

# Space - for physical activity

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

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## 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

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### 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?
<a href="#">Protocol article</a>	protocol	10/10/2011		Yes	No
<a href="#">Results article</a>	results	12/06/2014		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No