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

Submission date
26/08/2019

Recruitment status
No longer recruiting

Registration date
23/09/2019

Overall study status
Completed

Last Edited
06/11/2023

Condition category
Other

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

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
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Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Controlled pilot trial

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes