

Space - for physical activity

Submission date 07/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/07/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.forebyggelsescenter.dk/side.asp?side=8&id=12&ver=uk>

Contact information

Type(s)

Scientific

Contact name

Mr Jens Troelsen

Contact details

Campusvej 55

Odense M

Denmark

5230

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jtroelsen@health.sdu.dk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A block randomised controlled trial evaluating the effect of a multilevel intervention to promote physical activity in adolescents

Acronym

Space

Study objectives

The aim of the study is to assess the effect of a multilevel intervention on adolescent daily physical activity and physical fitness in seven intervention schools compared with seven control schools.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study has been considered by the Danish Ethical Committee and they concluded that formal ethics approval was not required. This project is registered at the Danish Data Protection Agency (Datatilsynet) (ref: 2009-41-3628).

Study design

Controlled randomised block design with 2-year follow up

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Physical activity and physical fitness

Interventions

The intervention will comprise four areas. The intervention areas will be aimed at:

1. Active transport
2. The school's outdoor areas
3. Playspots
4. Organised physical fitness

For each of the intervention areas, a number of physical improvements will be implemented in the districts to either modify existing structures or to establish new ones. Furthermore, the physical structural enhancement, distributed on the interventions, will be followed up by organisational interventions that support the possibilities of activity by use of, for instance, activity assistants, changed access conditions or traffic action plans. It is a common feature of the intervention areas that they will be manageable for a municipality to establish and maintain as far as size and financial level are concerned.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Average daily physical activity measured with accelerometer (counts/min/child/day).

The primary outcome will be supported by analyses of time spent in moderate to vigorous activity and time spent sedentary measured with accelerometer (min/day).

Secondary outcome measures

Secondary outcome measures:

1. Overweight measured with waist circumference (cm)
2. Physical fitness measured with 'the Andersen test' (metre)
3. Active transport to/from school measured with diary (times/week)
4. Physical activity in recess periods measured with accelerometer (counts/min)

Predefined explorative outcome measures:

1. The primary and secondary outcome measures will be analyzed for four different subpopulations defined by: physical activity at baseline, parental socioeconomic status, weight status at baseline and gender
2. Grip strength measured with digital hand dynamometer (kg)
3. Time spent on television viewing, computer or other sedentary activities measured with questionnaire (hours/day)
4. Time spent on biking measured with diary (times/week)
5. School satisfaction measured with questionnaire (index five categories of liking school)
6. Self-rated health measured with questionnaire (index four categories)
7. Social network measured with questionnaire (time spent with friends and family)
8. Experience of subjective health complaints measured with questionnaire (numbers and times of multiple experienced health complaints)

Overall study start date

01/04/2010

Completion date

30/06/2012

Eligibility

Key inclusion criteria

Children attending 5th or 6th grade at one of the 14 participating schools in April 2010

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

1348 in total (623 in the intervention group and 725 in the control group)

Key exclusion criteria

Children following special education classes

Date of first enrolment

01/04/2010

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

Denmark

Study participating centre

Campusvej 55

Odense M

Denmark

5230

Sponsor information

Organisation

Trygfonden (Denmark)

Sponsor details

Lyngby Hovedgade 4,2

Kgs. Lyngby

Denmark

2800

-

info@trygfonden.dk

Sponsor type

Industry

Website

<http://trygfonden.dk/>

ROR

<https://ror.org/02rcazp29>

Funder(s)

Funder type

Industry

Funder Name

Trygfonden (Denmark)

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	10/10/2011		Yes	No
Results article	results	12/06/2014		Yes	No
Results article	results	01/02/2017		Yes	No