DALI: Lifestyle pilot

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON38179

Source
ToetsingOnline

Brief title
DALI Lifestyle pilot

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Maternal complications of pregnancy

Synonym
gestational diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Europese Unie

Intervention

Keyword: Gestational diabetes, lifestyle, prevention

Outcome measures

Primary outcome

In order to achieve the research goals, the participants will be requested to fill out an evaluation questionnaire at the end of the lifestyle intervention. It consists of questions about time, cost, comprehensibility, lay-out and completeness concerning the different segments of the intervention such as the online baseline questionnaire, the tailored lifestyle advice, the face-to-face coaching session, the telephone coaching sessions, the measurements by the research assistant and the communication with the research team. For example *How much time did it take to fill out the baseline questionnaire? Do you think this is acceptable or non acceptable?* *How clear do you think the questions of the baseline questionnaire were? (1) unclear - (2) - (3) - (4) - (5) clear.*

Secondary outcome

NA

Study description

Background summary

Gestational Diabetes (GDM) is defined as 'carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy'. The prevalence of GDM in Europe is reported to vary considerably, in some populations GDM occurs already in up to 20 % of all pregnancies. There are few published studies about preventing GDM.

Study objective

The overall aim of the DALI study is to identify the best available measures to prevent GDM in an ongoing pregnancy, to provide a cost-benefit calculation of GDM prevention for health care systems, and to establish a pan-European cohort

of mother-offspring pairs for future analyses with a central biobank and data base. For this purpose, a randomised controlled trial will be conducted in 10 European countries. In this pilot study, the lifestyle interventions and measurement procedures will be tested in 12 women in each country.

Study design

Twelve women will be recruited at each site: 4 randomised to each of the lifestyle interventions that have been developed: Physical activity, diet and both physical activity and diet. Women will be followed up for approximately 7 months, from 12 weeks to delivery. This will be a full test of the main trial, using all planned materials and methods.

Intervention

In the programme, one-to-one contact will be offered, along with telephone booster calls. The same amount of time will be offered to each participant during the trial. The intervention will be provided in five sessions of approximately 30-45 minutes, and in four telephone calls of approximately 20 minutes. The on-to-one sessions will take place at the home of the participants or in hospital/midwife practice/general practice, depending on cultural acceptability of home visits.
To optimize rapport, it is expected that a lifestyle coach is made responsible for supporting a defined number of participants throughout the pregnancy period. The coach will have a PDA which will provide the framework for the visit and will help steer the coach to deliver the nutrition and/or physical activity package. Details will be entered into the PDA programme and at the end of the session, the synchronization button will be pressed to send the recorded data to the Trial coordination team.

* Physical activity
According to the ACOG guidelines, pregnant women are recommended to be moderately physically active for at least 30 minutes per day on at least 5 days of the week [13]. Given our population of obese women, low fitness and physical activity levels are to be expected. Activities such as swimming, walking and cycling are activities that the participants should be able to undertake during the course of their pregnancy. As pregnancy progresses through the third trimester, physical activity may decrease and this needs to be managed sympathetically, providing e.g. sitting and/or upper limb exercises as alternatives. They are advised to (1) incorporate active movement as much as possible into their daily life (e.g. by parking further away from destination), (2) reduce sedentary time, (3) incorporate upper and or lower limb resistance exercise as physical activity, (4) to increase the number of steps taken per day and (5) to be more active during the weekends. An action plan for increasing physical activity levels will be made during the first session, and evaluated in subsequent sessions. Participants will receive pedometers for

feedback on their behaviour and progress.

* Diet
The following dietary objectives will be set for each participant to achieve or to maintain: (1) to reduce intake of sugary drinks (replace with water), (2) to eat more non-starchy vegetables, (3) to choose high-fibre, over low fibre products (*5 g fibre/100 g), (4) to watch portion size, (5) to increase intake of proteins (e.g. meat, fish, beans), (6) to reduce fat intake (e.g. snack, candy, fast food, fried foods), and (7) to reduce intake of carbohydrates (e.g. potatoes, pasta, rice, snacks, candy) . An action plan for improving dietary behaviour will be made during the first session, and evaluated in subsequent sessions.

Coaches
Members of the research team will carry out the face-to-face counselling and the telephone booster sessions. They will receive a special training programme containing motivational interviewing techniques to overcome the ambivalence or barriers that keeps people from making desired lifestyle changes in their lives.

Study burden and risks

Risks and burden for the participant.
* Measurements
There are 3 moments of measurement in 6-7 months. The measurements consist of: blood samples (including OGTT), ultrasound, body weight measurement, wearing an accelerometer and filling out questionnaires about lifestyle and demographics. Height will be measured at baseline. In addition, at delivery a blood sample from the mother will be taken.

Most measurements can be performed shortly after the visit with the obstetrician, so it will not take extra time to come to the hospital for the measurement. The measurements will take about 30 minutes extra. At two points in time there will be an extra OGTT for this study. The OGTT will take 2.5 hours. Venesection does have a risk of bruising and discomfort, but no risk of serious harm.

* Interventions
The women will be asked to engage either physical activity, diet, or the combination thereof.

Potential risks of physical activity will be minimized by following the exercise-during-pregnancy- guidelines of the ACOG. In the event of an injury due to physical activity or of pregnancy complications, participants will be advised to consult their treating clinician (obstetrician or midwife) respectively.

Potential risk of diet include starvation ketogenesis. However, women will not be advised to severely restrict energy intake, but will be advised to eat different food products (eg whole grain bread instead of white bread). However, to check for starvation ketogenesis, 3-Beta Hydroxy-butyrate will be one of the monitored parameters.

Benefits
It is believed that the potential risks mentioned above are minimal, relative to the anticipated benefits. The women in this study are at risk for gestational diabetes and all interventions aim at reducing this risk in addition to other potential benefits (i.e. exercise improving mood and well-being) .

Relevance for expecting mothers:
GDM is associated with an increased risk for other pregnancy complications, such as preeclampsia, infection and postpartum haemorrhage, and an increased risk for developing diabetes after pregnancy [14].

Relevance for children:
The prevention of GDM is also relevant for the children, since it also puts the neonates at risk. GDM is associated with increased risk for macrosomia, jaundice and birth trauma. Later in life, children of gestational diabetic mothers have an increased risk for obesity, impaired glucose tolerance, and diabetes type 2 [14].

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- prepregnancy BMI (self-reported weight, measured height) is ><= 29 kg/m2)
- aged 18 years or more
- gestational age at recruitment < 12 weeks
- sufficiently fluent in Dutch
- being able to be moderately physically active
- giving written informed consent.

Exclusion criteria

- Pre-existing diabetes
- diagnosed with (gestational) diabetes mellitus before randomisation, defined as fasting glucose >=5.1 mmol/l and/or 1 hour glucose >= 10 mmol/l and/or 2 hour glucose *8.5 mmol/l at baseline measurement.
- not able to walk at least 100 meters safely
- requirement for complex diets
- advanced chronic conditions (eg valvular heart disease)
- significant psychiatric disease
- known abnormal calcium metabolism (hypo/hyperparathyroidism, nephrolithiasis,hypercalciuria) or hypercalciuria detected at screening (0.6 mmol/mmol creatinine in spot morning urine)
- twin pregnancy

Study design

Design

Study phase: 2

Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2011
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	06-06-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36065.029.11