The cost-effectiveness and cost-utility of monitoring foot temperature at home to prevent foot ulcer recurrence in patients with diabetes

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At-home infrared temperature monitoring of the foot in addition to usual care, is cost-effective and saves costs per quality adjusted life year gained in the prevention of foot ulcer recurrence in patients with diabetes, compared to usual care alone

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

Samenvatting

ID

NL-OMON25946

Bron
Nationaal Trial Register

Verkorte titel
DIATEMP

Aandoening

Diabetes mellitus, diabetic foot, foot ulcer

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Amsterdam
Overige ondersteuning: ZonMw, The Netherlands organization for Health Research and Development.

Dutch Society for Podiatrists

ProVoet, branche organisation for pedicures

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- The proportion of patients with a foot ulcer recurrence on the plantar foot or medial and lateral forefoot surface during 18 months follow-up
- Cost (savings) per patient without a recurrent foot ulcer and per quality adjusted life year

Toelichting onderzoek

Achtergrond van het onderzoek

In diabetic foot practice it proves difficult to prevent foot ulcer recurrence in patients with diabetes mellitus. Care providers and patients are in need of adjunctive ways to prevent foot ulcer recurrence. The home monitoring of foot temperatures, for early recognition and treatment of pre-signs of ulceration proves to be a promising approach. Despite that previous studies demonstrated the efficacy of the intervention, it is currently not (widely) applied in preventative foot care. Data that confirm earlier findings, data on cost-effectiveness and utility, and implementability are lacking.

This multicenter single-blinded randomized controlled trial with a patient follow-up of 18 months aims to assess the cost-effectiveness and cost-utility of at-home foot temperature monitoring to reduce the incidence of foot ulcer recurrence in patients with diabetes mellitus, in comparison to usual care.

Doel van het onderzoek

At-home infrared temperature monitoring of the foot in addition to usual care, is cost-effective and saves costs per quality adjusted life year gained in the prevention of foot ulcer recurrence in patients with diabetes, compared to usual care alone

Onderzoeksopzet

1. 0 months: Baseline screening assessment: medical history and physical assessment, randomization, study instructions

2. Within 3 months after baseline: Biomechanical and activity assessment: barefoot and in-shoe pressure measurement, one-week activity and adherence monitoring.

3. Every three months: Proces monitoring for primary outcome and medical consumption, cost-data, and quality of life.

Onderzoeksproduct en/of interventie

The intervention consists of usual care added with at-home daily measurement of foot temperature at 6 predefined locations on both feet + max 1 or 2 locations based on ulcer history or pre-ulcer status, if different than predefined locations. If foot temperature is abnormal (i.e. >2.2 degrees celcius between same locations on both feet) on 2 consecutive days, the patient is instructed to contact the podiatrist, possibly for further foot diagnosis, and to reduce ambulatory activity until temperatures are normalized.

Usual care consists of: once every 1-3 months foot screening and/or foot care by a fot care specialist, patient education, and, if indicated, therapeutic footwear

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diabetes mellitus type 1 or 2;

2. Age 18 or above;

3. Loss of protective sensation based on the presence of peripheral neuropathy;

4. Recent history of a foot ulcer or foot amputation (preceding 2 years)

5. Ability to provide informed consent

6. Ambulatory status

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active foot ulceration or open amputation site

2. Active Charcot neuro-osteo arthropathy.

3. Active foot infection, based on criteria of the PEDIS classification

4. Amputation proximal to the Chopart joint in boot feet

5. Critical limb ischemia (according to PEDIS classification)

5. Severe illness that would make 18-months survival unlikely, based on the clinical judgement by the physician or podiatrist.

6. Concomitant severe physical or mental conditions that limit the ability to follow the instructions for the study, based on the clinical judgment by the physician or podiatrist.

7. Current use of home-monitoring of foot temperature.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	304
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44744
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5294
NTR-old	NTR5403
CCMO	NL52735.018.15
OMON	NL-OMON44744

Resultaten

Samenvatting resultaten
None