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

Submission date	Recruitment status	[_] Prospectively registered
16/05/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/05/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/02/2013	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mireille NM van Poppel

Contact details
Afdeling Sociale Geneeskunde/EMGO Instituut
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 444 82 03
mnm.vanpoppel@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR32

Study information

Scientific Title

Acronym
New Life(style)

Study objectives
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). We expect that gaining weight within the guidelines has a positive effect on weight retention postpartum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee of VU University Medical Centre has approved the study design, protocols and informed consent procedure.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Weight-gain during pregnancy

Interventions
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.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
An assistant will perform the anthropometrical measurements and collect the blood samples at 15, 25 and 35 weeks of pregnancy and at 7, 25 and 51 weeks after delivery in the midwife practice to measure the following outcome measures:
1. Weight and body mass index (BMI) change
2. Height, 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 measures
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 skinfolds: biceps, triceps, subscapular and suprailiac according to the method described by Weiner and Lourie. During pregnancy the suprailliac skinfold measurement won't be executed. Therefore, the thigh skinfold is also measured on all occasions. All skinfolds will be assessed twice. A mean value of the two will be computed. In case the two measurements of a skinfold differ more than 10%, the skinfold 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). At 15 and 35 weeks of pregnancy and 26 weeks after delivery all participants will wear an (blinded) accelerometer for three consecutive days to gather additional data on the levels of physical activity. The focus of dietary intake will be on fat, fruit and vegetable intake. These questionnaires have been validated.
3. Blood samples: in order to study the influence of 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 seven, 25 and 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 one, insulin growth factor binding protein one and three, 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.

Overall study start date
01/01/2005

Completion date

31/12/2007

Eligibility

Key inclusion criteria
1. Healthy women who are approximately seven months pregnant with their first child (nullipara)
2. Visit the midwife within 14 weeks after the start of their last menstrual period
3. Pregnant for the first time

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
300 (150 in each group)

Key exclusion criteria
1. Those who are directly referred to a gynaecologist because of complications
2. Unable to read/write or communicate in Dutch

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Afdeling Sociale Geneeskunde/EMGO Instituut
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation

Netherlands Organisation for Health Research and Development (ZonMw)

Sponsor details
Laan van Nieuw Oost Indië 334
PO Box 93 245
The Hague
Netherlands
2509 AE
+31 (0)70 349 5111
info@zonmw.nl

Sponsor type
Research organisation

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands) (ref: project 4010.0017)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/06/2006		Yes	No
Results article	results	01/01/2013		Yes	No