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Pre-conception care for women with diabetes

Submission date
19/12/2014

Recruitment status
No longer recruiting

Registration date
15/01/2015

Overall study status
Completed

Last Edited
22/08/2017

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a global public health problem and one of the most common medical complications in pregnancy. Rates of diabetes in pregnancy are rapidly increasing, especially due to the projected growth in the number of women who are obese or overweight. Obesity can increase the risk of getting type 2 diabetes but both forms of pre-existing diabetes – type 1 and type 2 – can lead to serious complications. These risks to health can be modified and pre-conception care is known to make a difference. However, the uptake of pre-conception care is often low and it remains unclear how this can be improved. This study aims to review the existing literature in the field and conduct qualitative work to understand why women with pre-existing diabetes do, or do not, access pre-conception care, focusing specifically on the factors that facilitate or discourage uptake. A further objective is to investigate the views of staff and stakeholders at the frontline of service provision in order to explore their views.

Who can participate?
White British women and Pakistani women (whose preferred language is Urdu), with pre-existing Type 1 and Type 2 diabetes of childbearing age (between 16 and 45 years). Staff and stakeholders who are involved in caring for women with diabetes of reproductive age and/or the delivery of pre-conception care.

What does the study involve?
The study involves five phases. In Phase I a comprehensive review of the existing descriptive literature is conducted. In Phase II guided interviews are carried out with women and in Phase III, women participate in focus group discussions. Phase IV involves guided interviews with staff and stakeholders and participants in this phase of the study are invited to reflect on the views of service users, ensuring that the views of service users are at the centre of the project. Phase IV focuses on writing the project report and disseminating the findings of the project to maximise the potential impact of this work.

What are the possible benefits and risks of participating?
The great potential of this project is to improve women's health outcomes by increasing the uptake of pre-conception care through a better understanding of the factors influencing uptake. The risks involved in participating are minimal, although there is a small risk that participants

may find questions upsetting or intrusive. In relation to possible benefits of participating, participants may find the information available on the study website useful and will be provided with a summary of the major findings of the project.

Where is the study run from?
Sandwell and Birmingham CCG and Heartlands Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2014 to July 2016

Who is funding the study?
The Open University (UK)

Who is the main contact?
Dr Sarah Earle
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Study website
www.open.ac.uk/pcc

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 12/185/14

Study information

Scientific Title
Pre-conception care for women with type 1 or type 2 diabetes: what are the facilitators and barriers to uptake?

Acronym
PCC

Study objectives
1. To systematically review the descriptive research on pre-conception care for women with diabetes of childbearing age, and establish themes and gaps in knowledge.
2. Through qualitative work, identify views on the provision of, and facilitators and barriers to the uptake of pre-conception care.

This research study aims to gain a better understanding of the views of White British women and Pakistani women of childbearing age who have accessed pre-conception care in the last 3 years and those that have not. They are looking at what the facilitators and barriers in the uptake of pre-conception care are.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Berkshire NRES Committee, 05/03/2015, ref: 15/SC/0026

Study design
Observational multicentre study

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Diabetes in pregnancy

Interventions
The proposed study adopts a qualitative mixed-methods approach designed to explore the two key research questions, namely, to understand why women with diabetes of childbearing age do /do not access pre-conception care, and to elicit the views of staff and stakeholders on this and on future provision of this service. A better understanding of the views of women, and of the relevant staff and stakeholders, is needed in order to inform service design and delivery. The use of qualitative methods is best placed to explore views on the provision of, and the facilitators and barriers to, the uptake of pre-conception care. A qualitative mixed-methods design will be used to ensure that the views of service users are at the centre of the research. This design will also allow meaningful and nuanced data to emerge that reflects the views of services users, staff and stakeholders and can be used to understand how pre-conception care could be provided to optimise uptake and outcomes.

Intervention Type
Other

Primary outcome measure
1. To understand why women with diabetes of childbearing age do, or do not, access pre-conception care, with a view to informing services
2. To investigate the views of staff and stakeholders to explore existing and future provision of pre-conception care

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2014

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. White British women and Pakistani women (whose preferred language is Urdu), with pre-existing Type 1 and Type 2 diabetes of childbearing age between 16 and 45 years inclusive
2. Staff and stakeholders who are involved in caring for women with diabetes of reproductive age and/or the delivery of pre-conception care

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
40 women and 20 staff/stakeholders

Key exclusion criteria
1. Women with diagnosed mental health issues
2. Women <16 and >45 years

Date of first enrolment
30/01/2015

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sandwell and Birmingham CCG
Kingston House
438-450 High Street
West Bromwich
Birmingham
United Kingdom
B70 9LD

Study participating centre
Diabetes and Endocrinology Centre
Heartlands Hospital
Bordesley Green East
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B9 5SS

Sponsor information

Organisation
The Open University

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Sponsor type
University/education

ROR
https://ror.org/05mzfcs16

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository (https://figshare.com/s/d53346337f0db8e2f282) and available on request from Dr Sarah Earle
(sarah.earle@open.ac.uk).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No
HRA research summary			28/06/2023	No	No