Study Orthopedic Footwear Adherence (SOFA)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21554

Source
NTR

Brief title
SOFA

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
T. Lutjeboer, MSc.
Prof. dr. K. Postema
Source(s) of monetary or material Support: OntwikkelingsFonds voor Orthopedisch Maatschoen-technisch bedrijf (OFOM)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary objectives of both studies is to identify factors that influence the adherence of use of OS. The number of OS adjustments, the use of diaries and a questionnaire (MOS) about use and usability of OS will be assessed.

Study description

Background summary

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.

Study objective

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

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.

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.

Contacts

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Eligibility criteria

Inclusion criteria

• Patients with a prescription for their first pair of OS

• Mentally competent (“wilsbekwaam”)

• Aged 18 years and older.

• Able to read and speak Dutch

Exclusion criteria

• Previous experience with OS.

• Mentally incompetent.

• Aged 17 years old or younger.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-01-2017
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-01-2017
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	NL6186
NTR-old	NTR6342
Other	University Medical Center Groningen : METC 2016.506

Study results