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How and when is it most feasible to promote weight reduction after delivery in overweight women by motivational interviewing?

Submission date
21/10/2014

Recruitment status
No longer recruiting

Registration date
12/11/2014

Overall study status
Completed

Last Edited
17/08/2016

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In 2012, it was found that 36% of Swedish pregnant women were overweight or obese at their first visit to their antenatal care clinic. Being overweight during pregnancy increases the risk of complications occurring both before and after childbirth and can lead to health problems in the longer term. Antenatal care is free of charge in Sweden and almost all pregnant women visit a midwife. Motivational Interviewing (MI) is a patient-centred counselling session. There is a lot of evidence to suggest that MI works well as getting people to change their behaviour patterns, but more evidence is needed on whether it can successfully promote good eating and exercise habits. Here, we want to see whether antenatal care MI sessions will promote good diet and exercise habits in pregnant woman. We will investigate whether MI prevents pregnant woman from becoming overweight or help them to lose any weight gained during pregnancy once their child is born.

Who can participate?
Women aged between 18-39, pregnant with their first child and with a BMI 27.0-33.9 kg/m2. They should also be living in Stockholm County and fluent in Swedish.

What does the study involve?
First of all, all participants are weighed and their diet and physical activity assessed. They are then randomly allocated into one of four groups. Those in group 1 attend four MI sessions during their pregnancy. Those in group 2 attend four MI sessions 3-5 months after they have given birth. Those in group 3 have two MI sessions during pregnancy and two MI sessions after they have given birth. Those in group 4 are in a control group and are given their usual standard of care. The MI sessions are given by suitably trained counsellors and focus on eating and exercise habits. Weight, dietary and exercise habits, blood pressure and general quality of life are assed for all participants 52 weeks after giving birth.

What are the possible benefits and risks of participating?
Possible benefits include improvements in health for both mothers and their children. There are no risks for participants.

Where is the study run from?
1. Stockholm County Council (Centre for Epidemiology and Community Medicine) (Sweden)
2. Karolinska Institutet (Child and Adolescent Public Health Epidemiology, Department of Public Health Sciences), Stockholm, (Sweden)

When is the study starting and how long is it expected to run for?
November 2014 to December 2020

Who is funding the study?
1. Stockholm County Council (Sweden)
2. Karolinska Institutet (Sweden)

Who is the main contact?
Professor Finn Rasmussen
finn.rasmussen@ki.se

Study website
http://www.irisstudien.se/

Contact information

Type(s)
Scientific

Contact name
Prof Finn Rasmussen

Contact details
Department of Public Health Sciences
Karolinska Institutet
Stockholm
Sweden
171 77

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

IRIS: How and when is it most feasible and cost-effective to promote weight reduction after delivery in overweight
women by motivational interviewing? A randomised controlled trial

Acronym
IRIS

Study objectives
Motivational interviewing and feedback on dietary and physical activity habits can prevent postpartum weight retention among overweight/obese women and the effects differ depending on whether it is delivered during pregnancy, postpartum or both.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Board in Stockholm, Sweden; 19/03/2014; ref: 2014/350-31/2

Study design
Randomised parallel controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
http://www.irisstudien.se/delta

Health condition(s) or problem(s) studied
Prevention of obesity and promotion of healthy eating and physical activity habits

Interventions
Motivational interviewing (MI) is a brief psychological counselling method characterized by an emphasis on promoting motivation for behavior change by helping a client to explore and resolve ambivalence about change.

Women in the intervention arms are offered four individual MI consultations with a counsellor with high proficiency in MI. The MI sessions are either offered i) during the second trimester of pregnancy, ii) 3-5 months postpartum, or iii) both during pregnancy and postpartum. The first MI session is face-to-face and initiated by a feedback on the dietary and physical activity assessment. The second and third sessions are held via telephone and the fourth session is conducted in person or via telephone depending on preference of the woman.

In contrast, women allocated to the control group receive antenatal care as usual together with general calls about basic nutrition and physical activity knowledge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Postpartum weight retention 12 months after delivery. Weight and height are assessed by study staff the first MI session/general visit(approximately gestational week 15) by scale and height meter, and at follow-up 52 weeks postpartum. Weight is also measured at the routine visits in antenatal care (approximately gestational weeks 10-12, 25 and 37/38) and at delivery and data are assessed from medical records.

Secondary outcome measures
1. Dietary and physical activity habits. Diet is assessed at baseline (gestational week 11-13) and follow-up (1 year after delivery) by four-days food records using a web-based method. Physical activity is measured during seven consecutive days using an accelerometer at baseline, at the end of the second trimester, 5-6 months postpartum, and at follow-up (12 months after delivery).
2. Self-efficacy - measured by a questionnaire (an instrument developed by Kendall et al and back translated to Swedish) at baseline, at the end of the second trimester, 5-6 months postpartum, and at follow-up (12 months after delivery).
3. Blood pressure is registered in routine antenatal care (approximately gestational weeks 10-12) and data are drawn from medical records as well as at follow-up (12 months postpartum). Blood pressure will measured in a sitting position in the right arm after 5 minutes rest according to the antenatal care´s guidelines.
4. Body composition is assessed by bioelectric impedance at follow-up (12 months after delivery).
5. Gestational weight gain
6. Quality of life will be assessed for the health economic evaluation by a questionnaire (the SF-36 instrument) at baseline and follow-up (12 months after delivery).

Overall study start date
01/11/2014

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Nulliparous or primiparous women at gestational week 8-11
2. Age 18-39 years
3. BMI 27.0-34.9 kg/m2
4. Fluent in Swedish

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
39 Years

Sex
Female

Target number of participants
270 women

Key exclusion criteria
1. Severe psychologic or somatic illness
2. Bariatric surgery patient
3. Alcohol or narcotic addiction
4. Insulin-dependent diabetes

Date of first enrolment
01/11/2014

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Public Health Sciences
Stockholm
Sweden
171 77

Sponsor information

Organisation
Stockholm County Council (Sweden)

Sponsor details

Box 1497
Solna
Sweden
171 29

Sponsor type
Government

Website
http://www.sll.se/

ROR
https://ror.org/02zrae794

Funder(s)

Funder type
Government

Funder Name
Stockholm County Council (Sweden)

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

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