Treatment of forefoot problems in the elderly: a randomised trial of a standardised shoe & foot care advice in general practice versus podiatric treatment

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32489

Source
ToetsingOnline

Brief title
Treatment of forefoot problems: shoe advice versus podiatric tratment

Condition

- Other condition

Synonym
forefoot problems forefoot complaints

Health condition

bewegingsapparaat: voeten

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: foot problems, general practitioner, podiatry, shoes

Outcome measures

Primary outcome

For the primary aim of this study validated outcome measures will be assessed

at 3, 6, 9 and 12 months

using postal questionnaires. The primary outcome measures are: foot-related

disability; severity of foot

pain and limitations at work and other social activities.

Secondary outcome

Secondary outcome measures include foot function, self perceived deformity and

perceived benefit.

A process evaluation will be performed in all patients by questionnaire after 3

and 12 months in which

the adherence to the given advice and treatment will be assessed. In addition

an expert team will

perform an evaluation of the treatment in the podiatric treatment group and the

effect of orthosis

treatment on in-shoe plantar pressure will be evaluated in a sample of 25 of

these patients.

Study description

Background summary

Foot problems are common, increase with age and are associated with functional disability and reduced
well being. Forefoot problems are the most common of these problems. About one third to a half of all
people with foot problems consult their GP. Usual care often consists of advice by the GP or a referral
for podiatric treatment. However, the content of podiatric treatment is variable and there is little evidence
on the effectiveness of these commonly used interventions.

Study objective

The primary aim of this study is to study the effectiveness of podiatric treatment in elderly patients who
report disabling forefoot problems for a period of at least one month compared to a standardised shoe
advice given in general practice. Secondly, this study will carry out a process evaluation to explore the
potential influence on outcome of adherence to the treatment of patients and podiatrists. Additionally we
shall also study the changes in-shoe plantar foot pressure in a sample of 25 patients in the podiatric
treatment group

Study design

Patient selection will be performed in GP practices by a combination of retrospective recruitment based
on the medical records of the participating practices and advertisements in the practice and invitation by
GP*s. Patients will be selected by a screening survey followed by a baseline examination by a research
assistant. Eligible patients who are willing to participate will be randomised to receive either
standardised shoe & foot care advice in the general practice or to be referred for podiatric treatment.

Intervention

usual care podiatric treatment will be compared to the advice to wear fitting good quality shoes . This advice is supported by a information leaflet.

Study burden and risks

patients will be asked to perform a non invasive examination of foot function and foot posture (n=25 patients will be asked to undergo an additional examination of the same nature after completion of the podiatric treatment) fill in questionnaires of about 10 minutes duration.

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

Forefoot problems are caused by musculoskeletal conditions or deformities; Patients who indicate actual pain in the forefoot for a period of at least 1 months; Patients report disability as a result of the foot problem; Patients are able to fill in the questionnaires (if needed with help of others); Informed consent.

Exclusion criteria

The problem is caused by a recent trauma of the foot; previous foot operation; Treatment of the foot problem by a podiatrists, pedorthist or a physiotherapist in the previous year;Rheumatoid arthritis;Terminally ill or too frail to participate; Known to have dementia;Diabetes mellitus with reduced foot sensation secondary to peripheral neuropathy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2009
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	NL29927.029.09