# Comprehensive load-capacity model of diabetic foot ulcer healing

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To unravel underlying biomechanical and behavioural mechanisms of foot ulcer healing in a comprehensive load-capacity model, and design personalized education based on model outcomes. We hypothesise that: - Lower cumulative plantar tissue stress...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON28277

**Bron**
Nationaal Trial Register

**Verkorte titel**
DIALOAD

**Aandoening**

Diabetes mellitus, diabetic foot disease, foot ulcer

### Ondersteuning

**Primaire sponsor:** Amsterdam Movement Sciences and ZGT Wetenschapsfonds
**Overige ondersteuning:** Amsterdam Movement Sciences and ZGT Wetenschapsfonds

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Time to foot ulcer healing

# Toelichting onderzoek

### Achtergrond van het onderzoek

Diabetic foot ulcers pose an enormous burden on individuals and society. Better understanding and faster healing of these ulcers is paramount. With DIALOAD, we aim to unravel underlying biomechanical and behavioural mechanisms of diabetic foot ulcer healing in a comprehensive load-capacity model, and explore design of personalised education based on model outcomes.

DIALOAD is a 20-weeks prospective multicentre observational cohort study at Dutch hospitals (Amsterdam UMC, location AMC and VUmc; ZGT; Isala), including patients with diabetes mellitus and a plantar foot ulcer. Our comprehensive load-capacity model will be based on three key aspects of foot-loading: offloading device biomechanics, daily activity and device adherence.

For offloading device biomechanics, we will perform barefoot and in-device plantar pressure measurements during midgait steps. For daily activity, participants will be applied with an inertial sensor, to obtain detailed individual activity classification and daily-life gait patterns. Temperature sensors placed inside participants' offloading device are used to measure device usage on a continuous 20-weeks basis, and in combination with gait patterns device adherence will be assessed. Such detailed and long-term biomechanical, activity and adherence profiles will lead to the most comprehensive load-capacity model of diabetic foot ulcer healing currently existing.

Via multivariate regression modelling the association between the model and its components with diabetic foot ulcer healing will be established. Considering these profiles are amenable, based on the model outcomes and qualitative interviews with patients, we will explore the design of personalised education, to bridge this project with clinical applications and future research opportunities.

### Doel van het onderzoek

To unravel underlying biomechanical and behavioural mechanisms of foot ulcer healing in a comprehensive load-capacity model, and design personalized education based on model outcomes.

We hypothesise that:
- Lower cumulative plantar tissue stress shortens the time to ulcer healing.
- A comprehensive load-capacity model to calculate cumulative plantar tissue stress (as described in the summary) better predicts time to foot ulcer healing compared to the current model (Lazzarini et al., 2019).

### Onderzoeksopzet

First measurement (week 0) – hospital-visit: participant provides informed consent.

Participant is provided with offloading device, with an adherence sensor added to the device. A MoveMonitor (McRoberts, The Hague) will be provided to register daily activity during one-week following. Furthermore, logbook and fall calendar will be completed.

Second measurement (week 2) – hospital-visit: barefoot and in-shoe plantar pressure measurements during mid-gait steps. Furthermore, questionnaires (SF-36) will be completed.

Last measurement (ulcer healed or week 20) – hospital-visit: Questionnaires (SF-36) will be completed.

Week 0, 4 and 8: daily activity measurements for 1 week.

Entire measuring period (20 weeks): offloading device adherence measurements

If there is a biomechanical change of the foot or change of offloading device, barefoot and in-shoe plantar pressure measurements will be repeated.

**Onderzoeksproduct en/of interventie**

None

# Contactpersonen

## Publiek

Amsterdam UMC, location AMC
Chantal Hulshof

020-5666915

## Wetenschappelijk

Amsterdam UMC, location AMC
Chantal Hulshof

020-5666915

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen

## (Inclusiecriteria)

- Age ≥ 18 years
- Diabetes mellitus type 1 or 2
- Plantar foot ulcer – University of Texas grade 1A or 2A
- Loss of protective sensation
- Ambulatory status

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Treated with a non-removable total contact cast
- Open amputation site
- Active Charcot neuro-osteo arthropathy
- Plantar ulcer on the contralateral foot
- Wound, Ischemia, foot Infection (WIfI), ischemia score 3

# Onderzoeksopzet

## Opzet

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

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-01-2021 |
| Aantal proefpersonen: | 40 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

**Toelichting**
Not applicable

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 11-12-2020 |
| 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 | NL9117 |
| Ander register | METC AMC : W19_429 # 19.495 |

# Resultaten

**Samenvatting resultaten**
Not applicable