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PRIMROSE: Primary prevention of childhood obesity at child health centers

Submission date
09/08/2013

Recruitment status
No longer recruiting

Registration date
10/09/2013

Overall study status
Completed

Last Edited
06/08/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aim
Childhood obesity is a growing concern worldwide and its prevention is one of the key elements of current public health strategies in many countries including Sweden. Overweight and obese children run a high risk of becoming obese adults in later life and are likely to develop a number of non-communicable diseases. This study is based on the theoretical frameworks of social cognitive theory (SCT) and motivational interviewing (MI) and is designed to promote healthy eating and physical activity among pre-school children (9-48 months) and their parents. By this, the study aims to establish an intervention to reduce obesity among children in Sweden.

Who can participate?
The study is operating at Swedish child health centres (CHC) in eight counties. The services are free of charge and attended by nearly all families with young children irrespective of social position and ethnicity. Eligible were first-time mothers (parents) older than 18 years of age speaking Swedish coming to the CHCs.

What does the study involve?
Families are randomly allocated to either receive the intervention or the usual care. Nurses employed at the intervention CHC take part in a five-day course on nutrition, SCT and MI followed by supervised sessions, using recorded conversations, and then five sessions coded according to Motivational Treatment Integrity (MITI). The parents are offered an individual consultation held at home on health behavior (focusing on eating and physical activity habits) when their child is 8-9 months of age, a group consultation at 11 months of age held at the CHC, and thereafter individual consultations on health behavior at the CHC when their child is 1 year, 1 and a half years, 2 years, 3 years, and 4 years old. In addition, parents are offered telephone consultations when the child is 2 and a half and 3 and a half years of age. For each family the intervention thus comprises nine sessions/consultations with CHC nurses on children's health behavior (eating habits and physical activity.

What are the possible benefits and risks of participating?
Participating nurses can benefit from free education of SCT and MI. The main benefit for

participating families is the education in healthy eating and physical activity, which could have a positive impact on weight development in the child, but also on parents' weight development. There are no risks for any participants.

Where is the study run from?
The study is set up by the Karolinska Institutet, Stockholm, together with a team of international experts from the universities of Uppsala, Copenhagen and Göteborg, Sweden.

When is the study starting and how long is it expected to run for?
The enrolment of participating families started in May 2008 and ended in December 2010. Participants will be enrolled in the intervention program and 'regular' CHC services for about 4 years (December 2014). We anticipate finishing data collection in spring 2015.

Who is funding the study?
The study has been supported by grants from the following agencies: The Swedish Council for Working Life and Social Research the Swedish Research Council, the Research and Development Committee, Stockholm County Council, the Regional Research Council of the Uppsala and Örebro Health Care Region, Uppsala County Council, the Public Health Committee of Stockholm County Council, the Vårdal Foundation, AFA insurance, the Foundation of the Swedish Diabetes Society, the Karolinska Health Care Sciences Postgraduate School, and the Faculty Funds of Karolinska Institutet for PhD students .

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Primary prevention of childhood obesity through sessions at Swedish child health centers (CHC) addressing healthy eating habits and physical activity: a randomized population-based study (PRIMROSE)

Acronym
PRIMROSE

Study objectives
1. Body Mass Index (BMI) and waist circumference (WC) of children will be lower at follow-up in the intervention group compared to children in the control group.
2. BMI and WC of parents will be lower at follow-up in the intervention group compared to parents in the control group.
3. Children in the intervention group have healthier eating habits and physical activity at the age of 4, compared to the children in the control group.
4. Parents in the intervention group have healthier eating habits and physical activity at the children's age of 4, compared to the parents in the control group.
5. A health economic evaluation of the PRIMROSE intervention will demonstrate savings and health gains

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval (2006/525-31/2) was obtained from the Ethical Review Board in Stockholm, Sweden

Study design
Cluster-randomized population-based study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet [Swedish]

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

Interventions
The intervention is based on social cognitive theory (SCT) and Motivational Interviewing (MI), which has been shown in previous intervention studies to be successful in changing health behaviors. A core element in STC is the dynamic interplay between personal factors, health behaviors and environment. SCT aims at promoting self-efficacy, i.e. a person's trust in his or her own capacities to accomplish the anticipated health behaviour change. MI is a brief psychological treatment aiming at evoking the patient's intrinsic motivation for change. Proficiency in MI requires extensive training and structured feedback based on ratings of audio-recorded practice sessions according to validated coding systems, e.g. Motivational Treatment Integrity (MITI) code.

Nurses employed at the intervention CHCs took part in a five-day course on nutrition, SCT and MI followed by supervised recording sessions consisting of four training sessions and then five sessions coded according to MITI. The parents are offered an individual consultation held at home on health behavior (focusing on eating and physical activity habits) when their child is 8-9 months of age, a group consultation at 11 months of age held at the CHC, and thereafter individual consultations on health behavior at the CHC when their child is 1 year, 1.5 years, 2 years, 3 years, and 4 years old. In addition parents are offered telephone consultations when the child is 2.5 and 3.5 years of age. For each family the intervention thus comprises nine sessions /consultations with CHC nurses on children's health behavior (eating habits and physical activity). By contrast, families belonging to control CHCs are only offered traditional health check-ups at similar ages, with no systematic coverage of these subject matters.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
BMI and waist circumference (WC) of the participating children and their parents will be compared between the intervention group and the control group. Four-year-old children's and their parents' BMI and WC are primary outcomes, and will be used as indicators of obesity status. Nurses at the CHC measure children's and parents' height and weight by instruments which have been validated for measurement errors. Data from parents at baseline are self-reported.

In parents attending CHC waist circumference (WC) is measured by nurses using a measuring tape.
In 4-years old children attending CHC WC is also measured by nurses using a measuring tape.

Secondary outcome measures
Secondary outcomes are PA, eating habits (fruits, vegetables, fish, French fries, sugared drinks, leeway and regularity of eating). The eating habits of children and parents were assessed with a validated semi-quantitative food frequency questionnaire (FFQ). The FFQ includes questions about habitual dietary intake of certain food items as well as intake of beverages. The parent FFQ version includes 81-items and the child 79-items, and is complemented by questions about regularity of meals. The questions in the FFQs are intended to serve as indicators of healthy and unhealthy eating habits. Differences in physical activity (PA) between mothers and fathers in the

intervention group and their counterparts in the control group are investigated by the Baecke questionnaire, which has been shown to have good validity. Differences in PA between children in the intervention group and those in the control group are furthermore investigated objectively by an accelerometer for the period of one week, when children reached the age of 4. Mothers' and fathers' PAs are investigated at enrolment and again at 4 years of children's age, while the children's PA is examined only at 4 years of age.

Overall study start date
01/05/2008

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. First-time mothers
2. Receiving services in the participating CHC

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1000 (500 intervention, 500 control)

Total final enrolment
899

Key exclusion criteria
1. Do not speak/understand Swedish
2. Very serious social problems

Date of first enrolment
01/05/2008

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Tomtebodavägen 18A
Stockholm
Sweden
17177

Sponsor information

Organisation
Karolinska Institutet (Sweden)

Sponsor details
Child and Adolescent Public Health Epidemiology
Department of Public Health Sciences
Stockholm
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Sponsor type
University/education

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Research council

Funder Name
The Swedish Council for Working Life and Social Research (2006-0226 and 2011-0413) (Sweden)

Funder Name
The Swedish Research Council (K2006-27X-20069-01-3 and K2012-69X-22058-01-3) (Sweden)

Funder Name
The Research and Development Committee, Stockholm County Council (2006-0324) (Sweden)

Funder Name
The Regional Research Council of the Uppsala and Örebro Health Care Region (Sweden)

Funder Name
Uppsala County Council (Sweden)

Funder Name
The Public Health Committee of Stockholm County Council (0803-377) (Sweden)

Funder Name
The Vårdal Foundation (B2007-006) (UK)

Funder Name
AFA insurance (H-06:05/070001) (Australia)

Funder Name
The Foundation of the Swedish Diabetes Society (TMA2006-004) (Sweden)

Funder Name
The Karolinska Health Care Sciences Postgraduate School (2008) (Sweden)

Funder Name
Faculty Funds of Karolinska Institutet for PhD students (2012 and 2013) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/04/2014		Yes	No
Results article	results	01/08/2017	06/08/2020	Yes	No