The effect of motivational interviewing combined with digital shoe-fitting on adherence to orthopaedic shoes

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	**Adverse Event**
AVG	**Algemene verordening gegevensbescherming**
BMI	**Body Mass Index**
CEA	**Cost-Effectiveness Analysis**
DM	**Diabetes Mellitus**
DSMB	**Data Safety Monitoring Board**
EQ-5D-5L	**5-Level EuroQol Quality of Life scale**
EQ VAS	**EuroQol Visual Analogue Scale**
ICC	**Intraclass Correlation Coefficient**
iMCQ	**iMTA Medical Consumption Questionnaire**
iMTA	**Institute for Medical Technology Assessment**
iPCQ	**iMTA Productivity Cost Questionnaire**
ISO	**International Organization of Standardization**
GPs	**General Practitioners**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
MI	**Motivational Interviewing**
MOS	**Monitor Orthopedic Shoes**
PAV	**Perifieer Arterieel Vaatlijden**
PS	**Protectieve Sensibiliteit**
QALY	**Quality-Adjusted Life Year**
RAND-36	**Research and Development 36-item health survey**
(S)AE	**(Serious) Adverse Event**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
SUSAR	**Suspected Unexpected Serious Adverse Reaction**
UAVG	**Uitvoeringswet AVG**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: Diabetic foot ulcers are a leading cause of hospitalization, amputation and high treatment costs. Custom-made orthopaedic shoes are recommended in (inter)national guidelines to prevent (re)ulcerations, and adherence to these orthopaedic shoes is crucial. However, adherence to orthopaedic shoes is often low and there is a lack of insight in methods to improve this adherence. We propose a novel care approach, motivational interviewing (MI) and a new digital shoe-fitting procedure, to improve adherence to orthopaedic shoes and to be (cost-)effective. The aim of this trial is to assess the (cost-)effectiveness of this novel care approach (MI combined with digital fitting) compared to usual care (no MI and casting-based fitting) in terms of adherence to orthopaedic shoes and ulcer prevention.

Objective: *Primary objective:* To compare the proportion of participants who are sufficiently adherent to the use of their orthopaedic shoes, that is, take at least 80% of their total steps with orthopaedic shoes between the participants receiving the novel care approach and the usual care. *Secondary objectives:* To compare between novel care approach and usual care: 1) the level of adherence to the use of orthopaedic shoes of participants; 2) total wearing time; 3) the proportion of participants (re-) experiencing complications up to one year after receiving their orthopaedic shoes; 4) to assess the difference in costs and participant-perceived quality of life; 5) participants' knowledge about the aim of orthopaedic shoes; 6) satisfaction with information provided by the pedorthist; 7) participants' behavioural intentions; and 8) satisfaction with the orthopaedic shoes. We further aim to assess the MI-trained podiatrists' for knowledge about MI, and experiences and attitudes towards applying MI in this group of patients.

Study design: A randomized controlled trial with (cost-)effectiveness analysis and qualitative and quantitative process analyses.

Study population: 220 patients with diabetes mellitus, who are identified with risk profiles ("Zorgprofiel") 2, 3 or 4 and a prescription for orthopaedic shoes, will be included.

Intervention: The novel approach group will receive motivational interviewing combined with a new digital fitting procedure of orthopaedic shoes. The usual care group will receive no motivational interviewing combined with casting-based fitting of orthopaedic shoes.

Main study parameter: Adherence to orthopaedic shoes as measured with footwear-based sensors and activity monitors.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There will be no additional benefit for the participants from the study beyond the known benefits associated with orthopaedic shoes and there will be no risk to participate in the study. The burden of participating will be the time it will take to read out the footwear-based sensors, complete the questionnaires, and for a sub-population the in-depth interviews.

1. INTRODUCTION AND RATIONALE

Diabetes Mellitus (DM) is one of the most common chronic diseases worldwide. Currently 425 million adults have DM worldwide (1). It is expected that in 2035 this will increase to 600 million people due to population growth and aging (2). Foot ulcers occur in 19-34% of DM-patients and are a leading cause of hospitalization, amputation and high treatment costs (3). These costs can be mainly attributed to the development of foot ulcers, as these are a major risk factor for, and nearly always precede, foot infection and amputation. Diabetic foot ulcers reduce patient mobility and quality of life (4) and account for increased healthcare related costs due to hospital admissions, unemployment, immobility and social isolation (3, 5-9). If loss of productivity, isolation and home care needs are taken into account the costs are even higher (8, 9).

DM-patients who have recovered from an ulcer face a recurrence rate of 40% in one year and 65% in three years (3). Appropriate footwear, early detection of risks, self-management and personalized orthopaedic shoes are considered essential to prevent re-ulceration (10, 11). Adherence to these strategies is crucial, because patients who are adherent to these strategies have significantly better outcomes than those who are non-adherent (12).

Studies show that adherence to orthopaedic shoes is rather low, randomized trial has shown that only 46-49% of patients wear their orthopaedic shoes for at least 80% of total steps (13, 14). Research into interventions to increase this adherence is scarce. An explorative study on the use of motivational interviewing that showed some effect has been done by Keukenkamp et al (11). High-quality randomized trials are needed to better inform clinical practice about methods to further improve adherence to orthopaedic shoes (11, 12, 15). To increase awareness and knowledge and to improve adherence to the target of 80% of total steps with orthopaedic shoes, especially the combination of motivational techniques, education and properly fitting custom-made footwear is considered promising (10, 11).

The role of patient's motives and reasons for (not) adhering to wearing custom-made footwear is limited (10, 14, 15), and not studied systematically (10, 13, 14). Waaijman et al. (14) demonstrated some predictors of adherence (lower BMI, severe foot deformity, appealing footwear). However, their multivariate prediction model explained only 18% of the variance in adherence and implied that optimizing any of these predicting factors may have a limited effect on adherence. Like the study of Waaijman et al (14), most of the studies on diabetic footwear had a strong clinical focus, studying patients' physical characteristics rather than social and psychological characteristics, and as such ignore patient perspectives on wearing shoes and barriers, and ignore how they live and work in their social environment. Focusing only on clinical aspects (re-ulcerations) and the quality of orthopaedic shoes is not enough to improve adherence to orthopaedic shoes, wearing orthopaedic shoes also requires intrinsic motivation.

Educating patients in self-management was expected to increase the awareness and urgency of wearing foot equipment and recognizing their responsibilities for own health and well-being (16). However, the effects of education and self-management interventions have shown limited long term effects on adherence to wearing orthopaedic shoes at home (11) and to prevent ulcers compared to usual care (9), and systematic reviews showed insufficient evidence that patient education alone is effective in achieving reduction in ulcers and amputation (9, 10, 12). Therefore, a multidisciplinary and biopsychosocial approach is needed to improve diabetes foot care (17). Also the international and national guidelines to improve diabetic foot care (18, 19) recommend a multidisciplinary approach to prevent ulcers and to better inform patients. In particular it is suggested to involve a specialised podiatrist and a clinical expert to inform and help patients to personalize the shoe-fitting procedures, instead of just a ”technical” procedure done by a pedorthist to fit the shoes with patients.

In observational study designs it has been found that the communication between patient and caregivers was associated with increased long-term use (20, 21). This suggests that the shoe-fitting procedure plays an important role to create a working alliance between patient and podiatrist to overcome barriers to wearing orthopaedic shoes. Such a working alliance can be created via motivational interviewing (MI), to change motivation while also addressing the ambivalence related with behaviour change. Keukenkamp and colleagues concluded that the use of motivational interviewing seems feasible for the given purpose and patient group (11).

The other important factor is the optimal fit of orthopaedic shoes. Although perceived footwear comfort was no predictor of adherence in a previous study (14), the actual fit of orthopaedic shoes may influence the adherence to wearing orthopaedic shoes. An important component of the current procedures in fabricating custom-made shoes is the shoe last, the solid 3D mould around which a shoe is made (22). A shoe last is closely related to the foot and the design is based on factors such as the foot shape/size, comfort parameters, shoe fashion/style, and type of construction. Custom-made shoe lasts are almost always made using casting-based methods. However, these are expensive, time-consuming, and complicated to manufacture due to constraints imposed by manual measurements of several foot dimensions and manual crafting (trial-and-error) of a shoe last to fit the specific foot dimensions (23, 24). A digital fitting procedure can be more accurate, patient-friendly and time-efficient using high-end 3D scanners to scan the foot instead of creating a mould around the foot. The digital file of the foot obtained can be modelled to a specific last that can be milled by a last milling machine. Although slowly implemented in clinical practice, improvements in scanning methods are expected to further reduce time and to be (cost-)effective.

Currently there is little knowledge about the effectiveness of (biopsychosocial) interventions and the cost-effectiveness of adherence to orthopaedic shoes has not been studied at all (18). Therefore the aim of the current study is to assess the (cost-)effectiveness

of a novel care approach (MI combined with digital fitting) compared to usual care (no MI and casting-based fitting) in adherence to orthopaedic shoes and ulcer prevention. This study will generate insights into the socio-economic impact of the novel care approach on adherence to orthopaedic shoes. These are crucial steps towards better ulcer prevention in people with diabetes at high-risk.

2. OBJECTIVES

2.1 Primary Objective

- To compare the proportion of participants who are sufficiently adherent to the use of their orthopaedic shoes, that is, take at least 80% of their total steps with orthopaedic shoes between the participants receiving the novel care approach, motivational interviewing combined with a new digital scanning procedure, and participants receiving usual care.

2.2 Secondary Objectives

- To compare between the novel care approach and usual care:
    a. The level adherence to the use of orthopaedic shoes;
    b. The proportion of participants (re-)experiencing complications during one year follow-up;
    c. The cost-effectiveness;
    d. The difference in costs;
    e. The difference in participant-perceived quality of life;
    f. The participants' knowledge about the aim of orthopaedic shoes, satisfaction with information provided by the pedorthist, participants' behavioural intentions, and satisfaction with orthopaedic shoes.
- To assess the MI-trained podiatrists' knowledge about MI, experiences and attitudes towards applying MI in this group of patients.

3. STUDY DESIGN

A randomized controlled trial with (cost-)effectiveness analysis, and qualitative and quantitative process analyses. The participants will be monitored during one year after receiving their orthopaedic shoes.

The study will be performed in Voetencentrum Wender and Voetmax Orthopedie, situated in The Netherlands. Figure 1 represents a flow chart of the study design and the main procedures that the participants will undergo during the course of the study.

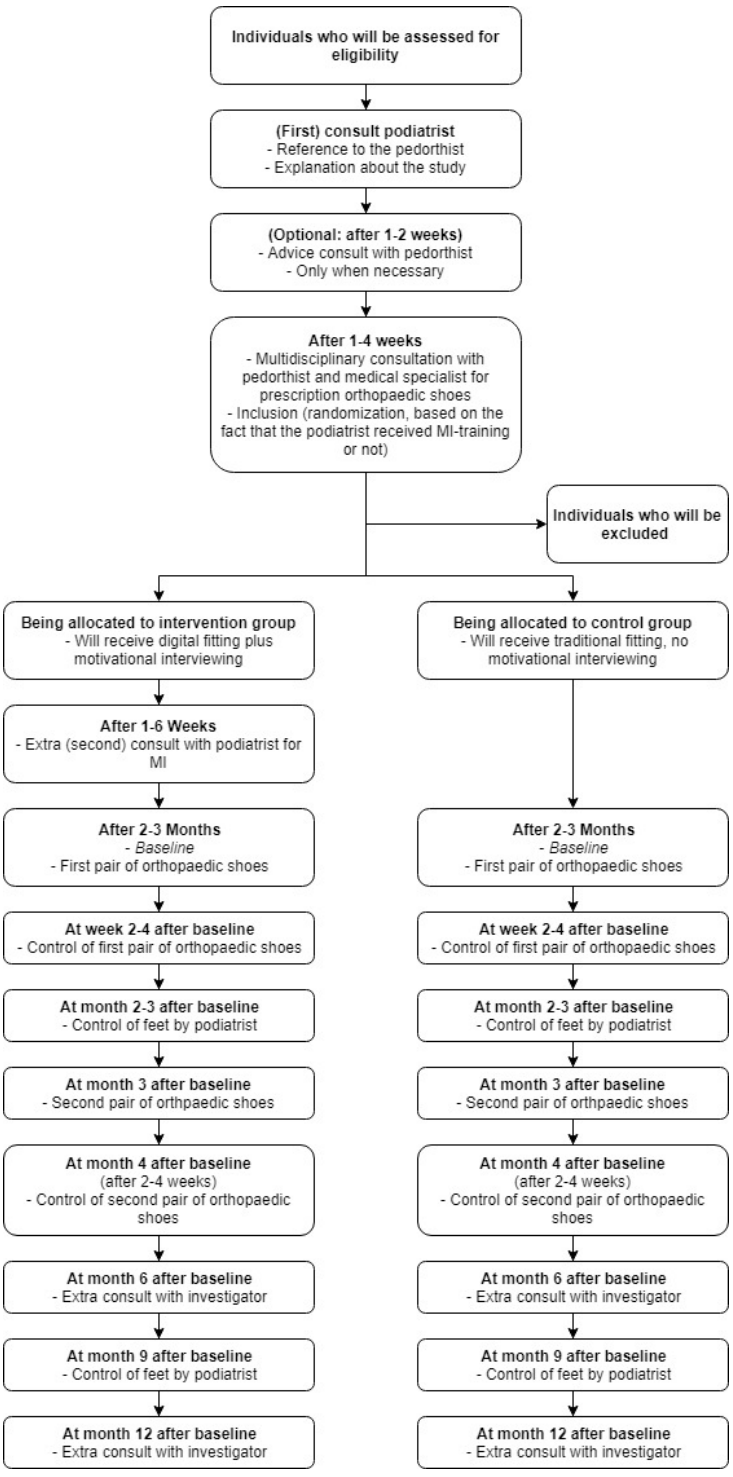

Figure 1. Flow chart of the study design

4. STUDY POPULATION

4.1 Population (base)

The population of this study will consist of patients with diabetes mellitus treated by a podiatrist of Voetencentrum Wender, for which foot care is reimbursed in the Dutch healthcare system.

4.2 Inclusion criteria

Patients who are 18 years or older, with a clinical diagnosis of diabetes mellitus type 1 or 2, and with or without previous ulcers or callus, will be included. They are identified with risk profiles 2, 3 or 4, according to the 'zorgmodule preventie diabetische voetulcera 2014' (25), see Table 1. These patients are eligible for a prescription of orthopaedic shoes.

Zorgprofiel	Risicoprofiel
-	Simm's 0 – geen verlies PS of PAV
1	Simm's 1 – Verlies PS of PAV[1] met zelfzorgcapaciteit
	Simm's 1 – Verlies PS of PAV[1] zonder zelfzorgcapaciteit[2]
2	Simm's 1 – Verlies PS of PAV met vastgesteld verhoog risico op huiddefecten/infectie[3]
	Simm's 1 – Verlies PS of PAV met vastgesteld verhoog risico op drukplekken[4]
	Simm's 2 – Verlies PS in combinatie met PAV
3	Simm's 2 – Verlies PS of PAV in combinatie met verhoogde druk
	Simm's 2 – Verlies PS en PAV in combinatie met verhoogde druk
4	Simm's 2/3 – Inactieve Charcot[5]
	Simm's 3 – Genezen ulcus of amputatie
	Actief ulcus – actief niet-plantair ulcus[6] met genezing binnen 2 weken
	Actief ulcus – Actief plantair ulcus[6] met genezing binnen 2 weken

Table 1. Zorgmodule preventie diabetische voetulcera 2014 (25). Note: PS: protectieve sensibiliteit, PAV = perifieer arterieel vaatlijden. [1] PAV Fontaine I, IIa; [2] Cognitieve, visuele, sociale, adipositionele en bewegingsbeperkingen die zelfzorg verhinderen; [3] Dit is het geval o.a. bij perifeer arterieel vaatlijden vanaf Fontaine IIb, nefropathie, gebruik van immunosuppressiva/prednison, chemotherapie; [4] Dit is het geval bij voetdeformiteiten en/of limited joint mobility, bijvoorbeeld door reumatoïde artritis; [5] Inactieve charcot met adequate schoenvoorziening; [6] Actief oppervlakkig ulcus zonder vaatlijden en zonder tekenen van infectie.

4.3 Exclusion criteria

Patients will be excluded if they did not receive custom-made orthopaedic shoes, but instead an adaption to convection shoes or semi-orthopaedic shoes. They will also be excluded if they have an active ulcer, active Charcot, active foot infection or are not able to walk, or if they are unable to read and understand the study instructions.

4.4 Sample size calculation

Given that standard MI has been found to increase adherence to orthopaedic shoes at home after 3 months from 31% (without MI) to 40% (with MI) (11), we conservatively anticipate that the MI provided by the podiatrists will improve adherence by at least 10%. Moreover, we estimate the use of a digital scanning and fitting procedure by the pedorthist rather than a casting-based fitting procedure to increase adherence with at least another 10%, due to the experienced improvement of last accuracy and orthopaedic shoe-fitting.

Based on the observed 3 months overall (at home and away) adherence of 59% for the usual care procedure (11), we expect the one-year overall adherence to drop to 40% for the usual care, and to be 40% + 10% + 10% = 60% for the novel care approach including the MI. Based on an alpha of 0.05, power of 0.80, and ICC of 0.01, demonstrating this effect in a generalized linear mixed model this would require 200 participants in total. Recognizing loss to follow-up, which occurred in (6+4=) 10 out of (85+86=) 171, participants in a recent study in this context (13), that is ~6%, we aim to include 220 participants in total.

5. TREATMENT OF SUBJECTS

5.1 Investigational treatment

5.1.1 Usual care

Participants will receive usual care from the podiatrist (no MI is provided at this moment in standard clinical practice in the Netherlands) and a casting-based fitting procedure by the pedorthist (26-29).

Usual care:

1. The diabetic patient undergoes a foot screening by the podiatrist
2. Referring patient to a pedorthist
3. Diabetic patient meeting the pedorthist
4. Functional research of the foot
5. Footwear approach
6. Bringing the foot in the right position and create a setup
7. Brining the foot in a comfortable casting position
8. Wrapping the diabetic foot with plastic to avoid skin plaster connection
9. Fitting the tricot (support stocking)
10. Applying the cutting strip
11. Wrapping the diabetic foot fully weight bearing with plaster (max 2 layers)
12. Bringing the foot in de setup again
13. Scanning de resulting cured mould
14. External modelling process of the last
15. Milling of the last
16. Adjust a custom-made insole
17. Fabricating a plastic test shoe
18. Fitting the test shoe
19. Identifying critical pressure points between plastic shoe and foot
20. Modifying the last with rubber/cork material
21. Repeating steps 13-15 if necessary (trail-and-error approach)
22. Finishing the final last for custom-made shoe production
23. Test the plantar pressure just before delivery of the orthopaedic shoes

5.1.2 Novel care approach

Participants will receive a combination of MI by the podiatrist and a new digital fitting procedure by the pedorthist.

The new shoe-fitting procedure will consist of using a digital iPad scanner with a scan frame where the foot will be scanned (half-)weight bearing. The participants foot rests on a glass-plate and the pedorthist scans the total foot. A calibrated length is used to scale the scan results to absolute dimensions.

Novel care approach:

1. The diabetic patient undergoes a foot screening
2. Podiatrist works with motivational interviewing approach to improve adherence
3. Referring patient to a pedorthist
4. Diabetic patient entering the pedorthist
5. Functional research of the foot
6. Footwear approach
7. Bringing the foot in the right position and create a setup
8. Register the created setup
9. Scan the foot (half-)weight bearing with a 3D iPad scanner
10. Registrate analogue the foot length and foot width as calibration
11. External modelling process of the last
12. Milling of the last
13. Adjust a custom-made insole
14. Fabricating a plastic test shoe
15. Fitting the test shoe
16. Identifying critical pressure points between plastic shoe and foot
17. Modifying the last with rubber/cork material
18. Repeating steps 13-15 if necessary (trail-and-error approach)
19. Finishing the final last for custom-made shoe production
20. Extra (second) consult with the podiatrist with MI approach to improve adherence
21. Test the plantar pressure just before delivery of the orthopaedic shoes

5.1.3 Motivational interviewing training of podiatrist

Motivational interviewing (MI) entails a number of general coaching principles, such as avoiding argumentation and direct confrontation but rolling with the existing reservations and supporting self-efficacy, optimism and behavioural intentions in patients to support active start or change of health behaviour. Podiatrists will be trained to incorporate the specific coaching techniques of MI in the integral and multidisciplinary based diabetic footwear and care with the aim to increase adherence to the orthopaedic shoes.

Eleven participating podiatrists will receive MI-training to provide MI to the participants included in the study.

5.2 Use of co-intervention

Not applicable.

5.3 Escape medication

Not applicable.

6. INVESTIGATIONAL PRODUCT

Not applicable.

7. NON-INVESTIGATIONAL PRODUCT

Not applicable.

8. METHODS

8.1 Study parameters

Table 2 shows an overview of the measurements of the study parameters during the study.

	Study period								
	Screening	Inclusion		Post-allocation					Close-out
Timepoint	-T2	-T1	T0	T1	T2	T3	T4	T5	T6
	(2-4m)	(2-3m)		(2-4w)	(3m)	(4m)	(6m)	(9m)	(12m)
Enrolment									
Initial eligibility screen	X								
Study information to participant	X								
Initial willingness to participate	X								
Crosscheck inclusion/exclusion criteria	X								
Informed consent		X							
Final eligibility screen		X							
Allocation		X							
Interventions									
Novel care approach		→	→	→	→	→	→	→	→
Usual care		→	→	→	→	→	→	→	→
Assessments									
Demographic and disease-related characteristics		X							
Physical characteristics		X							
RAND-36 V2.0		X					X		X
EQ-5D-5L		X					X		X
iMCQ		X							X
In-depth interview		X					X[1]		
MOS_{post}							X[1]		X
iPCQ[2]		X							X
Activity registration				X[3]		X[3]			
Data transfer shoe-sensors					X		X	X	X

Table 2. Overview of the measurements of the study parameters during the study. Note: [1] The participants, who will not be approached for the in-depth interview, will be asked to fill in MOS_{post} (see paragraph 8.1.2.3); [2] The iPCQ will also be taken from participants after (re-)experiencing complications; taken four weeks after the complication was diagnosed [3] Activity registration during 1 week. Abbreviation: w: weeks, m: months.

8.1.1 Main study parameter

8.1.1.1 Proportion participants being adherent

The main study parameter is the proportion of participants who adhere to the use of their orthopaedic shoes. We define adherence as minimally 80% of steps taken with orthopaedic shoes. The proportion of adherent participants will be objectively determined based on log data from sensors in the orthopaedic shoes of all participants (see paragraph 8.3.2.1), and using

the average of the data from the activity monitors provided to all participants measured at T3 and T6 (see paragraph 8.3.2.2).

The analysis of the main study parameter will be carried out blindly. The person who will analyse the results does not know to which group the participants belong to.

8.1.2 Secondary study parameters

8.1.2.1 Level of adherence to orthopaedic shoes

The level of adherence to orthopaedic shoes will be determined by the percentage of total steps during the full recording period that the orthopaedic shoes were worn and will be calculated as:

$$Adherence = \frac{\sum steps\ wearing\ orthopaedic\ shoes}{\sum steps}$$

Total steps wearing orthopaedic shoes will be based on log data from sensors in the orthopaedic shoes of all participants (see paragraph 8.3.2.1), and total steps will be based on using the average of the data from the activity monitors measured at T3 and T6 (see paragraph 8.3.2.2).

The wearing time of the orthopaedic shoes during the 12 month follow-up will be based on log data from sensors in the orthopaedic shoes of all participants (see paragraph 8.3.2.1).

8.1.2.2 Complications

The proportion of participants (re-)experiencing complications (i.e. one or more ulcers or callus, not present at baseline, or amputation) after receiving their shoes, up to one year after baseline. All complications will be registered and photographed by podiatrists, who are informed by the participant if complications occur (in >95% of complications cases, the podiatrist is the first to hear from the participants). If it is necessary to obtain details on specific complications GPs and orthopaedic surgeons will be contacted. Photographs will be assessed by blinded observers to confirm the outcome.

8.1.2.3 Economic evaluation

Healthcare resource use of participants will be determined using the iMCQ (30). Cost prices will be calculated according to the 2015 Dutch guideline for health economic evaluation (31). If relevant, costs of medication use will be derived from the Dutch formulary increased with a pharmacist's charge. Costs of diagnostic tests will be based on Dutch tariffs, and, if applicable, costs of over-the-counter medication and alternative medicines will be based on average retail prices. Costs of consulting a general practitioner or medical specialist, or other procedures and hospitalizations will be based on the 2015 Dutch guideline for health economic evaluation (31) or charges if no other estimates are available. The potential productivity losses from

complications of the diabetic foot/custom-made footwear will be assessed using the iPCQ instrument applied to all participants at baseline and 12 months after baseline, and to who present with complications, at four weeks after the complication was diagnosed (32). A friction cost approach will be applied to estimate the productivity losses as defined in the Dutch costing manual, and based on the reference costs of not being able to perform paid or unpaid work.

8.1.2.4 Health-related quality of life

The health-related quality of life of participants will be assessed with the EQ-5D-5L questionnaire and RAND-36 V2.0. The negative impact of complications on quality of life will be based on literature. Quality-adjusted life years (QALYs) will be calculated based on the quality of life calculated from the EQ-5D-5L and the time duration between measurements, or the time until the end of life.

8.1.2.5 Perspective of patient

A mixed methods approach will be applied to obtain the patient perspective. A quantitative questionnaire (MOS_{post} (33)) will be used to measure participant experiences on orthopaedic footwear, use and usability at six and 12 months after baseline. The information from the MOS_{post} will be complemented with data from in-depth interviews with 30 participants at baseline and six months after baseline. Participants will be selected randomly for the interviews; 15 participants of the intervention group and 15 of the control group.

8.1.2.6 Perspective of MI-trained podiatrist

A mixed methods approach will be applied to obtain the MI-trained podiatrist perspective, with quantitative analyse of application of MI by the MI-trained podiatrist scored with the MITI (34), and with interview results from all the MI-trained podiatrists. Between one or two months after the MI-training all podiatrists will record some conversations with the participants for assessment applying MI or not. A health psychologist, educated in training motivational interviewing by the Motivational Interviewing Network of Trainers (MINT), will be responsible for scoring the quality of the MI applied by the podiatrist with the MITI. To explore whether there is, as expected, a difference between the MI-trained podiatrist and the non-MI-trained podiatrist, also the non-MI-trained will be scored with the MITI. The in-depth interviews will be taking after the last participant had his/her last consultation with the podiatrist. Each podiatrist will provide written informed consent for contribution to the study.

8.1.3 Other study parameters

The following anthropometric data will be collected for all participants: demographic data (age, gender, ethnicity, height and weight), diabetes type and duration, risk profile (25), ambulatory status, history regarding the use of orthopaedic shoes, educational status, socioeconomic status, and capacity for self-care, and the presence of peripheral arterial disease, peripheral neuropathy, foot deformities, and history of previous foot ulceration and amputation (35).

8.2 Randomisation, blinding and treatment allocation

Randomization will be performed at the level of the podiatrists. Since the podiatrists differ widely in their number of patients seen and experience with the specific target group, stratified randomisation will be used. Four of the 22 podiatrists run special diabetic consultations, and are therefore likely more specialized in diabetic feet. The four podiatrists will be divided in two groups, based on the number of patients seen per year (based on last year figures), and equally randomized to the group who will receive MI-training or to the group who will not receive MI-training. The other 18 podiatrist will be randomized next, also stratified by the number of patients seen per year (based on 4 strata using last year figures). The randomisation will be done centrally by an independent researcher using www.sealedenvelope.com.

Participants will not be randomized, because the background assignment of the treating podiatrist (being trained in MI or not) will determine the treatment allocation of the participants. Each podiatrist will exclusively provide either the MI-intervention or usual care (see paragraph 5.1). Thereafter the pedorthist will provide the new digital shoe-fitting procedure for the intervention group of participants or casting-based fitting procedure for the control group (see paragraph 5.1). Therefore blinding and concealed treatment allocation are not feasible.

8.3 Study procedures

8.3.1 Protocol

The participants will be followed from inclusion up till 12 months after receiving their orthopaedic shoes, with visits planned at different moments during this period for consultations with the podiatrist, pedorthist and investigator (see Figure 1). During every consult with the investigator the participant will be asked about complications.

During the multidisciplinary consultation, the pedorthist and medical specialist will decide together which type of shoes the patient will need. When instead of custom-made orthopaedic shoes convection shoes or semi-orthopaedic shoes will be prescribed, the patient can not be included in the study. After the patient has been prescribed custom-made orthopaedic shoes and he/she decided to participate in this study, the demographic data (age, gender, ethnicity,

height and weight), diabetes type and duration, risk profile, ambulatory status, history regarding the use of orthopaedic shoes, educational status, socioeconomic status, and capacity for self-care will be collected. Subsequently, data on the presence of peripheral arterial disease, peripheral neuropathy, foot deformities and history of previous foot ulceration and amputation will be recorded and the participants will be asked to fill in some questionnaires (see -T1 at Table 2). Thereafter the orthopaedic shoes will be fitted by the pedorthist who will provide the new digital shoe-fitting procedure or the casting-based procedure (see paragraph 5.1.1 or 5.1.2) depending on whether the podiatrist is trained in MI or not.

In one to six weeks the participant will have another consultation with the MI-trained podiatrist (first consult: participant was referred to the pedorthist). The podiatrist will apply MI in this conversation. After the extra (second) consult with the podiatrist, 30 participants will be approached for an in-depth interview. This interview will be done by the investigator.

Two to three months after the multidisciplinary consultation the participants will receive their first pair of orthopaedic shoes including a microsensor, for determining adherence (baseline). The participants will have another consult (two to four weeks later) for shoe control and fitting the second pair of orthopaedic shoes. During this consult they receive an activity monitor and instruction from the investigator. The participants will be instructed to wear the activity monitor for a whole week starting the day after this consultation (24 hours per day).

Six months after the first consultation with the podiatrist most participants will have another regular consult with the podiatrist for control of their feet. If the podiatrist is MI-trained also in this consult MI will be applied.

To deliver the second pair of orthopaedic shoes, a regular consultation appointment will be made after three months after receiving the first pair of shoes. The second pair of shoes will also be provided with a microsensor. During this consult the sensor of the first pair of shoes will be read out with the reading device by the investigator. Two till four weeks after receiving the second pair of orthopaedic shoes another regular control consultation will be planned. Again the participants will receive an activity monitor to register their activities. The activity monitor will also be worn for one whole week (24 hours per day). Three months after receiving the second pair of orthopaedic shoes a consultation with the investigator will be made to read out the sensors of both pair of shoes. The participants will also be asked to fill in some questionnaires (see Table 2). The same 30 participants as before will be approached for a second in-depth interview and the other participants will be asked to fill in the MOS_{post} (see paragraph 8.3.2.7) instead.

One year after the first consultation with the podiatrist every participant will have a regular consultation with the podiatrist for control of their feet. During this consult the sensors of both pair of shoes will be read out by the investigator. And also as before, in de consultations with the MI-trained podiatrist MI will be applied.

A last consult with the investigator will be planned about six months after receiving the second pair of orthopaedic shoes to read out both pair of shoes and to fill in some questionnaires (see Table 2).

8.3.2 Instrumentation

8.3.2.1 Orthotimer & readerdevice

The Orthotimer® microsensor (Rollerwerk medical engineering & consulting, Balingen, Germany) will be used for continuous, long-term measurement of adherence and is a valid sensor to measure temperature in footwear (36). The sensor measures the temperature within the footwear every 15 minutes (96 measurements per day) and stores these data for 100 days before overwriting the oldest data. Longer observation periods will be possible by reading out the sensor data before this deadline. Every sensor reading will be stored with a date- and timestamp. In case participants will be prescribed more than one pair of orthopaedic shoes, in both pair of shoes a sensor will be placed and data from both sensors will be combined.

The microsensor is controlled with the wireless reading device and the saved wearing time dates are transferred to the respective software. The reading device can be connected with the computer via a USB-plug. The software is used to control the microsensor as well as to perform the wear time analysis of the patient data.

8.3.2.2 Activity monitor

The Misfit Shine 2™ (Misfit Wearable, Burlingame, California, USA) is a small tri-axial accelerometer which will be carried at the lower extremity. The Misfit Shine 2™ measures steps, calories burned, distance, activity types, sleep quality and duration. The Shine 2 holds up to 30 days of activity data. The reliability of the Misfit shine is good (37). Data can be transferred reliable and wireless to the Health app (iPhone) or Google Fit (Android phone), which will be connect to the Tiim app (BMSLab/UTwente), so the data will be collected at a secured server.

8.3.2.3 iPCQ

The Institute for Medical Technology Assessment (iMTA) Productivity Cost Questionnaire (iPCQ) is a generic questionnaire that measures the extent of productivity losses using questions related to presenteeism at or absenteeism from paid work and productivity losses from a reduction in unpaid work (38). The questionnaire is not disease specific, so the reference is made to productivity losses due to illness or as a result of physical or psychological problems, without identifying a specific clinical picture.

8.3.2.4 iMCQ

The iMTA Medical Consumption Questionnaire (iMCQ) is a non-disease-specific instrument for measuring medical resource use during the preceding three months (30). The questionnaire includes 31 questions related to frequently occurring contacts with healthcare providers.

8.3.2.5 EQ-5D-5L questionnaire

The 5-Level EuroQol Quality of Life Scale (EQ-5D-5L) questionnaire essentially consists of two pages: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS) (39).

The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The participants will be asked to indicate his/her current health state placing a cross in the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit score that describes the participant's current health state. Finally, a utility value (health-related quality of life score) will be calculated using the 5-digit score, based on the Dutch tariff established for the EQ-5D-5L (40).

The EQ VAS records the participant's self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS can be used as a quantitative measure of health outcome that reflects the participant's own judgement.

8.3.2.6 RAND-36 V2.0

The RAND-36 item Health Survey (RAND-36) is an abridged version of the RAND Health Insurance Study Questionnaire (41). The RAND-36 V2.0 is frequently used for measuring experienced health or health-related quality of life. The instrument contains scales for physical functioning, social functioning, role limitations by physical or emotional problems, mental health, energy, pain and general health experience. A high score corresponds to a better health condition.

8.3.2.7 Monitor Orthopedic Shoes (MOS)

The MOS is a practical and reproducible questionnaire that can be used for a wide range of patients (33). The MOS consists of a pre-part (MOS_{pre}) and a post-part (MOS_{pos}). For the purpose of this study, we will use only the post-part, which is designed to measure use and the most relevant factors of usability of orthopaedic shoes from a participant's perspective through multiple choice and visual analogue scale questions (33). The use of orthopaedic shoes has been associated with several aspects of usability. Usability is "the extent to which a

product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction, in a specified context of use" (International Organization of Standardization (ISO), 9241-11). Within the domains of usability, the following factors are measured: change in walking capacity, wound healing, change in pain, and change in sprains (domain effectiveness); donning and doffing orthopaedic shoes, fit of orthopaedic shoes, ease of walking with orthopaedic shoes, and weight of orthopaedic shoes (domain efficiency); cosmetic appearance, and communication with medical specialist and orthopaedic shoes technician (domain satisfaction).

8.3.2.8 Interview structure

The interviews will contain quantitative and qualitative questions and will be structured according to the relevant concepts for adherence to orthopaedic shoes. To gain insight into the perspective of patients, motivations for and experienced advantages and difficulties regarding frequency, properly fit and adequacy wearing of orthopaedic shoes will be discussed with the participants.

To examine the perspective of MI-trained professionals, the following topics structure the interview: knowledge, adoption and implementation of the motivational interviewing procedure among podiatrist (adoption rate), and their experiences and attitudes towards applying MI in this group of participants. The interview guides can be found as appendix (see documents F4) to this METC-application.

8.3.2.9 MITI

The Motivational Interviewing Treatment Integrity (MITI) is a behavioural coding system (34) that provides an answer to the question: How well or poorly is a clinician using motivational interviewing? The MITI also yields feedback that can be used to increase clinical skill in the practice of motivational interviewing. The MITI has two components: the global scores and the behaviour counts. Both the global scores and behaviour counts are assessed within a single review of the audio recording. A random 20-minute segment is the recommended duration for a coding sample.

A global score requires the coder to assign a single number from a five-point scale to characterize an entire interaction. Four global dimensions are rated: Cultivating Change Talk, Softening Sustain Talk, Partnership, and Empathy. This means that each MITI review will contain four global scores.

8.3.3 Withdrawal of individual subjects

Participants can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a participant from the study for urgent medical reasons.

8.3.4 Specific criteria for withdrawal

Not applicable.

8.4 Replacement of individual subjects after withdrawal

If participants drop out of the study additional participants will be included until N=220.

8.5 Follow-up of subjects withdrawn from treatment

Withdrawn participants will be approached maximally once, in order to ascertain reasons for drop-out.

8.6 Premature termination of the study

Given the low risk of the intervention, there are no criteria set for premature termination of the study, because this is not to be expected.

9. SAFETY REPORTING

9.1 Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise participants health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all participants are kept informed.

9.2 AEs, SAEs and SUSARs

9.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a participant during the study, whether or not considered related to the trial procedure. All adverse events reported spontaneously by the participant or observed by the investigator or her staff will be recorded.

9.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

The investigator shall report serious adverse events to the sponsor without undue delay after obtaining knowledge of the events, unless, for certain serious adverse events, the protocol provides that no immediate reporting is required.

The (principal) investigator will report the SAEs through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete

the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

9.2.3 Suspected unexpected serious adverse reactions (SUSARs)

Not applicable.

9.3 Annual safety report

Not applicable.

9.4 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.
SAEs need to be reported till end of study within the Netherlands, as defined in the protocol.

9.5 Data Safety Monitoring Board (DSMB) / Safety Committee

Not applicable.

10. STATISTICAL ANALYSIS

Adherence to orthopaedic shoes and daily step count will be assessed using raw data from the sensors using the R environment for statistical computing (R Foundation, Vienna, Austria (42)). Participants will be included in the analyses only if at least four complete days of recoding, including one weekend day, is available. When both the footwear-based sensor and the step activity monitor will show activity during recording, it will be assumed that the subject walked with the orthopaedic shoes. If only step activity will be recorded, it will be assumed that the participant was walking barefoot or walking in non-prescribed shoes. Adherence level will be defined as the percentage of total steps during the full recording period that the orthopaedic shoes are worn.

Statistical analysis will be carried out with R. For all analyses a significance level of $P < 0.05$ will be adopted.

10.1 Descriptive statistics

Anthropometric data, other patient characteristics and data from adherence to orthopaedic shoes and step count will be presented as mean or median with their standard deviation or the frequencies will be presented. Differences at baseline characteristics, between the participants receiving the novel care approach and usual care, will be tested with a t-test, Mann-Whitney U test, Chi-square test or Fisher's exact test, depending on the kind of variable and being normally distributed or not.

10.2 Primary study parameter

Differences in proportion of participants, who adhere to the use of their orthopaedic shoes, that is, take at least 80% of their total steps with orthopaedic shoes, between the participants receiving the novel care approach and usual care, will be tested using a generalized linear mixed model (GLMM).

10.3 Secondary study parameters

Differences in the level of adherence to the use of orthopaedic shoes of participants and differences in the proportion of participants (re-)experiencing complications after receiving their orthopaedic shoes, up to one year after baseline between the two groups of participants will be tested using a generalized linear mixed model. Also the quantitatively measured aspects of the patient perspective and the perspective of the MI-trained podiatrist, will be tested using a

generalized linear mixed model. The type of GLMM depends on the variable that will be tested in the model.

10.3.1 Patient perspective and perspective of MI-trained podiatrist

To analyse the patient perspective and the perspective of the MI-trained podiatrist a distinction will be made between quantitative and qualitative data. The differences in quantitative data of the perspective of the patient and the MI-trained podiatrist, will be tested as mentioned above. Besides, the quantitative data will be presented as mean or median with their standard deviation and the frequencies will be presented.

The qualitative (verbal) data of the perspective of the patient and the MI-trained podiatrist will be summarized with two code schemes (one for the patient perspective and one for the podiatrist perspective). The code schemes will be developed inductively, meaning that the coding will be data driven. Content and frequency of main themes will be compared for the two groups of participants and this information will be triangulated with the quantitative information on the perspective of patients to explain in more depth the results of adherence and in order to formulate implementation advises from the patients perspective. This triangulation approach will also be applied for the quantitative and verbal data of the MI-trained podiatrists.

10.3.2 Cost-effectiveness analysis (CEA)

The cost-effectiveness of the new digital shoe-fitting procedure compared with usual care will be determined by dividing the difference in mean costs (in Euros) and by the difference in mean health outcomes (in QALYs) to estimate the incremental cost-effectiveness ratio (ICER). For the trial-based, short-term CEA bootstrapping will be applied to determine the uncertainty in this ICER. For the model-based, long-term CEA, probabilistic sensitivity analysis will be applied to assess how uncertainty in model input parameters results in uncertainty in the ICER. Results will be presented in incremental cost-effectiveness planes and cost-effectiveness acceptability curves.

10.4 Other study parameters

Not applicable.

10.5 Interim analysis

Not applicable.

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (64th version, October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

11.2 Recruitment and consent

Eligible patients, who will be referred to the pedorthist for orthopaedic shoes, will be informed about the study by the podiatrist and will receive the information brochure and informed consent form (see document E1 & E2). The podiatrist will ask permission to send contact details to the research team. On receipt of that permission, the podiatrist will provide details of the patient to the coordinating investigator. The coordinating investigator will contact the patient in order to further explain the study and answer any questions the patient may have. After this contact the patient will be given minimal one week to decide to participate in this study. During the multidisciplinary consultation with pedorthist and medical specialist the patients will be asked if he/she decided to participate in this study. If he/she decided to participate, the investigator or the investigator's representative will ask the patient to sign informed consent.

11.3 Objection by minors or incapacitated subjects

Not applicable.

11.4 Benefits and risks assessment, group relatedness

There will be no direct benefit for the participants from the study. Improved insights into the socio-economic impact of the novel care approach on adherence to orthopaedic shoes, are crucial steps towards better ulcer prevention in people with diabetes at high-risk.

There will be no risk to participate in the study. The burden of the study will mainly be the time it will take to complete the questionnaires and the in-depth interviews.

11.5 Compensation for injury

The multicentre sites have a liability insurance which is in accordance with article 7 of the WMO.

The multicentre sites have an insurance which is in accordance with the legal requirements in the Netherlands (Article 7 WMO). This insurance provides cover for damage to research subjects through injury or death caused by the study.
The insurance applies to the damage that becomes apparent during the study or within 4 years after the end of the study.

11.6 Incentives

Not applicable.

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

Data will be pseudonymized by the coordinating investigator. Data cannot be traced back to the identity of participants. The key code will be stored on a different server than the data. The principle investigator will decide who of the research group will have access to the data. Name of the participants will only be recorded on the informed consent form, which will be kept in a locked cupboard with the coordinating investigator, separated from the digital data and without a possibility to trace the data. All study data will be entered anonymized in a central facility (LISA) of the University of Twente for storage and archiving. The handling of the data will be comply with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation (Uitvoeringswet AVG, UAVG). All study information will be saved for 10 years after the study ended.

12.2 Monitoring and Quality Assurance

The investigators are responsible for procedures of data monitoring. To facilitate compliance with Good Clinical Practice guidelines, the investigator will permit study-related monitoring, audits, and inspections by authorized organizations. Aspects that will be monitored may include: inclusion rate; informed consent progress; inclusion and exclusion criteria; trial master file; source data verification; safety reporting; trial procedures and closing and reporting.

12.3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion. All substantial amendments will be notified to the METC and to the competent authority. Non-substantial amendments will not be notified to the accredited METC and the competent authority, but will be recorded and filed by the sponsor.

12.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first participant, numbers of participants included and numbers of participants that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

12.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last participant's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

12.6 Public disclosure and publication policy

It is our intention to publish the findings of the study in (medical) scientific journals and to present them at scientific meetings. The responsibility for publication and presentation belongs to the investigators. Only those investigators making a significant contribution to the study design and/or the collection, analysis or interpretation of the study data will be eligible for authorship. No restrictions regarding the public disclosure and publication of the research data have, or will be made, by the funder.

13. STRUCTURED RISK ANALYSIS

Not applicable.

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