Versterk je Enkel; Blessurepreventie in je broekzak?

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It is hypothesized that use of the 'Versterk je Enkel' App will increase compliance to the neuromuscular program and, consequently, will decrease ankle sprain recurrence incidence.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21092

Bron
NTR

Aandoening

Ankle sprain, Prevention, App, implementation, Cost-effectiveness, Compliance, Enkelverstuiking, Preventie, Implementatie, Kosten-effectiviteitsanalyse, Compliantie

Ondersteuning

Primaire sponsor: EMGO Institute for Health and Care research of the VU University Medical Center
VeiligheidNL

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome measures will be compliance to the prescribed eight-week program.

Toelichting onderzoek

Achtergrond van het onderzoek

Summary

BACKGROUND

Ankle sprains continue to pose a significant burden to the individual athlete, as well as society as a whole. However, despite ankle sprains being the single most common athletic injury and despite an active approach by various Dutch organisations in implementing our epidemiological knowledge on cost-effectiveness, large-scale community uptake of preventive measures, and thus actual prevention of ankle sprains, is lagging well behind.
In an attempt to bridge this implementation gap, VeiligheidNL looked into the possible role of new (social) media and has developed an freely available interactive App ('Versterk je Enkel) that contains -next to general advice on bracing and taping - the cost-effective neuromuscular program. This provides the user with, amongst others, videos and an interactive exercise schedule.
It is a general belief that such interactive, online and mobile methods of information transfer are the way forward in implementation efforts. However, this has not yet been formally established for the uptake of evidence injury preventive measures and - although user reviews are possible - the 'Versterk je Enkel' App has not been evaluated against the 'regular' approach to advocate the neuromuscular program on paper and DVD.

AIM

The aim of the proposed project is to evaluation the implementation value of the 'Versterk je Enkel' App as compared to the usual practice of providing injured athletes written materials. Our hypothesis is that use of the 'Versterk je Enkel' App will increase compliance to the prescribed program and, consequently, will decrease ankle sprain recurrence incidence.

DESIGN

The proposed study will be a randomized controlled trial. After stratification for ankle sprain severity and main medical caregiver participants will be randomized to two study groups. One group will receive care as usual, i.e.. standardized eight-week proprioceptive training program consisting of a balance board and an instructional booklet. The other group will receive the same program and balance board. However, for this group the instructional booklet is exchanged by the interactive 'Versterk je Enkel' App.

OUTCOME MEASUREMENTS & FOLLOW-UP

Primary outcome measures will be compliance to the prescribed eight-week program. Secondary outcome measures include injury recurrence incidence, costs of injury (and cost-effectiveness of the intervention), as well as barriers and facilitators towards the use of the eight-week training program, including knowledge and attitude regarding the prevention of ankle sprain recurrences.
Compliance (primary outcome) follow-up measurements will commence after randomization and will take place weeks for the duration of the program (8 weeks). The follow-up measurements will gather information for each participant on the number, sets and repetitions of prescribed exercises undertakes. In addition, questions will be asked about the clarity of the instructions and the difficulty of the exercises.

After 8 weeks a follow-up questionnaire will measure residual complaints of the initial ankle sprain. Both pain and feeling of giving way will be scored on five-point Likert scale for a series of questions. At this last follow-up knowledge, attitude, barriers and facilitators regarding (recurrent) ankle sprain prevention will be measured again in all participants.

Recurrence injury incidence and cost of injury outcomes will take place once a month for a total of 12 months. The follow-up measurements will gather information for each participant on ankle sprains sustained during the preceding month, and time at risk during the preceding month (exposure). Finally, the follow-up questionnaires will measure residual complaints of the initial ankle sprain. Both pain and feeling of giving way will be scored on five-point Likert scale for a series of questions. At the last follow-up (12 months) knowledge, attitude, barriers and facilitators regarding (recurrent) ankle sprain prevention will be measured again in all participants.
In order to evaluate the cost-effectiveness of the allocated interventions, subjects who sustain an ankle sprain recurrence will receive a cost-diary. From these cost-diaries direct and indirect costs resulting from the sustained ankle sprain recurrence can be calculated for use in an economic evaluation. The economic evaluation will be performed from a societal perspective.

Countries of recruitment: The Netherlands

Doel van het onderzoek

It is hypothesized that use of the 'Versterk je Enkel' App will increase compliance to the neuromuscular program and, consequently, will decrease ankle sprain recurrence incidence.

Onderzoeksopzet

When a potential participant responds to one of our calls, he or she will be contacted by phone. During this initial contact the background and proceedings of the proposed study will be explained and an email will be sent containing a link to the baseline questionnaire and

informed consent, which he or she is required to complete within one week.

Compliance (primary outcome) follow-up measurements will commence after randomization and will take place weekly for the duration of the program (8 weeks). The follow-up measurements will gather information for each participant on the number, sets and repetitions of prescribed exercises undertakes. In addition, questions will be asked about the clarity of the instructions and the difficulty of the exercises.

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In order to evaluate the cost-effecitveness of the allocated interventions, subjects who sustain an ankle sprain recurrence will receive a cost-diary. From these cost-diaries direct and indirect costs resulting from the sustained ankle sprain recurrence can be calculated for use in an economic evaluation.

Onderzoeksproduct en/of interventie

After subjects have finished ankle sprain treatment by means of usual care, they will be randomized to any of the two study groups. Subjects allocated to the 'regular' intervention group will receive care as usual, i.e. a standardized eight-week proprioceptive training program consisting of a balance board (Avanco AB, Sweden) and an instructional booklet. This program has been shown to be effective in reducing recurrence injury risk in previous randomized controlled studies.

Subjects allocated to the 'App' group will also receive a balance board (Avanco AB, Sweden), but the standardized eight-week proprioceptive training program provided through an interactive smartphone application which is freely available for Android and iOs users. These two platforms are the most commonly used operating systems on smartphones (of all smartphones 46.9% runs on android, 28,7% on iOs).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Individuals who have sustained an ankle sprain within the past two months, and who are currently being treated for that injury by either a physiotherapist, physician, sports physician, or orthopedic surgeon are eligible for inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2013
Aantal proefpersonen:	190
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3839
NTR-old	NTR4027
Ander register	ZonMw : 50-52500-98-014
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A