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Use of reminders to support women with prior gestational diabetes on decision making on participation in screening for type 2 diabetes after birth

Submission date
21/04/2022

Recruitment status
No longer recruiting

Registration date
22/04/2022

Overall study status
Completed

Last Edited
24/01/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Women with pregnancy complicated by gestational diabetes are at an increased risk of developing type 2 diabetes later in life. These women are therefore urged to participate in life-long screening in general practice, 2-3 months after birth and every year, or a minimum of every third year after birth. The use of electronic reminders to women have been used to strengthen the insufficient participation found in follow-up screening. However, there are great variations in the effect of the reminders and reminder interventions which include a long-term perspective have not previous been investigated. The aim of this study is to determine the effectiveness of an electronic reminder intervention for women 1- 8 years after pregnancy complicated by gestational diabetes in increasing uptake in the recommended follow-up screening in general practice.

Who can participate?
Women of childbearing age who have had a pregnancy complicated by gestational diabetes.

What does the study involve?
Participants are randomly allocated into either an intervention group or a control group. Within each group the women are stratified by the year of birth of the child where the pregnancy was complicated by gestational diabetes (2012-2018). The reminder is sent out once to the intervention group through a national secured mailbox which all citizens in Denmark have and follow-ups are performed 6 months after. Usual care, which both groups received, includes information before discharge from hospital on the increased risk and recommendations on follow-up screening after birth and women have the responsibility for booking appointments for screening. Outcomes measured include screening tests performed and type 2 diabetes diagnosis.

What are the possible benefits and risks of participating?
Benefits for participants include being provided with information to support decision making on participation in the recommended screening after birth as well as the potential of early

detection of type 2 diabetes. No direct risks of participating are expected as no women are deprived of the opportunity to participate in screening. However, a feeling of increased stress and fear caused by risk communication could possibly occur for some women.

Where is the study run from?
University College of Northern Denmark (Denmark)

When is the study starting and for how long is it expected to run for?
January 2019 to May 2021

Who is funding the study?
1. University College of Northern Denmark (Denmark)
2. Aalborg University (Denmark)
3. Aalborg University Hospital (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
310599

Study information

Scientific Title
Reminders to support early detection of type 2 diabetes: a randomized controlled trial comparing the use of electronic reminders for screening after birth to usual care for women with previous gestational diabetes

Acronym
RemGDM

Study objectives
Reminders increase uptake in follow-up screening more than usual care where women with previous gestational diabetes (GDM) do not receive a reminder

Ethics approval required
Old ethics approval format

Ethics approval(s)
On 17/01/2019 the Science Ethics Committee for the North Denmark Region (Niels Bohrs Vej 30, 9220 Aalborg Ø, Denmark; +45 (0)97 64 84 40; vek@rn.dk) was asked if ethical approval was needed. It was decided that the project did not require ethical approval. This was based on the following reasoning: "none of the participants will be deprived of the opportunity for a screening examination".

Study design
Two-armed single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Screening

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
Early detection of type 2 diabetes among women with previous gestational diabetes

Interventions
A two-armed, single-blinded randomized controlled trial, where women are allocated to either the intervention group (usual care + reminder) or the control group (usual care). Within each group the women are stratified by the year of birth of the child where the pregnancy was

complicated by gestational diabetes (2012-2018). The randomization is performed within each strata using R Core Team (2020) and carried out using a computer-generated random allocation sequence to create a 1:1 ratio. The reminder is sent out once through a national secured mailbox which all citizens in Denmark have and a follow-up is performed 6 months after.

Intervention Type
Behavioural

Primary outcome measure
Participation in follow-up screening, defined as the performance of blood test for diabetes and measured through Danish National Registry Data 6 months after the reminder was sent out

Secondary outcome measures
Women diagnosed with type 2 diabetes measured through Danish National Registry Data 6 months after the reminder was sent out

Overall study start date
01/01/2019

Completion date
01/05/2021

Eligibility

Key inclusion criteria
Women of childbearing age and with previous pregnancy complicated by gestational diabetes

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1708

Total final enrolment
1708

Key exclusion criteria
1. Women with another diabetes diagnosis than GDM prior to birth
2. women with another diabetes diagnosis than GDM during/after pregnancy
3. Women who died
4. Women who no longer lived in the North Denmark Region

Date of first enrolment
27/08/2020

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
Denmark

Study participating centre
The North Denmark Region
Denmark
-

Sponsor information

Organisation
University College of Northern Denmark

Sponsor details
Selmalagerløfs vej 2
Aalborg Øst
Denmark
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+45 (0)72690975
GTC@ucn.dk

Sponsor type
University/education

Website
http://www.ucnorth.dk/Default.aspx

ROR
https://ror.org/056c4z730

Funder(s)

Funder type
University/education

Funder Name

University College of Northern Denmark

Funder Name
Aalborg Universitet

Alternative Name(s)
Aalborg University, AAU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Denmark

Funder Name
Aalborg Universitetshospital

Alternative Name(s)
Aalborg University Hospital

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Denmark

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
According to ethical or legal restrictions, the researchers are not able to make data available for the public. This project is based solely on already obtained registry-based data. All data were pseudonymized and consent from participants was according to Danish legislation not required.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/01/2023	24/01/2023	Yes	No