

A Healthy School Start

Submission date 13/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/02/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/02/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Parental support to promote healthy dietary and physical activity habits in children: a randomised controlled trial

Study objectives

The overall aim is to develop and evaluate a method to promote healthy dietary and physical activity habits in six-year-old children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board in Stockholm approved on the 23rd June 2010 (ref: 2010/934-31 /1)

Study design

Cluster randomised 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

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

Health condition(s) or problem(s) studied

Overweight, obesity

Interventions

The duration of the intervention is six months. Fourteen classes are randomised to intervention ($n = 7$) and control ($n = 7$) groups. This theory-based intervention (social cognitive theory) is directed at parents with six-year-old children who start school. The intervention consists of two components:

1. When parents in the intervention group have their regular meeting with the health care staff at school they are offered a motivational interview where they discuss issues related to diet, physical activity and sleep. A second motivational interview is offered three months later.
2. Children in class are exposed to ten teacher-led sessions aiming to "take home" messages to enforce parents.

The control groups carry on as usual. Parents and teachers will be offered the intervention components after the project has finished.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Physical activity in the children (counts per minute, intensity and time spent sedentary) will be measured objectively with accelerometers for seven consecutive days
2. Intake of food indicators (fruit/vegetables and energy dense products) will be measured with a self-reported questionnaire
3. Parents' self-efficacy will be measured by self-reported questionnaire
4. Experiences from the study will be collected by interviewing parents and teachers in focus groups

The data will be collected before and after the intervention. Data will also be collected six months after the intervention (follow-up). Data from the study will be analysed with parametric and non-parametric tests.

Secondary outcome measures

Body mass index and waist circumference in the children will be measured by the research team.

The data will be collected before and after the intervention. Data will also be collected six months after the intervention (follow-up). Data from the study will be analysed with parametric and non-parametric tests.

Overall study start date

01/01/2010

Completion date

30/06/2012

Eligibility**Key inclusion criteria**

Schools with families living in varied types of housing (blocks of flats, terraced houses and detached houses), where about 30% of families live in blocks of flats, are invited to participate in the study. Families in these schools with six-year-old children who are starting school are invited to participate in the project.

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

200 families

Key exclusion criteria

1. Schools with a high proportion of families with high socio-economic position
2. Parents/guardians that have difficulties with the Swedish language

Date of first enrolment

01/01/2010

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska Institutet

Stockholm

Sweden

104 62

Sponsor information

Organisation

Health Care Board and Management (Hälsö och sjukvårdens förvaltning) (Sweden)

Sponsor details

Folkhälsoanslaget

Box 6909

Stockholm

Sweden

102 39

Sponsor type

Government

ROR

<https://ror.org/04d5f4w73>

Funder(s)

Funder type

Government

Funder Name

Stockholm County Council (Folkhälsoanslaget) (Sweden) - Sweden and Signhild Engkvist Foundation

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?
Results article	results	13/02/2015		Yes	No