An intervention aimed at the prevention of excessive weight gain during pregnancy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28718

Source
Nationaal Trial Register

Brief title
New Life (style)

Intervention

Outcome measures

Primary outcome

An assistant will perform the anthropometrical measurements and collect the blood samples at 15, 25, 35 weeks of pregnancy and at 7, 25, 51 weeks after delivery in the midwife practice to measure the following outcome measures:

Weight and BMI (change): height is measured in bare feet with a portable height scale with a wide measuring slide and a heel plate. Both weight and height will be measured twice, and the mean value of the two measurements will be computed. Calibrated scales are used to determine weight while participants are only wearing light clothing (e.g. underwear) and no shoes.

Secondary outcome

1. Percentage body fat (sum of four skinfolds): a Harpenden calliper is used to assess percentage body fat. Percentage body fat is determined by measuring the sum of the thickness of four skin folds: biceps, triceps, subscapular and suprailiac according to the method described by Weiner and Lourie.11 During pregnancy the suprailliac skin fold measurement won't be executed. Therefore, the thigh skin fold is also measured on all occasions. All skin folds will be assessed twice. A mean value of the two will be computed. In case the two measurements of a skin fold differ more than 10%, the skin fold will be measured a third time. Also the circumference of arm and thigh will be measured.

2. Change in physical activity and dietary intake: physical activity will be assessed with the Short Questionnaire to Assess Health enhancing physical activity (SQUASH)12. At 15 and 35 weeks of pregnancy and 26 weeks after delivery all participants will wear an (blinded) accelerometer for 3 consecutive days to gather additional data on the levels of physical activity. The focus of dietary intake will be on fat 13,14, fruit and vegetable 15 intake. These questionnaires have been validated.

3. Blood samples: in order to study the influence lifestyle factors on energy homeostasis and weight gain, blood samples will be taken from the participants. Women will be asked for blood samples at 15, 25 and 35 weeks of pregnancy and at 7, 25, 51 weeks after delivery. If women refuse, they can still join the study. The midwives will take a blood sample from the umbilical cord. Collecting blood for routine test and the study will be combined as much as possible in order to limit the number of venapunctures for the participants. Blood levels of leptin, ghrelin, fasting insulin/glucose, insulin growth factor 1, insulin growth factor binding protein 1and 3, and cortisol will be measured. Analyses will take place at the laboratory of the VU University Medical Centre.

4. Data (questionnaires) will also be collected on: perceived health, stage of change (for weight management, physical activity and diet according to the model of Prochaska), self efficacy (concerning weight management, physical activity and eating habits), the duration and complications of labour, and complications during pregnancy such as gestational diabetes, pre-eclampsia, pregnancy related hypertension, pelvic pain. Possible confounders that will also be assessed by questionnaires include smoking behaviour, certain demographics (age (at menarche), education, family income, ethnicity, marital status, etc) and health conditions.

Study description

Background summary

Background:

For women, pregnancy is an independent risk factor for developing overweight. Previous studies describe an average weight retention of 2-3 kg, 6 to 12 months after delivery. Losing this "extra" weight after pregnancy proves to be difficult. Weight gain during pregnancy is

the most important determinant of postpartum weight retention.

Methods:

An RCT is performed to study the effect of an individually tailored intervention program on weight gain during pregnancy and postpartum weight retention. The main focus of this program is to help women to gain weight within guidelines for weight development during pregnancy, which are developed by the Institute of Medicine (IOM, 1990). In the intervention group, a counsellor surveys individual weight development during five sessions (18, 22, 30 and 36 weeks of pregnancy and 8 weeks postpartum) . Furthermore, personal lifestyle is discussed in order to be able to control individual weight development. Data are collected in the control and intervention group at 15, 25, and 35 weeks of pregnancy and at 8, 26, and 52 weeks after delivery by means of questionnaires and anthropometric measurements.

Conclusion:

Preventing excessive weight gain during pregnancy is important in the prevention of overweight and obesity among women of childbearing age. Caregivers and researchers in the field of health promotion are offered more insight in specific elements of the New Life(style) intervention program for pregnant women.

Study objective

Weight gain during pregnancy is the most important determinant of postpartum weight retention. In this study, the effect of an individually tailored intervention program is assessed on weight gain during pregnancy. The main focus of this program is to help women to gain weight within guidelines for weight development during pregnancy, which are developed by the Institute of Medicine (IOM, 1990). We expect that gaining weight within the guidelines has a positive effect on weight retention postpartum.

Study design

N/A

Intervention

The women will be randomly assigned to either the control group or the intervention group, and the women in the intervention group will receive advice on physical activity and diet during and after pregnancy.

Contacts

Public
VU University Medical Center, EMGO- Institute,
Van der Boechorststraat 7
Mireille N.M. Poppel, van
Van der Boechorststraat 7

Amsterdam 1081 BT
The Netherlands
+31 (0)20 4448203
Scientific
VU University Medical Center, EMGO- Institute,
Van der Boechorststraat 7
Mireille N.M. Poppel, van
Van der Boechorststraat 7

Amsterdam 1081 BT
The Netherlands
+31 (0)20 4448203

Eligibility criteria

Inclusion criteria

A cohort of 300 women (two times 150), who are approximately seven months pregnant of their first child (nullipara). All healthy women who visit the midwife within 14 weeks after the start of their last menstrual period, and who are pregnant for the first time, will be eligible for inclusion.

Exclusion criteria

Those who are directly referred to a gynaecologist because of complications, and those not able to read/write or communicate in Dutch will be excluded from the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion

Date:	11-03-2005
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	NL12

Register	ID
NTR-old	NTR32
Other	: N/A
ISRCTN	ISRCTN85313483

Study results

Summary results
N/A