

Adherence to orthopaedic shoes

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

Samenvatting

ID

NL-OMON22073

Bron

NTR

Verkorte titel

Adherence to orthopaedic shoes

Aandoening

Diabetic foot ulcer

Ondersteuning

Primaire sponsor: University of Twente

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion patients being adherent.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Diabetic foot ulcers are a leading cause of hospitalization, amputation and high treatment costs. Personalized orthopaedic shoes are considered essential to prevent (re)ulcerations, and adherence to this footwear is crucial. However, adherence to orthopaedic footwear is often low and there is a lack of insight in methods to improve this adherence. We propose a novel care approach, motivational interviewing (MI) and a digital shoe-fitting procedure, to improve adherence to custom-made footwear and to be (cost-) effective. The aim of this trial is to assess the (cost-)effectiveness of this novel care procedure (MI combined with digital fitting) compared to the usual care (no MI and traditional casting-based fitting) in terms of footwear adherence and ulcer prevention.

Objectives of the study:

Primary objective: To compare the proportion of patients who are sufficiently adherent to the use of their orthopaedic shoes, that is, take at least 80% of their total steps with custom-made footwear between the patients receiving the novel care procedure and the usual care. Secondary objectives: To compare the level of adherence to the use of orthopaedic shoes of patients between novel and usual care and the proportion of patients (re-) experiencing complications up to one year after receiving their shoes. To compare patients' knowledge about the aim of custom-made footwear, satisfaction with information given by podiatrists, patients' behavioural intentions and satisfaction with footwear. To assess the MI-trained podiatrists' knowledge about MI, experiences and attitudes towards applying MI in this group of patients. To assess the difference in costs and patient-perceived quality of life, between patients receiving novel care and usual care and the cost-effectiveness of the new digital scanning procedure with motivational interviewing compared with the traditional procedure.

Study design:

A randomized controlled trial with (cost-)effectiveness analysis and qualitative and quantitative process analyses.

Study population:

220 patients with diabetes mellitus, who are identified with risk profiles 2, 3 or 4, and with and without previous ulcers or callus, will be included. These patients have also a prescription for orthopaedic shoes.

Doel van het onderzoek

Currently there is little knowledge about the effectiveness of (biopsychosocial) interventions and the cost-effectiveness of adherence to orthopaedic shoes has not been studied at all. Therefore the aim of the current study is to assess the (cost-)effectiveness of a novel care procedure (MI combined with digital fitting) compared to the usual care (no MI and traditional casting-based fitting) in footwear adherence and ulcer prevention. This study will generate

insights into the socio-economic impact of the novel care procedure on adherence to orthopaedic shoes. These are crucial steps towards better ulcer prevention in people with diabetes at high-risk.

Onderzoeksopzet

-T2: Initial eligibility screen, study information to participant, initial willingness to participate and crosscheck inclusion/exclusion criteria

-T1: Informed consent, final eligibility screen, allocation and in depth interview

T0: Receiving first pair of orthopaedic shoes, demographic and disease-related characteristics, physical characteristics, RAND-36 V2.0, EQ-5D-5L, iMCQ

T1: Data transfer of shoe-sensors, activity registration

T2: Data transfer of shoe-sensors, activity registration, RAND-36 V2.0, EQ-5D-5L, and in depth interview or MOS2

T3: Data transfer of shoe-sensors

T4: Data transfer of shoe-sensors, RAND-36 V2.0, EQ-5D-5L, iMCQ and MOS2

The timepoint will as far as possible combined with consultation of usual care.

Onderzoeksproduct en/of interventie

One group will receive motivational interviewing combined digital fitting of orthopaedic shoes and the other group will receive no motivational interviewing combined with traditional fitting of orthopaedic shoes.

Contactpersonen

Publiek

Universiteit Twente
M. Jongebloed-Westra

0534896209

Wetenschappelijk

Universiteit Twente
M. Jongebloed-Westra

0534896209

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients who are 18 years or older, with a clinical diagnosis of diabetes mellitus type 1 or 2, and with or without previous ulcers or callus, will be included. They are identified with risk profiles 2, 3 or 4, according to the "zorgmodule preventie diabetische voetulcera 2014". Participants in the possession of a prescription for orthopaedic shoes (OSA).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients will be excluded if they didn't get a prescription for custom-made orthopaedic shoes, but instead a adaption to convection shoes (OVAC) or semi-orthopaedic shoes (OSB). They will also be excluded if they have an active ulcer, active Charcot, active foot infection or aren't able to walk, or if they are unable to read and understand the study instructions.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	03-06-2019
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL7710
Ander register	METC Arnhem-Nijmegen : METC 2019-5141

Resultaten