Treatment of acute ankle sprains in general practice

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To examine the effectiveness of an unsupervised e-health supported neuromuscular training program in combination with usual care in general practice compared to usual care alone in patients with acute lateral ankle sprains in general practice.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON44658

Source
ToetsingOnline

Brief title
trAPP study

Condition

- Joint disorders

Synonym
twisted ankle / ankle ligament injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Ankle, E-Health, Sprain, Treatment

Outcome measures

Primary outcome

a) The total number of re-sprains reported after 1-year follow-up.

A re-sprain is defined as *an ankle sprain occurring as a result of sports participation or other daily activities and which cause one or more of the following:

1. The subject has to stop the sports activity; and/or

2. Cannot (fully) participate in the next planned sports activity; and/or

3. Cannot go to work/school the next day; and/or

4. Needs medical attention (ranging from onsite care by e.g. GP, to personal care by e.g. sports physician

Secondary outcome

a) Subjective recovery after 1-year follow-up, measured on a 7-point Likert scale ranging from *completely recovered* to *worse than ever*. Patients are deemed to be recovered if they rate themselves as *fully recovered* or *strongly recovered* on the Likert scale, whereas those who rate themselves as *slightly recovered* to *worse than ever* are deemed to be not recovered.

b) Pain at rest and during activity (NRS)

c) Function (AFS)

d) Return to sport

e) Cost-effectiveness of the intervention

f) Compliance of the intervention: Subjects are defined to be compliant to the

intervention when they have completed at least 75% of the training sessions.

Study description

Background summary

Ankle sprains are the most frequent traumas of the musculoskeletal system, with yearly around 650.000 new sprains in the Netherlands. Of these, about 130.000 people will visit the general practitioner (GP) each year. The Dutch NHG-guideline summarizes the evidence on the potential treatments for acute ankle sprains; however there is very little guidance for treatment. No optimal treatment modality has proven to be effective in general practice.

Study objective

To examine the effectiveness of an unsupervised e-health supported neuromuscular training program in combination with usual care in general practice compared to usual care alone in patients with acute lateral ankle sprains in general practice.

Study design

Multi-centre open labeled randomized trial with a follow-up of 12 months

Intervention

The intervention group will receive a standardized eight-week neuromuscular training program guided by an App, in addition to the usual care. The control group will receive usual care in general practice alone.

Study burden and risks

There are no risks associated with participation. All patients included in our study will receive the usual care according to the clinical guideline. The only tests that are used are questionnaires, which will take about 10 minutes each to fill in every month. Altogether this will take the patient approximately 2 hours over a period of 1 year. The questionnaires that are used are not associated with physical or physiological discomfort.
In the intervention group, patients will most likely benefit from the used neuromuscular training program in our study, since it can reduce persistent complaints and re-sprains

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with an acute lateral ankle sprain and visit the general practitioner within three weeks of injury
- Between 14 and 65 years
- Informed consent

Exclusion criteria

- A history of an injury of the same ankle during the previous year
- A history of a fracture of the same ankle

- No understanding of Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2014
Enrollment:	169
Type:	Actual

Ethics review

Approved WMO Date:	15-07-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-10-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-12-2014
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-11-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-01-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48615.078.14