

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

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

Dr D.M. Collard

### Contact details

VU University Medical Center  
EMGO-Institute  
Van der Boechorststraat 7  
Amsterdam  
Netherlands  
1081 BT  
dorine.collard@vumc.nl

## 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

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

+31 (0)20 444 8180

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?
<a href="#">Results article</a>	results	23/11/2010		Yes	No