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Pre-pregnancy care for women with type 2 diabetes

Submission date	Recruitment status	[X] Prospectively registered
21/01/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2024	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will assess new ways to improve access to pre-pregnancy care for women living with Type 2 diabetes and reduce pregnancy complications and costs. Women with Type 2 diabetes account for 50% of pregnancies in those with established diabetes. Diabetes pregnancies are risky for both mother and baby, especially if unplanned. If the mother has high sugar levels or is taking medications that are unsafe in pregnancy, the baby may be harmed. The risk of a miscarriage is four times higher, and the risks of birth defects and stillbirths are doubled compared to those without diabetes. Half of these pregnancies have caesarean deliveries; a quarter of the women have large babies, and many babies require special care. Such outcomes are distressing for mothers and result in higher care costs. Most women with Type 2 diabetes do not know these risks. Only 10% of women with Type 2 diabetes receive pre-pregnancy care, which reduces risks by improving blood sugar levels, stopping harmful medications and giving high-dose folic acid. Therefore, improving access to pre-pregnancy care for women with Type 2 diabetes is a high priority. The researchers reviewed previous studies on pre-pregnancy care uptake and talked to women and health professionals. A key barrier is the location of pre-pregnancy care in hospitals, rather than in primary care where most women with Type 2 diabetes are seen. Pre-pregnancy care access should improve if it is delivered in a primary care setting.

Who can participate?
Women aged 18-45 years living with Type 2 diabetes and attending one of the participating GP practices in Lambeth and Southwark

What does the study involve?
The researchers have developed a package of primary care-based interventions to ensure that women receive regular reproductive support. The interventions include:
1. A clear set of instructions about what care women should receive
2. Training for health professionals who usually care for women with Type 2 diabetes including clear guidance on what to do and when
3. Information for women
4. Recording information about the health of the women and baby at birth (in those who become pregnant) to see if the help made a difference
The researchers will assess the impact of the intervention by doing an audit of pre-pregnancy

care uptake and pregnancy outcomes at regular intervals in 30 general practices in areas with high deprivation and with mixed ethnic groups. Using multiple types of data collection, the researchers will audit the uptake of pre-pregnancy care and ask women and health professionals about their experiences in the study. As the study progresses, they will identify how to improve the interventions and how best to implement the interventions in the NHS. They will hold an event with women, health professionals and managers to share what we have learnt and identify if there are any further changes needed, and to plan how the package of care could be used by others who care for women.

What are the possible benefits and risks of participating?
At the end of the study, the researchers will share their findings widely (including with patients). If successful they will make the interventions and an implementation plan available to the NHS, so as to improve pregnancy outcomes for this growing population. The benefits for participating GP practices will be exposure to supportive strategies and tools to embed reproductive healthcare into the routine care for women living with Type 2 diabetes. Women living with Type 2 diabetes who participate will have the opportunity to share their experiences and make recommendations on future iterations of the study interventions.

Where is the study run from?
King’s College London (UK)

When is the study starting and how long is it expected to run for?
October 2021 to December 2024

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
1. Prof Angus Forbes, angus.forbes@kcl.ac.uk
2. Dr Rita Forde, rita.forde@kcl.ac.uk

Study website
https://www.kcl.ac.uk/research/prepared-study

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297153

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51180, IRAS 297153

Study information

Scientific Title
An integrated primary care-based programme of pre-pregnancy care to improve pregnancy outcomes in women with type 2 diabetes: a multi-method study of implementation, system adaptation and performance.

Acronym
PREPARED

Study objectives
1. What are the optimal interventional strategies for increasing the uptake of pre-pregnancy care and reducing unplanned pregnancies in women with type 2 diabetes mellitus?
2. What behavioural (woman with type 2 diabetes/health professional), and system-level factors mediate the implementation of interventions to enhance the uptake of pre-pregnancy care in women with type 2 diabetes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/12/2021, Camden and King's Cross London Research Ethics Committee (address: not available; +44 (0)207 104 8086, +44 (0)207 104 8068, +44 (0)207 104 8233; camdenandkingscross.rec@hra.nhs.uk), REC ref: 21/LO/0823

Study design
Non-randomized; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pre-pregnancy care for women living with type 2 diabetes

Interventions
The intervention will include adjusting GP practice electronic records to promote the identification of and treatment plans for women of reproductive age living with type 2 diabetes. It will also include education support for healthcare professionals in primary care and resources for women living with type 2 diabetes. The researchers will use repeat measures to assess the utility of these strategies and iterative amend these to optimise pre-pregnancy care for this group.

There will be an 18-month observation period during which the researchers will iteratively refine the intervention components – strategies to embed pre-pregnancy care into routine care.

Intervention Type
Other

Primary outcome measure
Extracted in anonymised format from a template embedded into the electronic records within each of the participating GP practices at baseline and quarterly during the observation period at study months 10, 14, 18 and 22:
1. HbA1c testing and results (number of patients ≤48 mmol/mol [6.5%])
2. Number of patients commencing on folic acid 5 mg
3. Number of patients ceasing potentially teratogenic therapies

Secondary outcome measures
Extracted in anonymised format from a template embedded into the electronic records within each of the participating GP practices at baseline and quarterly during the observation period at study months 10, 14, 18 and 22:
1. Number of patients having a reproductive review and care plan instigated
2. Number of patients engaged in the pre-pregnancy care pathway - referred to intermediate or hospital diabetes teams
3. Number of patients instigated on contraception

Overall study start date
01/10/2021

Completion date

31/12/2024

Eligibility

Key inclusion criteria
1. Women living with Type 2 diabetes aged 18-45 years attending one of the participating GP practices
2. GP practice participation is limited to those in Lambeth and Southwark with more than 25 women meeting the eligibility criteria registered to the practice.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
Planned Sample Size: 750; UK Sample Size: 750

Key exclusion criteria
1. Women who do not have Type 2 diabetes or are not attending one of the participating GP practices
2. GP practice participation in Lambeth and Southwark with less than 25 women meeting the eligibility criteria registered to the practice

Date of first enrolment
14/02/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

GP practices in Lambeth and Southwark
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
King's College London

Sponsor details
King's College London
James Clerk Maxwell Building
57 Waterloo Road
London
England
United Kingdom
SE1 8WA
+44 (0)2078483224
reza.razavi@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
R&D Department
16th Floor, Tower Wing
Great Maze Pond
London
England
United Kingdom
SE1 9RT
+44 (0)20 7188 7188
R&D@gstt.nhs.uk

Sponsor type

Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Publication and dissemination plan
The researchers plan to publish the protocol and will disseminate their findings widely through academic journals; NHS and service-user networks; and through the study website and social media. A protocol manuscript has been submitted for review.

The researchers have a strong Patient and Public Involvement (PPI) and advisory group with patients, health professionals and representatives from women's and patient organisations. The PPI group guided the design of this study and will be part of the study advisory board which will be co-led by the patient co-applicant.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
Participant level data will not be publicly available as the is the potential to progress to a larger trial and these data will be reserved to support this. All data will be stored securely and anonymously at King's College London.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/04/2022	18/01/2023	Yes	No
HRA research summary			28/06/2023	No	No