# The effectiveness of plantar pressure assessment and monitoring in prescription footwear to reduce re-ulceration in diabetic patients: a randomised controlled trial

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To what extent does the use of therapeutic footwear, which is prescribed and monitored using plantar pressure distribution assessment, result in a reduced plantar ulcer recurrence rate compared to the use of therapeutic footwear which is prescribed...

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|---|---|
| **Ethical review** | - |
| **Status** | Pending |
| **Health condition type** | Diabetic complications |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30851

**Source**
ToetsingOnline

**Brief title**
DIAFOS

### Condition

- Diabetic complications
- Peripheral neuropathies

**Synonym**
Diabetes, Diabetic foot

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,ZonMW

## Intervention

**Keyword:** Diabetes, Pantar pressure, Re-ulceration, Therapeutic footwear

## Outcome measures

### Primary outcome

Proportion of patients with a recurrent plantar foot ulcer in 18 months

### Secondary outcome

- Cost-effectiveness and const-utility of using in-shoe plantar pressure

analysis

- Perceive usability of therapeutic footwear

- Compliance of shoe use

- Daily activity level

# Study description

### Background summary

The diabetic foot ulcer is a major complication in diabetic patients with neuropathy; about 1 of the 6 patients with diabetes will have a foot ulcer. Despite the improved health care, ulceration often results in infection and finally in amputation. Furthermore, foot ulcers often recur. Therefore, prevention of foot ulceration is an important goal.

Most foot ulcers develop on the plantar surface of the foot. Therapeutic footwear seems to be essential in preventing this complication. However, evidence on the effectiveness of therapeutic footwear to prevent recurrent ulcers is lacking. This may be due to the fact that none of the studies have used plantar pressure measurements which make it difficult to determine what the pressure-relieving characteristics of the footwear were and its role on preventing ulceration.

In current practice, shoes are prescribed based on the experience and expertise of physician and shoe technician. In-shoe pressure measurements during this process guarantee a more objective approach, which can result in a better pressure distribution with an expected lower chance for developing recurrent plantar ulceration.

## Study objective

To what extent does the use of therapeutic footwear, which is prescribed and monitored using plantar pressure distribution assessment, result in a reduced plantar ulcer recurrence rate compared to the use of therapeutic footwear which is prescribed according to current practice

## Study design

In a multicenter randomized controlled trial, diabetic patients with a history of plantar foot ulceration who are prescribed with therapeutic footwear will be randomized to either a control group or an experimental group. In the control group footwear will be prescribed and modified based on current practice; in the experimental group this will be done based on in-shoe plantar pressure measurements. Both groups will be followed for 18 months. Every 3 months plantar pressure monitoring will take place. Furthermore, shoe use and daily activity level will be assessed twice for 4 consecutive days during the study. Quality of life will be assessed during the study, partly for use in a cost-effectiveness and cost-utility analysis of using plantar pressure measurements.

## Intervention

The intervention consists of the 3-monthly use of in-shoe pressure analysis for the optimization of therapeutic footwear in diabetic patients with a prior plantar foot ulcer.

## Study burden and risks

Patients will be asked to visit their hospital/centre for a baseline assessment, an entry measurement and 6 follow-up measurements. The baseline assessment will take approximately 80 minutes, all other assessments between 60 and 90 minutes. Additionally, patients will be asked to complete several questionnaires.
There are no known risks with plantar pressure measurement. Patients who will develop an ulcer during the study period will be excluded from further pressure measurements, but will be followed with respect to a cost-effectiveness analysis.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Age >18 and <85 years old
2. Diagnosis of diabetes mellitus Type 1 or 2
3. Loss of protective sensation due to peripheral neuropathy
4. A history of plantar foot ulceration within the last 18 months
5. A new therapeutic footwear prescription (OSA or OSB)

## Exclusion criteria

1. Active foot ulceration
2. Amputation proximal to the metatarsal bones in the foot
3. Severe illness that would make 18-months survival unlikely

4. The use of walking aids that contribute to offloading the foot (wheel chair, more than one crutch)
5. Parallel participation in another study that may influence the outcomes of this study.
6. Concomitant severe physical or mental conditions that limit the ability to follow instructions for the study.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Prevention |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-07-2007 |
| Enrollment: | 240 |
| Type: | Anticipated |

## Medical products/devices used

| | |
|---|---|
| Generic name: | Therapeutic shoe |
| Registration: | No |

# Ethics review

Not available

# 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 |
| --- | --- |
| CCMO | NL17525.018.07 |