Treatment of acute ankle sprains in general practice

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25828

Source
Nationaal Trial Register

Brief title
trAPP-study

Health condition

Acute ankle sprain

Sponsors and support

Primary sponsor: Erasmus Medical Center, Department of General Practice
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

a) Subjective recovery after 1-year follow-up, on a 7-point Likert scale. Patients are deemed to be recovered if they rate themselves as “fully recovered” or “strongly recovered”.

b) Pain at rest and during activity (11 point-NRS)

c) Function (Ankle Function Score)

d) Return to sport

e) Cost-effectiveness of the intervention

f) Compliance of the intervention (completed at least 75% of the training sessions)

Study description

Background summary

Rationale: 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.

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: Randomized Controlled Trial (RCT)

Study population: Patients with an acute lateral ankle sprain, aged between 14 and 65 years, and visiting the general practitioner within three weeks of injury.

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

Main study parameters/endpoints: The total number of re-sprains reported after 1-year follow-up.

Study objective

An unsupervised e-health supported neuromuscular training program, in addition to usual care in general practice, is more effective compared to usual care alone as a treatment for

patients with acute lateral ankle sprains in general practice.

Study design

Online questionnaires will be administered monthly: at baseline, after 4, 8, 12, 16, 21, 26, 31, 35, 39, 43, 47, and 52 weeks follow-up.

Intervention

Group 1. The neuromuscular training program:
Subjects allocated to the intervention group receive a standardized eight-week neuromuscular training program, based on the training program described by Hupperets et al. (2008), in addition to usual care (information leaflet).

Contacts

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Eligibility criteria

Inclusion criteria

Patients with an acute lateral ankle sprain are eligible for this study if they are aged between 14 and 65 years, visit the general practitioner within three weeks of injury and sign an informed consent.

Exclusion criteria

Patients are excluded if: they have a history of an injury of the same ankle during the previous year; they have had a fracture of the same ankle; they have 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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	169
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-09-2014
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	NL4614
NTR-old	NTR4765
Other	80-83910-98-13003 : MEC-2014-250

Study results

Summary results
NA