An integrated personalised assistive devices approach to reduce the risk of foot ulcer recurrence in diabetes (DIASSIST)

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Primary ObjectivesTo assess, as primary economic outcome measure, cost-utility of a personalised multimodal orthotic treatment approach to reduce the risk of plantar foot ulcer recurrence in diabetes.And, as primary patient-related outcome measure,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON52177

Source
ToetsingOnline

Brief title
Personalised assistive devices approach for diabetic foot ulcer prevention

Condition

- Diabetic complications

Synonym
'diabetic foot' 'foot ulcers'

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: cost-utility, diabetes, foot ulcer, prevention

Outcome measures

Primary outcome

There are three main study parameters:

• Cost-utility (as the primary economic outcome), defined as the ratio between costs related to foot care and quality-adjusted life year, based on the health utilities associated with the scoring profiles on the EQ-5D-5L with Dutch reference scores.

• Adherence to wearing custom-made footwear (as the primary patient-related outcome), defined as the percentage of steps taken in appropriate, calculated by combining physical activity and wearing time measurements.

• Foot ulcer recurrence during the 12-months follow-up (as the primary clinical outcome), defined as *a break of the skin of the foot that involves as a minimum the epidermis and part of the dermis, in a person who has a history of foot ulceration, irrespective of location and time since the previous foot ulcer*.

Secondary outcome

Major secondary study parameters:

• Cost-effectiveness, defined as the ratio between costs related to foot care and foot ulcer recurrence on any location of the foot, as defined at the primary study parameters.

• Plantar foot ulcer recurrence, following the definition of foot ulcer

recurrence in the primary study parameters section, only limited to the plantar area of the foot.

• Foot ulcer recurrence at the three predefined high-risk locations (see treatment section 5.2.3 in the protocol), following the definition of foot ulcer recurrence in the primary study parameters section, only limited to the before mentioned high risk locations.

• Costs related to foot care (from a societal and medical perspective). Costs will be calculated for each participant as the product sum of resource volume data and their respective unit costs. Resource volume data will be obtained from the completed study specific versions of the institute for Medical Technology Assessment (iMTA) Medical Consumption Questionnaire (iMCQ) and iMTA Productivity Cost Questionnaire (iPCQ), as these contain the volume data on healthcare resource utilization, out-of-pocket expenses and loss of productivity related to foot care. Foot care includes both care for ulcer prevention (e.g. podiatry appointments, rehabilitation physician consultations) and for ulcer treatment (e.g. multidisciplinary treatment, hospitalization, surgery). Reference prices for unit costs will be based on the most recent Dutch manual for costing in healthcare research available at the time of analysis. All costs will be summed during the entire study period.

• Quality-adjusted life years, based on the health utilities associated with the scoring profiles on the EQ-5D-5L with Dutch reference scores. This will be monitored during the entire study period.

Minor secondary study parameters:

• Ulcer-free survival days in 12 months time (defined in accordance with Van Netten et al)

• Time to ulceration

• Cumulative plantar tissue stress (defined as the average daily tissue stress in the week prior to the final visit, measured according to the formula of Lazzarini et al (2019))

• Plantar pressure (plantar pressures in all appropriate footwear measured using the Pedar-X system (Novel, GmbH, Munich, Germany); defined as the average of the average peak plantar pressure at the risk location(s) in all appropriate footwear at final study visit)

• Physical activity (average number of daily steps and average daily amount of time spent doing weight-bearing activity in the week prior to the final visit)

• Wearing time of custom-made footwear (average daily wearing time of appropriate footwear during the study)

Other study parameters (if applicable):

• Treatment and footwear satisfaction (measured with a study-specified version of the Monitor Orthopaedic Shoes)

• Quality of life (scores on the SF-36, and - in participants with a foot ulcer - scores on the Cardiff Wound Impact Schedule)

• Footwear wear-and-tear (score on the footwear wear-and-tear scale at final visit)

• Ulcer risk (ulcer risk prediction score at final visit)

• Foot-related self-care

• Knowledge of foot care using a translated and study specific adjusted version of the Patient*s Interpretation of Neuropathy (PIN) questionnaire

• Capabilities, Opportunities and Motivations to wear custom-made shoes assessed by a questionnaire (COM-B)

• Motivational interviewing (conducted by phone calls, randomly recorded and scored with the motivational interviewing treatment integrity coding manual)

• Falls (participant*s self-report)

• Referral time (in patients with an ulcer only)

• Time to healing (in patients with an ulcer only)

• Ulcer severity (in patients with an ulcer only; as measured with the University of Texas Wound Classification and with the WIfI-score)

Study description

Background summary

Globally, every 20 seconds a lower limb is lost due to diabetes. Most amputations are preceded by a foot ulcer, which in itself has a lifetime risk up to 34% and annual incidence rate of 2.2% in persons with diabetes. In particular, the risk for ulcer recurrence is high: 40% within one year after healing. Ulcers and amputations are key outcomes of diabetic foot disease, that ranks 10th in leading causes of global disease burden, and have a significant negative impact on quality of life and patient mobility. Furthermore, the treatment of these foot ulcers is costly, due to high risk of infection, including hospitalization, and amputation, and amounts to about ¤10.000 per ulcer episode. Thus, ulcer prevention is an important means to decrease this patient and healthcare burden.

Foot ulcers are caused by repetitive stress due to weight-bearing activity, that goes unrecognized because of loss of protective sensation due to neuropathy. To prevent plantar foot ulcer recurrence, guidelines recommend an approach consisting of multiple modalities, including: custom-made shoes with a

demonstrated plantar pressure-relieving effect that is constantly worn by the patient, patient and family education, regular foot inspection and care, and instructing patients to perform self-management by means of monitoring their own foot temperature. Nevertheless, ulcer recurrence rates remain high.

For these high recurrence rates, a variety of potential explanations can be given. First, above recommendations are likely insufficiently implemented, as these multiple modalities are currently provided by a variety of healthcare professionals in an unstructured and uncoordinated approach. Lack of insight in costs and effectiveness of these modalities plays a role in this insufficient implementation, as these interventions have only been studied from the perspective of a single modality, but never from a multi-modal intervention perspective, and no cost-utility or cost-effectiveness studies are available. Second, even when implemented, modalities are not of state-of-the-art quality in daily practice. For example, state-of-the-art knowledge on effective custom-made footwear designs is frequently not part of clinical practice, and patient education in practice is unstructured and non-personalised. Third, non-adherence to preventative treatment by patients is high, which reduces effectiveness of the interventions. For example, non-adherence to wearing prescription custom-made footwear is particularly high when patients are in their house, due to the perception of the footwear being heavy, difficult to don and doff, warm and dirty, and because of habit. Additionally, if patients perceive their footwear as less beneficial, footwear will be worn less frequently. Also, patients sense the daily self-management required for ulcer prevention as a burden, and daily thermometry adds to that burden, explaining some of the low adherence to that intervention seen in the only study that reported this outcome. To overcome these reasons and to better help prevent ulcer recurrence in diabetes, a state-of-the-art multimodal ulcer prevention intervention is needed, and its cost-utility, cost-effectiveness and effects on patient adherence should be investigated.

Study objective

Primary Objectives
To assess, as primary economic outcome measure, cost-utility of a personalised multimodal orthotic treatment approach to reduce the risk of plantar foot ulcer recurrence in diabetes.
And, as primary patient-related outcome measure, to assess adherence to wearing custom-made footwear following a personalised multimodal orthotic treatment approach to reduce the risk of plantar foot ulcer recurrence in diabetes.
And, as primary clinical outcome measure, to assess foot ulcer recurrence following a personalised multimodal orthotic treatment approach.

Secondary Objectives
To assess cost-effectiveness, plantar foot ulcer recurrence, foot ulcer recurrence at high-risk locations, costs, quality-adjusted life years, ulcer-free survival days, time to ulceration, cumulative plantar tissue stress,

plantar pressure, physical activity, wearing time, serious adverse events, treatment satisfaction, quality of life, footwear usability, footwear wear-and-tear, ulcer risk, foot-related self-care, knowledge of foot care, and (in case of ulceration) referral time, time to healing and ulcer severity, following a personalised multimodal orthotic treatment approach to reduce the risk of plantar foot ulcer recurrence in diabetes.

Study design

The study design of the current study is a multi-centre single-blinded (outcome assessor) parallel-group randomized controlled trial with two study arms:
1. Multimodal care, which includes usual care as provided in the Netherlands and, in addition, a personalised multimodal orthotic treatment approach (experimental group).
2. Usual care as provided in the Netherlands (control group).

Setting of the study:
Recruitment will take place from three university or community-based hospitals with a multidisciplinary diabetic foot clinic in different regions in the Netherlands, and from professional practices of podiatrists who participate in the multidisciplinary team. Each diabetic foot clinic will operate as one of the study centres where all the study assessments take place. Within each centre, a physician, podiatrist and an orthopaedic shoe technician will be involved. The participating hospitals are: Amsterdam UMC (location AMC and location VUmc), Maxima Medisch Centrum (Veldhoven), Reinier de Graaf Gasthuis (Delft).

Some parts of multimodal care may take place at the patient*s home or via telephone.

Duration of the study:
Patients who consent to participate will be randomized to multimodal or usual care. Each participant will be followed for 12 months. Participants who have an ulcer or active Charcot's neuroarthropathy at 12 months will be followed for another 6 months or until two weeks after healing (whichever comes first), to obtain cost and healing outcomes associated with that ulcer.

Intervention

The treatment of participants who are randomized to multimodal care will consist of usual care, and in addition a personalised state-of-the-art multimodal orthotic treatment approach that contains:

• Custom-made shoes, evaluated and optimized using in-shoe pressure analysis, and re-evaluated after 6 months
• Custom-made indoor shoes for specific use indoors, also pressure-optimized

and evaluated over time
• Personalised at-home daily foot temperature monitoring at high-risk regions
• Personalised patient education consisting of quantitative feedback on in-shoe pressures, temperature measurements and footwear use and, in addition, motivational interviewing where indicated and needed to improve device use

The intervention in this RCT is *multimodal care*. This multimodal care consists of 4 modalities. While all these modalities can, theoretically, be offered to individual participants as part of usual care, their combined prescription is unique and currently not available in the Netherlands or anywhere globally. Moreover, in the current study the intervention does not only consist of the four modalities, but applies these in a structured and strictly protocolled manner, ensuring that all participants will receive state-of-the-art care. And, lastly, the four modalities are offered in a personalised approach, to match the individual participant*s clinical situation and personal needs. With that, this intervention differs from usual care, where some of these modalities might be offered, but unstructured, without state-of-the-art protocols, and without personalised approach.

Study burden and risks

There are no known risks for the participants in this study. By participating in the study, foot status may be checked more regularly in the multimodal care group. Participation in the trial will give insight into the cause of the arising foot problems in the patient. Positive outcomes on multimodal care could lead to further integration of in the intervention in Dutch Health Care.

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

1. Diabetes mellitus type 1 or 2
2. Age 18 years or above
3. Loss of protective sensation based on the presence of peripheral neuropathy
4. A healed plantar foot ulcer or foot amputation in the preceding 4 years until two weeks before study inclusion
5. In possession of custom-made orthopaedic shoes, defined as *Orthopaedic shoes type A* or *Orthopaedic shoes type B* , or Orthopaedic Provision in Regular Footwear (OVAC), according to the Dutch healthcare system
6. Ability to provide informed consent

Exclusion criteria

1. Foot ulcer or open amputation site(s)
2. Active Charcot*s neuroarthropathy
3. Foot infection, based on criteria of the PEDIS classification
4. Amputation proximal to the metatarsal bones in both feet
5. Ulcer on the apex of digitus 2-5 as the only ulcer location in the past 4 years, as surgical intervention (flexor tenotomy) is a more likely and guideline-recommended treatment for such patients, rather than the multimodal care under investigation
6. Severe illness that would make 12-months survival unlikely, based on the clinical judgment by the physician
7. Concomitant severe physical or mental conditions that limit the ability to follow instructions for the study, based on the clinical judgment by the physician

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2022
Enrollment:	126
Type:	Actual

Medical products/devices used

Generic name:	Multimodal: a) in-shoe pressure measurement system Pedar-X; b) custom-made shoes; c) custom-made hou
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-12-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-03-2024
Application type:	Amendment

Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL78943.018.21