

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	<input type="checkbox"/> Prospectively registered
Registration date 22/04/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/01/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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Sponsor information

Organisation

University College of Northern Denmark

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

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