Braces versus proprioceptive exercise for the secondary prevention of ankle sprains: a randomised controlled trial.

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The proposed four-way randomised controlled trial evaluates the cost-effectiveness the current ruling widespread Royal Dutch Physiotherapy Association (KNGF) guideline (i.e. this guideline is being used by physical therapists, (sports) physicians,...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23783

Bron
NTR

Verkorte titel
ABBA3

Aandoening

Recurrent ankle sprains

Ondersteuning

Primaire sponsor: VU University medical center
Overige ondersteuning: The Netherlands Organisation for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Objective(s) / research question(s):

To evaluate the cost-effectiveness the current ruling widespread Royal Dutch Physiotherapy Association guideline, in which the combined use of braces and proprioceptive training after ankle sprain treatment is advocated (usual care), against the use of no secondary preventive measures, as well as braces and proprioceptive training as separate secondary preventive measures.

Study Design:

Randomised Controlled Trial.

Study Population(s) / datasets:

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 orthopaedic surgeon are eligible for inclusion.

Intervention:

Subjects allocated to either the ‘usual care’ or brace group will receive an Aircast A60 ankle brace. They will be strongly advised to wear this ankle brace during competition, as in the current ruling KNGF guideline.
Subjects of either the ‘usual care’ or proprioceptive group will receive a standardized eight-week proprioceptive training programme.

Outcome measures:

The primary outcome measures will be incidence of ankle sprain recurrences. Secondary outcome measures include recurrence severity, residual complaints, and knowledge and attitude regarding the prevention of ankle sprain recurrences.

Sample size calculation / data analysis:

A total of 476 participants is required at baseline. All analyses will be carried out according to the intention-to-treat principle. Cox-regression analysis will be used to compare ankle recurrence risk between the intervention and control groups.

Economic evaluation:

The aim of the economic evaluation will be to determine and compare the total costs for subjects in all four trial arms, and to relate these costs to the effects of these groups. The economic evaluation will be performed alongside the randomised controlled trial and from a societal perspective.

Time schedule:

The proposed study will have a duration of 3 years and will start in September 2009. Recruitment will last 9 months until September 2010. Follow-up lasts exactly 12 months for each subject, final measurements will take place in September 2011.

Doel van het onderzoek

The proposed four-way randomised controlled trial evaluates the cost-effectiveness the current ruling widespread Royal Dutch Physiotherapy Association (KNGF) guideline (i.e. this guideline is being used by physical therapists, (sports) physicians, as well as orthopaedic surgeons), in which the combined use of braces and proprioceptive training after ankle sprain treatment is advocated (usual care), against the use of no secondary preventive measures, as well as braces and proprioceptive training as separate secondary preventive measures. This overall aim can be subdivided in the three main research questions that will be addressed in the proposed study:

1. Is there a difference in effectiveness on the incidence of recurrent ankle sprains between the four groups?

2. Is there a difference in direct and indirect costs related to recurrent ankle sprains between the four groups?

3. Is there a difference in other related ankle sprain complaints (e.g. chronic instability, pain, feeling of giving way) between the four groups?

Onderzoeksopzet

The proposed study will have a duration of 3 years (36 months) and will start in January 2010. After a start-up period of three months, the recruitment for the intervention is intended to start in March 2010. Recruitment will last 9 months until December 2010. Although this might

seem as a rather long inclusion period this period will span the second half of the Dutch 2009-2010 sporting season, as well as the start of the 2010-2011 season. Since the follow-up lasts exactly 12 months for each subject, final measurements will take place in December 2011. Following the intervention, 12 months are available for analyses and interpretation of the data, as well as communicating results to the field of practice.

Onderzoeksproduct en/of interventie

After subjects have finished ankle sprain treatment by means of usual care, they will be randomised to any of the four study groups.

Subjects allocated to the ‘usual care’ and brace group will receive an Aircast A60 ankle brace. They will be strongly advised to wear this ankle brace during competition, as in the current ruling KNGF guideline.

Subjects of the ‘usual care’ and proprioceptive group will receive a standardized eight-week proprioceptive training programme. The programme is a modification of the low intensity programme previously proven effective for the prevention of ankle sprain recurrences in volleyball and is recently proven effective as a home based individual training programme in another RCT. Each subject of the intervention group will receive a balance board (Avanco AB, Sweden), and an instructional booklet.

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 orthopaedic surgeon are eligible for inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Individuals with ankle fractures.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	476
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-01-2010
Soort:	Eerste indiening

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	NL2040
NTR-old	NTR2157
CCMO	NL31221.029.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A