TOwards Prepared Mums 2 - A lifestyle intervention to reduce gestational weight gain and smoking in pregnant women to prevent perinatal morbidity

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21149

Source
Nationaal Trial Register

Brief title
TOP-mums 2

Health condition

n.a.

Sponsors and support

Primary sponsor: MUMC+
Source(s) of monetary or material Support: MUMC+

Intervention

Outcome measures

Primary outcome

Gestational weight gain

Secondary outcome

• Postpartum weight retention,
• Smoking cessation
• Dietary habits: 7 day food diary, Three Factor Eating Questionnaire (TFEQ)
• Physical activity habits: accelerometry, Baecke questionnaire
• Miscarriage: defined as the loss of the fetus before the 20th week of pregnancy.
• Pregnancy complications
• Vitamin D status:
• Childbirth complications
• Dysmaturity and macrosomia
• Prematurity
• Metabolic derangement: blood glucose levels, insulin resistance (HOMA-IR), lipid profile and liver enzymes, OGTT .
• Cardiovascular alterations: blood pressure (BP) and pulse wave velocity (PWV), arteriovenous ratio (AV-ratio) derived from retina image.
• Microbial flora of the mother(fecal, vaginal, oral) and child (fecal)
• Epigenetics (biopsy placenta)
• Cord blood glucose, insulin and lipids
• Metabolic derangement of the child: bloodglucose, insulin levels and lipid profile of the infants at 1y.
• Breast milk composition
• Body composition (deuterium method)
• Marital status;
• Education;
• Medical history;
• Number of previous pregnancies;
• Previouw perinatal complications;
• Smoking: pack years.

Study description

Background summary

Rationale: The negative perinatal consequences of obesity and smoking during and after pregnancy for mothers and children are significant. Examples of these negative consequences are a higher risk of dysmaturity, prematurity, gestational diabetes mellitus, pregnancy induced hypertension and caesarean delivery. Furthermore, the offspring has a higher chance of developing asthma, obesity and metabolic abberations in childhood, carrying adulthood. Therefore, it is important to break the vicious circle of transferring harmful lifestyle influences from generation to generation.
Objective: The overall aim of this non-randomized intervention study is to evaluate the effects of a lifestyle intervention for young women starting early in pregnancy (≤ 12 weeks of gestational age) and have a high risk on perinatal morbidity because of prepregnancy

overweight or obesity and, if applicable, smoking on weight, lifestyle habits, perinatal morbidity, maternal body composition, epigenetics, breast milk composition, metabolic and cardiovascular markers in mother and child, microbial flora of mother and child and lung function of the child.
Intervention: The intervention an integral and multidisciplinary lifestyle intervention consisting of a healthy diet, appropriate physical activity and, if applicable, smoking cessation, customised to the needs of the women.
Main study parameters/endpoints: Primary study parameter is gestational weight gain within the guidelines of the Institute of Medicine. Secondary study parameters are gestational weight gain, postpartum weight retention, smoking cessation, pregnancy and delivery complications. Associations will be determined between gestational weight gain and metabolic and cardiovascular markers in mother and child, maternal body composition, breast milk composition, microbial flora of mother and child, epigenetics and lung function of the child.

Study objective

Via the support of healthy lifestyle in the intervention group, the hypothesis is that more women will have a GWG according the guidelines of the Institute of Medicine (IOM) compared to the control group. It is expected that limited GWG will have beneficial health effects for both the women and their children.

Study design

12, 20, 26, 32, 36 and 40 weeks of pregnancy, 6 weeks postpartum, 3, 6, 9 and 12 months postpartum

Intervention

personalized lifestyle intervention

Contacts

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Eligibility criteria

Inclusion criteria

• Pregnant women (gestational age ≤ 12 weeks)
• Age 18-40 years
• Prepregnancy overweight/obesity (BMI ≥ 25.0 kg/m2). Self-reported prepregnancy weight and measured height at baseline will be used to calculate prepregnancy BMI.

Exclusion criteria

• Haemodynamically significant heart disease;
• Restrictive lung disease;
• Congenital metabolic disease;
• Mentally retarded;
• Bariatric surgery;
• Diabetes type II, dependent on medicine.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-07-2018
Enrollment:	52
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-05-2021
Application type:	First submission

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
NTR-new	NL9456
Other	METC azM/UM : METC172027

Study results