

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

No registrations found.

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Positive opinion |
| <b>Status</b>                | Recruiting       |
| <b>Health condition type</b> | -                |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON23954

### Source

Nationaal Trial Register

### 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**

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## Scientific

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## 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