

# the effect of felted foam on peak pressure relief and preservation in the feet of healthy individuals

Published: 28-04-2014

Last updated: 21-04-2024

The current research project will investigate the pressure relieving and preservation effects of felted foam. The aim of this study is to find the type of felted foam that is most effective in reducing plantar peak pressures. Furthermore, this study...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Diabetic complications
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON40631

### Source

ToetsingOnline

### Brief title

pressure reduction of felted foam

### Condition

- Diabetic complications

### Synonym

diabetic foot

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** diabetes, felted foam, offloading

## Outcome measures

### Primary outcome

Peak pressure during walking at a location in the forefoot where ulcers in patients often occur.

### Secondary outcome

walking speed and daily step count

## Study description

### Background summary

Felted foam is used frequently in clinical practice to offload plantar foot ulcers in patients with diabetes. Although widely implemented, evidence for the offloading effectiveness of felted foam is scarce, and from the many different felted foams available it is unknown which best offloads the foot and how pressure change over the short term of several days of use.

### Study objective

The current research project will investigate the pressure relieving and preservation effects of felted foam. The aim of this study is to find the type of felted foam that is most effective in reducing plantar peak pressures. Furthermore, this study will investigate how the pressure relieving effect of felted foam changes over time in four consecutive days.

### Study design

A cross-sectional study design comparing different types of felted foam and a longitudinal study design to compare the pressure relieving effect of felted foam over 4 consecutive days. In the first part we investigate what kind of felt is most effective in lowering the pressure at a specific location under the foot while walking. The foot pressure is measured with and without the felted foam. In the second part, we investigate how long the felt is effective in lowering the pressure. The subject is asked to walk with a selective felted

foam during 4 days, the foot pressure will be measured every day.

### **Study burden and risks**

No risks

## **Contacts**

### **Public**

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105AZ  
NL

### **Scientific**

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105AZ  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

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

### **Inclusion criteria**

age between 18-65

## Exclusion criteria

current or history of foot surgery  
diseases that effect the foot

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-05-2014

Enrollment: 16

Type: Actual

### Medical products/devices used

Generic name: felted foam

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 28-04-2014

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL48814.018.14