Study Orthopedic Footwear Adherence (SOFA)

Gepubliceerd: 16-01-2017 Laatst bijgewerkt: 13-12-2022

Rationale: Custom-made orthopedic shoes (OS) are frequently prescribed to patients with various pathologies like: diabetes, to prevent originating or recurrence of foot ulcers; rheumatoid disorders or degenerative foot disorders, to reduce pain and...

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

Samenvatting

ID

NL-OMON21554

Bron
NTR

Verkorte titel
SOFA

Aandoening

Studied health conditions:
Diabetes Mellitus, rheumatoid disorders, degenerative foot deformities, central neurologic disorders ,and other pathologies

Ondersteuning

Primaire sponsor: University Medical Center Groningen
T. Lutjeboer, MSc.
Prof. dr. K. Postema
Overige ondersteuning: OntwikkelingsFonds voor Orthopedisch Maatschoen-technisch bedrijf (OFOM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The objective of the intervention study is to examine whether a simple intervention (knowledge about the actual purpose of the study (monitoring adherence) and feedback on their actual use of OS compared to the intended use of OS) has an effect on the patient’s use of OS.

The objective of the longitudinal study is to objectively evaluate the adherence of use of OS in a population with various pathologies over a period of 18 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Custom-made orthopedic shoes (OS) are frequently prescribed to patients with various pathologies like: diabetes, to prevent originating or recurrence of foot ulcers; rheumatoid disorders or degenerative foot disorders, to reduce pain and support anatomical foot deformities; and muscle disorders, to enhance stability. The prerequisite of the effect of OS is their use. The assessment of adherence of use of OS is necessary for effective and efficient treatment planning. Nowadays, adherence of use of OS has been assessed using subjective methods like: questionnaires, interviews or diaries. These subjective methods have issues with accuracy and reliability that may lead to recall and response bias or missing data points. A new technology to objectively assess OS adherence is now available. This small temperature sensor can be embedded in the insole of a patient’s shoe. The technology of using temperature to assess use and non-use of OS is validated and proven reliable. The “Monitor Orthopaedic Shoes” (MOS) questionnaire will be used to identify factors that influence use of OS. The effect of OS adjustments on their use will be assessed.

Objective: To evaluate the adherence of patient’s use of OS.
Study design: An intervention study (3 months, 300 participants) and a longitudinal study (18 months, 1000 participants (300 from the intervention study and 700 new participants)).
Study population: 1000 patients with various pathologies with their first-ever prescribed OS.
Intervention: 300 participants are included in the intervention study: 100 in the control group without knowledge about the actual purpose of the study (adherence monitoring based on temperature data inside the shoe), 100 in intervention group1 with knowledge about the actual purpose of the study (adherence monitoring based on temperature data inside the shoe) and 100 in intervention group2 with knowledge about the actual purpose of the study (adherence monitoring based on temperature data inside the shoe) and provided with feedback about their actual use of OS compared to their intended use of OS. The control group and intervention group1 receive no feedback at all. After 3 months the 300 participants transfer to the longitudinal study accompanied with 700 new participants. The intervention groups will be viewed as separate groups in the longitudinal study. The duration

of the longitudinal study is 18 months.

Main study parameters: Objective (Orthotimer sensor) and subjective (diary and MOS) use of OS (in days/week and hours/days), relative use of OS (actual use of OS as a percentage of intended use of OS), number of OS adjustments, use and usability of OS measured with a validated questionnaire (MOS).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks associated with participating in these studies are negligible. The sensor embedded in the insole of the shoe provides no limitations to the function of the OS. The sensor is not visible and covered with the regular cover. The burden for the patient consists of six extra appointments with the OS company for data collection and filling in a 7-days diary and a short questionnaire (MOS) before these six appointments.

Doel van het onderzoek

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Objective: To evaluate the adherence of patient’s use of OS.

Onderzoeksopzet

Intervention data analyses will be assessed after n=300 completed 3 months of the total 18 months.

Longitudinal data analyses will be assessed after n=1000 completed the 18 months of data collection.

Onderzoeksproduct en/of interventie

: 300 participants are included in the intervention study: 100 in the control group without knowledge about the actual purpose of the study (adherence monitoring based on temperature data inside the shoe), 100 in intervention group1 with knowledge about the

actual purpose of the study (adherence monitoring based on temperature data inside the shoe) and 100 in intervention group2 with knowledge about the actual purpose of the study (adherence monitoring based on temperature data inside the shoe) and provided with feedback about their actual use of OS compared to their intended use of OS. The control group and intervention group1 receive no feedback at all. After 3 months the 300 participants transfer to the longitudinal study accompanied with 700 new participants. The intervention groups will be viewed as separate groups in the longitudinal study. The duration of the longitudinal study is 18 months.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients with a prescription for their first pair of OS

• Mentally competent (“wilsbekwaam”)

• Aged 18 years and older.

• Able to read and speak Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Previous experience with OS.

• Mentally incompetent.

• Aged 17 years old or younger.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	17-01-2017
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-01-2017
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	NL6186
NTR-old	NTR6342
Ander register	University Medical Center Groningen : METC 2016.506

Resultaten