regardless of the group that they belong, will be advised to continue monitoring their blood glucose and ketones, and will receive medical management according to the best available practice.

Qualitative interviews:
Participants in the intervention group will be invited after their follow-up visit to complete an in-depth discussion with a member of the study team or the person who delivered the intervention, on the phone about their experiences. This feedback will inform any future full-scale trial. The data will be transcribed and analysed using thematic analysis.

Updated 31/05/2022: the baseline visit was changed from “before 15 weeks of pregnancy” to “before 20 weeks of pregnancy”.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility progression criteria:
1. Adoption of the intervention: mean reduction in total carbohydrate intake per day in the intervention group, assessed by dietary composition analysis at the baseline visit (<20 weeks’ gestation) and at the follow-up visit (24-28 weeks’ gestation)
2. Retention rate: proportion of participants from whom OGTT data is available at the follow-up visit, documented during the follow-up visit at 24-28 weeks’ gestation

Updated 31/05/2022: the baseline visit was changed from “<15 weeks’ gestation” to “<20 weeks’ gestation”.

Key secondary outcome(s)
Secondary outcome measures:
1. Change in fasting plasma glucose and 1h and 2h post glucose drink blood glucose, assessed with analysis of blood samples collected as part of an Oral Glucose Tolerance Test (OGTT) at the baseline visit (<20 weeks’ gestation), and at the follow-up visit at 24-28 week’s gestation
2. Change in HbA1c (glycated haemoglobin), assessed with analysis of blood samples collected as part of an OGTT at the baseline visit (<20 weeks’ gestation), and at the follow-up visit at 24-28 weeks gestation
3. Change in fasting plasma insulin, assessed with analysis of blood samples collected as part of an OGTT at the baseline visit (<20 weeks’ gestation), and at the follow-up visit at 24-28 weeks gestation
4. Change in insulin resistance, assessed with Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) based on fasting plasma insulin levels analysed from blood samples collected as part of an OGTT at the baseline visit (<20 weeks’ gestation), and at the follow-up visit at 24-28 week’s gestation
5. Proportion of participants who are diagnosed with GDM following an OGTT, documented at the baseline visit (<20 weeks’ gestation) and at the follow-up visit at 24-28 weeks’ gestation
6. Gestational weight gain (GWG), assessed as the change between weight at the baseline visit (<20 weeks’ gestation) and at around 36 weeks’ gestation - updated 28/06/2022: at the baseline visit (<20 weeks’ gestation) and before delivery, or 36 weeks’ gestation if pre-delivery weight is not available
7. Proportion of participants meeting the Institute of Medicine’s recommendations for GWG, assessed as the change between weight at the baseline visit (<20 weeks’ gestation) and at around 36 weeks’ gestation

8. Total carbohydrate intake (g/day), assessed by dietary composition analysis at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)
9. Total energy intake (MJ/day), assessed by dietary composition analysis at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)
10. Percentage of daily total energy intake from carbohydrates, assessed by dietary composition analysis at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)

Updated 28/06/2022: moved from process outcomes:
11. Range, median, mean, standard deviation (SD), interquartile range (IQR) of the distribution of capillary blood glucose levels across gestational age, in each group, and comparison between the groups, through self-monitoring from participants twice a week from baseline (<20 weeks' gestation) until before delivery
12. Range, median, mean, standard deviation (SD), interquartile range (IQR) of the distribution of capillary blood ketone levels across gestational age, in each group, and comparison between the groups, through self-monitoring from participants twice a week from baseline (<20 weeks' gestation) until before delivery

Process outcomes:
1. Number of approached eligible women who enrol into the study per month, documented on every recruitment day from the start of recruitment until the end of recruitment
2. Percentage of intervention participants who attend/complete the initial intervention session and subsequent support intervention sessions, documented at the baseline visit (week 0 of the study), week 2, week 4, week 8, week 16, week 20 and week 24 from baseline
3. Percentage of participants in each group who attend the follow-up visit, documented during the follow-up visit at 24-28 weeks' gestation (week 16 from baseline)
4. Percentage of participants for whom weight is available towards the end of pregnancy, assessed by availability of weight measurements at around 36 weeks gestation
5. Proportion of participants who record their blood glucose and blood ketones every week, documented every week from baseline visit (<20 weeks' gestation) until before delivery
6. Proportion of participants in the intervention group who self-monitor their weight every week, documented every week from baseline visit (<20 weeks' gestation) until before delivery
7. Proportion of participants in the control group who, after randomisation, follow a reduced-carbohydrate diet (contamination of the control group), assessed via dietary composition analysis at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)
8. Proportion of essential elements included in intervention delivery sessions (initial and support sessions), assessed through evaluation of audio-recorded consultations against a checklist of essential elements (baseline visit, and weeks 2, 4, 8, 16, 20 and 24 from baseline)

Exploratory outcomes:
1. Percentage of daily total energy intake from total fat, saturated fat and protein, assessed by dietary composition analysis at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)
2. Fibre intake (g/day), assessed by dietary composition analysis at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)
3. Change in systolic and diastolic blood pressure, assessed through blood pressure measurements at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)
4. Maternal and neonatal clinical outcomes extracted from electronic medical records after delivery: Requirement for insulin or oral diabetic medication during pregnancy; Incidence of gestational hypertension; Incidence of pre-eclampsia; Mode of delivery (spontaneous vaginal,

emergency caesarean section, planned caesarean section, assisted vaginal birth); Rates of induction of labour; Gestational age at delivery; Birthweight; Sex of baby; Rates of macrosomia (> 4500 g) (INTERGROWTH standards); Rates of large-for-gestational-age (LGA) infant (>90th percentile) (INTERGROWTH standards); rates of small-for-gestational-age (SGA) infant (<10th percentile) (INTERGROWTH standards); Neonatal Intensive Care Unit (NICU) admission; Shoulder dystocia/birth trauma; Neonatal hypoglycaemia requiring intravenous glucose; Neonatal hyper-bilirubinaemia requiring phototherapy
5. EQ-5D (EuroQol) questionnaire score, assessed through EuroQol questionnaire completion at the baseline visit (<20 weeks' gestation) and at the follow-up visit (24-28 weeks' gestation)
6. Acceptability and overall experience of the intervention, assessed through qualitative interviews with participants from the intervention group, any time after the follow-up visit at 24-28 weeks' gestation and delivery

Updated 31/05/2022: the baseline visit was changed from "<15 weeks' gestation" to "<20 weeks' gestation".

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/10/2021:
1. Pregnant women at <20 weeks' gestation
2. 18 years of age and above
3. BMI ≥30 kg/m² at baseline assessment
4. Planned antenatal care at the study setting until delivery
5. Women who are able to provide written informed consent

Previous inclusion criteria:
1. Pregnant women at <15 weeks' gestation
2. 18 years of age and above
3. BMI ≥30 kg/m² at baseline assessment
4. Planned antenatal care at the study setting until delivery
5. Women who are able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
51

Key exclusion criteria
1. Severe congenital anomaly (confirmed by ultrasound)
2. Planned termination of pregnancy
3. Pre-pregnancy diagnosis of diabetes (type 1 or type 2), renal disease, severe liver disease, organ transplant, cardiac failure (Grade II New York Heart Association, and more severe), severe neurological disorder (including epilepsy), severe psychiatric disease requiring in-patient admission
4. A fasting plasma glucose level of 5.6 mmol/l or above or a 2-hour plasma glucose level of 7.8 mmol/l or above, at the baseline OGTT
5. Taking metformin, as it affects glycaemia
6. History or suspicion of, eating disorder
7. Hyperemesis gravidarum
8. Women unable to understand spoken and written English
9. Previous bariatric surgery
10. Women participating in other intervention research studies that may affect their weight, health behaviours or blood glucose control
11. Any other significant disease or disorder which, in the opinion of the Chief Investigator or clinical co-investigators, may either put the participants at risk because of participation in the trial, or may influence the result of the study, or the participant's ability to participate in the study

Date of first enrolment
01/04/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council; Grant Codes: 19/20_MSD_1297604

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR Oxford Biomedical Research Centre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets and/or statistical code generated during and/or analysed during the current study are available upon reasonable request. Requests should be directed to PrimDISC (Primary Care Hosted Research Datasets Independent Scientific Committee) via primdisc@phc.ox.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/01/2024	22/01/2024	Yes	No
Protocol article		01/09/2022	29/12/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.1	05/01/2021	01/03/2021	No	Yes
Participant information sheet	version V1.1	05/01/2021	01/03/2021	No	Yes
Participant information sheet	version V1.1	05/01/2021	01/03/2021	No	Yes
Participant information sheet	version 1.2	12/07/2021	12/01/2022	No	Yes
Participant information sheet	version 1.2	12/07/2021	12/01/2022	No	Yes