# A lifestyle intervention to reduce gestational weight gain and smoking in pregnant women to prevent perinatal morbidity

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The overall aim is to study the effects of a lifestyle intervention for young women who are pregnant

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON48998

**Source**
ToetsingOnline

**Brief title**
Lifestyle intervention in pregnant women

### 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:** Ministerie van OC&W

## Intervention

**Keyword:** lifestyle, perinatal complications, Pregnancy

## Outcome measures

### Primary outcome

Gestational weight gain within the IOM guidelines and the mean

weight-for-length z-score of the children at the age of 12 months.

### Secondary outcome

- Postpartum weight retention: defined as weight at the beginning of the

pregnancy to the weight 6 months postpartum.

- Smoking cessation: measured with questionnaires, when 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.

- 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.

- Endothelial-dependent vasodilatation of the child: in infants endothelial-dependent vasodilatation will be measured by laser-Doppler combined with iontophoresis on response to acetylcholine and nitroprusside.

- 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.

- Feeding and activity pattern of the child: using a diary parents will report the feeding and activity pattern of their child.

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

- Lung function of the child: functional residual capacity, lung clearance index, airway resistance and tidal breathing indices will be measured.

- 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 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 on asthma, obesity and metabolic abberations in childhood, progressing in adulthood. Therefore, it is important to break the vicious circle of transferring harmful lifestyle influences from generation to generation. However, it is unknown what the right time span is in the period around pregnancy to start with a lifestyle intervention. Previous studies have shown that a lifestyle intervention started after approximately 12-16 weeks of gestational age is insufficient to improve perinatal outcomes. For the effecitiveness of a lifestyle intervention started before 12 weeks of gestational age is insufficient evidence available. Therefore, we offer women who are pregnant before 12 weeks of gestational age a lifestyle intervention and we evaluate the effect of the lifestyle intervention in the current study.

**Study objective**

The overall aim is to study the effects of a lifestyle intervention for young women who are pregnant <= 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.

**Study design**

Non-randomised intervention study with a pre-postdesign. All women included in this study will participate in the lifestyle intervention.

**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 can consist of different components. 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 lifestyle intervention will consist of specific lifestyle advices during different phases of their life (during pregnancy and postpartum). 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 women 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 will visit the hospital, CO-EUR 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. Participating women will attend the clinic for 11-12 extra visits in order to improve lifestyle, this will take around 8 hours. Moreover, they will participate in a physical activity program, 1 time a week (1 hour). Women should adapt their lifestyle in order to achieve a healthier lifestyle. This will entail a certain degree of effort. Subjects are more likely to benefit from this research. The intervention could have beneficial effects for the study population like improving their health status and inducing less pregnancy and delivery complications. Finally, at the long term the global public health will benefit as well. Data that will be collected, consisted of questionnaires (TFEQ, EQ-5D-5L, Baecke questionnaire and smoking behaviour), measurements of weight, anthropometry, blood pressure, CO measurements (11-12 times), body composition (3 times), glucose, insulin, lipid profile and liver enzymes (6 times), OGTT (3 times), PWV and retinal image (5 times) and urine cotinine (6 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 1 time. 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. Sampling of a vaginal swab and breast milk will take place. Taking these samples are considered to be minimal invasive, but can bound up with some burdens for the women.

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, these advices will be reinforced within the lifestyle intervention. The child will not be exposed to risks. In which way parents adhere to these advices will be monitored by a feeding and activity diary. 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), measurement of the endothelial-dependent vasodilatation and lung function and collection of the microbial flora (faeces and throat swab) for 2 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 degree of gestational weight gain and/or smoking reduction 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

- Pregnant women with a gestational age <= 12 weeks + 6 days;
- Aged 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

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

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| Recruitment status: | Completed |
| Start date (anticipated): | 06-07-2018 |
| Enrollment: | 106 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 29-11-2017 |
| Application type: | First submission |
| 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 |
|---|---|
| CCMO | NL63016.068.17 |

# Study results

Date completed: 27-03-2024

**Summary results**
Trial ended prematurely