TOwards Prepared mums (TOP-mums), for a healthy start: A lifestyle intervention to reduce overweight and smoking in women with a pregnancy wish to prevent perinatal morbidity

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The overall objective of the study is to investigate a lifestyle intervention for women with a pregnancy wish or pregnant women in their first trimester, and a high risk on perinatal morbidity because of (prepregnancy) overweight or obesity. With an...

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

Summary

ID

NL-OMON55392

Source
ToetsingOnline

Brief title
TOP-mums, for a healthy start

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
perinatal complications, Unhealthy lifestyle

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: academisch ziekenhuis Maastricht

Intervention

Keyword: Obesity, Pregnancy wish, Prevention, Smoking

Outcome measures

Primary outcome

- Reduction in body weight: reduction in body weight is measured from baseline, or self-reported body weight in case of inclusion during pregnancy, to 6 weeks postpartum.

Secondary outcome

- Gestational weight gain: defined as weight at the beginning of the pregnancy (at the first appointment with the midwife, approximately at 6 weeks gestational age) to the weight at 36 weeks of gestation.
- Postpartum weight retention: defined as weight at the beginning of the pregnancy to the weight 6 months postpartum.
- Smoking cessation: measured with questionnaires, is smoking is present at inclusion.
- Biochemical verification of tobacco use, if smoking is present at inclusion: the amount of carbon monoxide (CO) in exhaled breath will be measured using a CO monitor. Biochemical verification will also be done by measurement of urine cotinine.
- Dietary habits: for several times, women will be asked to fill in a food

diary for seven days. Furthermore, the full-length version of the Three Factor Eating Questionnaire (TFEQ) will be used to assess all of the characteristics of dietary restrain.

- Physical activity habits: to measure their daily activity, women will be asked to wear an accelerometer for seven full days for several times. The Baecke questionnaire measures work, sport and leisure activities.

- Miscarriage: defined as loss of the fetus before the 20th week of pregnancy.

- Time to pregnancy.

- Vitamin D status: vitamin D insufficiency is defined as a measurement < 50 nmol/L.

- Pregnancy complications: gestational diabetes mellitus, pregnancy induced hypertension, preeclampsia.

- Childbirth complications: caesarean section, induction of labour, vacuum extraction, postpartum haemorrhage, maternal hospital stay, shoulder dystocia.

- Dysmaturity and macrosomia: dysmaturity is defined as a birth weight below the -2.5 standard deviation score (SDS) and macrosomia is defined as a birth weight above the + 2.5 SDS of normal values for gestational age and gender.

- Prematurity: defined as birth before 37 weeks of gestation.

- Epigenetics: samples of the placenta and of the cord blood will be taken and stored.

- Metabolic derangement: blood glucose leves, insulin resistancy (HOMA-IR), dyslipidemia and liver enzymes. Furthermore, an oral glucose tolerance test (OGTT) will be performed.

- Cardiovascular alterations: blood pressure, pulse wave velocity and

arteriovenous ratio by a retinal image will be measured.

- Microbial flora: in mothers, samples of the faeces, throat and vaginal swabs will be taken. In children, samples of the faeces and throat swabs will be taken. The samples will be stored at -80*C until analysis.

- Metabolic derangement of the child: bloodglucose, insulin levels and lipid profile will be determined.

- Breast milk composition (if the mother breastfeed the child): breast milk will be collected by using an electric breast pump. The samples will be stored at -80*C until analysis.

- Body composition: the two-compartment model will be applied.

Study description

Background summary

The world suffers a global epidemic in non communicable diseases such as diabetes mellitus, heart diseases and dyslipidaemia. Non-communicable diseases can emerge because of exposure to an unhealthy lifestyle involving (second hand) tobacco use, a lack of regular physical activity, and consumption of diets rich in highly saturated fats, sugars and salt. The influences of exposure to an unhealthy lifestyle can start very early in life, namely already before and during pregnancy. Among the adverse lifestyle of women in reproductive age, smoking and obesity are the most potentially modifiable factors.

Obesity is detrimental for reproduction. Once pregnant, overweight and obese women are at increased risk of pregnancy complications, including gestational diabetes mellitus, pregnancy induced hypertension, preeclampsia and caesarean delivery. Foetuses of overweight and obese pregnant women are at increases risk of stillbirth, congenital anomalies and childhood obesity.

Smoking of the mother during pregnancy has several adverse effects for mother and child. It not only reduces the fertility rate but also increases the risk on spontaneous abortion, ectopic pregnancy, placental disorders, premature rupture of membranes and higher rate of urinary tract infections. Moreover, the

risk on dysmaturity, prematurity, sudden infant death syndrome and asthmatic disease greatly increases in the case of in utero exposure to cigarette smoke.

From a societal and clinical point of view there is an urgent need for an intervention that break the vicious circle of transferring harmful lifestyle influences from generation to generation. Therefore, this study will investigate the effectiveness of an early-life intervention. The potential beneficial health effects of a preconceptionally started lifestyle intervention for mother and child are impressive. It may lead to better fertility, less preeclampsia, less prematurity, less dysmaturity, less respiratory symptoms and infections and a lower prevalence of childhood obesity.

Study objective

The overall objective of the study is to investigate a lifestyle intervention for women with a pregnancy wish or pregnant women in their first trimester, and a high risk on perinatal morbidity because of (prepregnancy) overweight or obesity. With an effective intervention directed towards healthy living, including reduction of overweight or obesity and, if applicable, smoking reduction, health problems in mothers and their offspring can be prevented.

Study design

The study design will be a randomised controlled trial regarding a lifestyle intervention directed towards a healthy diet, adequate physical activity and, if applicable, smoking reduction. A 1 : 1 randomisation will be applied. The intervention group will receive the lifestyle intervention. The control group will receive usual care and 1 recipe for a healthy meal per week. Block randomisation will be stratified for the presence of different lifestyle behavior factors: overweight (BMI 25.0-29.9 kg/m2), obesity (BMI >= 30.0 kg/m2), overweight and smoking or obesity and smoking. The program and follow-up continues during pregnancy, until 1 year after delivery.

Intervention

The investigational treatment consists of a lifestyle intervention and will directed towards a healthy diet, adequate physical activity and, if applicable, smoking cessation. The program will start with a personal screening of the women at the website of Slimmer Zwanger. The women receive information about their unhealthy and healthy lifestyle habits, making visible with a figure and supporting text. Thereafter, the coaching part of Slimmer Zwanger will start. Through digital posts, women will get tips, tricks, rewards and recipes for healthy meals. The advices are customised according to the results of the personal screening and are offered at least three times a week.

The lifestyle intervention regarding a healthy diet and adequate physical

activity will be divided in two parts. First, women can participate in the program of the Centre for Obesity and eating disorders Europe (CO-EUR). CO-EUR is a second-line mental health institution and is specialised in treatment of patients with obesity and eating disorders and their related comorbidities. The treatment of CO-EUR is based on evidence based treatment methods. The short program (4 months of duration) will be offered to the women participating in this study.

Furthermore, the guidance consists of consultations with a dietician and a physical activity program. During different phases in their life (preconception, during pregnancy and postpartum), each phase will be accompanied by specific lifestyle advices, and the women will be supported to persevere the lifestyle changes they made earlier. The lifestyle intervention targeted at overweight and obesity is based on the recommendations of the CBO guideline *Diagnostics and treatment of obesity in adults and children* and consists of a structured lifestyle program targeted at:
- Changing the dietary pattern;
- Stimulating physical activity of moderate intensity;
- Self-monitoring;
- Involvement of the partner.

Each woman will have her personal lifestyle coach. This personal coach will have an overview over the lifestyle intervention and guide the women through their personal program. Moreover, this personal coach is involved with the smoking cessation coaching if smoking is present at inclusion. Smoking cessation will be stimulated by coaching of the website of Slimmer Zwanger. Moreover, the personal coach will stimulate the women to stop smoking by direct feedback by use of carbon monoxide (CO)-measurements. The CO-gauger will show the CO concentration in the blood of the foetus as well.

Study burden and risks

For the women, there are no associated risks in this study and the intervention is non-invasive. The lifestyle intervention will be performed according to the current guidelines and are under stringent supervision. Women in the intervention group will visit the hospital, CO-EUR, dietician or sport activities on a regular basis. This requires time and effort of the women. To limit the burden as much as possible, the activities will be adapted as much as possible to work and other activities of the women. Furthermore, the study visits will be combined as much as possible with appointments with the midwife or at the child well-being centre. Women that are randomised in the intervention arm or who are pregnant at inclusion will attend the clinic for 4-12 extra visits in order to improve lifestyle, this will take around 11,5-19h. Moreover, they will be encouraged to participate in a physical activity program). Women in the intervention group should adapt their lifestyle in order to a healthier lifestyle. This will entail a certain degree of effort. The control group will receive usual care. Therefore, they will not be

restrained from the standard care. They will not be restrained when they want to search for guidance in improving their lifestyle. Subjects in the intervention group are more likely to benefit from this research. The intervention could have beneficial effects for the study population like improving their health status, pregnancy rate and inducing less pregnancy and delivery complications. Finally, not only the subjects in the intervention group will benefit from this study but at the long term the global public health as well. Data that will be collected, consisted of questionnaires (TFEQ, EQ-5D-5L, Baecke questionnaire, smoking behaviour and health care cost questionnaire), measurements of weight, anthropometry, blood pressure, CO measurements (4-11times), body composition (2-4 times), glucose, insulin, lipid profile and liver enzymes (3-7 times), OGTT (2-3 times), PWV and retinal image (4-8 times) and urine cotinine (6-7 times) in the mother. Furthermore, samples of microbial flora (faeces, vaginal swab and throat swab) will be collected each 3 months and samples of breast milk will be collected at every visit postapartum in case the mother is still breastfeeding (1-4x). The health risks of most of the measurements are considered as negligible, since the methods are routinely used in both research and in clinical practice.

The intervention and measurements will take place mainly in the mother during the study. However, a part of the intervention is targeted on the child and a couple of measurements will be executed in the children. The part of the intervention that is targeted on the child will exists of advices to the parents among nutrition and physical activity for their child. Examples of these advices are the introduction of solid food and sufficient physical activity. In usual care, these advices are already implemented in the child well being centers. However, in the intervention group, these advices will be reinforced. The child will not be exposed to risks. Moreover, in all children a couple of measurements will be executed. In general, these measurements are considered as a minimal burden and the health risks are negligible. In the children, data collection will consist of 2 times a blood sample (of which 1 time is taken from the cord blood), and collection of the microbial flora (faeces) for 4 times.

We believe that the burden of the measurements will be compensated by the social interest of the outcome of these measurements. With these measurements we can study the effects of the lifestyle intervention on the health of the mother and child. Moreover, with the data that will be collected, more insight into the causes and relationships between the transition of harmful lifestyle influences and the development of non-communicable diseases will be derived. The lifestyle intervention is set up in that way, that implementation in usual care would be very easy. When the lifestyle intervention will turn out to be effective, this can be easy implemented in the already existing health care. With this in mind, this study will contribute to the global public health. Namely, not only the health of the mother will improve, but also the health of the child will be guaranteed by an intervention that break the vicious circle

of transferring harmful lifestyle influences from generation to generation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a women must meet all of the following criteria:
- Women with a pregnancy wish within 1 year
- Aged 18-40 years;
- (Preconceptional) overweight/obesity (BMI >= 25 kg/m2).

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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-07-2016
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO

Date:	23-11-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Not approved

Date:	01-02-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT02703753
CCMO	NL52452.068.15