

# Comprehensive load-capacity model of diabetic foot ulcer healing

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON28277

### Source

Nationaal Trial Register

### Brief title

DIALOAD

### Health condition

Diabetes mellitus, diabetic foot disease, foot ulcer

## Sponsors and support

**Primary sponsor:** Amsterdam Movement Sciences and ZGT Wetenschapsfonds

**Source(s) of monetary or material Support:** Amsterdam Movement Sciences and ZGT Wetenschapsfonds

## Intervention

## Outcome measures

### Primary outcome

Time to foot ulcer healing

### Secondary outcome

- Percentage healed foot ulcers at 12 weeks. We hypothesize the same for percentage healed foot ulcers at 12 weeks as for the primary outcome.
- Percentage healed foot ulcers at 20 weeks. We hypothesize the same for percentage healed foot ulcers at 20 weeks as for the primary outcome.
- Barefoot and in-device plantar pressures: peak pressure, pressure time integral, pressure gradient. We hypothesize that lower peak pressure and pressure time integral shortens the time to ulcer healing. Pressure gradient is an exploratory outcome.
- Weight-bearing activity: number of daily steps, variation in daily steps, bouts, bout duration, walking symmetry, variability, stability and regularity. We hypothesize that lower number of daily steps is associated with shorter ulcer healing times. The other outcomes are exploratory, as barely or no previous research on these outcomes is available in this population.
- Device adherence: percentage of steps / hours per day, percentage of steps / daily hours per weight-bearing activities duration, percentage of steps / hours per day indoor/outdoor. We hypothesize that higher device adherence is associated with shorter ulcer healing times.
- Offloading device wearing time: see outcomes device adherence. We hypothesize that device wearing time is highly associated with device adherence, and the same hypotheses apply.
- Amputations. This is a descriptive outcome.
- Quality of life. This is a descriptive outcome.
- Cardiff Wound Impact Scale. We hypothesize that higher score on the Cardiff Wound Impact Scale (0-100, poor-good health-related quality of life) is associated with shorter ulcer healing times.
- Falls. This is an exploratory and a safety outcome (offloading devices could result in falls).

## Study description

### Background summary

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.

## **Study objective**

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).

## **Study design**

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.

## **Intervention**

None

## Contacts

### Public

Amsterdam UMC, location AMC  
Chantal Hulshof

020-5666915

### Scientific

Amsterdam UMC, location AMC  
Chantal Hulshof

020-5666915

## Eligibility criteria

### Inclusion criteria

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

### Exclusion criteria

- 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

## Study design

### Design

Study type: Observational non invasive  
Intervention model: Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	40
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

### Plan description

Not applicable

## Ethics review

Positive opinion	
Date:	11-12-2020
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**

NTR-new

Other

**ID**

NL9117

METC AMC : W19\_429 # 19.495

## Study results

**Summary results**

Not applicable