

# The effect of age on the model of the foot in elderly - an observational study

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Age related factors
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON36774

### Source

ToetsingOnline

### Brief title

Effect of age on foot model

### Condition

- Age related factors

### Synonym

age-related foot model abnormalities and changes in the foot model

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

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

## Intervention

**Keyword:** age effect, model of the foot

## Outcome measures

### Primary outcome

The main study parameter is the difference in the model of the foot between four different age groups.

### Secondary outcome

The age related decreases in foot sole sensitivity

## Study description

### Background summary

A great number of elderly experiences foot problems such as hammertoes, clawtoes, valgustoes and splayfoot. These foot problems can contribute to pain during walking. Therefore it can influence mobility, balance and dependency negatively at the expense of the quality of life. Deformities in the foot can result in ill-fitting footwear, so walking on these shoes can become painful. It is also possible that changes in the model of the foot, by aging, contribute to ill-fitting footwear with comparable painful consequences. Clinical practice gives the impression that the model of the foot changes with age. The fit of standard footwear is based on the \*mean\* model of the feet of adults and not on the model of the foot of elderly.

### Study objective

To give an insight of the development of the foot model over age. The research focuses on the footmodel in the elderly as it exists in the daily situation. At this stage we are not interested in the causes of any changes in the model of the foot. The found model of the foot should be able to read any last modifications for new standard footwear.

### Study design

Cross-sectional observational study

## Study burden and risks

The subjects get a blueprint of their feet. This is a carbon paper where the subjects need to stand on. Then the areas of the foot which touched the ground can be seen on this paper. After this, several sizes of the feet are measured. The subjects can sit in a chair during these measurements. An important aspect of aging of the foot is the decrease of proprioceptive sense (foot sole sensitivity). This is determined with the biothesiometer. This is a device regular used at Clinical Neurophysiology. An increasing vibration is held against the subjects foot, until they report to feel the vibration. This vibration is often experienced as a non annoying tickling. The degree of vibration is a measure for the decreased proprioceptive sense. Then the subjects are asked to stand with one foot in a foam box and the foot is scanned. The subjects need to stand still for this for several minutes. They can stand with a little support, if necessary. At last a questionnaire about pain during walking and balance is conducted.

## 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

Older than 40 years old and within the following age groups (40-45, 50-55, 60-65, 70-75 year old) at the time of execution of the investigation

Able to stand for some minutes with little support if necessary

## Exclusion criteria

foot wounds

footwear modifications, including individual insoles

amputations of the lower extremity

less then 6 months ago being treated by a doctor for foot pain

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 21-03-2011

Enrollment: 64

Type: Actual

## Ethics review

Approved WMO

Date:	10-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL35098.042.10