The effects of an exercise program on insulin sensitivity and plasma glucose levels in women at high risk for gestational diabetes.

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Increasing levels of physical activity during pregnancy may be an effective strategy for the prevention of GDM.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20927

Bron
NTR

Verkorte titel
FitFor2

Aandoening

1. Gestational diabetes;

2. exercise;

3. physical activity;

4. pregnancy;

5. prevention.

(NLD: zwangerschapsdiabetes; lichamelijke activiteit; beweegprogramma; zwanger; preventie).

Ondersteuning

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Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary maternal outcome measures are fasting plasma glucose and relative increase in insulin resistance.
Primary neonatal outcome is birth weight.

Toelichting onderzoek

Achtergrond van het onderzoek

Pregnancy is a period in the live of women that may result in decreased daily physical activity and/or exercise. This change often occurs despite the fact that there is no medical reason for women to reduce their daily physical activity levels and/or exercise. However, maintaining adequate levels of daily physical activity during pregnancy may be important for mother and child. Studies of daily physical activity or exercise and the occurrence of maternal pregnancy related disorders suggest that moderate daily physical activity and exercise during pregnancy may be associated with reductions in the risk of gestational diabetes mellitus (GDM). However, at the moment, physical activity is not routinely advised or prescribed for women at risk for gestational diabetes in the Netherlands.

In this study we aim to assess whether an exercise program can improve insulin sensitivity and fasting plasma glucose levels of women at high risk for gestational diabetes, assuming that this will normalise their risk of gestational diabetes.

This study is a randomised controlled trial. 160 women at risk for gestational diabetes will be randomly allocated to two groups; an intervention (n = 80) and a control group (n = 80). The intervention group will receive an exercise program twice a week in addition to usual care, and the control group will receive usual care only.

Primary maternal outcome measures are fasting plasma glucose and relative increase in insulin resistance. Primary neonatal outcome is birth weight.
Secondary outcome measures are: maternal serum triglycerides, maternal weight gain during pregnancy, maternal physical activity level, fetal growth.
The intervention will be an exercise program twice a week during the remaining duration of the pregnancy. Trainers have expertise with providing exercise training for pregnant women. Exercises will be adjusted to the fitness and endurance level of the women at the start of the intervention and later on to their stage of pregnancy.

Doel van het onderzoek

Increasing levels of physical activity during pregnancy may be an effective strategy for the prevention of GDM.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

An exercise program consisting of aerobic and strength exercises will be provided twice a week during the remaining duration of the pregnancy after randomisation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Between 14 and 20 weeks of pregnancy;

2. at risk for gestational diabetes mellitus;

3. over 25 years of age;

4. sufficiently fluent in Dutch;

5. being able to be moderately physically active;

6. giving written informed consent.

Women will be considered to be at risk for GDM when they are overweight (BMI of 27 or more) AND have at least one of the three following characteristics:

1. history of macrosomia;

2. history of abnormal glucose tolerance;

3. first grade relative with diabetes mellitus type 2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diagnosed with (gestational) diabetes mellitus before randomisation;

2. hypertension;

3. systolic pressure >160mmHg and/or diastolic pressure >100mmHg;

4. alcohol abuse (i.e. 2 glasses alcohol or more per day);

5. use of drugs (except for incidental analgesic drugs);

6. serious pulmonary impairment; COPD, exercise-induced asthma;

7. serious cardiac impairment; angina pectoris, cardiac decompensation, history with cardiovascular disease;

8. serious hepatic impairment; 3 times the upper limit of normal;

9. serious renal impairment; serum creatinine > 150 ìmol/l;

10. malignant disease;

11. serious mental or physical impairment i.e. preventing to understand or implement the study protocol/aim.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-11-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1104
NTR-old	NTR1139
Ander register	METC : 07/133.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A