The effectiveness and cost-effectiveness of a proprioceptive balance board training programme for the prevention of recurrent acute lateral ankle sprains; a randomised control trial.

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The proposed study evaluates the effect of a proprioceptive balance board training programme on ankle sprain recurrences that is applied to individual athletes after rehabilitation and treatment by usual care.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON30120

Source
ToetsingOnline

Brief title
2BFit

Condition

- Bone and joint injuries

Synonym
ankle sprain; lateral ankle injury

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZONMw

Intervention

Keyword: ankle sprain, effectiveness, prevention, proprioceptive training

Outcome measures

Primary outcome

The primary outcome measure will be incidence of ankle sprain recurrences.

Secondary outcome

Secondary outcome measures will include recurrence severity, pain, feeling of instability, direct and indirect injury costs, and intermediary factors such as knowledge and attitude regarding the prevention of ankle sprain recurrences.

Study description

Background summary

There is strong evidence that athletes have a twofold risk for re-injury after a previous ankle sprain, especially during the first year post-injury. These ankle sprain recurrences can result in disability and can lead to chronic pain or instability in 20 to 50% of these cases. When looking at the high rate of ankle sprain recurrences prolonged rehabilitation is needed in all athletes with ankle sprains in order to prevent ankle sprain recurrences. This prolonged rehabilitation does not need to be supervised by a sports physician or (sports) physical therapist and might also suffice if the injured athletes are encouraged to follow a preventive programme for a certain period of time after their *usual care*. Such an unsupervised preventive programme would keep the medical costs associated with a prolonged rehabilitation to a minimum, would have no additional demand on medical practitioners, and would have large potential positive effects in terms of health and direct medical costs due to ankle sprain recurrences.
The three main research questions that will be addressed in the proposed study are:
1. what is the effectiveness of an unsupervised proprioceptive balance board

training programme given in addition to *usual care* on the incidence of ankle sprain recurrences?
2. what is the cost-effectiveness of an unsupervised proprioceptive balance board training programme given in addition to *usual care* and aimed at the prevention of ankle sprain recurrences?
3. what is the compliance with an unsupervised proprioceptive balance board training programme given in addition to *usual care* and aimed at the prevention of ankle sprain recurrences?
Next to these questions, the link between balance training and the prevention of ankle sprain recurrences will be established from a mechanical and functional point of view.

Study objective

The proposed study evaluates the effect of a proprioceptive balance board training programme on ankle sprain recurrences that is applied to individual athletes after rehabilitation and treatment by usual care.

Study design

Injured athletes will be recruited through emergency rooms, and will be randomised to an intervention group and a control group.

Intervention

The intervention consists of a proprioceptive balance board training programme lasting 8 weeks. Three times a week (30 minutes per session), participants perform 6 different strength and proprioceptive exercises.

Study burden and risks

The participant will be asked to complete a questionnaire each month for 12 months. This questionnaire contains questions on sports participation, working situation and ankle sprains.
In case the participant suffers a nwe ankle sprain, he/she will be asked to complete an injury registration form and a cost-diary.
The intervention is thought not to cause any inconvenience for the subjects in the intervention group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Athlete gets diagnosed with a lateral ankle sprain due to sports
Athlete is at least 18 years of age

Exclusion criteria

Athlete is under the age of 18
Athlete gets diagnosed with another ankle injury than a lateral ankle sprain

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	1052
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL11891.029.06