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

Submission date Recruitment status [X] Prospectively registered 08/03/2006 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 08/03/2006 Completed [X] Results [ ] Individual participant data Condition category Last Edited Other 15/08/2011

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number 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

# Study type(s)

Prevention

## 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(s)

- 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.

# Key secondary outcome(s))

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

# Completion date

30/07/2007

# **Eligibility**

## Key inclusion criteria

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

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

10 years

## Upper age limit

12 years

#### Sex

Αll

#### 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)

#### **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**

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