Sensor Validity

Gepubliceerd: 19-12-2016 Laatst bijgewerkt: 18-08-2022

Asses the validity and feasibility of a temperature sensor for adherence monitoring in orthopedic footwear

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22890

Bron
Nationaal Trial Register

Aandoening

healthy individuals

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: OntwikkelingsFonds voor Orthopedisch Maatschoen-technisch bedrijf (OFOM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

use of footwear in hours per day based on sensor
use of footwear in hours per day based on camera

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND: Orthopedic footwear is frequently prescribed to a wide variety of patients. Adherence of use of orthopedic footwear is a prerequisite of their effectiveness, but has mostly been assessed using methods, like questionnaires, interviews or diaries, with poor accuracy and reliability. A recent study has shown that temperature can be used to assess orthopedic footwear adherence, however, the sensor used could only collect data over a short period of time and had relatively large dimensions. A new technology is available, comprising a temperature sensor that is small and capable of long-term data collection (>100 days).

AIM: To assess the validity and feasibility of a new temperature sensor for measuring footwear use and nonuse in healthy individuals.

METHOD: In ten healthy volunteers, the validity of a new temperature sensor to discriminate between time periods of use and nonuse of footwear over a period of 48 hours was assessed. Footwear use measured with the sensor was compared to footwear use measured with a 1-minute time-lapse sports camera secured to the shoelace and focused on the lower leg. The correlation coefficient between footwear use based on the sensor and camera was calculated. The ease of the installation of the sensor in the insole and the data collection and analysis were assessed as feasibility criteria.

RESULTS: Mean footwear use measured with the camera was 8.10 (±2.46) hours per day, and measured with the sensor 8.16 (±2.37) hours per day. There was a strong correlation between footwear use assessed by camera and by sensor, r = 0.995.

DISCUSSION & CONCLUSION: The temperature sensor is valid and feasible for adherence monitoring in (orthopedic) footwear. The installation of the sensor, in the insole of the subjects' preferred footwear, and the data collection were performed easily.

Doel van het onderzoek

Asses the validity and feasibility of a temperature sensor for adherence monitoring in orthopedic footwear

Onderzoeksopzet

footwear use was determined over a period of 48 hours with both sensor and camera

Onderzoeksproduct en/of interventie

n.a

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

healthy individual

shoe size between 37 and 45

in possession of a shoe with shoe laces

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

n.a.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-08-2016
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-12-2016
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	NL6185
NTR-old	NTR6341
Ander register	University Medical Center Groningen : METC 2016.323

Resultaten