

The prevention of lower extremity physical activity injuries: a school-based randomised controlled trial in children aged 10 - 12 years

Submission date 08/03/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/08/2011	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR580

Study information

Scientific Title

Acronym

iPlay

Study objectives

The promotion of safe sports participation proves effective in a physical education setting, resulting in a reduction of lower extremity injuries in children.

Please note that as of 19/12/2008 the anticipated start and end dates in this record were amended. The previous dates are as follows:

Initial anticipated start date: 01/10/2005

Initial anticipated end date: 01/10/2008

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Ethics Committee of Vrije University Medical Centre approved the study design, protocols and informed consent procedures on 6th July 2006

Study design

Randomised active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

No condition, healthy person

Interventions

The study will be carried out during one school year in primary schools, reaching boys and girls aged 10 - 12 years (7th and 8th grade). Schools will serve as randomisation units to avoid spill-over of the intervention within schools and to enhance control over intervention adherence and compliance.

The injury prevention programme aimed at lower extremity injuries in children aged 10 - 12 years was constructed based on an intervention mapping protocol. In general the injury prevention programme focuses on injury prevention in general and focuses on injury awareness, physical fitness and coordination (motor control). In addition the programme focuses on soccer, tennis, basketball, inline skating and snowboarding. These are the most commonly practiced activities in this age group. The injury prevention programme will be given by the children's teachers as a 9 month course.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Incidence of lower extremity injuries
2. Costs associated with lower extremity injuries

Primary and secondary outcomes measured September/October 2006 and June/July 2007.

Secondary outcome measures

Change in attitudes and behaviour with regards to injury and injury prevention. Primary and secondary outcomes measured September/October 2006 and June/July 2007.

Overall study start date

01/09/2006

Completion date

30/07/2007

Eligibility**Key inclusion criteria**

Primary schools: boys and girls aged 10 - 12 years.

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

2280

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/09/2006

Date of final enrolment

30/07/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1081 BT

Sponsor information**Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

EMGO Institute

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emgo@vumc.nl

Sponsor type

Hospital/treatment centre

Website

<http://www.vumc.nl/>

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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?
Results article	results	23/11/2010		Yes	No