

A Healthy School Start II

Submission date 16/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/01/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/04/2019	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

Background and study aims

Chronic diseases constitute the major part of the disease burden worldwide and also in Sweden and early prevention is strongly recommended. There is a lack of universal parental support programmes focusing on a healthy diet and physical activity in children. These factors are important determinants of health and are also strongly influenced by the socioeconomic status of families. Importantly, a broad implementation of the programme may lead to better public health and reduce social inequalities in health. The aim of the current project is to study the effectiveness of a novel theory-based parental support programme targeting childrens dietary habits, physical activity and body weight in low-income areas.

Who can participate?

All families in these schools with children who are starting school are invited to participate.

What does the study involve?

The Healthy school start programme will take place in approximately 30 school classes in 3 city districts of Stockholm, Sweden, and will be randomly allocated to intervention (programme group) and control groups. The programme consists of three components:

1. Health information material
2. Motivational interviewing (MI) with the parents
3. Teacher-led classroom activities with the children

The control groups carry on as usual. Parents and teachers will be offered the programme after the project has finished. The Healthy school start programme has been tested once and preliminary results are positive. Based on these findings we have adjusted the programme and are planning to start a second round of evaluation in three city districts in Stockholm with a high proportion of inhabitants with a low socio-economic background.

What are the possible benefits and risks of participating?

Participation may lead to better health for the children. There are no risks for the participants taking part in the programme.

Where is the study run from?

The programme will be led by researchers from Karolinska Institutet

When is the study starting and how long is it expected to run for?
The study started in December 2012 and will run till December 2013

Who is funding the study?
The Public Health Fund, Stockholm County Council is funding the project

Who is the main contact?
Dr Gisela Nyberg
gisela.nyberg@ki.se

Contact information

Type(s)
Scientific

Contact name
Dr Gisela Nyberg

Contact details
Karolinska Institutet
Norrbacka plan 3
Stockholm
Sweden
171 76
-
gisela.nyberg@ki.se

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 in pre-school class: a cluster randomised controlled trial

Study objectives

1. The children in the intervention group will significantly decrease the mean BMI z-score compared to the control group
2. The children in the intervention group will significantly increase the mean physical activity and reduce the mean time spent sedentary compared to the control group
3. The children in the intervention group will significantly increase the mean intake of healthy

indicator foods and decrease the mean intake of unhealthy indicator foods

4. The expected effects of the intervention will be moderated by the socio-economic status of the families

5. The expected effects will be mediated by parental self-efficacy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board in Stockholm, Sweden, 15 June 2012, ref: 2012/877-31/5

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

Promotion of diet and physical activity and prevention of overweight and obesity in children

Interventions

The duration of the intervention is six months. Approximately 30 school classes will be randomised to intervention and control groups. This theory-based intervention (social cognitive theory) is directed at parents with six-year-old children who start school. The intervention consists of three components:

1. Health information material
2. Motivational interviewing (MI) with the parents
3. Teacher-led classroom activities with the children

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

Intervention fidelity is paid attention to through coding of MI-sessions and recording of all activities. Process evaluation will be studied by performing interviews and focus group with parents, school staff and decision makers.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The data will be collected before and after the intervention. Data will also be collected six months after the intervention (follow-up). The long term effects will be studied by collecting data 4 years after the intervention.

1. Body mass index and waist circumference in the children will be measured by the research team.
2. Physical activity of the children (counts per minute, time in moderate to vigorous physical activity and time spent sedentary) will be measured objectively with accelerometers for seven consecutive days.
3. Intake of indicators foods (fruit/vegetables and energy dense products) will be measured with a self-reported questionnaire (EPAQ).

Data from the study will be analysed with both quantitative and qualitative methods (mixed method evaluation).

Secondary outcome measures

Parents' self-efficacy will be assessed by self-reported questionnaire

Overall study start date

01/12/2012

Completion date

31/12/2013

Eligibility**Key inclusion criteria**

1. Schools in three city districts of Stockholm with low socio-economic status
2. All families in these schools with children who are starting school are invited to participate

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

Thirty school classes with 350 families.

Total final enrolment

215

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/12/2012

Date of final enrolment

31/12/2013

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska Institutet

Stockholm

Sweden

171 76

Sponsor information

Organisation

Stockholm County Council (Sweden)

Sponsor details

The Public Health Fund

Box 22550

Stockholm

Sweden

104 22

-

landstinget@sll.se

Sponsor type

Government

Website

<http://www.sll.se/>

ROR

<https://ror.org/02zrae794>

Funder(s)

Funder type
Government

Funder Name
Stockholm County Council - Public Health Fund (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?
Results article	results	11/04/2019	15/04/2019	Yes	No