

The preventive effect of an ankle brace, especially designed for soccer players, on acute ankle injuries in girls amateur soccer players.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23954

Source

NTR

Brief title

Bracing Ankles in Girls Soccer (BAGS)

Health condition

Acute ankle sprain injuries

Sponsors and support

Primary sponsor: Department of Rehabilitation, Physiotherapy Science & Sports, University Medical Center Utrecht, Utrecht, The Netherlands.

Source(s) of monetary or material Support: ZON-MW, the Netherlands Organization for Health Research and Development (financial support)

NEA International BV (supplier of the PSB Sports Kick ankle braces)

Intervention

Outcome measures

Primary outcome

Injury incidence (injuries per 1000 playing hours) and injury severity (soccer-absenteeism).

Secondary outcome

- Brace effectivity in primary and secondary prevention of acute ankle injuries.
- Prognostic value of generalized joint hypermobility on the risk of acute ankle injuries.
- Prognostic value of active (ankle)stability on the risk of acute ankle injuries.
- The effect of the PSB Sports Kick ankle brace on ankle-related functional limitation, experiences by the players during sport activities (e.g. running, jumping, turning).
- Compliance of the intervention group, wearing PSB Sports ankle braces

Study description

Background summary

An ankle sprain, mainly of the inversion type, is one of the most common injuries in soccer and often results in time-loss from play. This disabling injury can cause residual complaints such as instability, chronic ankle pain and functional limitation over time and has a high proportion of recurrences.

A number of measures reduce the incidence of ankle sprains in soccer players. These include neuromuscular (proprioceptive and coordination) training and/ or the use of an external support to decrease inversion and eversion range of movement of the ankle joint (like taping or a semi-rigid braces). The key element in the success of a preventive measure is compliance. We know that this element is higher for the use of ankle braces than the performance of neuromuscular training. Dutch soccer players do not often wear braces during their sport. A national survey in 2007 among Dutch soccer players reported that this is the result of a supposed lack of good fit of the available braces and pinching of the feet in the soccer shoes due to the thickness of the braces and the fear of reduced ball control. Using an ankle brace specifically developed for and in cooperation with soccer players to prevent (recurrent) ankle sprains (PSB Sports Kicx), may very likely contribute to the removal of the above-suggested barriers to wear braces during soccer play. We hypothesize that this brace will reduce the incidence of ankle sprain injuries among amateur girls' soccer players by 50%.

Study objective

We hypothesize that a semi-rigid ankle brace especially designed for soccer players, will reduce the incidence of ankle sprain injuries among amateur girls soccer players by 50%.

Study design

Weekly registration starts 05-09-2016

Intervention starts 31-10-2016

Follow-up ends 29-05-2017

Baseline measurements (e.g. length, weight, single leg balance tests, Beighton score) and questionnaires (e.g. player characteristics and injury history) will be performed < 31-10-2016.

Weekly registration by SMS or e-mail, containing questions about ankle complaints, exposure hours, other injuries, compliance to intervention.

In case of ankle injury: information regarding diagnosis, etiology, injury date, contact vs non-contact, recovery date, medical treatment, absenteeism from school-/ work).

Intervention

The intervention in this study is the Push Sports Kicx ankle brace, a semi-rigid ankle brace especially designed for soccer players. This brace will be used on both sides during all soccer-related activities (training and match).

Contacts

Public

Department of Rehabilitation, Physical Therapy Science & Sports, University Medical Center Utrecht, Utrecht, The Netherlands.

K.M. Thijs

postbus 85500

Utrecht 3508 GA

The Netherlands

Tel: +31652783060

Scientific

Department of Rehabilitation, Physical Therapy Science & Sports, University Medical Center Utrecht, Utrecht, The Netherlands.

K.M. Thijs

postbus 85500

Utrecht 3508 GA

The Netherlands

Tel: +31652783060

Eligibility criteria

Inclusion criteria

The study will comprise soccer clubs from one geographically district affiliated with the KNVB (i.e. the Royal Netherlands Football Association). Clubs are eligible if they have at least one girls team participating in the U19 or U17 competition.

Players are eligible if they are aged 14 - 18 years.

Exclusion criteria

Players will be excluded if they do not master the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated):	05-09-2016
Enrollment:	704
Type:	Anticipated

Ethics review

Positive opinion	
Date:	08-09-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5873
NTR-old	NTR6045
Other	16/298 : METC protocol number

Study results