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Active Living

Submission date 19/10/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 21/10/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 03/06/2019	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Active Living is a programme (or intervention) that looks at the effects of the social and physical environment on the physical activity of children aged 8-12 living in low socioeconomic (i.e. poor or deprived) areas in the Southern-Limburg region of the Netherlands. The aim of this study is to investigate whether children attending schools running the Active Living programme become more active and less sedentary that children attending schools not running the programme.

Who can participate?
All children attending the 6th and 7th grade of participating primary schools.

What does the study involve?
Schools participating in the study are randomly allocated to either the intervention group or the control group. Working groups are formed at intervention schools. These working groups include local stakeholders, parents and an advisor of the Public Health Services (GGD). They try to develop initiatives that encourage children in the neighbourhood to take part in physical activity. The initiatives focus on stimulating physical activity during recess, using active transport to school, and physical activity after school. Schools in the control groups carry on as usual. The effects of the environment and the initiatives on the physical activity of children are investigated four times – in the autumn of 2012, spring 2013, spring 2014, and spring 2015. Children are asked to wear an accelerometer and some of them also asked to wear a GPS device. Furthermore, during each measurement period children and their parents are asked to fill out a questionnaire.

What are the possible benefits and risks of participating?
Potential benefit includes increasing physical activity and decreasing sedentary behavior among primary school children by contributing to the establishment of physical activity-friendly school environments. No risks were identified by taking part in the Active Living project.

Where is the study run from?
A total of 20 schools attended by children from low socioeconomic areas in South Limburg, the Netherlands.

When is the study starting and how long is it expected to run for?
October 2011 to September 2015

Who is funding the study?
Netherlands Organisation for Health Research and Development

Who is the main contact?
Mr Dave Van Kann
d.vankann@fontys.nl

Contact information

Type(s)
Scientific

Contact name
Mr Dave Van Kann

ORCID ID
http://orcid.org/0000-0002-1473-0843

Contact details
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 433884274
d.vankann@fontys.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Active Living: physical activity as a daily habit for primary school children through adaptations in social and physical environment

Study objectives
Children attending Active Living schools are hypothesized to increase physical activity and decrease sedentary behavior more than children attending control schools after changing the physical and social environment.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the University Hospital Maastricht, 26/11/2012, ref: METC 12-4-077

Study design
The intervention study uses a quasi-experimental design with 10 intervention schools and 10 matched control schools. Children (8-12 years-old) attending these schools are measured multiple times, i.e. at baseline, after 6 months, after 18 months, and after 30 months.

Primary study design
Interventional

Secondary study design

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Increasing physical activity and decreasing sedentary behavior.

Interventions
The Active Living study used a quasi-experimental design. In total, 10 schools were included in the Active Living project as intervention schools. A local working group at each school defined the needs of the school and children. They developed and implemented physical and social environmental interventions targeting at either:
1. Stimulating active school transportation
2. Promoting physical activity at school or
3. Promoting physical activity in leisure time
All intervention schools were matched to a control school. These control schools only participated in the measurement, but did not receive any interventions such as the intervention schools did.

Intervention Type
Behavioural

Primary outcome measure
Children's physical activity levels, measured by wearing an accelerometer. Some children were also asked to wear a GPS device. Data was collected at the end of 2012, spring 2013, spring 2014 and spring 2015.

Secondary outcome measures
Neighborhood perceptions, collected using questionnaires given to the children and their parents. Data was collected at the end of 2012, spring 2013, spring 2014 and spring 2015.

Overall study start date
01/10/2011

Completion date
01/09/2015

Eligibility

Key inclusion criteria
1. All children attending 6th and 7th grade of participating primary schools. At baseline, the age range is 8-12 years old
2. Both boys and girls are included

Participant type(s)
All

Age group
Child

Sex
Both

Target number of participants
800

Key exclusion criteria
No exclusion criteria were formulated. All children attending participating primary schools were invited to participate in this study.

Date of first enrolment
01/08/2012

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Maastricht University
P.O. Box 616
Maastricht
Netherlands
6200 MD

Study participating centre
Public Health Services
P.O. Box 2022
Geleen
Netherlands
6160 HA

Sponsor information

Organisation
Maastricht University

Sponsor details
P.O. Box 616
Maastricht
Netherlands
6200 MD

Sponsor type
University/education

Website
www.maastrichtuniversity.nl

Organisation
Public Health Services

Sponsor details
P.O. Box 2022
Geleen
Netherlands
6160 HA

Sponsor type
Other

Website
www.ggdzl.nl

Organisation
Maastricht University

Sponsor details

Sponsor type
Not defined

Website
http://www.maastrichtuniversity.nl/

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Government

Funder Name
Netherlands Organisation for Health Research and Development

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
In a short notice, we intend to publish a development article in which the process of development and the quasi-experimental evaluation will be presented. Furthermore, we intend to publish studies on the effectiveness of interventions on children's physical activity and sedentary behavior during recess. Moreover, we intend to publish an effect evaluation of the Active Living project on daily physical activity levels and sedentary behavior. Besides, we intend to publish several cross-sectional studies using these data. The detailed research questions for these studies have to be formulated in the near future. We hope to submit both effectiveness studies by the end of 2015 or begin 2016.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/12/2015		Yes	No
Results article	results	01/08/2016	03/06/2019	Yes	No