







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	 Prospectively registered
		 Protocol not yet added
Registration date 08/03/2006	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 15/08/2011	Condition category Not Applicable	 Raw data not yet added
		 Study completed

Plain English Summary

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

Protocol/serial number

Study information

Scientific Title

Acronym

iPlay

Study hypothesis

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

Condition

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

Overall study end date

30/07/2007

Eligibility

Participant 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

Participant exclusion criteria

Does not comply with the above inclusion criteria

Recruitment start date

01/09/2006

Recruitment end date

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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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?
Results article	results	23/11/2010		Yes	No