Cost-effectiveness of footwear modification for first metatarsophalangeal joint osteoarthritis

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON57221

Source
ToetsingOnline

Brief title
MTP-1 OA Trial

Condition

- Joint disorders

Synonym
MTP-1 joint osteoarthritis; big too arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cost-effectiveness, Footwear modification, MTP-1 Osteoarthritis, Primary care, RCT

Outcome measures

Primary outcome

Walking pain (11-point NRS) at 6 months follow-up

Quality-Adjusted Life-Years (EQ-5D) at 6 months follow-up

Societal costs over 6 months, using iMCQ and iPCQ questionnaires

Secondary outcome

Self-reported recovery (GROC), foot function (FHSQ) and PASS at 6 and 12 months

follow-up*

Barriers and facilitators of patients and health care professionals for the

implementation of the intervention in general practice

Study description

Background summary

OA is a chronic condition characterized by pain and impaired function. Symptomatic radiographic OA of the foot affects 16.7% of people aged over 50 years and the most affected joint in the foot is the first metatarsophalangeal (MTP-1) joint. Symptomatic MTP-1 OA is highly disabling and has a significant impact on quality of life. Non-surgical and non-pharmacological interventions are in general recommended as first line treatment for OA. Though, specific guidelines for the non-surgical management of foot OA are lacking as only few randomized trials have been conducted. Only one pilot study has so far compared a footwear intervention with usual general practice care. This study was however not powered to investigate the effectives of treatment. Another RCT (N=100) compared shoe stiffening to a sham shoe insert and concluded that the intervention was more effective at reducing foot pain than sham inserts at 12 weeks follow-up with a NNT of 4. There is therefore urgency to study the cost-effectiveness of this frequently applied intervention in near future.

Study objective

The general aim of this project is to determine the (cost-)effectiveness of footwear modification in addition to GP-led usual care, compared to GP-led usual care alone for patients with first MTP joint osteoarthritis (OA) at 6 months of follow-up.**

Study design

Randomized clinical trial

Intervention

Patients randomized to the intervention group will, in addition to usual GP care, be referred to an orthopedic shoemaker. The intervention will consist of at least 3 types of footwear modification (OVAC) of ready-made footwear (confection shoes).

Study burden and risks

The burden to participants of the intervention; the time spent to complete the online questionnaires (5x, max. 15 minutes);
meetings (minimal 2) with a local orthopedic shoe professional (incl traveling) as per standard of care;
The burden to participants of part 2 the time spent for the interview (max. 30 minutes)

The benefit is that participants of the intervention will probably receive the treatment (footwear modification) earlier that in the standard of care (wait and see) and might not need surgery in the (next) future.

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

- aged over 45 years
- confirmed diagnosis of MTP-1 joint OA by a health care professional.
- pain in the foot needs to be present on most days of last month and
- either no morning joint-related stiffness or
- morning stiffness that lasts no longer than 30 minutes

Exclusion criteria

Patients that have already received footwear modifications in the past for big toe complaints will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-03-2025
Enrollment:	136
Type:	Anticipated

Medical products/devices used

Generic name:	footwear modification
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-12-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL87646.078.24