Cost-effectiveness of footwear modification for first metatarsophalangeal joint osteoarthritis

Published: 11-11-2024
Last updated: 07-06-2025

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57221

Source
ToetsingOnline

Brief title
MTP-1 OA Trial

Condition

- Joint disorders

Synonym
MTP-1 joint osteoarthritis; big toe arthritis

Research involving
Human

Sponsors and support

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

Intervention

- Medical device

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

Explanation

N.a.

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 is defined as OVAC, which stands for footwear modification of ready-made footwear (confection shoes), including the following options, depending on patient needs: sole-stiffening and support, sole and heel modifications to enhance heel-toe-gait and arch-support.

Study burden and risks

The burden to participants of the intervention; the time spent to complete the online questionnaires (5x around 60 minutes, 8x around 5 minutes), meetings (minimal 2) with a local orthopedic shoemaker (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

Trial sites in the Netherlands

Erasmus MC, Universitair Medisch Centrum Rotterdam
Target size: 136

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- aged 45 years or older
- able to walk with or without assistance devices
- proficient in Dutch language
- 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 or custom- made orthopedic shoes in the past.
- Patients that have undergone surgery as treatment for MTP-1 osteoarthritis.
- Patients that are contraindicative to receive an OVAC, because they use a splint or brace, or because their feet will not fit in an OVAC because of other foot problems.

- Patients that are insured with ASR, DSW, ENO or Menzis, which require a secondary care specialist to provide referral for the OVAC.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Other type of control
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-04-2025
Enrollment:	136
Duration:	12 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	Medical device
Generic name:	footwear modification
Registration:	Yes - CE intended use

IPD sharing statement

Plan to share IPD: Yes

Plan description
De gecodeerde onderzoeksgegevens worden bewaard in de OA Trial Bank vanaf het moment dat dit onderzoek stopt met het verzamelen van nieuwe onderzoeksgegevens. In de OA Trial Bank worden gegevens van studies wereldwijd verzameld en beveiligd opgeslagen zodat er (vervolg) wetenschappelijk onderzoek mee gedaan kan worden. De toetsingscommissie van

de OA Trialbank beoordeelt elk verzoek op kwaliteit, inclusief de bescherming van uw privacy op gelijkwaardig niveau.

Ethics review

Approved WMO Date:	19-12-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-04-2025
Application type:	Amendment
Review commission:	METC Erasmus MC

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
Research portal	NL-005193