# A healthy generation: a programme to promote physical activity and a healthy lifestyle in children and their families in socioeconomically disadvantaged areas

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
26/08/2019		☐ Protocol		
Registration date 23/09/2019	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/11/2023	Other			

## Plain English summary of protocol

Background and study aims:

There are large social inequalities, seen already from an early age, in dietary habits, physical activity and prevalence of obesity to the disadvantage of children from families with low socioeconomic status. Therefore, it is of importance to promote physical activity and a healthy lifestyle early in life. Effective strategies are needed in order to reach those at highest risk of diseases. Interventions have shown to be more successful when parents are involved. The aim was to study if a preventive lifestyle programme "A Healthy Generation" leads to a physically active and healthy lifestyle, a decreased risk of cardiovascular disease, improved quality of life for children and their families from disadvantaged areas.

## Who can participate?

In this controlled pilot study, all children in grade two (8-9 years), their siblings and their parents living in a socioeconomically disadvantaged municipality outside Stockholm were invited through four schools. Families from two schools that had accepted an invitation to take part in the programme (intervention group) and families from two similar schools in the same area that had not yet implemented the programme (control group) were invited to participate in the study.

## What does the study involve?

The programme consisted of four intervention components, 1) activity sessions, 2) healthy meals, 3) health information and 4) parental support groups. Families with children in grade two (6-7 years) were offered different physical activities at no cost during nine months in collaboration with local organisations and schools. The activity sessions were followed by healthy meals and during the meal sessions the health coordinator discussed different health themes. The parents were also invited to parental support group sessions which were led by qualified staff and organised by the municipality.

What are the possible benefits and risks of participating?

Participation may lead to better health for the families. The risks for the participants taking part in the intervention are minimal.

Where is the study run from?

The evaluation will be led by researchers from the Department of Public Health Sciences at Karolinska Institutet, Sweden.

When is the study starting and how long is it expected to run for? March 2016 to December 2018

Who is funding the study
The Swedish Heart-Lung Foundation and Skandia are 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

#### **ORCID ID**

https://orcid.org/0000-0003-0004-8533

## Contact details

Karolinska Insitutet Solnavägen 1E Stockholm Sweden 113 65 +46766009179 Gisela.Nyberg@ki.se

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

Nil known

# Study information

## Scientific Title

A Healthy Generation - a programme to promote physical activity and a healthy lifestyle in children and their families in socioeconomically disadvantaged areas

## **Study objectives**

The programme will increase physical activity, decrease cardiovascular risk, improve psychosocial health, well-being and quality of life and promote a healthy lifestyle in children and their families in socioeconomically disadvantaged areas

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 30/03/2016, the Regional Ethical Board in Stockholm (Etikprövningsmyndigheten, Tomtebodavägen 18A, 17165 Solna, Sverige; registrator@etikprovning.se; +46-(0)10-475 08 00) ref: 2016/447-31/2, 2016/1254-32, 2017/2379-32

## Study design

Controlled pilot trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Lifestyle habits among families in socioeconomically disadvantaged settings.

#### Interventions

The study was designed as a controlled pilot study. All children in grade two (8-9 years), their siblings and their parents living in a socioeconomically disadvantaged municipality outside Stockholm were recruited through four schools. Families from two schools that had accepted an invitation to take part in the programme (intervention group) and families from two similar schools in the same area that had not yet implemented the programme (control group) were invited to participate in the study.

The duration of the intervention was nine months with four intervention components:

- 1. Activity sessions
- 2. Healthy meals
- 3. Health information
- 4. Parental support groups.

The families in the intervention group engaged in the activity sessions for one hour, twice a week, on one weekday and one weekend day. The activities were free of charge and coordinated by qualified health educators in cooperation with local organisations. At least one parent had to attend on each occasion. The activity sessions were followed by healthy meals and during the meal sessions, the health coordinator discussed different health themes. The parents were also

invited to parental support group sessions which were led by qualified staff and organised by the municipality. The families in the control group were offered to participate in the programme after the intervention, one year later.

## Intervention Type

**Behavioural** 

## Primary outcome(s)

Physical activity measured with accelerometers (GT3X+, Actigragh, LCC, Pensacola, USA) for seven consecutive days.

## Key secondary outcome(s))

Measurements in the children, their siblings and their parents have been carried out by trained research assistants.

- 1. Sedentary time measured with accelerometers (GT3X+, Actigraph, LCC, Pensacola, USA) for seven consecutive days
- 2. Physical activity habits and sedentary behaviour measured with a questionnaire
- 3. Height, weight, sagittal abdominal height, waist circumference and blood pressure measurements measured according to standardised procedures
- 4. Body composition measured with bioelectric impedance
- 5. Muscular strength measured with a maximal step-up test
- 6. Cardiorespiratory fitness measured with a step-up test (KPR-test).
- 7. Cardiovascular/metabolic risk factors; insulin, glucose, cholesterol, CRP and liver enzymes (ALAT/ASAT) measured in blood
- 8. Health related quality of life measured in children and their siblings (the Pediatric Quality of Life Inventory 4.0) and their parents (the Gothenburg Quality of Life Instrument)
- 9. Fidelity to the intervention measured by documenting the families' participation in the programme
- 10. Psychosocial health and well-being explored by individual interviews with the parents and the children
- 11. Experiences of the programme explored by focus groups with the parents and the children
- 12. Facilitating factors for the participating families to continue being physically active after the intervention studied in the families by a questionnaire and by focus groups and individual interviews

## Completion date

20/12/2018

# **Eligibility**

## Key inclusion criteria

1. Families with children in grade two (8-9 years) from two schools that had accepted an intervention to take part in the programme (intervention group) and families from two similar schools in the same area that had not yet implemented the programme (control group)

## Participant type(s)

All

## Healthy volunteers allowed

No

## Age group

Mixed

## Sex

All

## Total final enrolment

67

## Key exclusion criteria

If anyone in the family had already participated in the programme in an earlier school year

## Date of first enrolment

02/03/2016

## Date of final enrolment

20/12/2018

## Locations

## Countries of recruitment

Sweden

## Study participating centre

Karolinska Institutet, Department of Public Health Sciences

Tomtebodavägen 18 A Stockholm Sweden 17177

# Sponsor information

## Organisation

Karolinska Institutet

## **ROR**

https://ror.org/04hmgwg30

# Funder(s)

## Funder type

Not defined

## **Funder Name**

**SKANDIA** 

## **Funder Name**

The Swedish Heart-Lung Foundation

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Data generated and analysed during the study are stored in KI ELN, an electronic notebook. Webpage: https://staff.ki.se/ki-eln-the-electronic-notebook?\_ga=2. 27139514.649422456.1567001962-595697067.1566049627

Type of stored data: ethical applications and approval, material used in data collection, raw data, data analysis files, important correspondence, research notes and publications.

Data storage and sharing: Data will be stored for 10 years and variables can be shared on relevant request, for example to other researchers doing systematic reviews.

Written informed consent has been obtained from all participants.

Anonymisation: All data is anonymised using a code for each participant. The code is stored separately from the data.

Legal restrictions: Sweden, as part of the European Union, adhere to the General Data Protection Regulation (GDPR).

## IPD sharing plan summary

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	results	29/05/2020	01/06 /2020	Yes	No
Results article	results	14/12/2020	16/12 /2020	Yes	No
Results article	Primary and secondary outcomes	27/05/2020	06/11 /2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
Study website	Study website	11/11/2025	11/11 /2025	No	Yes