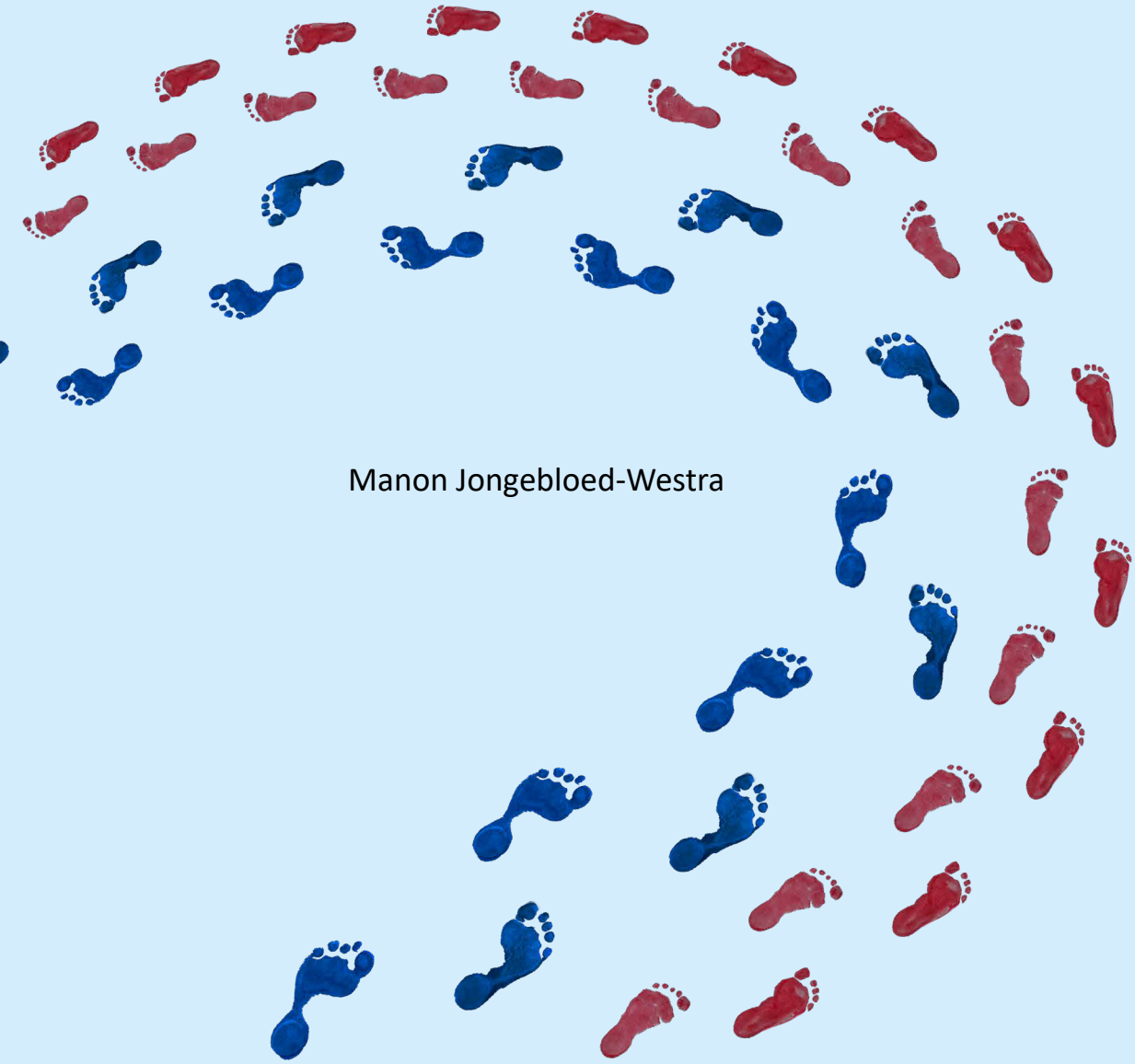
PREVENTION AND HEALING OF DIABETES-RELATED FOOT ULCERS

MOTIVATIONAL INTERVIEWING, OBJECTIVE ADHERENCE AND OFFLOADING



Manon Jongebloed-Westra

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DISSERTATION

To obtain the degree of
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prof.dr.ir. A. Veldkamp,
on account of the decision of the Doctorate Board
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By
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CONTENTS

Chapter 1

General introduction

Diabetes mellitus is one of the most common chronic diseases worldwide. In 2021, one in every ten adults worldwide (537 million people) were living with diabetes (1). According to estimates of the International Diabetes Federation this number will increase by 46% to 783 million people by 2045 (1). In the Netherlands, over 1.1 million people had diabetes in 2019, a number that is expect to increase to almost 1.5 million in 2040 (2). These increasing rates are caused by a longer life-expectancy and our changing lifestyle (e.g., physical inactivity, overweight and obesity). These developments are alarming because people with diabetes are at risk of developing numerous complications, including heart attacks, strokes, retinopathy and nephropathy. Another, and one of the most common serious and debilitating complications is diabetes-related foot disease (3, 4).

Diabetes-related foot disease is defined as "disease of the foot of a person with current or previously diagnosed diabetes mellitus that includes one or more of the following: peripheral neuropathy, peripheral artery disease (PAD), infection, ulcer(s), neuro-osteoarthropathy, gangrene, or amputation" (5). Among people with diabetes, diabetes-related foot ulcers have a yearly incidence of 2-4% and a life-time prevalence of 19-34% (6). The estimated annual prevalence of these foot ulcers in the Netherlands is close to 60,000, while the current global prevalence of foot ulceration is estimated at 18.6 million (7). These diabetes-related foot ulcers have a serious impact on the person's health and life. First of all, even after successful healing, 40% of the people develop a recurrent foot ulcer within one year and even 60% within three years (6). Besides, these foot ulcers significantly increase the risk of infection and amputation, are the most frequently reason for hospitalization (6, 8), and can cause immobility and a reduced quality of life (9). In addition to these health-related effects, diabetes-related foot ulcers incur high costs due to unemployment (loss of productivity), hospital admissions, and home care (6, 10-14). Therefore, prevention of diabetic-related foot ulcers has high priority to reduce the burden on people with diabetes, healthcare systems and society (6, 9-14).

PREVENTION OF FOOT (RE)ULCERATION

For ulcer prevention, insights in the pathogenesis of diabetes-related foot ulceration and its risk factors are important. Diabetes-related foot ulcers are caused by a simultaneous action of multiple contributing causes (8). The most relevant underlying pathologic conditions are peripheral nerve damage and vascular dysfunction (15). The most important risk factor for diabetes-related foot ulceration is peripheral neuropathy which is present in approximately 30-50% of all people with diabetes. As a result of peripheral neuropathy, people experience loss of sensory, motor, and/or automatic nerve function. Peripheral sensory neuropathy leads to loss of protective sensation (LOPS) of the feet, resulting in the inability to recognize (minor) trauma, biomechanical load, pain, friction or heat (8). Missing this protective sensation makes the treatment of people with LOPS of the feet complex, because a different kind of motivation is needed to achieve a specific goal. Besides, peripheral motor neuropathy can result in muscle atrophy in the foot muscles and subsequent changes in the shape of the foot that can lead to abnormal biomechanical loading on the foot (6, 16, 17). A dry skin and decreased sweating caused by peripheral autonomic neuropathy can lead to hyperkeratosis (15, 18). These pre-signs for diabetes-related foot ulcers together with foot deformities and edema, lead to poor fit of shoes and high peak plantar pressures (15, 18). In

combination with peripheral sensory neuropathy, these high peak plantar pressures during ambulatory activity such as walking on insensitive foot are an important risk factor for foot ulcer formation and persistence (6, 19, 20).

To treat these pre-signs for diabetes-related foot ulcers people at high-risk of developing foot ulcers are recommended to see a podiatrist once every 1-3 months, as compared to every 12 months or less for those not at high-risk (21). Besides, offloading areas of high plantar pressure by redistributing the pressure from these areas to other plantar areas that are at lower risk for ulceration is the cornerstone to prevent (re)ulceration and heal foot ulcers (21-28). Adherence to wearing orthopedic shoes (i.e., custom-made insoles in custom-made shoes) is considered essential for preventing (re)ulceration, because these shoes are optimized for high pressure reduction at locations that are at high risk for ulceration (27). A reliable and accurate method to objectively assess wearing time of orthopedic shoes is based on temperature measurements inside these shoes (29, 30). However, previous studies that used objective temperature-based sensors to measure wearing time, had some limitations regarding the limited measurement period and sample size (31-33). No robust data on longer-term wearing patterns (e.g., six months or more) of orthopedic shoes in people with diabetes at moderate-to-high risk of diabetic-related foot ulceration is currently available. Besides, these previous studies showed large variations in wearing time between participants which suggests that differences between participants might explain the differences the wearing pattern of orthopedic shoes (31-33). However, previous studies have not provided conclusive evidence for any factors to be predictive of adherence to wearing orthopedic shoes (34). Therefore, more research is needed to identify potential factors associated with adherence to wearing orthopedic shoes to improve adherence and reduce foot ulcerations in people with diabetes.

Adherence

Adherence is defined as “the extent to which a person’s behavior corresponds with agreed recommendations for treatment from a healthcare provider” (35). Despite that those who adhere to foot self-care have significantly better outcomes, a randomized trial in The Netherlands found that adherence to orthopedic shoes is rather low. The results showed that only 46-49% of the participants wore their orthopedic shoes for at least 80% of daily total steps (27, 31). As targeting general predicting factors may have a limited effect on adherence, also other factors have to be taken into consideration for improving adherence substantially (34). Nevertheless, most studies on diabetes-related footwear to date have focused on physical and clinical characteristics rather than social and psychological factors (34). Recent guidelines have stressed that it is essential to enhance patients’ motivation to act and adhere to the advice, to ensure sufficient foot self-care skills in people diabetes, because they often have LOPS of their feet (8). Especially in these people adherence to foot self-care (among other things wearing orthopedic shoes), and stimulation and facilitation of behavioral change are crucial to improve outcomes and prevent (re)ulceration for people at high-risk of developing foot ulcers (6, 8, 36-40).

Since podiatrists provide long-term foot care to people with diabetes, they are a key professional for stimulating adherence to foot self-care and behavioral change (8, 41-43). To improve foot self-care, patient education is often used to increase the person’s skills and

knowledge (14, 21, 38, 44). However, previous studies also showed that merely informing at-risk people with diabetes about the advantages of foot self-care is insufficient to realize behavioral change (14, 21, 38, 44). While people at-risk of foot ulcers generally have the required knowledge about prevention and risks, and high perceived self-efficacy (14, 45), their actual adherence to self-care behavior is consistently low (21, 31, 36, 46). Therefore, techniques other than mere knowledge transfer are important to stimulate behavioral change and improve adherence to foot self-care.

Motivational interviewing

One key determinant of behavior change is a person's motivation. Montano et al. (47) described that recommended behaviors must be considered important enough by the person for them to become adherent to these behaviors. A healthcare provider's communication style can affect a person's motivation to become adherent, and thus contribute to behavioral change (14, 48, 49). Previous studies showed that communication with the healthcare provider is essential to influence a person's decision to use orthopedic shoes and is associated with increased long-term use of orthopedic shoes (50, 51). To influence adherence to foot self-care behaviors, a healthcare provider's communication style that results in a working alliance or partnership between the healthcare provider and patient may be needed. A working alliance or partnership means that the healthcare provider and patient work together to increase adherence by changing the patient's behavior regarding foot self-care (48, 49). However, until now, most podiatrists still use a traditional communication style in patient education, which is usually directive and one-sided, and is focused on giving expert advice instead of behavioral change (48, 49, 52, 53). Like other healthcare providers, podiatrists generally receive communication training but not specifically on building a working alliance with their patients or specific person-centered communication techniques to elicit behavioral change and avoid resistant reactions in people (52, 54). Without developing these shared decision-making skills, podiatrists may be limited in changing the foot self-care behavior of people at high-risk of developing foot ulcers (55-58). Podiatrists could apply a more person-centered approach with shared decision-making, in which behavioral change is the aim (55-58), by learning to listen to and engage with the patient's perspectives of their situation. Furthermore, podiatrists can discuss patient expectations and acceptance of the recommended treatment.

Motivational interviewing (MI) is one promising person-centered communication style designed to stimulate and enhance behavioral change. MI is "a collaborative goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion" (59). MI consists of two active components: a relational component, which focuses on empathy and the interpersonal spirit of MI, and a technical component, which involves the differential evocation and reinforcement of a person's change (60). MI requires the healthcare provider to engage in a working alliance with the patient as an equal partner by shared decision making and to use communication skills that stimulate behavioral changes (60). MI is aimed at avoiding giving unsolicited advice or directing, confronting, warning, or instructing the patient (59). Systematic reviews and meta-analysis show that MI has been used successfully in a wide array of health behavior or lifestyle problems and has

demonstrated robust effects in a variety of clinical settings and diseases (61-66). However, it has also been shown in various healthcare contexts that mastering MI requires training and practice (67, 68), and that time investment, self-awareness and discipline from the healthcare provider are needed to apply an MI-communication style (69). This also applies to diabetes healthcare providers (70).

Since podiatrists work at the front lines of diabetic foot care for people with diabetes at high-risk of foot ulcers and are motivated to help guide these persons toward better self-care, there is a great opportunity for podiatrists to explore MI to change patients' behavior (52). However, the podiatrists' attitudes and experience towards the use of MI and the implementation of the MI-techniques in their work with people with diabetes at risk of foot ulcers are unknown. Kaczmarek and colleagues found that training podiatrists in MI has the potential to improve their MI-related communication skills (53). Another explorative study that used a short, feedback-driven training program showed that the investigators were sufficiently trained to enhance motivation for change in people with diabetes at high-risk of foot ulcers (71). However, Kaczmarek et al. conducted their study without a control group (53) and Keukenkamp et al. trained investigators who had no direct clinical experience treating people with diabetes instead of training podiatrists (71). To better understand the application and effects of MI in consultations in daily practice requires a controlled study setting comparing MI-trained and non-MI-trained podiatrists.

The literature reviewed above suggests that a psychosocial approach may improve adherence to wearing orthopedic shoes meaningfully (52, 53, 71). However, there is little knowledge about the effectiveness of MI applied by podiatrists in this specific patient group, and the cost-effectiveness has not been studies at all (21). A well-powered randomized controlled trial would generate insights into the socio-economic impact of motivational interviewing on adherence to orthopedic shoes and are crucial steps toward better ulcer prevention in people with diabetes at low-to-high risk of foot ulceration and to improve their quality of life.

HEALING OF FOOT ULCERS

As mentioned before, the cornerstone to healing foot ulcers is offloading areas of high plantar pressure to other plantar areas that are at lower risk for ulceration (22, 23, 25, 26). However, when a foot (re)ulceration does occur, different offloading devices are available, which differ from each other in device characteristics: e.g., knee-high vs. ankle-high, non-removable vs. removable, and custom-made vs. prefabricated. These different design characteristics all contribute to the potential offloading effect of such a device (22, 23, 25, 26). The international guidelines recommend the use of non-removable knee-high devices as first option of treatment (8). Meta-analyses and health technology assessments showed that these devices have higher healing rates than other devices (22, 23, 25, 26). Knee-high devices are more effective in reducing plantar pressure than below-the-ankle-devices, mostly because the shaft of a knee-high device can pick up a significant portion of the load on the lower-extremity (72, 73). The knee-high devices in these studies were either removable or non-removable (72, 73), and it can be questioned whether the removability influences the offloading capacity. However, the (relative) contribution of the different

design characteristics of the different devices are insufficiently studied. To better understand the design characteristics, to drive development of standardized casting protocols, and to improve clinical decision-making in the offloading treatment of diabetic plantar forefoot ulcers a controlled study setting comparing the different design characteristics is needed.

AIM OF THIS THESIS

This thesis was part of one of the calls of the program "Goed Gebruik Hulpmiddelenzorg thuis" of ZonMw. Therefore, the overall aim of this thesis is to expand our knowledge and understanding of objectively measured long-term adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration, the potential of the application of motivational interviewing by podiatrists to change adherence behavior and to prevent (re)ulcerations, and the value of different offloading devices for healing of diabetes-related foot ulcers in (clinical) daily practice. Specifically, this thesis has the following objectives:

1. To objectively assess long-term wearing patterns and identify factors associated with wearing of orthopedic shoes in a large group of people with diabetes at moderate-to-high risk of ulceration.
2. To analyze the application of MI in consultations carried out by MI-trained podiatrists and the way of communication of the non-MI-trained podiatrists in daily clinical practice, and to explore the podiatrists' attitudes and experiences towards the use of MI and the implementation of the MI-techniques in their work with people with diabetes at high-risk of foot ulcers.
3. To evaluate the effectiveness of MI performed by an MI-trained podiatrist, in improving objectively measured 3- and 6-months adherence to wearing orthopedic shoes and 1-year ulcer prevention in comparison to usual care in people with diabetes at low-to-high risk of foot ulceration.
4. To investigate the offloading effect of the different design characteristics that make up a non-removable knee-high cast for people with diabetes and active or previous plantar forefoot ulcers.

OUTLINE OF THIS THESIS

Chapter 2 presents a study that objectively measured long-term wearing patterns and identified factors associated with wearing of orthopedic shoes in a large group of people with diabetes at moderate-to-high risk of ulceration. In chapter 3 the rationale and design of our trial to examine the effect of MI on adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration are provided. Chapter 4 shows the results of a mixed-methods study on the application of MI in consultation carried out by MI-trained podiatrists and the way of communication of the non-MI-trained podiatrists in daily practice. Results of quantitative and qualitative components were combined through triangulation to obtain outcomes from different perspectives and contextualize the results of the MI-training. Chapter 5 presents the results of our trial on the effectiveness of MI performed by an MI-trained podiatrist, in improving objectively measured 3- and 6-months adherence to wearing orthopedic shoes and 1-year ulcer prevention in comparison to usual care in people with diabetes at low-to-high risk of foot ulceration. To contextualize the results of the effectiveness of MI in improving adherence to wearing orthopedic shoes and ulcer

prevention, the participants' experiences on the use and usability of their orthopedic shoes and health-related quality of life (HRQoL) were also assessed. Chapter 6 describes a study in which the effect of the different casting design characteristics on offloading devices for the diabetic foot are determined. Finally, in chapter 7, the main findings of the studies in this thesis are discussed in the context of the currently available literature. Furthermore, critical reflections of the methodologies used, implications for clinical practice and future research are described, and finally a general conclusion is provided.

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Chapter 2

Objectively assessed long-term wearing patterns and predictors of wearing orthopaedic shoes in people with diabetes at moderate-to-high risk of foot ulceration: a 12 months observational study

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ABSTRACT

Background: Orthopaedic footwear can only be effective in preventing diabetic foot ulcers if worn by the patient. Robust data on long-term wearing time of orthopaedic footwear are not available, and needed to gain more insights into wearing patterns and associated factors (i.e. participants' demographic, disease-related characteristics, and footwear usability). We aimed to objectively assess long-term wearing patterns and identify factors associated with wearing orthopaedic footwear in people with diabetes at moderate-to-high risk of ulceration.

Methods: People diagnosed with diabetes mellitus type 1 and 2 with loss of protective sensation and/or peripheral artery disease and prescribed with orthopaedic footwear were included and followed for 12 months. The primary outcome was mean daily wearing time, continuously measured using a temperature sensor inside the footwear (Orthotimer®). Adherence to wearing orthopaedic footwear was calculated as percentage of wearing time of a total assumed 16 h out-of-bed daytime, where adherence <60% was a pre-determined non-adherent threshold. Wearing time patterns were assessed by calculating participants' wearing (in)consistency. One-way analyses of variance tested for wearing time differences between subgroups, weekdays, and weekend days. Factors potentially associated with wearing time were collected by questionnaires and medical files. Univariately associated factors were included in multivariate linear regression analysis.

Results: Sixty one participants were included (mean (SD) age: 68.0 (7.4) years; females: N=17; type 2 diabetes mellitus: N=54). Mean (SD) overall daily wearing time was 8.3 (6.1) hours/day. A total of 40 (66%) participants were non-adherent. Participants with a consistent wearing pattern showed higher daily wearing times than participants with an inconsistent pattern. Mean (SD) wearing times were 12.7 (4.3) vs 3.6 (4.8) hours/day, respectively ($p<0.001$). Mean (SD) wearing time was significantly higher ($p<0.010$) during weekdays (8.7 (6.0) hours/day) compared to Saturday (8.0 (6.1) hours/day) and Sunday (6.9 (6.2) hours/day). In the multivariate model ($R2=0.28$), "satisfaction with my wear of orthopaedic footwear" was positively associated ($p<0.001$) with wearing time. The other seven multivariate model factors (four demographic variables and three footwear usability variables) were not associated with wearing time.

Conclusions: Only one out of three people at moderate to high risk of foot ulceration were sufficiently adherent to wearing their orthopaedic footwear. Changing people's wearing behaviour to a more stable pattern seems a potential avenue to improve long-term adherence to wearing orthopaedic footwear. Investigated factors are not associated with daily wearing time. Based on these factors the daily wearing time cannot be estimated in daily practice.

Trial registration Netherlands Trial Register NL7710. Registered: 6 May 2019

INTRODUCTION

In 2019 approximately 463 million adults aged 20-79 were living with diabetes mellitus (1). These people have an increased risk of developing foot ulcers due to reducing or absence of sensory feedback, presence of peripheral artery disease and presence of foot deformities, leading to high plantar pressures (2). When an ulcer is healed, 40% of people with diabetes develop a recurring ulcer within one year, and this increases to 60% within three years (3). Offloading interventions including orthopaedic footwear help to reduce plantar pressure and thereby prevent plantar diabetic foot ulcer recurrence (4-6). Adherence to wearing orthopaedic footwear is essential to prevent ulcer recurrence, but this is challenging because most patients are dissatisfied with usability of their orthopaedic shoes (7).

The first studies on footwear adherence in people with diabetes, performed in the '90s and '00s, showed that only 22-36% of those at risk of foot ulceration wore their prescribed footwear all day (7, 8) or at least 80% of daytime (9). However, none of these studies were conducted in the last decade, limiting comparison to current practice that has changed with new improved footwear and new guidelines now available (10). Furthermore, these previous studies used questionnaires or interviews to assess self-reported adherence to orthopaedic footwear, which may have low accuracy because of recall and response bias (11). A more reliable and accurate method to objectively assess adherence is based on temperature measurements inside the footwear to identify (non-)wearing of that footwear (12). Such an objective temperature-based sensor was used in three more recent studies on wearing diabetic footwear (13-15).

Waaijman et al. objectively measured orthopaedic shoe use in combination with daily step counts during seven consecutive days in 107 participants (14). They showed that on average 71% of all steps were taken in orthopaedic footwear, but individual adherence rates varied widely (10–100%) (14). Later, Ehrmann et al. showed a mean (standard deviation (SD)) wearing time of prescribed custom-made footwear (i.e. custom insoles in an extra-depth, stiff, rocker shoe) of 4.2 (3.6) h/day in 26 participants over a mean of 133.5 observed days (15). Most recently, Lutjeboer et al. monitored wearing time in 11 persons with diabetes over the first 12 weeks after delivery of the orthopaedic footwear. They showed a mean wearing time of 6.95h/day and 2.42h/day in, respectively, the group aware of being monitored on wearing time (N=6) and the no awareness group (N=5) (16). However, these studies had limitations in measurement period (seven days only in the largest study (14), 3-5 months in the smaller studies (15, 16), and in sample size (N=26 and N=11 in the studies with longer follow-up (15, 16)). Robust data on longer-term wearing patterns (e.g. six months or more) of orthopaedic shoes in people with diabetes at risk of foot ulceration are still lacking. These data are necessary to gain a better insight into wearing patterns in daily practice, because we hypothesize that wearing time is not constant throughout one year follow-up.

All three previous studies showed large variations in wearing time between participants, which suggest that differences between participants might be important in adherence to wearing orthopaedic footwear. Previous studies to factors associated with adherence to wearing orthopaedic footwear had similar limitations (e.g. short measurement period, small sample sizes, self-reported adherence) and did not result in definitive conclusions

(17). As such, there is more in-depth knowledge needed about potential factors associated with adherence to wearing prescribed footwear in people with diabetes.

The aim of the current study was to objectively assess long-term wearing time, wearing patterns and identify factors associated with wearing of orthopaedic footwear (i.e. custom-made insoles in custom-made shoes) in a large group of people with diabetes at moderate-to-high risk of ulceration.

METHODS

Study design

The cohort investigated in the current study was a control group of a 12-month cluster-randomized controlled trial (C-RCT) assessing the (cost-)effectiveness of a novel care approach (motivational interviewing) compared to usual care in improving adherence to wearing orthopaedic footwear (18). The trial was registered in the Netherlands Trial Register, NL7710 (18) (Available on the International Clinical Trials Registry Platform). The trial was assessed as exempt from medical ethical approval by the ethical committee region Arnhem–Nijmegen, the Netherlands (NL68567.091.19) according to Dutch law, and its protocol has been published in detail elsewhere (18). The study protocol was approved by the Ethical Committee of Behavioural, Management and Social Sciences faculty of the University of Twente (file number 190141) (18).

All participants had a temperature sensor built in their orthopaedic footwear to monitor daily wearing time (hours/day) during 12-month follow-up. The primary study outcome was mean overall daily wearing time. The secondary outcomes were wearing time patterns, assessed by calculating participants' (in)consistency of wearing orthopaedic footwear, comparing differences between weekdays (Monday through Friday) and weekend days (Saturday and Sunday), and investigating seasonal differences. Factors potentially associated with orthopaedic footwear (i.e. participants' demographic, disease-related characteristics, and footwear usability) were collected by questionnaires and from participants' medical files.

Setting

Participants were recruited at locations of Voetencentrum Wender and Voetmax Orthopedie, located in the east of The Netherlands. Eligible participants were informed about the study by the podiatrist and received an information brochure and informed consent form. After participant's permission, the coordinating investigator contacted the participant in order to further explain the study. Thereafter, the participant had minimal one week to decide to participate. Recruitment started in July 2019 and was completed in January 2021. Participants were followed for 12 months. The orthopaedic footwear were prescribed by a medical specialist who was experienced in treating people with diabetic foot disease. Participants received usual care, as provided in standard clinical practice in the Netherlands in accordance with evidence-based guidelines (19).

Participants
Inclusion criteria were: diagnosis of diabetes mellitus type 1 and 2 patients; age ≥ 18 years; loss of protective sensation (LOPS) and/or peripheral artery disease (PAD), and prescribed with orthopaedic footwear for foot deformities (International Working Group on the Diabetic Foot (IWGDF) risk 2-3) (11). All participants were screened for eligibility by trained podiatrists. LOPS was measured using the 10 g Semmes-Weinstein monofilament (20) and PAD using an audible handheld Doppler (Huntley Digital Doppler®; Huntleigh Healthcare Ltd, Cardiff, Wales), with the diagnosis based on presence or absence of triphasic pedal Doppler waveforms (21). Exclusion criteria were: inability to follow study instructions; active Charcot's neuro-arthropathy; foot infection; or being unable to walk. Written informed consent was obtained from each participant prior to inclusion in the trial.

On the informed consent form, participants agreed to the sensor placement and data storage. In both the information brochure and informed consent form participants were not notified that the sensor was used to monitor daily wearing time; it was only described as temperature monitoring sensor. Logged temperature data were collected from the microsensors every three months. These moments were mostly combined with regular appointments with a pedorthist or podiatrist. Otherwise data were read out during an additional appointment or at the participant's home. Participants who withdrew or were deceased before the first sensor reading were excluded from further analysis. Drop-outs after the three-month mark were included in the analysis, including reason registration for withdrawn.

Measuring days from periods in which participants (re-)experienced complications (e.g. diabetic foot ulcer, lower-extremity amputation, or hospitalization) that could have affected wearing time were excluded from analysis. These complication periods were selected by retrospectively screening participants' medical files after study completion. Whenever either the start or end date of a complication period was unknown, an exclusion period of 165 days was used based on diabetic foot ulcer (DFU) healing time showed in a recent study conducted in the same geographical region (22).

Instrumentation
Every pair of orthopaedic footwear that participants possessed and used at study entry (i.e. earlier prescriptions) or that was prescribed and provided during follow-up was included in the study and equipped with a microsensor (Orthotimer®; Rollerwerk medical engineering & consulting, Balingen, Germany). The sensor was placed in the medial arch of the shoe insole because of sufficient place in the insole, relatively low pressure from the foot, and its previous validation at this location (23). The sensor stored temperature with a date- and timestamp every 20 minutes and had a storage capacity of 133 days before overwriting the oldest data. At 12 months, participants were asked to fill in the Monitor Orthopaedic Shoes (MOS) questionnaire to measure their perception regarding their orthopaedic footwear use and usability, and their subjective assessment of their wearing behaviour (24).

Variables

Wearing time

The total daily wearing time of all pairs of orthopaedic footwear during the 12-month follow-up was based on logged temperature data with date- and timestamps from the sensors, and calculated with the validated Groningen algorithm, version 2, using Matlab (R2017a, The MathWorks, Inc., Natick, Massachusetts, United States) (23, 25). The primary outcome was the participants' mean overall daily wearing time (hours/day) during the study, and was calculated as:

$$Mean\ daily\ wearing\ time = \frac{\sum_{i=1}^{n\ days} \sum_{i=1}^{n\ sensors} daily\ wearing\ time\ (\frac{hours}{day})}{n_{days}}$$

Besides wearing time, adherence to wearing orthopaedic footwear was calculated as percentage of wearing time of a total assumed 16 hours out-of-bed daytime, to compare outcomes with previous studies using the same adherence definition (adherent ≥80%, medium adherent ≥60%<80%, non-adherent <60%) (10, 14, 26). Missing data (i.e. due to delayed sensor readings or drop-outs after three-months) or invalid data (i.e. summed daily wearing time ≥24 hours or measuring days from periods in which participants (re-)experienced complications) were not imputed.

Wearing time patterns

Secondary outcomes were the wearing time patterns and factors potentially associated with wearing time. Patterns based on (in)consistency of wearing orthopaedic footwear were assessed by calculating the coefficient of variation (CV) for each participant over the 12-month follow-up, defined as the ratio of the standard deviation to the mean wearing time (27). The CV is a standardized measure of dispersion. Participants were split into tertiles from low to high CV. Participants in the low CV tertile had the most consistent wearing pattern and those in the high CV tertile had the most inconsistent wearing pattern. To assess seasonal differences in wearing time, astronomical seasonal periods were used; Spring (21st of March – 20th of June), Summer (21st of June – 20th September), Autumn (21st of September – 20th of December), and Winter (21st of December – 20th of March). Participants were included in the comparison of seasonal wearing times when at least 50% of seasonal days were assigned as valid during each season.

Predictors

Demographic data (i.e. gender, age, body mass index (BMI), education level, working situation, living situation, self-reliance, dependence on an assistive device) and disease-related characteristics (i.e. diabetes type, diabetes duration, IWGDF risk profile) were collected using participants' medical files and self-report at study entry. Footwear usability variables (i.e. walking ability, perceived walking change by orthopaedic footwear, shoe fit, shoe walking, shoe weight, donning and doffing, aesthetic, aesthetic perceived by others, number of orthopaedic footwear pairs, footwear possession, owns regular off-the-shelf shoes, satisfaction with my wear of orthopaedic footwear, orthopaedic footwear wearing goal reached) were collected using the MOS-questionnaire at 12 months.

Statistical analyses

Statistical analysis was performed using SPSS statistical software (V28.0, SPSS, New York, USA), with significance level of $p<0.05$. Wearing time was stated to fit a normal distribution (Anderson-Darling test; $p=0.368$). Descriptive statistics for wearing time were calculated as the mean (SD) for all participants, wearing (in)consistency subgroups (low CV, medium CV, and high CV), adherent subgroups (non-adherent, medium adherent, adherent), weekdays, and weekend days.

One-way analyses of variance (ANOVA) tested for differences between (in)consistency subgroups, adherent subgroups, week and weekend days, and seasonal periods. Tukey-Kramer post-hoc analyses were applied for pairwise comparisons. Univariate linear regression tested the associations with the dependent variable daily wearing time for all dichotomous and continuous independent variables. Variables with $p<0.20$ were entered into a forward multivariate linear regression analysis to identify unique determinants of wearing time. Collinearity between independent variables was tested by linear regression, where Pearson's correlation coefficients ≥0.70 were defined as correlated. In the event of collinearity where both variables also had a near significant ($p<0.20$) correlation with wearing time, only the variable with highest association with daily wearing time was entered in the multivariate linear regression model. Post-hoc power analyses based on a two-sided alpha of 0.05 and power of 0.80 were performed (version 3.1.9.7, G*Power, Germany) to test whether the sample size met for subgroups comparisons and multivariate linear regression analysis.

RESULTS

A study flowchart is shown in Figure 1, and a summary of the participants' data is shown in is Table 1.

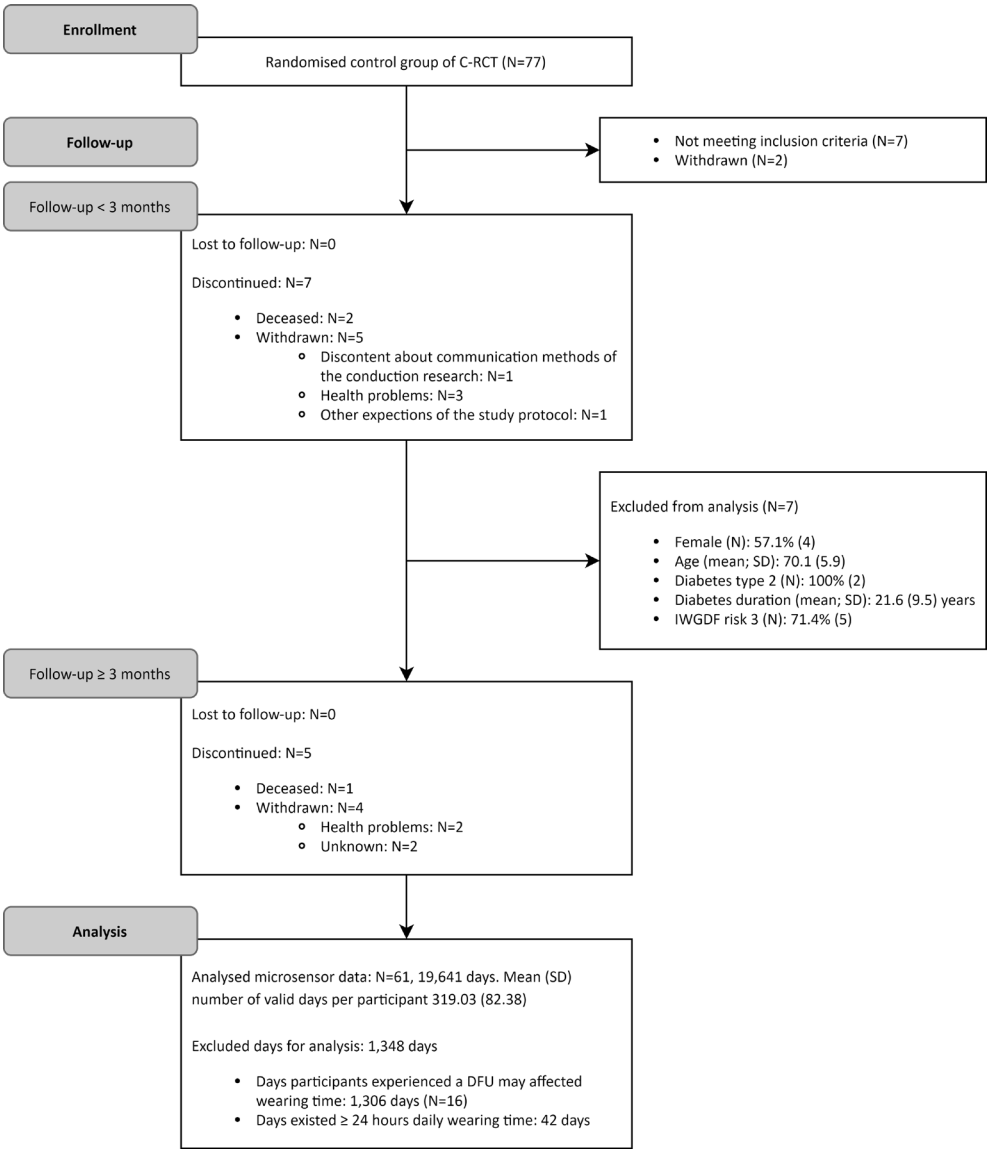

Figure 1. Flowchart of participants included in this study. Abbreviations: IWGDF: international working group on the diabetic foot, SD: standard deviation, DFU: diabetic foot ulcer, C-RCT: cluster-randomized controlled trial.

Table 1. Descriptive statistics, univariate regression, and multivariate regression of investigated variables in relation to daily wearing time.

Characteristic	Mean (SD)	% (N)	Wearing time Mean (SD)	Univariate regression			Multivariate regression	
				B	β	p-value	β	p-value
Demographics								
Gender								
Male		72 (44)	7.9 (5.9)	2.03	0.21	0.100[a]	0.12	0.356
Female		28 (17)	9.4 (6.2)					
Age (years)	68.0 (7.4)	100 (61)	8.3 (6.1)	0.13	0.22	0.083[a]	0.13	0.322
BMI	30.5 (5.7)	100 (61)	8.3 (6.1)	-0.14	-0.19	0.145[a]	-0.15	0.242
Education level								
Low		49 (30)	9.6 (5.8)	-2.95	-0.34	0.007[a]	-0.19	0.138
Medium/High		51 (31)	7.1 (6.0)					
Working situation								
Paid work		28 (17)	7.8 (6.3)	0.88	0.09	0.480		
No paid work		72 (44)	8.5 (6.0)					
Living situation								
Living with someone		71 (43)	8.2 (6.1)	0.11	0.01	0.926		
Living alone		30 (18)	8.5 (5.8)					
Self-reliant								
Yes		16 (10)	8.3 (5.6)	-0.37	-0.03	0.809		
No		84 (51)	8.3 (6.1)					
Dependence on assistive device								
Yes		34 (21)	8.2 (6.1)	0.40	0.04	0.735		
No		66 (40)	8.4 (6.0)					
Disease characteristics								
Diabetes type								
Type 1		11 (7)	7.8 (6.3)	0.44	0.03	0.801		
Type 2		89 (54)	8.4 (6.0)					
Diabetes duration (years)	17.3 (11.4)			0.05	0.14	0.303		
IWGDF risk profile								
IWGDF risk 2		44 (27)	8.5 (6.1)	-0.82	-0.10	0.465		
IWGDF risk 3		56 (34)	8.1 (6.0)					
Footwear usability								
Walking ability								
<1000m		70 (35)	8.1 (6.0)					
≥1000m		30 (15)	8.8 (6.3)	0.41	0.04	0.762		
Perceived walking change by orthopaedic footwear								
Improved by orthopaedic footwear		52 (26)	9.2 (5.7)					
Not improved by orthopaedic footwear		48 (24)	7.2 (6.4)	-1.56	-0.18	0.207		
Shoe fit[†]	80.7 (18.4)	82 (50)	8.3 (6.1)	0.03	0.11	0.461		
Shoe walking[†]	78.6 (24.5)	80 (49)	8.3 (6.1)	0.04	0.24	0.093[a]	-0.18	0.283
Shoe weight[†]	56.5 (22.0)	79 (48)	8.3 (6.1)	-0.05	-0.25	0.086[a]	-0.02	0.884
Donning and doffing[†]	68.0 (26.3)	79 (48)	8.4 (6.1)	0.005	0.03	0.852		

Aesthetic†	75.9 (21.0)	80 (49)	8.3 (6.1)	<0.001	0.01	0.975		
Aesthetic perceived by others		84 (51)						
Not attractive		43 (22)	7.8 (5.8)					
Attractive		57 (29)	8.7 (6.3)	0.80	0.09	0.514		
Number of orthopaedic footwear pairs	2.9 (1.1)	100 (61)	8.3 (6.1)	0.65	0.17	0.204		
Footwear possession								
First-ever pair		13.1 (8)	9.3 (5.8)					
Subsequent pair		86.9 (53)	8.2 (6.1)	-0.47	-0.04	0.776		
Owns regular off-the-shelf shoes								
Yes		20 (12)	6.2 (5.6)					
No		80 (49)	8.9 (6.0)	2.34	0.22	0.093[a]	0.15	0.238
Satisfaction with my wear of orthopaedic footwear†	80.1 (20.9)	82 (50)	8.3 (6.1)	0.11	0.52	<0.001[a]	0.55	<0.001[b]
Orthopaedic footwear wearing goal reached								
Yes		81 (39)	8.8 (6.1)					
No		19 (9)	6.1 (5.6)	-1.85	-0.17	0.264		

Percentages may not added up to 100 due to rounding. Abbreviations: SD: standard deviation, B: unstandardized coefficients, β: standardized coefficients, BMI: body mass index, IWGDF: International working group on the diabetic foot. [a]Variables with p-values <0.20 in the univariate regression were entered in the multivariate regression model. †Scores could range from 0 (lowest/most negative score possible) to 100 (highest/most positive score possible). [b]p<0.05 in the multivariate regression analysis. Multivariate regression model $F(1,44)=18.64$, $p<0.001$, $R^2=0.28$.

Wearing time

Over the total group of participants (N=61), mean (SD) wearing time was 8.3 (6.1) hours/day (Table 2). A total of 34% (N=21) were adherent (≥60% of out-of-bed daytime), while 66% (N=40) were non-adherent (<60% of out-of-bed daytime).

Table 2. Daily wearing time (hours/day) for all days, Saturday, Sunday, and weekdays per subgroup.

Subgroup	% (N)	Full measurement period	Weekdays†	Saturday	Sunday
Total	100 (61)	8.3 (6.1)	8.7 (6.0)[gi]	8.0 (6.1)[di]	6.9 (6.2)cf
Non-adherent (<60%)	66 (40)	5.8 (5.3)[a]	6.2 (5.3)[fi]	5.4 (5.3)[ci]	4.3 (5.0)cf
Medium adherent (≥60<80%)	16 (10)	11.4 (4.8)[a]	12.0 (4.6)	11.0 (4.2)	9.1 (5.7)
Adherent (≥80%)	18 (11)	14.7 (3.1)[a]	14.8 (3.1)	14.7 (3.1)	14.3 (2.9)
CV_{low}	33 (20)	12.7 (4.3)[b]	13.0 (4.2)	12.3 (4.2)	11.6 (4.8)
CV_{mid}	34 (21)	8.0 (5.3)[b]	8.4 (5.2)[j]	8.2 (5.4)[j]	6.1 (5.4)dg
CV_{high}	33 (20)	3.6 (4.8)[b]	4.0 (4.9)[hj]	2.8 (4.5)[e]	2.3 (4.4)d

Data are expressed as mean (standard deviation). Abbreviations: †Weekdays: Monday through Friday, CV: coefficient of variation. CV tertile cut-off levels: $CV_{low} \leq 0.45$, $CV_{high} > 0.81$. [a]p<0.01 significantly differences between adherent subgroups. [b]p<0.001 significantly differences between CV tertiles. [c]p<0.001, [d]p<0.01, [e]p<0.05 significantly different from weekdays. [f]p<0.001, [g]p<0.01, [h]p<0.05 significantly different from Saturday. [i]p<0.001, [j]p<0.01, significantly different from Sunday.

Wearing time patterns

Wearing time was higher during weekdays compared to Saturday and Sunday (p<0.010; Table 2). This pattern was the same for all subgroups, but the difference was not always statistically significant in the subgroups (Table 2). Participants in the smallest CV tertile (i.e. most consistent wearing time during 12 months) showed the highest wearing time, while those in the largest CV tertile (i.e. most inconsistent wearing pattern) showed the lowest (p<0.001; Figure 2; Table 2). Seasonal differences between mean (SD) daily wearing time

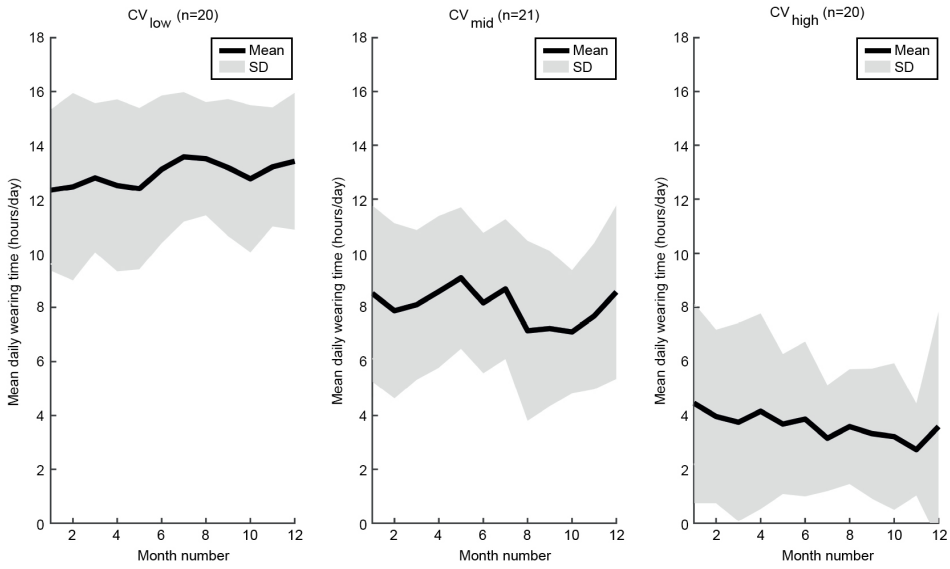

Figure 2. Daily wearing time over one year follow-up for participants split into CV tertiles. Abbreviations: CV: coefficient of variation, SD: standard deviation. Cut-off levels: $CV_{low} \leq 0.45$, $CV_{high} > 0.81$.

were small (Spring: 8.2 (6.0), Summer: 8.4 (6.1), Autumn: 8.0 (6.0), and Winter: 8.5 (6.2) hours/day) and non-significant (p=0.312).

Predictors

Univariate analyses of participant demographics showed higher wearing times for female participants, older participants, participants with a lower BMI, and those with a lower educational level (p<0.20; Table 1). Four variables of footwear usability showed a univariate association with wearing time (p<0.20; Table 1). No variables associated with wearing time showed any collinearity. In the multivariate regression model, the variable "satisfaction with my wear of orthopaedic footwear" remained significantly positively associated (p<0.001; Table 1) with wearing time. The model consisted of eight variables (four demographic variables and four footwear usability variables) and explained 28% of the variance in wearing time.

Post-hoc power calculations

Post-hoc power sensitivity analyses indicated that this study had sufficient power (80%) to significantly (p<0.05) detect large between-group differences (F=0.41–0.44) for 3 to 4 subgroups. For multivariate linear regression analysis with 8 potential predictors and 80% power, a medium to large proportion of variance could be explained (F2=0.28; R2=0.22).

DISCUSSION

The aim of the study was to investigate objectively measured long-term wearing time of orthopaedic footwear, wearing patterns, and identify factors associated with wearing in people with diabetes at moderate-to-high risk of ulceration. A wide range in daily wearing

time was found, indicating large differences between participants. The mean daily wearing time was 8.3 hours, which we consider low given an average 16 hours daily out of bed time. Wearing times were higher during weekdays compared to Saturday and Sunday, with Sunday also less than Saturday. Participants with a stable wearing pattern (i.e. a low CV) showed on average higher daily wearing time than participants with more fluctuations in their wearing pattern (i.e. a high CV). Seasonal differences between wearing time were negligible. Of all demographics, disease-related characteristics, and footwear usability variables, only "satisfaction with my wear of orthopaedic footwear" was statistically significantly associated with daily wearing time in multivariate analysis.

Our study shows similar daily wearing time compared to two quantitative studies (9.4±4.4 and 7.0±4.7 h/day) (14, 16), whereas compared to third quantitative study available (4.2±3.6 h/day) the current study shows higher wearing time (15). All studies on this topic to date show low wearing times and large differences between participants. This supports the idea that reasons for wearing orthopaedic footwear is an individual matter and should be improved. In this study, 66% of participants wore their orthopaedic footwear <60% of daily out of bed time, where ≥60% was thought to reduce the rate of ulceration (28). One quantitative (14) and two qualitative studies (10, 26) showed respectively 33% and 58% of participants with wearing times <60% of daily out of bed time,. The selection criteria in the previous quantitative study (14) (i.e. history of a recent plantar DFU) may partly explain the difference with the current study result, as we also included participants without an ulcer history, or with an ulcer longer ago and therefore were at lower risk of developing a diabetic foot ulcer (11). However, adherence to wearing orthopaedic footwear is suboptimal in most participants and must improve to prevent diabetic foot ulcers.

We found higher wearing times during weekdays compared to weekend days, similar to a previous quantitative study (14). This effect was largest for subgroups with the lowest wearing times. Participants and clinicians should be aware of the importance to wear orthopaedic footwear every day, also – or especially – during weekend days. A new finding in this study concerned the (in)consistency in wearing patterns, where participants with a consistent wearing pattern (CV_{low}) showed significantly higher daily wearing times than participants with an inconsistent pattern. This suggests that a stable wearing pattern is mostly associated with high daily wearing time, those participants likely formed habits to often wear their orthopaedic footwear. This is supported by a recent qualitative study that showed that consistent choices about which footwear type to wear was positively associated with adherence to wearing therapeutic footwear (29). Therefore, changing patients' wearing behaviour to a more stable pattern may be a potential avenue to improve long-term adherence to wearing orthopaedic footwear.

The multivariate model explained 28% of the wearing time variance, and showed that "satisfaction with my wear of orthopaedic footwear" was positively significantly associated with wearing time. The model showed that a low education level was associated with higher wearing time, although not significantly. This was unexpected and the reason remains unclear. Previous studies did not found any impact from education level on adherence (14, 29). Despite, the explained variance was higher compared to multivariate models in previous studies (6-18%) containing similar variables (14, 29), there was still a substantial

amount of unexplained variance. Both quantitative and qualitative studies were previously conducted to investigate similar factors associated with adherence to wearing footwear, showing both supportive and contradictory results (11, 14, 26, 29, 30) Combining the results from these multiple studies, it seems that demographics, disease-related characteristics, and footwear usability variables are not useful for predicting orthopaedic footwear wearing time in people with diabetes. Patients' adherence to wearing orthopaedic footwear cannot be estimated by clinicians based on these factors. Other previous studies showed that someone's decision to use orthopaedic footwear can be influenced by the communication style of the healthcare provider, which is associated with increased long-term footwear use (31, 32). However, adequately powered randomized controlled trials are needed to establish the efficacy of communication styles in improving adherence to wearing orthopaedic shoes (33-35). Therefore, to determine patients' adherence to wearing orthopaedic footwear in daily practice it should be objectively measured on an individual level rather than estimated.

Limitations

The results of this study may be limited by the following: firstly, recruitment took place during the COVID-19 pandemic (July 2019–January 2021). During this period people were recommended to work from home or not to work at all. Because of this, participants have likely spent more time at home than usual. This may have influenced wearing times (14), since wearing time is often higher away from home than at home (14).

Secondly, participants were asked to bring every pair of orthopaedic footwear they already possessed at study entry to the first study appointment, so all these footwear could be equipped with a sensor. However, during the study it was found that some participants had more orthopaedic footwear than they brought during the first appointment. This may have resulted in an underestimation of wearing time.

Thirdly, participants were not notified that the sensor was used to monitor daily wearing time. This is in line with the information given by the researcher on an unaware group in a previous study showing a positive effect of awareness of being monitored on wearing orthopaedic footwear (16). As such, we consider that participants could be regarded as being unaware. We did not assess at the end of the study whether the participants believed this or not, and whether this affected wearing times.

Finally, it should be noted that with 61 participants in the current study, this study lacked statistical power to detect small differences between subgroups or to detect independent factors that may be predictive of wearing time as statistically significant. However, the current study results are in line with a previous study with a larger sample size that fail to detect strong associations with wearing time for similar variables (29).

Future research

First, inconsistent long-term wearing patterns were seen in participants with low daily wearing time. Changing wearing time to a more consistent pattern may result in new habits that contribute to higher long-term wearing times (29). Therefore, future research should explore strategies to change wearing behaviour to a stable pattern. Clinicians can discuss these strategies with patients to form new footwear habits, so wearing orthopaedic

footwear become the default option without conscious effort.

Secondly, since adherence to wearing orthopaedic footwear cannot be explained by investigated factors, we recommend that the communication style of the healthcare provider, and the influence of other factors like individual patients' perspective with regard to their orthopaedic footwear should be investigated. Moreover, it is known that patients have different perceptions with regard to what characteristics of orthopaedic footwear are important to them (26, 31, 35). Mixed-method research combining objectively measured wearing time with qualitative components through triangulation is needed to obtain the effect of patients' perspective on their orthopaedic footwear to daily wearing time. Thereafter, these individual perspectives might be used in questionnaires to assess patients orthopaedic footwear use and usability in daily practice.

Conclusion

Only one out of three people with diabetes at moderate-to-high risk of foot ulceration were sufficiently adherent to wearing their orthopaedic footwear during 12 months. People with a consistent wearing pattern show higher daily wearing times than people with an inconsistent pattern. Further, people wear their orthopaedic footwear less during weekend days compared to weekdays. By changing wearing behaviour to a more stable pattern seems a potential avenue to improve long-term adherence to wearing orthopaedic footwear. Only self-reported "satisfaction with my wear of orthopaedic footwear" is positively associated with wearing time. All other investigated factors are not associated with wearing time. Based on these factors patients' daily wearing time cannot be estimated in daily practice.

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Chapter 3

Using motivational interviewing combined with digital shoe-fitting to improve adherence to wearing orthopaedic shoes in people with diabetes at risk of foot ulceration: study protocol for a cluster-randomized controlled trial

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ABSTRACT

Background: Diabetic foot ulcers have a high impact on mobility and daily functioning and lead to high treatment costs, for example, by hospitalization and amputation. To prevent (re) ulcerations, custom-made orthopaedic shoes are considered essential. However, adherence to wearing the orthopaedic shoes is low, and improving adherence was not successful in the past. We propose a novel care approach that combines motivational interviewing (MI) with a digital shoe-fitting procedure to improve adherence to orthopaedic shoes. The aim of this trial is to assess the (cost-)effectiveness of this novel care approach compared to usual care (no MI and casting-based shoe-fitting) in promoting footwear adherence and ulcer prevention.

Methods: The trial will include people with diabetes, with IWGDF Risk categories 1–3, who have been prescribed orthopaedic shoes. Participants will be randomized at the level of the podiatrist to the novel care approach or usual care. The primary outcome is the proportion of participants who adhere to the use of their orthopaedic shoes, that is, who take at least 80% of their total daily steps with orthopaedic shoes. A temperature microsensor will be built into the participants' orthopaedic shoes to measure wearing time continuously over 12 months. In addition, daily activity will be measured periodically using log data with an activity monitor. Data from the temperature microsensor and activity monitor will be combined to calculate adherence. (Re-)experienced complications after receiving orthopaedic shoes will be registered. Questionnaires and interviews will measure the experiences of participants regarding orthopaedic shoes, experiences of podiatrists regarding motivational interviewing, care consumption, and quality of life. Differences in costs and quality of life will be determined in a cost-effectiveness analysis.

Discussion: This trial will generate novel insights into the socio-economic and well-being impact and the clinical effectiveness of the novel care approach on adherence to wearing orthopaedic shoes.

Trial registration: Netherlands Trial Register NL7710. Registered on 6 May 2019

INTRODUCTION

Background and rationale {6a}

Diabetes Mellitus is one of the most common chronic diseases worldwide. The disease currently affects 425 million adults worldwide (1) and this number is expected to increase to 600 million people by 2035, due to population growth and aging (2). A significant number of people with diabetes have foot ulcers (lifetime prevalence of 19-34%) leading to foot infection, amputation and hospitalization (3), to immobility and a reduced quality of life (4). In addition, diabetic foot ulcers account for high costs due to unemployment (loss of productivity) and social isolation, and healthcare related costs due to treatment, hospital admissions and home care (3, 5-9). Therefore prevention of foot ulcers has high priority (3-9).

Early detection of risks, self-management and protective footwear such as orthopaedic shoes are considered essential to prevent re-ulceration (10, 11). Adherence is crucial because patients who adhere to these strategies have significantly better outcomes than those who do not (12). However, a randomized trial in the Netherlands found that adherence to orthopaedic shoes is rather low, with only 46-49% of patients wearing their orthopaedic shoes for at least 80% of daily total steps (13, 14). Research into interventions to improve this adherence is scarce (15), but the explorative study by Keukenkamp et al (11) showed that motivational interviewing (MI) has short-term positive effects on adherence. Motivational interviewing increased adherence to orthopaedic shoes at home after 3 months from 31% (without MI) to 40% (with MI) indicating the beneficial consequences of this communication method (11). Well powered high-quality randomized trials are needed to better inform clinical practice about different methods to improve adherence to wearing orthopaedic shoes (11, 12, 16).

The role of people's motives and reasons for (not) adhere to wearing orthopaedic shoes is largely unknown (10, 14, 16, 17), and has not been studied systematically (10, 13, 14). Waaijman et al (14) demonstrated some predictive value of lower BMI, severe foot deformity, and more appealing orthopaedic shoes on adherence. However, their multivariate prediction model explained only 18% of the variance in adherence. This means that optimizing these predicting factors may have a limited effect on adherence and that other factors have to be taken into consideration for improving adherence substantially. Similar to the study of Waaijman et al (14), most of the studies on diabetic footwear focused on patients' physical and clinical characteristics rather than social and psychological factors. Until now, the patient perspective on wearing orthopaedic shoes, possible psychological barriers, and living and working environments were neglected in adherence studies. However, clinical practice shows that 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 (18).

To improve motivation and adherence, various authors have recommended a combination of improved education and communication with better fitting orthopaedic shoes (10, 11). First, an observational study found that higher patient satisfaction with the communication between patient and caregivers was associated with increased long-term

use of orthopaedic shoes (19). We believe that such a working alliance can be created via motivational interviewing since "motivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion" (20). Keukenkamp et al concluded that motivational interviewing is a promising method for the given purpose and patient group (11). However, motivational interviewing requires the caregiver to engage with the patient as an equal partner and to not give unsolicited advice or direct, confront, warn or instruct the patient. Motivational interviewing requires discipline and self-awareness from the caregiver, and mastering motivational interviewing takes practice and time (21). Podiatrists work at the front lines of diabetic foot care and work with high-risk diabetic patients, and are motivated to help guide patients toward better self-care. However they do not necessarily have the skills to do so effectively. Gabbay et al believe that there is a great opportunity for podiatrists to explore motivational interviewing to change patient behaviour (22). This suggests that the shoe-fitting procedure plays an important role in creating a working alliance between patient and podiatrist to increase acceptance of and adherence with orthopaedic shoes by shared decision making embedded in person-centred communication (23).

A second factor to increase adherence may be a better fit of the orthopaedic shoes. Although perceived orthopaedic shoe comfort was not found to be a predictor of adherence for people with diabetes in a previous study (14), van Netten et al. (24) found that all aspects of usability are relevant in relation to the use of orthopaedic shoes in people with different pathologies. Therefore the fit of orthopaedic shoes will likely affect adherence of people with diabetes in practice. Currently, orthopaedic shoes are mostly produced using a solid 3D mould known as a 'shoe last' (25). These lasts are traditionally made using casting-based methods. However, casting methods are expensive, time-consuming, and complicated due to constraints imposed by manual measurements of several foot dimensions and manual crafting (trial-and-error) of the shoe last to fit the patient's foot dimensions (26, 27). A digital shoe-fitting procedure, using a high-end 3D scanner to scan the foot instead of creating a mould around the foot, might be more accurate, patient-friendly and time-efficient. In this method, the digital scan of the foot is modelled into a patient-specific last that can be milled by a last-milling machine. Although slowly implemented in clinical practice, improvements in scanning methods are expected to lead to a better fit of the orthopaedic shoes, and therefore to improve adherence to wearing orthopaedic shoes.

The factors reviewed above suggest that a multidisciplinary and biopsychosocial approach can help to improve adherence to wearing orthopaedic shoes (28) since different aspects have to be taken into account simultaneously to improve adherence meaningfully. However, there is little knowledge about the effectiveness of interventions and the cost-effectiveness of the novel care approach (motivational interviewing combined with digital shoe-fitting) has not been studied at all (29). Therefore, the aim of the current study is to assess the (cost-)effectiveness of this novel care approach compared to usual care (no motivational support and casting-based shoe-fitting) in improving adherence to wearing 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 high-risk people with diabetes and to improve their quality of life.

Objectives {7}
The primary objective is to compare the proportion of participants who sufficiently adhere to using their orthopaedic shoes (that is, who take at least 80% of their total daily steps with orthopaedic shoes) between participants receiving the novel care approach which consists of motivational interviewing combined with a new digital shoe-fitting procedure, and participants receiving usual care.

The secondary objectives are to compare between the novel care approach and usual care: 1) the level of adherence to the use of orthopaedic shoes; 2) change in adherence; 3) total wearing time; 4) the proportion of participants (re-)experiencing complications during one year follow-up; 5) the participant-perceived quality of life; 6) the experiences of participants regarding: their knowledge about the aim of orthopaedic shoes, their satisfaction with communication with the pedorthist regarding wearing orthopaedic shoes, their intentions to change wearing behaviour and their satisfaction with orthopaedic shoes. In addition, 7) to determine the experiences of podiatrists regarding: their knowledge about MI, their experiences and attitudes towards applying MI in this group of patients; 8) the differences in the application of MI between the MI-trained and non-MI-trained podiatrists. And 9) to calculate the differences in costs between the novel care approach and usual care, and to assess 10) the cost-effectiveness of the novel care approach compared with usual care.

Trial design {8}
A multicentre, cluster-randomized controlled trial with (cost-)effectiveness analysis, and qualitative and quantitative process analyses.

METHODS: PARTICIPANTS, INTERVENTION AND OUTCOMES

Study setting {9}
People with diabetes treated by a pedorthist of Voetmax Orthopedie, for whom foot care is reimbursed in the Dutch healthcare system, will be recruited at different locations of Voetencentrum Wender and Voetmax Orthopedie, located in the East of the Netherlands. Randomization will be performed at the level of the podiatrists (see 'Sequence generation {16a}').

Eligibility criteria {10}
In order to be eligible to participate in this study, a participant must meet all of the following inclusion criteria:

- A clinical diagnosis of diabetes mellitus type 1 or 2
- Aged 18 years or older
- With or without previous callus
- With or without previous ulcers
- Identified with risk profiles 2, 3 or 4, according to the 'zorgmodule preventie diabetische voetulcera 2014' (30). Internationally better known as the IWGDF Risk 1-3 (31), see Table 1.

- Eligible for a prescription of orthopaedic shoes

Participants will be excluded when they meet any of the following exclusion criteria:

- Did not receive orthopaedic shoes, but instead an adaption to confection shoes or semi-orthopaedic shoes
- Have a foot ulcer
- Active Charcot's neuro-arthropathy
- Have a foot infection
- Unable to walk
- Unable to read and understand the study instructions

Who will take informed consent? {26a}

During a multidisciplinary consultation with the pedorthist and medical specialist the patient 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.

All podiatrists will provide written informed consent for contribution to the study. They will be asked by the coordinating investigator.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

On the informed consent form, participants will be asked if they agree to storage and use of their personal information for future research on adherence to orthopaedic shoes. By signing the informed consent form participants give permission to inform their podiatrist and pedorthist about their participation in the study and inform them when there are unexpected findings that are or could be important to the health of the participant, record one of the consultations with their podiatrist, for the research team to request medical information from their medical files, and when necessary to share data with the competent authorities. Biological specimens will not be collected for this trial.

INTERVENTIONS

Explanation for the choice of comparators {6b}

The novel care approach will be compared to the usual care as this is standard clinical practice in the Netherlands.

Intervention description {11a}

Novel care approach

Participants will receive a combination of MI by the podiatrist to improve acceptance of orthopaedic shoes and adherence, and a new digital shoe-fitting procedure by the pedorthist. When the participant needs orthopaedic shoes the podiatrist will refer the participant to a pedorthist to measure for orthopaedic footwear. See Figure 1 for further details.

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. A calibrated length is used to scale the scan results to absolute dimensions.

Table 1. Care profile 2-4 versus IWGDF Risk 1-3 for eligible patients.

Care profile	Category	Ulcer Risk	Characteristics
2	1	Moderate	LOPS + PAD
3	2	Moderate	LOPS + foot deformity PAD + foot deformity
4	3	High	LOPS or PAD, and one or more of the following: • History of a foot ulcer • A lower-extremity amputation • End-stage renal disease

Note: LOPS: loss of protective sensation, PAD: peripheral artery disease.

Usual care

MI is currently not provided in standard clinical practice in the Netherlands. Usual care will consist of foot care from the podiatrist. When the participant needs custom-made shoes the podiatrist will refer the participant to a pedorthist to measure for orthopaedic footwear by a casting-based shoe-fitting procedure (32-35). See Figure 1 for further details.

Motivational interviewing training of podiatrist

Motivational interviewing 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 change of behaviour with regard to wearing orthopaedic shoes (20). A certified MI-trainer (Motivational Interviewing Network of Trainers (MINT)) will be training the podiatrists in MI during a three-day basic training. The podiatrists will be trained to incorporate the specific coaching and communication techniques of MI in their consultation hours with the aim to increase adherence to wearing orthopaedic shoes in our target group.

Criteria for discontinuing or modifying allocated interventions {11b}

Participants can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can also decide to withdraw a participant from the study for urgent medical reasons. The outcomes will no longer be collected and participants data that have been collected up to that moment will be included in the analysis. If participants drop out of the study additional participants will be included until N=220.

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.

Strategies to improve adherence to interventions {11c}

All participants will be contacted by the coordinating investigator before all their consultations during the study to remind them about the consultation and to bring their orthopaedic shoes equipped with a temperature microsensor. If they received questionnaires and/or an activity monitor during the consultation, and this is not returned in two weeks after the consult, the participant will be contacted by the coordinating investigator to fill in the questionnaires and return them and/or return the activity monitor.

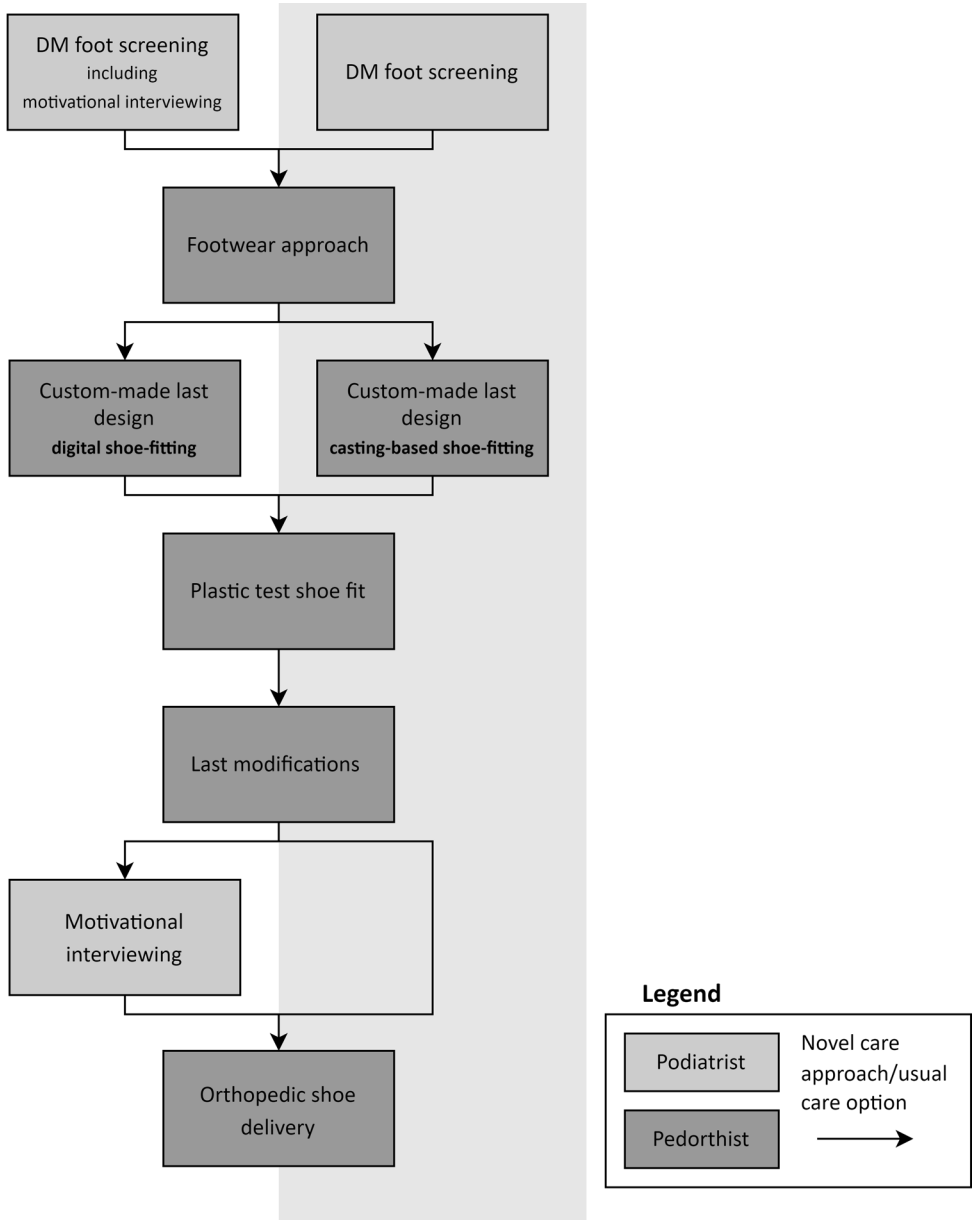

Figure 1. Novel care approach versus usual care.

Relevant concomitant care permitted or prohibited during the trial {11d}

All participants are allowed to receive any form of (foot)care that they need, e.g. regular appointments with podiatrist and/or diabetes pedicure, if necessary wound treatment at a multidisciplinary diabetic foot clinic and regular appointments with the pedorthist regarding their orthopaedic shoes. This (foot)care will be measured with the iMCQ (Institute for Medical Technology Assessment (iMTA) Medical Consumption Questionnaire).

Provisions for post-trial care {30}
The multicentre sites have a liability insurance which is in accordance with article 7 of the WMO (36). 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. There are no other provisions for post-trial care.

Outcomes {12}
The primary outcome is the proportion of participants who adhere to wearing their orthopaedic shoes (see below 'Proportion participants being adherent'). We define adherence as minimally 80% of daily steps taken with orthopaedic shoes based on data of a randomized trial in the Netherlands (13, 14).

Secondary outcomes are: 1) the level of adherence to wearing orthopaedic shoes during one week at three and six months after inclusion; 2) the change in adherence between three and six months after inclusion; 3) total wearing time during one year follow-up; 4) the proportion of participants (re-)experiencing complications during one year follow-up; 5) the participant-perceived quality of life at inclusion and three and six months after inclusion; 6) the experiences of participants regarding: their knowledge about the aim of orthopaedic shoes, their satisfaction with communication with the pedorthist regarding wearing orthopaedic shoes, their behavioural intentions and their satisfaction with orthopaedic shoes, at inclusion and 6 month after inclusion; 7) the experiences of podiatrists regarding: their knowledge about motivational interviewing, their experiences and attitudes towards applying motivational interviewing in this group of patients, after all participants are included; 8) the application of motivational interviewing; and 9) footcare-related costs during one year follow-up. For an overview of all timepoints see Table 2 (see 'Participant timeline {13}').

Proportion participants being adherent
The main study parameter is the proportion of participants who adhere to wearing their orthopaedic shoes, defined as minimally 80% of steps taken with orthopaedic shoes. The level of adherence (see 'Level of adherence to orthopaedic shoes') will be based on log data from temperature microsensors in the orthopaedic shoes and data from the activity monitors provided to all participants over two one-week periods measured at timepoint "T1" and timepoint "T3" (Table 2). The proportion of adherent participants will be objectively determined based on the combined level of adherence of the two measurements (the mean of timepoint "T1" and timepoint "T3").

Level of adherence to orthopaedic shoes
The level of adherence to the use of 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:

$$Adherence = \frac{\sum steps\ wearing\ orthopaedic\ shoes}{\sum steps} \times 100\%$$

Total steps wearing orthopaedic shoes will be based on log data from temperature microsensors in the orthopaedic shoes of all participants and total steps will be based on using the data from the activity monitors over two times one week period measured at timepoint ”T1” and timepoint “T3” (Table 2).

Adherence to wearing orthopaedic shoes and daily step count will be assessed using raw data from the temperature microsensors using and processed by MATLAB (The MathWorks Inc., Natick, Massachusetts, United States of America). Participants will be included in the analyses only if at least four complete days of recording, including one weekend day, is available (14). When both the temperature microsensor and the step activity monitor show activity during recording, it will be assumed that the participant walked with the orthopaedic shoes. If only step activity is recorded, it will be assumed that the participant was walking barefoot or walking in non-prescribed shoes.

Change in adherence
The change in adherence will be determined by the mean of the level of adherence to the use of orthopaedic shoes measured six months after inclusion minus the mean of the level of adherence to the use of orthopaedic shoes measured three months after inclusion.

Total wearing time
The total wearing time of the orthopaedic shoes during the 12 month follow-up will be based on log data from temperature microsensors in the orthopaedic shoes of all participants, and will be analysed for different periods.

Complications
The proportion of participants (re-)experiencing complications (i.e. one or more ulcers or abundant callus that requires debridement, not present at baseline, or lower-extremity amputation) will be determined by the registration of (re-)experienced complications after receiving their orthopaedic 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 general practitioners or orthopaedic surgeons will be contacted. Photographs will be assessed by observers blinded to treatment allocation to confirm the type and/or severity of the complication.

Participant-perceived quality of life
The participant-perceived quality of life of participants will be assessed with the 5-Level EuroQol Quality of Life Scale (EQ-5D-5L) questionnaire (37) and RAND-36 item Health Survey V2.0 (RAND-36 V2.0) (38). 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, based on the Dutch tariff established for the EQ-5D-5L (39).

Table 2. Overview of the measurements of the study parameters during the study.

	Study period								
	Screening	Inclusion		Post-allocation					Close-out
Timepoint	**-T2** (2-4m)	**-T1** (2-3m)	**T0**	**T1** (2-4wk)	**T2** (3m)	**T3** (4m)	**T4** (6m)	**T5** (9m)	**T6** (12m)
Enrolment									
Initial eligibility screen	X								
Study information to participant	X								
Initial willingness to participate	X								
Cross-check 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							
Participant-perceived quality of life									
RAND-36 V2.0 (38)		X					X		X
EQ-5D-5L (37)		X					X		X
Economic evaluation									
iMCQ (42)		X							X
iPCQ2 (44)		X							X
Experiences of patient									
In-depth interview		X					X[1]		
MOS (40)							X[1]		X
Level of adherence to orthopaedic shoes									
Activity registration				X[3] →		X[3] →			
Data registration temperature microsensors			→	→	→	→	→	→	→
Data transfer temperature microsensors					X		X	X	X

Note: [1]The participants, who will not be approached for the in-depth interview, will be asked to fill in MOS. [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 one week. Abbreviation: EQ-5D-5L: 5-Level EuroQol Quality of Life Scale, iMCQ: iMTA Medical Consumption Questionnaire, iPCQ: iMTA Productivity Cost Questionnaire, m: months, MOS: Monitor Orthopaedic Shoes post-part, RAND-36 V2.0: Research and Development 36-item Health Survey version 2.0, wk: weeks.

Experiences of participant

A mixed methods approach will be applied to obtain the participants' experiences and perspectives regarding their knowledge about the aim of orthopaedic shoes, their satisfaction with communication with the pedorthist regarding wearing orthopaedic shoes, their intentions to change wearing behaviour and their satisfaction with orthopaedic shoes. A quantitative questionnaire (Monitor Orthopaedic Shoes post-part (MOS) (40)) will be used to measure participant experiences on orthopaedic shoes, use and usability at six and 12 months after baseline. The information from the MOS 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.

Experiences of podiatrist
A mixed methods approach will be applied to obtain the MI-trained podiatrist experiences, with quantitative analysis of observed application of MI by the MI-trained podiatrist scored with the Motivational Interviewing Treatment Integrity (MITI) (41), and with interview results. The in-depth interviews will be taken after the last participant had his/her last consultation with the podiatrist.

Application of motivational interviewing
Between one or two months after the MI-training all podiatrists (the MI-trained and the non-MI-trained) will audio record some conversations with the participants for the assessment of applying MI or not. A health psychologist, educated in training motivational interviewing by the 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 podiatrists and the non-MI-trained podiatrists in the application of MI principles, also conversations from the non-MI-trained podiatrists will be scored with the MITI.

Footcare-related costs
Healthcare resource use of participants will be determined using the Institute for Medical Technology Assessment (iMTA) Medical Consumption Questionnaire (iMCQ) (42). Cost prices will be calculated according to the 2015 Dutch guideline for health economic evaluation (43). 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 foot or the orthopaedic shoes will be assessed using the iMTA Productivity Cost Questionnaire (iPCQ) instrument among all participants at baseline and 12 months after baseline, and additionally among participants 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.

Participant timeline {13}
An overview of the study design and the main procedures that participants will undergo during the course of the study are shown in Table 2. The participant will receive the novel care approach or usual care. All standardized instruments used in the study procedure are described in Table 2.

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. During every study consultation with the investigator the participant will be asked about complications.

Timepoint "-T2" – Screening
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. 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.

Timepoint "-T1" – Inclusion
After referral of the podiatrist, the pedorthist and medical specialist will decide together, during a multidisciplinary consultation, 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 cannot be included in the study. After the patient has been prescribed custom-made orthopaedic shoes he/she will be asked if he/she decided to participate in this study, the investigator or the investigator's representative will ask the patient to sign informed consent. Also 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 are completed. Subsequently, data on the presence of peripheral artery 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 specific questionnaires (timepoint "-T1" at Table 2).

Thereafter during a consult with the pedorthist the orthopaedic shoes will be fitted. The pedorthist will provide the new digital shoe-fitting procedure or the casting-based procedure depending on whether the podiatrist is trained in MI or not.

Within one to six weeks the participant from the intervention group 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. From all included participants, thirty participants, 15 from both groups, will be approached for an in-depth interview about their perspective on and experiences with orthopaedic shoes before receiving these shoes. This interview will be performed by one of the investigators.

Timepoint "T0" – Receiving first pair of orthopaedic shoes (baseline)
Two to three months after the multidisciplinary consultation the participant will receive their first pair of orthopaedic shoes during a consultation with the pedorthist. A temperature microsensor (Orthotimer®) is embedded in the insole of the orthopaedic shoes for determining adherence by measuring and recording wearing time.

Timepoint "T1" – Shoe control after receiving first pair of orthopaedic shoes
The participants will have another consultation with the pedorthist (two to four weeks later) for shoe control and fitting the second pair of orthopaedic shoes. During this consultation they receive an activity monitor and instructions from the investigator. The participants will

be instructed to wear the activity monitor (Misfit Shine 2™) 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 consultation with the podiatrist for footcare. If the podiatrist is MI-trained also in this consult MI will be applied.

Timepoint "T2" – Receiving second pair of orthopaedic shoes
To deliver the second pair of orthopaedic shoes, a regular consultation will be made with the pedorthist three months after receiving the first pair of shoes. The second pair of shoes will also be provided with a temperature microsensor (Orthotimer® microsensor) embedded in the insole of the orthopaedic shoes. During this consult the temperature microsensor of the first pair of shoes will be read out with the reading device (Orthotimer® reader device) by the investigator.

Timepoint "T3" – Shoe control after receiving second pair of orthopaedic shoes
Two till four weeks after receiving the second pair of orthopaedic shoes another regular control consultation will be planned. Again the s will receive an activity monitor to register their activities. The activity monitor (Misfit Shine 2™) will also be worn again for one whole week (24 hours per day).

Timepoint "T4" – Consultation with the investigator
Three months after receiving the second pair of orthopaedic shoes a consultation with the investigator will be made to read out the temperature microsensors of both pair of shoes. The participants will also be asked to fill in some questionnaires (timepoint "T4" Table 2). The same 30 participants as before will be approached for a second in-depth interview about their perspective about and experiences with orthopaedic shoes and the other participants will be asked to fill in the MOS instead.

Timepoint "T5" – Consultation with the podiatrist
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 temperature microsensors of both pair of shoes will be read out by the investigator. And also as before, in the consultations with a MI-trained podiatrist MI will be applied.

Timepoint "T6" – Close out
A last consult with the investigator will be planned about six months after receiving the second pair of orthopaedic shoes to read the temperature microsensors out both pair of shoes and to fill in some questionnaires (timepoint "T6" Table 2).

Sample size {14}
In this study 220 eligible participants will be required (110 in both arms), accounting for potential dropout. Given that MI has been found to increase adherence to orthopaedic shoes at home after three 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 shoe-fitting procedure by the

pedorthist rather than a casting-based shoe-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 three months 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. Adherence often decreases over a longer term as shown in the study of Keukenkamp et al: over time the improved adherence returned to baseline levels (11).

The sample size calculation is performed using the 'clusterPower' package in R, based on a two-sided alpha of 0.05, power of 0.80, and intraclass correlation of 0.01 of patients within podiatrists. This demonstrated that this effect in a generalized linear mixed model 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 conservatively aim to include 220 participants in total.

Recruitment {15}
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. 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. During a multidisciplinary consultation with pedorthist and medical specialist the patient 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.

ASSIGNMENT OF INTERVENTIONS: ALLOCATION

Sequence generation {16a}
Randomization will be performed at the level of the podiatrists. Based on their working location, (distance from Voetmax Orthopedie locations), working calendar, working days and number of patients with diabetes, we included 20 podiatrists of Voetencentrum Wender in this study. Since the podiatrists still differ widely in their number of patients seen and experience with the specific target group, stratified randomization will be used for the group of podiatrists. Four of the 20 podiatrists run special consultations for people with diabetes, and are therefore likely more specialized in diabetic foot disease. These four podiatrists are split in two groups, based on the number of patients seen per year (based on the figures of 2019), and equally randomized to the group who receive MI-training or to the group who don't receive MI-training. The other 16 podiatrist are randomized next, also stratified by the number of patients seen per year (based on four strata using last year figures). The randomization is done centrally by an independent researcher using www.sealedenvelope.com.

Each podiatrist will exclusively provide either the MI-intervention or usual care. Thereafter the pedorthist will provide the new digital shoe-fitting procedure for the intervention group of participants or the casting-based shoe-fitting procedure for the control group.

Concealment mechanism {16b}
The participants are not randomized themselves, because the background assignment of the treating podiatrist (being trained in MI or not) will determine the treatment allocation of the participants. Randomization is performed at the level of the podiatrists to avoid contamination between intervention and control participants. Therefore, the randomization sequence will not be concealed from the podiatrists. Because each podiatrist will exclusively provide either the MI-intervention or usual care and thereafter the pedorthist will provide the new digital shoe-fitting procedure for the intervention group of participants or the casting-based shoe-fitting procedure for the control group, the randomization sequence will also not be concealed from the pedorthists.

All participant data is pseudonymized, but because the investigators have access to the coding of the personal data of the participants the randomization sequence will also not be concealed from them.

Implementation {16c}
Not applicable, because participants will not be randomized. Randomization will be performed at the level of the podiatrists (see 'Sequence generation {16a}').

ASSIGNMENT OF INTERVENTIONS: BLINDING

Who will be blinded {17a}
Blinding and concealed treatment allocation for podiatrists is not feasible, because of the way of randomization (see 'Concealment mechanism {16b}'). Outcome assessments and analyses are not performed by independent staff, but by the investigators them self, and therefore they are also not blinded to treatment allocation (see 'Concealment mechanism {16b}').

Procedure for unblinding if needed {17b}
Not applicable, because this is an open label trial and because the outcome assessments and analyses are not performed by independent staff (see 'Concealment mechanism {16b}').

DATA COLLECTION AND MANAGEMENT

Plans for assessment and collection of outcomes {18a}
All standardized instruments used in the study procedure are described in Table 2. Information of the other study instruments can be found below.

Orthotimer® & reader device
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 (45). The microsensor 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 temperature microsensor data before this deadline. Every temperature microsensor 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 temperature microsensor will be placed and data from both temperature microsensors will be combined.

The temperature 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 temperature microsensor as well as to perform the wearing time analysis of the participant data.

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 (46). 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 (BMS Lab, University of Twente), so the data will be collected at a secured server.

Interview structure
The interviews will contain open-ended and closed questions, and will be structured according to the relevant concepts for adherence to orthopaedic shoes. To gain insight into the perspective of participants, motivations for and experienced advantages and difficulties regarding frequency, proper fit and adequate wearing of orthopaedic shoes will be discussed with the participants.

To examine the experiences of MI-trained podiatrists, the following topics will be discussed in the interview: knowledge, adoption and implementation of the motivational interviewing procedure among podiatrist, and their experiences and attitudes towards applying MI in this group of participants.

Plans to promote participant retention and complete follow-up {18b}
The patients will receive extensive information about the study set-up and requirements during the recruitment. Once in the study, to promote complete follow-up, all participants receive a phone call before all their consultations during the study to remember them about the consultation (see 'Strategies to improve adherence to interventions {11c}').

Data management {19}
As required by the funder (ZonMw), a data management plan has been developed for this study. The participants will be coded by the letter of the participating centre (one letter) and the letter of intervention or control group (one letter) followed by the number of the participant (four digits). All personally identifiable information will be saved in a locked cupboard with the coordinating investigator and on a computer protected with a password.

All data will be collected on paper and then entered electronically in an Excel database by the investigator. All pseudonymized study data will be entered in a specific server facility (LISA) of the University of Twente for storage and archiving. The handling of the data will 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 ends in DANS (Data Archiving and Network Services). Access to original data on paper will be kept in a locked cupboard at the University with the coordinating investigator during the study.

Confidentiality {27}
All collected data will be pseudonymized by the coordinating investigator. The key code will be stored on a different secured server than the data and will be password protected. The principle investigator will decide who of the research group will have access to the data. Names 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.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}
Not applicable, because no samples will be collected.

STATISTICAL METHODS

Statistical methods for primary and secondary outcomes {20a}
Statistical analysis and the cost-effectiveness analysis will be carried out with R environment for statistical computing (R Foundation, Vienna, Austria (47)). For statistical analyses a significance level of $p<0.05$ will be adopted.

Descriptive statistics
Anthropometric data, other participant 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 in 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 type of variables and being normally distributed or not.

Primary study outcome
Between-group differences in the 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 will be tested using a generalized linear mixed model (GLMM). A logistic link function will be used for the binary outcome on participant level (adherent yes/no) and random effects for podiatrists will be included.

Secondary study outcome
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 also be tested using appropriate generalized linear mixed models. The quantitatively measured aspects of the participant experiences and the experiences of the MI-trained podiatrist, will be tested using the same approach. The type of GLMM depends on the variable that will be tested in the model.

The qualitative (verbal) interview data of the experiences of the participant and the MI-trained podiatrist will be summarized with two code schemes (one for the participants experiences and one for the podiatrists experiences). The code schemes will be developed by combining inductive and deductive thematic analysis. 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 experiences of participants to explain in more depth the results of adherence and in order to formulate implementation recommendations from the patients perspective. This triangulation approach will also be applied for the quantitative and qualitative data of the MI-trained podiatrists.

Interim analyses {21b}
Not applicable, because no interim analyses are planned because there are no anticipated risks to participation in this study.

Methods for additional analyses (e.g. subgroup analyses) {20b}
Cost-effectiveness analysis (CEA)
The cost-effectiveness of the novel care approach compared with usual care will be determined by dividing the difference in mean costs (in Euros) by the difference in mean health outcomes (in QALYs) to estimate the incremental cost-effectiveness ratio (ICER). For this trial-based, short-term cost-effectiveness analysis (CEA) with one year time horizon bootstrapping will be applied to determine the uncertainty in this ICER. The cost-effectiveness analysis for a lifetime time horizon will be model-based, using data from literature as well as the trial data. Here, 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.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}
Between-group differences in the proportion of participants who adhere to the use of their orthopaedic shoes, that is, who take at least 80% of their total daily steps with orthopaedic shoes will be tested in an intention-to-treat analysis using a generalized linear mixed model (GLMM) which can inherently deal with data missing at random.

Plans to give access to the full protocol, participant level-data and statistical code {31c}
The full protocol, pseudonymized data set and statistical code will be available on request after the results of the study have been published.

OVERSIGHT AND MONITORING

Composition of the coordinating centre and trial steering committee {5d}
This is a multicentred study designed, performed and coordinated at the University of Twente, Voetmax Orthopedie and Voetencentrum Wender. Support for the trial is provided by:

- Principal investigator: takes supervision of the trial.
- Coordinating investigator: preparation of protocol and revisions, ethics committee application, trial registration, visits the podiatrists and pedorthists during the start-up phase, organizes the MI-trainings given by MI-trainers to podiatrists, supports the logistics for patient accrual, take informed consents, monitors inclusion of patients, coordinates study visits, repeated measurements and collection of log data from sensors, organizes data acquisition, collection and storage, analyses and manages the primary and secondary outcome data, prepares first draft of the manuscripts and prepares progress reports for the project team/steering committee.
- Project team/steering committee: design of the study, check study progress and approve protocol amendments and recommendations, and approve publication of study reports. Meets monthly.
- Study physicians (podiatrists/pedorthist): identify potential recruitments and take informed consent if possible.
- Patient experience experts: advice project team during inclusion period.
- Advisory board: discuss the findings and implementation strategy with the project team and with the international network of the advisory board.

Composition of the data monitoring committee, its role and reporting structure {21a}
Because of the low burden and minimal risks, no data monitoring committee was appointed. The investigators are responsible for procedures of data monitoring.

Adverse event reporting and harms {22}
Adverse events are defined as any undesirable experience occurring to a participant during the study, whether or not considered related to the trial procedure. Because this trial was exempt from full medical ethical approval, all adverse events reported spontaneously by the participants or observed by the podiatrist, pedorthist or the investigator or her staff, will be registered by the investigator in the Excel database and consequences will be discussed in the project team. As always, it is possible that problems may arise with the participant's feet or orthopaedic shoes, for which the participant will receive usual care performed by the podiatrist and/or pedorthist (see 'Relevant concomitant care permitted or prohibited during the trial {11d}').

Frequency and plans for auditing trial conduct {23}
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. Given the low risk of the intervention and because this trial was exempt from full medical ethical approval, extensive auditing is not considered necessary.

Therefore, no audits are planned at this time as the principal investigator will be present to oversee all study activities as data are being collected.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}
Amendments are defined as changes made to the research. This trial was exempt from full medical ethical approval by the CMO region Arnhem – Nijmegen according to the Dutch Law. The study protocol was subsequently reviewed and approved by de Ethical Committee of the BMS faculty of the University of Twente. Therefore, all substantial amendments will only be notified to the Ethical Committee of the BMS faculty of the University of Twente. Non-substantial amendments will be recorded and filed by the sponsor. The online trial registry will be updated accordingly and changes will be communicated in the publication of the results of this study.

Dissemination plans {31a}
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 publications and presentations lies with 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.

DISCUSSION

Currently there is little knowledge about the effectiveness of interventions and the cost-effectiveness of the novel care approach (motivational interviewing combined with digital shoe-fitting) has not been studied at all (29). Therefore the aim of this randomized controlled trial is to assess the (cost-)effectiveness of this novel care approach compared to usual care in terms of adherence to wearing orthopaedic shoes and ulcer prevention. Since the start of including the first participants in our study, we improved and modified our initial protocol based on operational and logistic issues and new insights; the most important changes are described and explained below.

As in any trial, patient recruitment is crucial. Based on the above-mentioned power-analysis the required sample size, including loss to follow-up, for this study was estimated at 220 participants. These participants were to be included in a period of nine months throughout the Netherlands. However, for practical reasons it was not feasible to include throughout the Netherlands and therefore inclusion will only take place in the East of the Netherlands. Because of this change and the outbreak of COVID-19, the goal of 220 participants is no longer realistic with the initially defined criteria and design in the intended period. In order to include as many participants as possible we were forced to make some changes to the original study protocol.

First, we no longer include only patients receiving their first pair of orthopaedic shoes, but we also include patients who already had orthopaedic shoes and are eligible for a new pair of orthopaedic shoes. Therefore, the pedorthist is now also actively involved in participant

recruitment.

Second, due to this new role of the pedorthist, the background assignment of the treating podiatrist (being trained in MI or not) no longer determines the shoe-fitting procedure by the pedorthist. Each pedorthist has his own procedure of shoe-fitting: the new digital shoe-fitting procedure or the casting-based shoe-fitting procedure. In addition, the existing last is also used for an extra pair of orthopaedic shoes and thereby the shoe-fitting procedure is already determined for each subsequent pair of orthopaedic shoes. However, the background assignment of the treating podiatrist remains leading over the shoe-fitting procedure with regard to which group the participant belongs to (intervention or control group), because most participants have been treated by the same podiatrist for years and we do not want to change that for this study. The participants in the intervention group will have an appointment with their podiatrist or one of the other MI-trained podiatrists to perform motivational interviewing before or as soon as possible after they receive their first or new pair of orthopaedic shoes.

Last, a second group of 12 additional podiatrists received MI-training and 16 podiatrists have been added to the control group to further increase inclusion. Because the inclusion in the intervention group lagged behind the control group, the second group of podiatrists, who received MI-training, consists of the podiatrists who see most patients with diabetes. This in contrast to the original group of podiatrists, who were assigned to one of the groups based on stratified randomization.

In addition, a few small changes to the number of study consultations have also been made: (1) We reduced the number of six consultations that the participants would have with one of the investigators by two consultations. The investigator sees the participant at the delivery of the orthopaedic shoes (T0), and three months (T1), six months (T2), nine months (T3) and 12 months (T4) after the participant received their orthopaedic shoes. (2) As a result of this change the participants will receive the activity monitor during T1 (three months) and T2 (six months) instead of T1 (two till four weeks) and T3 (four months) as shown in Table 2. (3) All participants will be asked to fill in the MOS six months after receiving their orthopaedic shoes, also the participants who will be approached for a second in-depth interview. (4) During every consultation with one of the investigators the participant will be asked if they have a ulcer or have had a ulcer in the last three months. If so, the participant will be asked to fill in the iPCQ.

In conclusion, this trial aims to assess the (cost-)effectiveness of this novel care approach compared to usual care in terms of adherence to orthopaedic shoes and ulcer prevention. The outcomes of this trial will generate insights into the socio-economic impact of the novel care approach on adherence to orthopaedic shoes. These are crucial steps toward better ulcer prevention in high-risk diabetes patients.

Trial status

The first version of this study protocol (January 22, 2019), was registered at the Netherlands Trial Register (registration number NL7710, https://www.trialregister.nl/trial/7710) on 6 May, 2019. The trial commenced recruitment in July 2019. Inclusion is currently ongoing

and expected to be completed in December 2020.

Abbreviations
AVG: Algemene verordening gegevensbescherming; BMI: Body Mass Index; BMS Lab: Behavioural Management and Social Sciences Lab; CEA: Cost-Effectiveness Analysis; CMO: Commissie Mensgebonden Onderzoek; COVID; COronaVIrus Disease; DANS; Data Archiving and Network Services; EQ-5D-5L: 5-Level EuroQol Quality of Life scale; EU: European Union; GLMM: Generalized Linear Mixed Model; ICER: Incremental Cost-Effectiveness Ratio; iMCQ: iMTA Medical Consumption Questionnaire; iMTA: Institute for Medical Technology Assessment; iPCQ: iMTA Productivity Cost Questionnaire; IWGDF: International Working Group on the Diabetic Foot; LISA: Library, ICT Services & Archive; LOPS: Loss Of Protective Sensation; MI: Motivational Interviewing; MINT: Motivational Interviewing Network of Trainers; MITI: Motivational Interviewing Treatment Integrity; MOS: Monitor Orthopaedic Shoes; PAD: Peripheral Artery Disease; QALY: Quality-Adjusted Life Year; RAND-36; Research and Development 36-item Health Survey; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; TIIM: The Incredible Intervention Machine; UAVG: Uitvoeringswet AVG; USA; United States of America; WMO: Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen.

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Author's contributions {31b}
JvGP, CB, HK, SE conceived and designed this trial. MJW, CB, HK, JvN, PtK, SE, JvGP drafted or edited the trial protocols. MJW obtained ethical approval. PtK developed the statistical analysis plan. HK developed the plan for the cost-effectiveness analysis. MJW drafted the article and CB, HK, JvN, PtK, SE and JvGP critically revised the article, and approved the final version of the manuscript.

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Availability of data and materials {29}
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request after publication of the results.

Ethics approval and consent to participate {24}
The trial was exempt from full medical ethical approval by the CMO region Arnhem – Nijmegen (NL 68567.091.19) according to the Dutch Law. The study protocol was subsequently reviewed and approved by de Ethical Committee of the BMS faculty of the University of Twente (190141). Informed consent to participate in the trial is obtained

from all participants. The study is 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).

Consent for publication {32}
This manuscript does not contain individual personal data from participants.

Competing interests {28}
The authors declare that they have no competing interests.

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Chapter 4

Attitudes and experiences towards the application of motivational interviewing by podiatrists working with people with diabetes at high-risk of developing foot ulcers: a mixed-methods study

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ABSTRACT

Background: Podiatrists are key professionals in promoting adequate foot self-care for people with diabetes at high-risk of developing foot ulcers. However, merely informing patients about the advantages of foot self-care is insufficient to realise behavioural change. Motivational interviewing (MI) is a promising person-centred communication style that could help to create a working alliance between healthcare providers and patient to improve foot self-care. This study aims to observe and analyse the application of MI in consultations carried out by MI-trained and non-MI-trained podiatrists with their patients, and explore podiatrists' attitudes and experiences towards MI.

Methods: Eighteen podiatrists (median age: 28.5 years, 10 female and 8 male) followed a three-day basic training in MI and 4 podiatrists (median age: 38.5 years, 4 female) were not trained in MI. To observe and rate the MI-fidelity in daily clinical practice, audio recordings from the MI-trained and non-MI-trained podiatrists were scored with the Motivational Interviewing Treatment Integrity code. Individual, semi-structed, in-depth interviews were conducted with the MI-trained podiatrists to explore their attitudes towards and experiences with MI. These data sources were triangulated to describe the effect of training podiatrists in MI for their clinical practice.

Results: The MI-trained podiatrists scored significantly higher than the non-MI-trained podiatrists on two of four global MI-related communication skills (empathy, p=0.008 and change talk, p=0.008), on one of five core MI-adherent behaviours (affirmation, p=0.041) and on one of the other behaviour counts (simple reflections, p=0.008). The podiatrists mainly reported their attitudes and experiences regarding partnership and cultivating change talk, during the interviews. In addition, they also mentioned facilitators and barriers to using MI and indicated whether they experienced MI as having added value.

Conclusions: The MI-trained podiatrists used the principles of MI at a solid beginner proficiency level in their clinical practice in comparison to the non-MI-trained podiatrists, who did not reach this level. This achievement is in accordance with the basic MI-training they received. This multi-method study reveals that podiatrists can be effectively trained in applying MI in daily clinical practice.

Trial registration: Netherlands Trial Register NL7710. Registered: 6 May 2019.

BACKGROUND

People with diabetes have a 19–34% lifetime risk of developing foot ulcers (1). Diabetes-relatevd foot ulcers (2) can lead to foot infection, amputation, hospitalisation, immobility and a reduced quality of life (1, 3). Therefore, people at high-risk of developing foot ulcers are recommended to see a podiatrist once every 1–3 months, as compared to every 12 months or less for those not at high-risk (4). In addition to podiatric medical care, stimulation and facilitation of behavioural change and adherence to foot self-care are crucial to improve the ' outcomes for people at high-risk of developing foot ulcers (1, 5-8). Behavioural change and adherence to foot self-care includes wearing orthopaedic shoes, attending foot-care appointments, not walking barefoot, and daily self-monitoring of foot temperature and for signs of impending ulceration (1, 5, 7). Since podiatrists provide long-term foot care to people with diabetes, they are a key professional in for stimulating behavioural change and adherence to foot self-care (9-11).

Adherence is defined as the extent to which a person's behaviour corresponds with agreed recommendations for treatment from a healthcare provider (12). To improve foot self-care, patient education is often used to increase the person's skills and knowledge (4, 8, 13, 14). However, previous studies also show that merely informing at-risk people with diabetes about the advantages of foot self-care is insufficient to realise behavioural change (13-17). While people at high risk of foot ulcer generally have the required knowledge about prevention and risks (13, 18), and a high perceived self-efficacy (13, 18), their adherence to self-care behaviour is consistently low (4, 5, 19, 20). Therefore, techniques other than mere knowledge transfer are important to stimulate behavioural change and improve adherence to foot self-care.

One key factor to change behaviour is a person's motivation. Montano et al (21) described that recommended behaviours must be considered important enough by that person for them to become adherent to these behaviours. A healthcare provider's communication style and behaviour can affect a person's motivation to become adherent, and thus contribute to behavioural change (13, 22, 23). To influence adherence to foot self-care behaviour, a working alliance or partnership between the podiatrist and patient is needed. A working alliance or partnership means that the podiatrist and patient have to work together to increase adherence by changing the person's behaviour regarding foot self-care. This is instead of the podiatrist using traditional health education approaches such as taking the expert role, thereby that negatively impacting the change of behaviour (22, 23). However, until now, most podiatrists still use a traditional communication style in patient education, which is directive and one-sided, and focused on giving expert advice (24, 25). Like other healthcare providers, podiatrists generally receive communication training, but not specifically on building working alliances with their patients or specific person-centred communication techniques to elicit behavioural change and avoid resistant reactions in people (24, 26). Without developing these shared decision-making skills, podiatrists have a reduced effectiveness for changing the foot self-care behaviour of people at high-risk of developing foot ulcers. Podiatrists could apply a more person-centred approach with shared decision-making, in which behavioural change is the aim (27-30), by learning to listen to and engage with patient perspectives of their own situation. Furthermore, podiatrists can

discuss patient expectation and acceptance of the recommended treatment.

Motivational interviewing (MI) is one promising person-centred communication style designed to stimulate and enhance behavioural change. MI is a collaborative, goal-oriented style of communication with particular attention on the language of change. MI consists of two active components: a relational component, which focuses on empathy and the interpersonal spirit of MI, and a technical component, which involves the differential evocation and reinforcement of client change (31). MI is designed to strengthen personal motivation and commitment to a specific goal by eliciting and exploring a person's own reasons for change within an atmosphere of acceptance and compassion (32). MI requires the healthcare provider to engage in a working alliance with the patient as equal partner, and use communication skills that stimulate behavioural changes. This is without giving unsolicited advice or directing, confronting, warning, or instructing the patient. Systematic reviews and meta-analyses show that MI has been used successfully in a wide array of health behaviour or lifestyle problems, and has demonstrated robust effects in a variety of clinical settings and diseases (33-38). However, it has also been shown in various healthcare contexts that mastering MI requires training and practice (39, 40) and that time investment, self-awareness and discipline from the healthcare provider are needed to apply an MI-communication style (41). This also applies to diabetes healthcare providers (42).

Recently Kaczmarek and colleagues found that training podiatrists in MI has the potential to improve their MI-related communication skills (25). These podiatrists showed a small increase in MI-related skills two weeks after training, however, these changes were short-lived and 12 weeks after training improvements were no longer detectable (25). In addition, another explorative study that used a short, feedback-driven training program showed that the investigators were sufficiently trained to enhance motivation for change in people with diabetes at high-risk of foot ulcers (41). However, Kaczmarek et al. conducted their study without a control group (25) and Keukenkamp et al. trained investigators who had no direct clinical experience in MI instead of using podiatrists (43).

Therefore, our aims were to analyse the application of MI in consultations carried out by MI-trained and non-MI-trained podiatrists in daily clinical practice, and to explore the podiatrists' attitudes and experiences towards the use of MI and the implementation of the MI-techniques in their work with people with diabetes at high-risk of foot ulcers.

METHODS

This study is part of a randomised controlled trial (RCT) examining the effectiveness of using MI combined with digital shoe-fitting to improve adherence to wearing orthopaedic shoes (44). In the RCT, patients were randomised over the intervention (motivational interviewing + digital shoe-fitting) and control (usual care) condition at the level of the treating podiatrist. All patients in the intervention group received one face-to-face MI-appointment with their MI-trained podiatrist in addition to their usual appointments. The study was exempt from full medical ethical approval by the CMO region Arnhem – Nijmegen (NL 68567.091.19), because the CMO judged that the participants in the RCT were imposed to such actions or behaviours that the study was not regarded to fall under the Medical Research Involving

Human Subjects Act (WMO). Besides this, in accordance with the Medical Device Regulation (MDR) the study did not require a positive recommendation by the CMO, because the sensor used in the study has a CE marking, and the sensor and software were not regarded as medical devices. The study protocol was subsequently reviewed and approved by the Ethical Committee of the Faculty of Behavioural, Management and Social Sciences, University of Twente (file number 190141).

The current mixed-methods study consisted of standardised scoring of recorded patient consultations from MI-trained and non-MI-trained podiatrists and semi-structured in-depth interviews with the MI-trained podiatrists. The quantitative component consisted of audio recorded clinical consultations to measure the application of MI-skills in MI-trained podiatrists in comparison with non-MI-trained podiatrists. This was scored with the Motivational Interviewing Treatment Integrity (MITI) code (45). The qualitative component consisted of in-depth interviews with the MI-trained podiatrists regarding their attitudes and experiences towards the use of MI and the implementation of the MI-techniques in daily clinical practice. This mixed-methods study design was chosen to obtain outcomes from different perspectives and contextualise the results of the MI-training (46). Therefore, the results of the quantitative and qualitative components were combined through triangulation to integrate results, to come to a deeper understanding of both qualitative and quantitative results (47).

Participants

The participants in this study were employed podiatrists at “Voetencentrum Wender”, which is a health organisation in the Netherlands, among others, providing treatment for people with diabetes foot disease. Only podiatrists located in the East of the Netherlands and treating one or more patients who participated in the RCT were included in the current study. The description of the stratified randomisation process of the podiatrists in the RCT is described in detail elsewhere (44). Each participant in the RCT has been treated by their own MI-trained or non-MI-trained podiatrist or one of the other podiatrists from the same group (MI-trained or non-MI-trained) during the one-year follow-up.

Because in the RCT the ratio between patients in the intervention and control group became unbalanced, more podiatrists had to be trained than initially scheduled. This has also resulted in a skewed ratio between the number of podiatrists in the control and intervention group of the current study. This was due to the fact that one of the non-MI-trained podiatrists treated 37.7% (N=26) of the patients in the control group. All podiatrists provided written informed consent to participate in the study.

Intervention

An MI-trainer, affiliated with MINT (Motivational Interviewing Network of Trainers), trained two groups of podiatrists in MI during a three-day (21 hours) basic training. The first group of podiatrists (N=7) also received a one-day (7 hours) online booster training a year after the face-to-face basic training. The second group of podiatrists (N=11) received only a three-day (21 hours) basic training online (due to COVID-19 restrictions). The podiatrists were trained to incorporate the specific coaching and communication techniques of MI in their consultations with the aim to increase adherence to wearing orthopaedic shoes in people

with diabetes foot disease.

During the basic training, MI and the four processes of MI were explained, and different MI-techniques were discussed and practiced. The MI-techniques that were discussed are: asking Open questions, Affirmation, Reflective listening, and Summarising (OARS). These techniques were combined with giving information and advice with permission, how to elicit and strengthen change talk, handling ambivalence, softening sustain talk and reacting to discord (48). The training varied in the mode of instruction including videos, theory and roleplay exercises with feedback. The training consisted of two consecutive days and a third training day after 10 days. In this way the podiatrists could become familiar with the principles of MI during the first two days and could use the learned MI-techniques directly in their consultations with their patients. On the third training day, there was a discussion about their practice experiences of applying MI. Based on a consultation of one of the podiatrists, that was audiotaped in clinical practice, in the training group they reflected on what went well and identified improvements. This learning process was supplemented with additional exercises and theory to strengthen and consolidate the experiences already gained.

Previous research demonstrated that the training effects might diminish quickly (25, 39, 40) and changes in communication style might not be maintained. Therefore, the MI-trainer sent monthly emails to encourage the podiatrists to keep using MI. In every email a short piece of theory was repeated, and an example of what the podiatrists could do to continue their MI approach was provided.

Quantitative measures

To systematically observe and rate the application of MI, also called MI-fidelity, in the daily clinical practice of podiatrists, audio recordings were scored with the Motivational Interviewing Treatment Integrity 4.2.1. (MITI 4.2.1) coding system (49). After the first training was completed the MI-trained and non-MI-trained podiatrists were asked to audio record at least one consultation with their patients. The researchers choose which consultations were to be audio recorded. Besides this, the consultations carried out by the MI-trained and non-MI-trained podiatrists had the same length. The MITI 4.2.1. is a reliable behavioural coding system that assesses which MI-related skills are applied during interactions, also called treatment fidelity, by coding the verbal communication behaviours of care professionals (49). The MITI 4.2.1. consists of two components: global scores and behaviour counts. The global scores include a relational (partnership, empathy) and a technical (cultivating change talk, softening sustain talk) component to assess the use of MI. These were scored on a Likert scale from 1 (low) to 5 (high). In addition, fidelity was measured by counting ten behaviours: three main MI-adherent behaviours (affirmation, seeking collaboration, emphasising autonomy), two non-MI-adherent behaviours (persuading and confronting) and five other relevant behaviours (giving information, persuasion with permission, questions, simple and complex reflections). See 'Additional file 1' for a summary description of the MITI codes. With these scores the summary scores were calculated and compared with previously published, expert-derived "fair" thresholds. These "fair" thresholds, a beginner proficiency level, were considered the minimum extent of MI-application needed to obtain the desired behaviour change effects on clients (49):

1. The relational score is the average of the partnership and empathy global scores. The "fair" threshold is set at 3.5. Higher scores indicate podiatrists foster a more collaborative approach and genuinely seek to understand a patient's perspective.
2. The technical score is the average of the softening sustain talk and cultivating change talk global scores. The "fair" threshold is set at 3. Higher scores indicate podiatrists actively eliciting the patient's arguments in favour of positive change and softening the patient's sustain talk.
3. The reflection to question ratio is calculated, with the "fair" threshold set at one reflection to one question. Higher scores indicate that the podiatrist focuses on evocation and engagement.
4. The percentage of complex reflections is compared to the sum of complex and simple reflections. The "fair" threshold is set as ≥40%.

The coding was performed independently by an experienced MINT coder (JdJ) and a senior researcher (AB) who had been trained and supervised by the MINT coder (JdJ). Both coders were blinded to the MI-training status of the podiatrists. The interrater agreement for MITI coding was assessed on five randomly chosen recordings (20% of total recordings) between the two coders based on the intraclass correlation coefficients (ICCs). The ICCs were calculated using two way mixed effect models for absolute agreement of average measures (50). The mean (±SD) interrater agreement between two coders was good (ICC=0.70±0.16). All intraclass correlation coefficients ranged between good for 'affirmations' (ICC=0.62) and excellent for 'giving information' (ICC=0.86), but only fair for 'persuade' (ICC=0.56) and complex reflections (ICC=0.48), and even poor for the behavioural count confront (ICC=0.37) (51). Due to lack of variance among the scores of the recording ratings, the ICCs for the global score on 'softening sustain talk' and the behavioural count on 'seeking collaboration' and 'emphasising autonomy' could not be calculated. For the five recordings that were scored by both coders, the average of both raters' scores was calculated. The other recordings were scored by only one of the coders.

Qualitative measures

Individual semi-structured in-depth interviews with the MI-trained podiatrists were conducted and recorded online via Microsoft Teams (Version 1.4, Microsoft, 2021) by two of the authors (BB and MJW) between mid-January and early February 2021. This was after the last patient was included in the RCT and respectively 9–19 months after the basic training of the second and first group of podiatrists. The following topics were discussed during the interview (see 'Additional file 2'): podiatrists' attitudes and experiences towards the use of MI and the implementation of the MI-techniques in daily clinical practice with people with diabetes at high-risk of foot ulcers (questions 7–10).

Data analyses

Demographic data of the podiatrists and quantitative data of the MITI coding were analysed using IBM SPSS Statistics 27.0 (IBM, New York, USA). For the qualitative data analyses the research software ATLAS.ti 8.4 (Scientific Software Development GmbH) was used.

First, the two MI-trained groups of podiatrists were compared to each other, to make sure that they did not differ significantly from each other. Since they did not (p=0.364-0.944) both groups were taken together for further analyses. Thereafter differences in demographics

and quantitative data between independent groups for nominal data were assessed with Pearson chi-square tests. Differences in dependent ordinal data and continuous variables (due to skewed distributions) were assessed with Mann-Whitney U tests. A significance level of $p<0.05$ was adopted for all statistical tests.

To explore whether there was a difference in communication style between the MI-trained and non-MI-trained podiatrists in the use of MI-related skills, consultations were scored from both groups of podiatrists. Only the consultations with a duration of 15 minutes or longer were coded according to the MITI guidelines (49). The median of the coded consultation length was 20 minutes (range: 15–20). For the consultations with a duration of less than 20 minutes the whole consultation was coded and for the consultations longer than 20 minutes, a 20-minute segment was coded, starting at 1.30 minutes until 21.30 minutes (49). The first recorded consultation of each podiatrist was used in the analysis, unless the second recorded consultation was the one that was scored by both coders. This was the case in one of the five double coded recordings. The means, standard deviations, and ranges for the behaviour counts and summary scores across podiatrists, were calculated per group. The number of interactions reaching the "fair" threshold was counted for each consultation.

The in-depth interviews were conducted with 17 instead of 18 MI-trained podiatrists, because one of the podiatrists was no longer employed at the company. The audio recordings of the qualitative interview data of the MI-trained podiatrists were transcribed verbatim. After transcription, thematic analysis was conducted (52). This procedure started with familiarisation of the data and generation of the initial codes. Then, the codes were transformed into topics and subtopics. The initial codes, topics and subtopics were identified by one of the authors (MJW) and discussed with two other authors (BB and CB). This was repeated until no new codes emerged. A second assessor (BB) assigned codes independently to 41 quotations, 10% of the total quotations. Thereafter, the interrater agreement (59%) was calculated, and the two assessors discussed any coding differences until consensus was reached and all interviews were checked to apply the consensus coding. The code scheme was developed by combining inductive and deductive thematic analysis (53) and can be found in 'Additional file 3'. The main topics were set a priori by the researchers in the semi-structured in-depth interviews and the subtopics represent the content mentioned by the podiatrists during the interviews. The results of the interviews are structured according to the relational and technical components of MI to allow triangulation of the qualitative and quantitative results.

RESULTS

During the study 22 podiatrists treated one or more persons from the RCT who experienced diabetes and were at high-risk of developing foot ulcers. Eighteen podiatrists followed the three-day basic training or the three-day basic and one-day booster training, and four podiatrists were not trained in MI (Table 1). Participating podiatrists were aged between 25 and 51 years (median 29.5), 12 (54.5%) were female, and experience as podiatrist ranged from 2 to 26 years (median 7.00). Non-MI-trained podiatrists were only women ($p=0.044$) and had more years of experience ($p=0.039$) than the MI-trained podiatrists. Seven podiatrists, five of the MI-trained and two of the non-MI-trained podiatrists, had little MI

Table 1. Demographic data of the podiatrists.

	MI-trained podiatrists (N=18)	Non-MI-trained podiatrists (N=4)	p-values
Age (median (y), IQR)	28.5 (26–34.75)	38.5 (31.5–47.5)	0.060
Gender (M/F)	10/8	0/4	0.044*
Experience as podiatrist (median (y), IQR)	4.5 (2.5–10.75)	14.75 (8.00–23.25)	0.039*
Experiences with MI			0.706
Unknown	1 (5.6%)	-	
Unfamiliar with MI	3 (16.7%)	-	
Familiar with the name MI	9 (50.0%)	2 (50.0%)	
MI knowledge	5 (27.8%)	2 (50.0%)	

Note: F female. IQR interquartile range. M male. MI motivational interviewing. N number. y year. Percentages may not add up to 100 due to rounding.
*Significantly difference, p<0.05

knowledge before the start of the study via a course/lecture during their podiatry training or through self-study.

MITI results

Fourteen audio recordings from the MI-trained and four audio recordings from the non-MI-trained podiatrists were 15 minutes or longer and were rated with the MITI. These recorded consultations occurred between 6 and 22 months after following the MI-training.

Two of the four "global scores" (empathy and change talk), one of the five core "behaviour counts" (affirm) and one of the other behaviour counts (simple reflections) were rated significantly higher for the MI-trained podiatrists (Table 2). Comparing the results of the four MITI summary scores with the "beginner proficiency level" thresholds (49), one MI-

Table 2. MITI coding results of audiotaped interactions of MI-trained (N=14) and non-MI-trained podiatrists (N=4).

MITI Variable	MI-trained Podiatrists Mean (SD; Range)	Non-MI-trained podiatrists (N=4) Non-MI-trained Podiatrists	p-values
Global scores – Relational			
Partnership	2.71 (0.70; 1.50–4.00)	2.13 (0.25; 2.00–2.50)	0.114
Empathy	3.57 (0.78; 2.00–5.00)	1.75 (0.96; 1.00–3.00)	0.008*
Global scores – Technical			
Change talk	3.18 (1.03; 1.00–5.00)	1.25 (0.50; 1.00–2.00)	0.008*
Soften sustain	3.04 (0.57; 2.00–4.00)	3.00 (0.00; 3.00–3.00)	0.788
Behaviour counts			
Questions	13.75 (7.68; 4.00–31.00)	8.75 (6.40; 0.00–14.00)	0.489
Simple Reflection	9.11 (5.60; 2.00–21.00)	1.38 (1.49; 0.00–3.50)	0.008*
Complex Reflection	3.00 (2.65; 0.00–9.00)	1.50 (1.68; 0.50–4.00)	0.179
Giving Information†	2.86 (2.11; 0.00–7.00)	5.00 (7.44; 0.00—6.00)	0.788
Persuade with Permission	0.57 (0.94; 0.00–2.00)	0.25 (0.50; 0.00–1.00)	0.684
MI-adherent behaviour			
Affirm	3.75 (3.33; 0.00–12.00)	0.63 (0.95; 0.00–2.00)	0.036*
Seeking Collaboration	0.57 (0.85; 0.00–3.00)	0.25 (0.50; 0.00–1.00)	0.496
Emphasising Autonomy	0.11 (0.30; 0.00–1.00)	0.25 (0.50; 0.00–1.00)	0.567
MI-adherent behaviour total	4.43 (3.94; 0.00-15.00)	1.13 (1.93;0.00–4.00)	0.076

MI-non-adherent behaviour			
Persuade†	3.36 (2.73; 0.00–8.00)	1.38 (1.25; 0.00–3.00)	0.197
Confront	0.50 (0.96; 0.00–3.50)	0.13 (0.25; 0.00–0.50)	0.526
MI-non-adherent behaviour total	3.86 (3.49;0.00–11.50)	1.50 (1.29; 0.00–3.00)	0.216
MITI summary scores			
Relational score	3.14 (0.71; 2.00–4.50)	1.94 (0.43; 1.50–2.50)	0.009*
Technical score	3.11 (0.66; 1.50–4.50)	2.13 (0.25; 2.00–2.50)	0.011*
Reflection to question ratio	1.02 (0.64; 0.10–2.83)	0.29 (0.10; 0.19–0.38)	0.023*
Percentage complex reflections	23.42 (15.35; 0.00–57.14)	56.46 (40.49; 12.50–100.00)	0.136

Note: SD standard deviation. *Significantly different between groups, p<0.05; †Lower Persuade or Giving Information scores indicate better MI-adherence.

trained podiatrist met all four thresholds, four MI-trained podiatrists met three thresholds and also four MI-trained podiatrists met two thresholds (Table 3). Two MI-trained podiatrists and two of the non-MI-trained podiatrists met none of the four thresholds.

Table 3. MITI summary scores of audiotaped interactions of MI-trained (N=14) and non-MI-trained podiatrists (N=4).

MITI summary scores	Threshold†	Threshold reached N (%)	MI-trained/Non-MI-trained	p-values
Relational score	≥3.50	8 (44)	8/0	0.043*
Technical score	≥3.00	11 (61)	11/0	0.004*
Reflection to question ratio	≥1.00	7 (39)	7/0	0.070
Percentage complex reflections	≥40	4 (22)	2/2	0.130

Note: *Significantly different between groups, p<0.05; †The fair threshold was used (49).

Interview resultsv

The interviews had a median interview length of 17 minutes (range 13–32 minutes). The interview results can be found below described in the five main topics. From the interviews 28 subtopics were identified (see 'Additional file 3'). Only quotes with rich value for understanding of the sub codes are mentioned below. A complete list with all quotes belonging to each subtopic is provided in 'Additional file 4'.

Main topic 1. Podiatrists' perspective regarding the goal of MI

The podiatrists indicated partnership (relational component of MI), cultivating change talk (technical component of MI) and motivating patients as the goals of MI. They thought that MI helped them to speak with patients on an equal level and gave them the possibility to achieve a specific goal together with the patient. Besides this, MI enabled them to encourage patients to think about their own perspectives.

> *"That you make the patient think about why something might (not) work for him/her and very often then they come to new insights" (Pod07)*

MI moreover addressed the intrinsic motivation of patients to change their behaviour.

> *"The goal of MI is to activate people from within themselves to apply to something, as in this study a certain therapy. So it is not something that is imposed by us, but that they understand themselves why it is necessary and*

that it comes from themselves, intrinsic motivation" (Pod02)

Additionally, podiatrists indicated that MI involves using other communication techniques, such as reflective listening, asking reflective questions and softening sustain talk.

Main topic 2. Experiences related to MI-training

Subtopic 2.1. New insights

During and after the MI-training, the podiatrists gained new insights. They indicated they had learned that partnership (relational component of MI) means to speak with patients on an equal level, that it is important to reflect on patients' ideas, and that their task is broader than only providing information. The podiatrists also realised that it is not beneficial to persuade without the patient's permission, that it is important to express fewer prejudices towards the patient and that they should try to avoid conflict in their working alliance with the patient. In addition, the podiatrists also gained new insight regarding cultivating change talk (aspect belonging to the technical component of MI). Changing the podiatrists' communication style helped patients to think from their own perspective. With regards to the other MI-techniques the podiatrists learned that asking open questions instead of closed ones led to more insight into the patients' motives and needs, and that using silences could be useful to let patients think from their own perspective instead of overwhelming them with expertise-based advice.

Subtopic 2.2. Behavioural change for podiatrist

Some of the podiatrists realised that the use of the MI-techniques will be a substantial behaviour change for themselves, because they recognised that their traditional communication techniques were (very) different from the MI-techniques.

> *"It really made me realise that I was used to use such a different [traditional] communication technique during the last years, and it also made me realise that it is also a very substantial adjustment for me to change that" (Pod04)*

Subtopic 2.3. Applicability of MI

Other podiatrists indicated that the MI-techniques would easily be applicable since their usual communication techniques were similar to those used in MI. Also, the practice-oriented approach and the use of many examples during the MI-training made applying MI in practice easy for the podiatrists.

> *"I found out that I actually already unconsciously applied certain things in practice in the same way. That's all named as motivational interviewing. I thought that sounds very familiar to me...It was nice to hear that you actually already did something and they tell you how to do it. That you think: I actually already did that unconsciously" (Pod01)*

Nevertheless, some podiatrists indicated that as point for improvement it would even be better to match the MI-training content more closely to the specific target groups, the examples given should be more related to the users and recipients of MI. A second point for improvement, most podiatrists reported that they would like to have feedback regarding

their application of MI, so it is clear to them whether they apply the MI-techniques correctly in practice.

Subtopic 2.4. Multimodal training method
With regards to the multimodal training method, podiatrists experienced alternating between listening, interaction with the trainer, and exercises with each other during the MI-training, and the small training group pleasant. They also valued that the trainer was able to tailor the MI-training content to their knowledge. Besides these positive experiences, some podiatrists had also some points for improvement and suggested that the experience of the MI-training would have been better if it had been possible to meet physically instead of video conferencing (due to COVID-19 restrictions), and they felt that the quantity of information supplied was too much for the relatively short training time.

Subtopic 2.5. Importance of repeating MI-training information
Repetition of the (content of) MI-trainings was indicated as important. It was particularly useful for the podiatrists to receive the monthly emails, and to have the one-day booster training to refresh their knowledge and remind them to consciously apply MI in practice. However, as a point for improvement, the podiatrists mentioned that more repetition of the (content of) MI-trainings was necessary so to become familiar with using MI in daily clinical practice.

Main topic 3. Podiatrists' experiences with MI in practice
Subtopic 3.1. Partnership
Within the relational component of MI, the podiatrists experienced that partnership was normal to them because they were used to collaborating with the patient. The podiatrists reported that this partnership became easier due to thinking along and/or asking questions; that it ensured the podiatrist spoke with the patient on an equal level; that working together was easier with a motivated patient; and that the use of MI even led to better results of podiatry (less diabetic foot problems) or behavioural changes in patients.

MI-adherent behaviours like affirmation and seeking collaboration were experienced as necessary to keep a patient motivated. It was important to connect with the patient and not only to provide information. Other MI-techniques, such as giving information and persuasion with permission were mentioned as important because patients are not always familiar with the possible treatment options for their diabetic feet. However, the podiatrists realised that they needed permission to persuade, otherwise patients would probably not show a behavioural change. Yet there was one podiatrist who found it difficult to stop automatic repair and advice reflexes which means that the podiatrist tries to solve the problem for the patient.

Subtopic 3.2. Change talk
The experiences of the podiatrists differed regarding cultivating change talk within the technical component of MI. Some podiatrists mentioned positive experiences, e.g., that the use of MI by the cultivation of change talk made patients think from their own perspective and that it provided in-depth conversations between the podiatrist and patient. On the other hand, several podiatrists reported negative experiences, e.g., they experienced this

technique as difficult because it was novel for them and therefore was a point for self-. Change talk was also experienced as difficult by the podiatrists, because some patients in this patient group were not always familiar with the treatment options for diabetes foot disease.

Subtopic 3.3. Acceptance

Within the relational component empathy, the podiatrists had different experiences with acceptance of the patient's choice, opinion and/or behaviour. They thought it was natural to accept the patients' choices, opinions, and/or behaviours, and they experienced that by accepting this the podiatrist was letting the patients think for themselves. However, the podiatrists realised that they also needed to give the patients time to let them think for themselves about possible changes.

> *"And if it really doesn't work right away, then I'll just take a little longer and let the patient come back sometime or give them more time to think about it… The more compelling I come across, or the more I demand of the patient, the greater the patient's shield becomes against me, so therefore I give people a little more rest and time [to think]" (Pod16)*

Besides this, the podiatrists also mentioned that it can be difficult to accept the wishes of non-cooperative patients.

Subtopic 3.4. Compassion

The podiatrists mentioned that they did not experience any problems with compassion within the relational component empathy, because they thought that helping others without benefiting themselves belonged to their mindset towards patients as a healthcare provider.

Subtopic 3.5. Ask open questions

Regarding the MI-technique open questions, the podiatrists' experiences differed. Some podiatrists mentioned that they found it easy to ask open questions, while others experienced more difficulty in asking open questions than expected, particularly asking about the reason why a patient did not want to change.

> *"Especially asking questions, asking open questions is more difficult than I thought, because you actually think you always ask open questions, but you actually ask much more closed questions [than you think]. And if you have someone who is very closed off and you ask closed questions, you actually get very little information" (Pod03)*

Subtopic 3.6. Applicability of MI

The podiatrists had different experiences regarding the applicability of MI. Some podiatrists reported that they experienced no problems changing from their usual approach to the MI-related communication techniques. This was because these communication techniques were similar to their own techniques. Conversely, some other podiatrists mentioned that applying the tips and tricks of the MI-training made the use of MI feel unnatural and

uncomfortable, because the podiatrist had to ask the patient more questions than usual. However, the application of MI during a foot examination made the use of MI feel more natural.

There were also other reasons why the podiatrists experienced difficulties using MI. A couple of them mentioned that it was difficult because there were other matters that had to be discussed during an appointment, and also due to their own working method. Furthermore, the podiatrist's empathy of the patient's situation made it difficult to continue using the MI-techniques, as evidenced by Pod04 comment:

> *"For example, there is a home situation in which people very quickly say 'I'll take my shoes off'. I find it very difficult to motivate those people, because I understand why those people take their shoes off" (Pod04)*

There were some podiatrists who reported that the use of MI was difficult due to negative experiences and because other communication techniques seemed more effective to them. This created doubts about the applicability of MI in practice.

The podiatrists experienced that the application opportunities for MI depended on the characteristics of the patient and on the level of their familiarity with the patient. For example, the use of MI was easier with established patient relationships and more difficult with unknown patients. Some podiatrists mentioned that the use of MI was also experienced as difficult if the patient was not engaging, while others mentioned that a "challenging" patient encouraged them to apply MI.

> *"With certain difficult patients where communication does not run completely smoothly, then you would rather think of applying MI. You think about, how can I collaborate with the patient, so that we can work together towards one goal" (Pod13)*

<u>*Subtopic 3.7. Behavioural change for podiatrist*</u>
Some podiatrists experienced the use of MI as development or even led to a behavioural change for themselves.

> *"I've been working as a podiatrist for 10 years so you're also completely set in your own ways and your own things…it is indeed a complete change, the use [of MI] itself is still quite difficult" (Pod15)*

Therefore, the podiatrists mentioned that they had not (yet) always applied MI in daily clinical practice, despite some of them being aware that the traditional communication techniques were no longer the solution. In general, the podiatrists realised that to ensure an integrated, fruitful, or smoother application of MI, that frequent use of MI was required. This would be necessary because there is a risk that information from the MI-training would become diluted or completely forgotten from usage. Some podiatrists thought that they applied MI already unconsciously, because they were already using it; others reported to be consciously engaged. In addition, not all podiatrists used the exact theoretical version of

the MI-techniques as taught during the MI-training, but used the details that they thought they could apply to themselves.

Subtopic 3.8. Added value of MI
Many of the podiatrists believed MI was of added value, especially cultivating change talk, one of the technical components of MI. The use of MI helped to make patients think for themselves, to make conscious choices and even led to behavioural changes in patients. In addition, it was reported that cultivating change talk was especially of added value for podiatrists who had difficulty evocating a behavioural change in their patients.

The podiatrists also reported that the added value of MI depended on the characteristics of the patient, whereby MI was of added value for, e.g., non-adherent/uninformed/ unmotivated patients. Besides this, they experienced that patients have to be open minded to MI in order for it to have added value and that MI had only an added value for patients with whom they had frequent contact.

Subtopic 3.9. Dealing with resistance to orthopaedic shoes
A combination of some of the MI-techniques were used by a few podiatrists to deal with resistance to orthopaedic shoes, including partnership, which is one of the relational MI components. In addition, the podiatrists accepted the patients' resistance and informed patients about the treatment options for their foot disease. By informing patients about these unfamiliar possibilities, the podiatrist encouraged the patients to think for themselves.

Main topic 4. Patients' experiences observed and mentioned by the podiatrist
In addition to their own experiences, the podiatrists were also asked about the observed experiences of the patients regarding the use of MI in their consultations. Related to partnership (relational component of MI) and cultivating change talk (technical component of MI) the podiatrists mentioned different observed patients' experiences. Many podiatrists reported that the patients experienced working together with the podiatrist as pleasant. Besides this, a single podiatrist reported that some patients showed a more open attitude. However, they also mentioned that it took time for some patients to get used to working together with the podiatrist, because they were unfamiliar with this way of communicating with their podiatrist. They also observed that cultivating change talk made the patients realise that they themselves could contribute to behavioural change and made them see the importance of wearing orthopaedic shoes. However, it also gave the patient insight into their behaviour which was not always welcomed, because this was confronting for the patient. In addition, within the MI-adherent behaviours, the podiatrists mentioned that the confirmation from the podiatrist that things were going well was experienced as pleasant by the patient. Conversely, the podiatrists reported that some patients experienced the (open) questions in MI-style as unpleasant. Because of their digital patient reporting system the podiatrist already had to ask a lot of questions, and therefore in some cases the use of MI might not be applicable.

Main topic 5. Recommendations
Most podiatrists in this study recommended MI to all other podiatrists, where they emphasised partnership within the relational component of MI and cultivation of change

talk within the technical component. This is because working together with the patients ensured that behavioural change could be reached through cultivating change talks, which made the patient think for them self. The podiatrists also reported other outcomes with the use of MI. It provided the podiatrist with some background knowledge about communication techniques and led to better conversations. MI also sensitises the podiatrist to quickly recognize whether a patient showed sustain talk or change talk.

Some podiatrists even recommended adding MI within the primary podiatry education, because this would ensure regular repetition of the content of MI-training. In addition, it also provided the podiatrist with insight into and allow them to focus on patients' expectations and wishes from the beginning of their education. However, a couple of podiatrists recommended the use of MI, but had doubts about including MI in the podiatry training since it might be better to follow an MI-training once the podiatrists had obtained experience in practice.

Data triangulation

The results of the quantitative and qualitative components were combined through triangulation to obtain outcomes from different perspectives and contextualise the results of the MI-training. The MI-trained podiatrists appeared to have acquired basic knowledge and skills regarding MI, but had not yet become MI-experts. The observed communication behaviours in the MITI-scored consultations showed that the podiatrists applied less complex MI-related skills with regard to the relational and technical components of MI that is supported by what they were able to mention during the interviews. The MI-trained podiatrists showed clearly better MITI results on partnership, empathy and cultivating change talk compared to the non-MI-trained podiatrists and demonstrated their understanding of partnership and cultivating change talk in the interviews. The acquired knowledge and skills enabled the communication between podiatrists and their patients in a collaborative and empathetic way, which stimulated behaviour change in the patient towards adherence with recommended foot self-care. However, more complex MI-related skills were minimally applied by the podiatrists in practice and were not mentioned in the interviews with the MI-trained podiatrists. One of those skills was applying complex reflections. The MITI results showed that the threshold for complex reflections was only achieved by two of the fourteen MI-trained podiatrists, compared to two of the four non-MI-trained podiatrists. However, the MI-trained podiatrists used many more reflections, both simple and complex, compared to the non-MI-trained podiatrists.

Most MITI results correspond well with the interview results, although one contradiction was found. The MITI results showed a difference between the MI-trained and non-MI-trained podiatrists on the MI non-adherent behaviour variable 'persuade without permission'. Here, the non-MI-trained podiatrists tended to score better. Possibly, MI-trained podiatrists know that giving advice is allowed, but that they simply forgot to ask the patient for permission to give advice or to ask what the patient thinks of their advice. This means that the MI-trained podiatrists use the MI-techniques only partially and that the non-MI-trained podiatrists give less advice than the trained podiatrists. This is in line with the interview results, because only one MI-trained podiatrist realised that giving advice without permission may not lead to a behaviour change in the patient. Additionally, the qualitative results showed that

the podiatrists experienced the use of MI as patient dependent, e.g., MI is more difficult to apply with an already motivated person or a person who is not open to it. This is also clearly seen in the MITI results per podiatrist. During one conversation with a patient, the podiatrist applied the basic principles of MI at a beginner's level, while during another conversation the same podiatrist did not apply MI at all. However, the MITI results also showed a contradiction with the interview results. The fact that the MI-trained podiatrists scored significantly better on the relational component empathy than the non-MI-trained podiatrists was unexpected, because during the interviews the podiatrists indicated that compassion belongs to their mindset towards patients.

DISCUSSION

The current study aimed to analyse the MI-fidelity in consultations carried out by MI-trained and non-MI-trained podiatrists. It also explored podiatrists' attitudes and experiences towards the implementation of the MI-techniques in practice. The main findings of this mixed methods study indicate after data triangulation that at 6 to 22 months after following the MI-training, the MI-trained podiatrists used the principles of MI at a solid beginner proficiency level, fair scores on the MITI, which is in accordance with the basic MI-training they received. As expected, MI-trained podiatrists did this significantly better than non-MI-trained podiatrists. The MI-trained podiatrists scored significantly better on partnership within the relational component of MI and cultivating change talk within the technical component of MI. These were also the specific MI-related skills that the podiatrists themselves described relating to their attitudes and experiences of using MI in practice. However, they are not able to reproduce all MI-related skills that have been taught. This corresponds to the podiatrists' comments that they have learned and realised that MI is not a trick to be applied, but is a new communication technique to acquire and takes time to apply correctly and fully in practice.

The results of the data-triangulation of this study are in line with previous research on MI-training for diabetes healthcare providers. Two studies by Brug et al. and Welch et al. showed that facilitating change talk and asking open questions are the MI-related skills that most frequently improved following training (54, 55). Kaczmarek and colleagues suggested that the reason for this may be that these skills are less complex to learn and easier to apply during clinical practice compared to some other MI-related skills (42). In the studies by Brug et al. and Magill et al., empathy and the MI spirit were also increased (54, 56). Other MI-related skills, for example complex reflections, seem to be more difficult to acquire and apply during clinical practice (25, 42). Doherty and colleagues also noted that reduction of confrontation is experienced as a complex MI-related skill for diabetes healthcare providers (57). The duration of the MI-training in the current study (21 hours and 28 hours) was similar to the duration of the MI-training in the studies included in the systematic review by Kaczmarek and colleagues (42), which ranged from 2–40 hours. The training in the current study also consisted of didactic training in concepts of MI, role play, and video examples such as the MI-training in previous studies (42). Like Kaczmarek et al., we can conclude that podiatrists can be trained in MI (25). However, in contrast to their results that no improvements in MI-related skills remained after 12 weeks, the podiatrists in the current study still used the principle of MI at a solid beginner proficiency level 6–22

months after following the MI-training (25). This may be due to the fact that the podiatrists in the current study had many more hours of MI-training than in the study of Kaczmarek et al. and that the podiatrists in the current study received monthly emails to support them to keep using MI in daily clinical practice (25). It might be seen as a limitation of this study that also in the non-MI-trained group two podiatrists have heard about MI and two others described themselves as having MI knowledge, the results showed that only substantial training in MI helps podiatrists to implement this communication approach reliable in their clinical practice.

Regarding the implementation of MI in practice, the current study provides some recommendations. First, we recommend that the digital patient reporting system should be adapted in such a way the podiatrists can integrate MI-techniques more easily into their work. The use and maintenance of new skills in routine practice should be facilitated and not hindered by contextual factors as the current reporting system (58, 59), as also mentioned by the podiatrists. The digital patient reporting system they use already requires to ask many questions to complete a patient file. This might lead to an overload of topics to discuss with a patient during one consultation when implementing MI. Second, we recommend including MI within the primary podiatry education. This will promote a successful use of MI in practice, because of regular repetition of the content of the MI-training and the provision of frequent feedback. This prevents the podiatrist from reverting to their usual communication techniques. In addition, the inclusion of MI in the podiatry education from the beginning of their education provides the podiatrist with insight into and focus on patients' expectations and wishes.

A strength of this study is the mixed-method approach with data triangulation, providing more robust evidence than in the previous pilot studies (25, 43). Further, the audio recorded consultations carried out by the MI-trained and non-MI-trained podiatrists were assessed by two independent external coders who were blinded to the MI-training status of the podiatrists. Finally, the coders only counted the behaviours of the podiatrists on relevant aspects of the consultations, so the behaviours of the podiatrists during off-topic speaking were not counted (60).

The results of this study may be limited by the following. Firstly, by the skewed ratio between the number of podiatrists in the intervention and in the control group, which means that the results of this study must be interpreted with caution. This skewed distribution was unavoidable, because the current study was part of the RCT which took place in clinical practice (44). The purpose of the RCT was to investigate the good clinical use of medical resources, in this case orthopaedic shoes. The importance of highly external valid outcomes overrode aspects of internal validity, such as normal distribution of the podiatrists. However, this high external validity makes the results of the study applicable for education and training purposes in practice (61). Besides, doing research in clinical settings with vulnerable patients requires flexibility in study design. Therefore, we think the mixed-methods study design is very helpful to collect data in a concise way. Secondly, the mean ICC levels for persuade and complex reflection were only fair and, even poor for the behavioural count confront (51), despite both coders agreement on the description of the MITI codes, which are standardised and valid (49). There can be different causes of a low

ICC. This low ICC can reflect the low degree of rater agreement but might also be related to the lack of variability among the sampled subjects, the small number of subjects, and the small number of raters being tested (62, 63). In the current study within the coding of reflections one of the coders seemed to be stricter in assigning a complex reflections than the other. This affected the results of the percentage complex reflection, one of the MITI summary scores, which means that the podiatrists rated by this coder was less likely to reach the "fair" threshold. Within the behavioural count confront a small difference in coding between both coders had a big impact on the ICC level of this code, because it was only applied a few times by the podiatrists. Therefore it would be better to have more than two coders or have all recordings rated by both coders. In addition, due to lack of variance, the ICCs for the global score on softening sustain talk and the behavioural count on seeking collaboration and emphasising autonomy could not be calculated at all. For softening sustain talk this may be since the description of this MITI codes was so clear for both coders that the variance between them was small or none. Besides this, when seeking collaboration and emphasising autonomy this lack of variance can possibly be caused due to the podiatrists hardly applying these behaviours. These are more complex MI-related skills that may require more training to apply in daily clinical practice.

Conclusion

Following the triangulation of the qualitative and quantitative results it can be concluded that after a basic MI-training, podiatrists can be effectively apply MI in daily clinical practice at a solid beginner level, with fair scores on the MITI. Furthermore, the findings of the current study support implementation of MI in practice but encourage MI training in the primary podiatrist training and maintenance training for daily clinical practice.

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Additional file 1. Summary description of Motivational Interviewing Treatment Integrity (MITI) codes

MITI codes	Short description
Global scores - Relational	
Partnership	How well is the podiatrist in sharing power with the patient and stimulating equal participation during the conversation.
Empathy	How well does the podiatrist appear to achieve a deeper understanding of the patient during the conversation.
Global scores - Technical	
Cultivating change talk	How well is the podiatrist working on evoking and cultivating change talk during the conversation.
Soften sustain talk	How well is the podiatrist working on softening and leading attention away from sustain talk during the conversation.
Behaviour counts	
Questions	The podiatrist asks the patient a question.
Simple Reflection	The podiatrist reflects solely on what the patient has said.
Complex Reflection	The podiatrist reflects beyond what the patient has said, introducing new meaning and direction.
Giving Information	The podiatrist shares information, with attempting to persuade.
Persuade with Permission	The podiatrist asks for permission before advising or informing the patient on how to change behaviour.
MI adherent behaviour	
Affirm	The podiatrist positively affirms the patient's behaviour, intentions or strengths.
Seeking Collaboration	The podiatrist asks for permission to share information or advice, sharing power with the patient.
Emphasising Autonomy	The podiatrist states that the patient has the freedom to make his/her own decisions.
MI non-adherent behaviour	
Persuade	The podiatrist gives unsolicited advice and persuades the patient to change behaviour.
Confront	The podiatrist argues, blames, judges or moralised the patient's behaviour or decisions.

Additional file 2. Overview of the main questions of the in-depth interview

Interviewer Question
1. Can you explain the purpose of motivational interviewing? (in your own words)
2. What has it meant for you to apply motivational interviewing?
3. How did you experience the MI-training? (0 = not useful at all and 10 = very useful)
4. Has the MI-training led to new insights for you? (0 = no new insights at all and 10 = a lot of new insights)
5. How did you experience the change from your usual patient approach to applying motivational interviewing?
6. How did you experience communicating with the patient taking into account the basic principles of MI (partnership, evocation, acceptance and compassion)?
7. How do you think your patients experienced your use of MI? (0 = very negative and 10 = very positive)
8. Is the use of MI seen by the patient as an added value?
9. In your opinion, is MI of added value in this group of patients compared to your normal patient approach?
10. Have you encountered resistance from your patients with regard to wearing orthopaedic shoes? If so, how did you deal with this?
11. Would you recommend applying MI to all podiatrists? In which way do you recommend the use of MI to all podiatrists?
12. Did you miss something with regard to the MI-training and/or in the period after the training? What would you advise to improve in the future?

Additional file 3. Main topics based on the interview outcomes

Main topic	Subtopics	
1. Podiatrists' perspective with regard to the goal of MI	1.1. Partnership	
	1.2. Change talk	
	1.3. Motivating by podiatrist	
2. Experiences related to MI-training	2.1. New insights	2.1.1. Partnership
		2.1.2. Change talk
		2.1.3. Ask open questions
		2.1.4. Allow for silences
	2.2. Behavioural change for podiatrist	
	2.3. Applicability of MI	
	2.4. Multimodal training method	
	2.5. Importance of repeating MI-training information	
	2.6. Points of improvement	2.6.1. Applicability of MI
		2.6.2. Multimodal training method
		2.6.3. Importance of repeating MI-training information
3. Podiatrists' experiences with MI in practice	3.1. Partnership	
	3.2. Change talk	
	3.3. Acceptance	
	3.4. Compassion	
	3.5. Ask open questions	
	3.6. Applicability of MI	
	3.7. Behavioural change for podiatrist	
	3.8. Added value of MI	3.8.1. Change talk
		3.8.2. Patient dependent
	3.9. Dealing with resistance to orthopaedic shoes	3.9.1. Partnership
4. Patients' experiences observed and mentioned by the podiatrist	4.1. Partnership	
	4.2. Change talk	
5. Recommendations	5.1. Application MI by all podiatrists	5.1.1. Partnership
		5.1.2. Change talk
	5.2. Include MI in the primary podiatry education	

Additional file 4. Supplementary quotes – (Pod = Podiatrist)

1. Podiatrist's vision with regard to the goal of MI	
1.1. Partnership	"So, I actually think that there is much more communication on an equal level with the patients about the possibilities and what they prefer to do, to ensure that it [the wound] closes and they won't have complaints anymore" (Pod09)
1.2. Change talk	"That you make the patient think about why something might (not) work for him/her and very often than they come to new insights" (Pod07)
	"You do not impose anything on people, but you actually address the intrinsic motivation of the patient" (Pod17)
1.3. Motivating by podiatrist	"Motivate your patients or clients to do something through communication techniques" (Pod06)
2. Experiences related to MI-training	
2.1. New insights	
2.1.1. Partnership	"Speak with the patient on an equal level" (Pod09)
	"Let much more [information] come from your patient instead of working from the offering role" (Pod02)
	"That you really like to throw your advice on the table, and without that man or woman perhaps being open to it" (Pod11)
	"…What I actually learned through the exercises that we did during the courses, that I sometimes have to express my prejudices a little less quickly…" (Pod14)
	"That you have to try to stay out of conflict with your patient, that's just clearly explained in this course" (Pod14)
2.1.2. Change talk	"…that a patient should actually give the answer himself, or should think for himself… That you really must have the reaction of the patient in order to be able to take a step towards behavioural change" (Pod05)
2.1.3. Ask open questions	"…you very quickly ask closed questions, and then you do not always get the correct information or underlying information. So I also learned to ask questions differently so that they [the questions] become open and patients also have to tell a bit more" (Pod16)
	"That allowing silences can be very useful every now and then" (Pod02)
2.2. Behavioural change for podiatrist	"It really made me realise that I already use/used such a different communication technique during the last years, and it also made me realise that it is also a very substantial adjustment for me to change that" (Pod04)
2.3. Applicability of MI	"I found out that I actually already unconsciously applied certain things in practice in the same way. That's all told as motivational interviewing. I thought that sounds very familiar to me...It was nice to hear that you actually already did something and they tell you how to do it. That you think: I actually already did that unconsciously" (Pod01)
	"Super practical, very good practical examples, you can immediately start using it [MI] the day after [the training]. Because of that it is the advantage also is that you can actually make progress with the information you get there [during the MI-training], you can apply it" (Pod08)
2.4. Multimodal training method	"There was also room for interaction, so if there were any questions you could just raise your hand and fill in. So you didn't have to listen for 1.5 or 2.0 hours continuously…so the interaction was good. We had to do exercises ourselves, I also thought that was good. It was just a good mix of theory and practice" (Pod14)
	"…I also liked that we didn't had a too large group, so that everyone actually participated very actively during the meetings" (Pod07)
	"During the course, he [the trainer] really listened to what we were already doing and what we might already be able to do. Then he just adapted it [the MI-training], he could adjust it [the MI-training] à la minute. I thought that was very nice" (Pod12)
2.5. Importance of repeating MI-training information	"I received then an email as refresher of that course [the MI-training]. I save the content of that email, and every now and then I think what did it mean again. Sometimes it fades again, and then I find it useful to refresh it [the MI-training content]" (Pod17)
	"I've to say that I also liked the booster training via teams. That is also the power of repetition, and you notice that with a lot of things, you just got a little better in it [the application of MI]" (Pod04)

2.6.	**Points of improvement**	
2.6.1.	Applicability of MI	"Sometimes I thought it [the MI-training] was kept so broad, that I found it very difficult to project it [the MI-training content] on my own profession. I just found that difficult, if it had been a little more specific to our target group, then I would probably have experienced it differently…That's because sometimes I really felt that is wasn't always applicable or something" (Pod02)
		"I missed the feedback on that what you applied in practice" (Pod13)
2.6.2.	Multimodal training method	"Well, of course we had him [the MI-training] through Teams, which I thought was very well arranged…However I personally like face-to-face courses better, because it just makes it a bit easier to spar" (Pod16)
		"I have to stay that it was a lot of new material. In the beginning I really thought…gosh what a lot of information…Sometimes the days were long but that's part of things like that [training/ courses]. However, I am more a practical person than a congress person, so such a day is long" (Pod05)
2.6.3.	Importance of repeating MI-training information	"If you want to implement motivational interviewing well, than you should actually have a booster session now and then over a longer period of time" (Pod05)
		"I thought there was a bit of repetition in it [the MI-training]" (Pod12)
3.	**Podiatrist's experiences with MI in practice**	
3.1.	**Partnership**	"Well the collaboration…I had the idea for myself that I actually always worked together , to a certain extent, and perhaps also a bit more unconsciously than consciously" (Pod15)
		"That motivational interviewing is aimed that you have an equal conversation" (Pod10)
		"I find it difficult to get the repair reflex out" (Pod03)
		"The combination of working together, and providing applicable solutions , or thinking along, is often very experienced as very pleasant by them [the patients]" (Pod09)
		"The combination of working together and providing an applicable solution, or thinking along, they [the patients] experience that often as very pleasant and it also works much easier…" (Pod10)
		"So I think that if people start to change themselves, already want something, then it is of course much easier to go with that…but a patient with diabetes who actually does not know what he wants and has no idea what is good for him, that is a different story" (Pod10)
		"Give confirmation that it is going very well, and try to ensure that he [the patient] also remains positive and motivated about that, so that he is also in the long term motivated" (Pod13)
		"Well I recognise that…you just send it [information]…but without reaching that person" (Pod17)
		"So I often try to show those people with an introductory meeting at the pedorthist what the possibilities are [with regard to orthopaedic shoes], to plant a seed there" (Pod05)
		"It's just a different approach…you always run into the same thing, you give people advice, but they don't do anything with it" (Pod11)
3.2.	**Change talk**	"You give them [the patients] insight in what is actually good for them, so they think about it themselves, instead of you saying that you [the patient] should wear those shoes. That you say: 'So you prefer you current shoes and getting a wound, instead of keep using the good shoes and stay ahead of a wound, so you don't have to go to the hospital?' Then you see that they [the patients] start thinking and they say: 'I hadn't thought about it like that…By giving them the facts, you make them think and realise that they didn't looked at it that way" (Pod03)
		"It's nice, you can go a bit more in-depth with such conversations. It makes it possible that you sometimes can look at certain topics in a better way by asking question about why and how. In the end that has really been an enrichment for me" (Pod10)
		"I noticed that evocation, it is very interesting and I also think it is very meaningful... but that has not always been my way to do it…I noticed that I have trouble applying that" (Pod04)
		"It is of course a target group that very often does not know how and what, and then you have to elicit that" (Pod02)

3.3. Acceptance	"…I also think that acceptance is very logical…" (Pod15)
	"…Accepting if a patient does not want to cooperate, I still have a hard time with that" (Pod05)
	"And if it really doesn't work right away, then I'll just take a little longer and let the patient come back sometime or give them more time to think about it…The more compelling I come across, or them more I demand of the patient, the greater the patient's shield becomes against me, so therefore I give people a little more rest and time [to think]" (Pod16)
3.4. Compassion	"Well I think that is also one of the reasons why you went working into care I think. To help someone actually, you don't do that to become better of it yourself" (Pod15)
3.5. Ask open questions	"Especially asking questions, asking open questions is more difficult than I thought, because you actually think you always ask open questions, but you actually ask much more closed questions [than you think]. And if you have someone who is very closed off and you ask closed questions, you actually get very little information [from/about the patient]" (Pod03)
	"But if you really have to take the last step and ask him what would you do, what's so bad about changing something? I found that last step the most difficult [one] to take, and also to get the patient on board" (Pod12)
	"I think I am very handy with certain questions that we have been given" (Pod06)
	"So I found that difficult, because at some point you feel a bit of a whiner when you come up with those extra questions every time" (Pod12)
3.6. Applicability of MI	"I actually never had any trouble motivating someone to wear orthopaedic shoes. That was never a problem for me. For some colleagues it was a life-changing thing, but not for me, I had no problem with it" (Pod01)
	"I actually already did it a bit, in the same way, but without a name" (Pod09)
	"If I have MI-conversation, then I try to use the tips and tricks [from the MI-training], although I it feels very unnatural…because you're really going to question things, and then I just switch back to the normal approach" (Pod01)
	"I think you can use it [MI[then [in combination with a foot examination] much more into your story. That's why feels more natural" (Pod02)
	"I still use it [MI] a lot, also besides the study" (Pod16)
	"Well sometimes it is difficult [to apply MI], it also depends a little bit on who is sitting opposite of you…With one patient I succeed very well in pointing out to them that their decision is wrong without coming into conflict, but with other patients you just keep that it there is always friction" (Pod14)
	"I found it easier when it was a patient I already knew in practice" (Pod02)
	"Every now and then you got a patient that you didn't know, and sometimes I found it difficult to start applying MI right away, because you actually have no idea who or what you are dealing with" (Pod02)
	"I think especially with the slight more closed patient. It costs a lot of energy to get out that part that you actually want to hear [from him/her]" (Pod07)
	"It's not that I am afraid, but I am especially curious or find it exciting how someone reacts… especially a certain age category. I am more afraid of [patients who are] 50+ than people who are younger" (Pod06)
	"With certain difficult patient where communication does not run completely smoothly, then you would rather think of applying MI. You think about, how can I collaborate with the patient, so that we can work together towards one goal" (Pod13)
	"I think it's difficult to be very conscious using it [MI] all the time…that you very easily do what you were used to do…because you are purely focused on the complaint…then you will do those things that you have to do actually" (Pod05)
	"For example, there is a home situation in which people very quickly say 'I'll take my shoes off'. I find it very difficult to motivate those people, because I understand why those people take their shoes off" (Pod04)
	"Then you think maybe I shouldn't do it [apply MI] next time, that's the risk" (Pod12)
	"I have gained new insights, but then you might also come to the applicability…I find that difficult…I think there are sometimes other conversation techniques that are better" (Pod15)

3.7.	**Behavioural change for podiatrist**	"I notice that in myself, I am now very aware of that, that I very quickly tend to offer solutions immediately, while you very often miss the point" (Pod02)
		"I've been working as a podiatrist for 10 years so you're also completely in your own ways and your own things…it is indeed a complete change, the application [of MI] itself is still quite difficult" (Pod15)
		"In the beginning it was a bit of a struggle about what exactly I am going to say, which sentences I am going to use, but if you do that more often, you quickly become handy" (Pod14)
		"I noticed that if you're not working with it [applying MI] every day, it quickly disappears into the background" (Pod03)
		"I do try to [apply MI] more and more…I don't always think about it yet, but the more you focus on it, the more you become aware of it" (Pod13)
		"I am now a little more aware of motivational interviewing. I work with it a little more consciously and I am more aware that it exists" (Pod17)
		"But I do apply it [MI] continuously, but am not so strongly aware that I do so. I do not think in the morning, now I am going to apply MI, it has become my own" (Pod08)
		"I have absolutely not been involved with the patient exactly with those four basic principles" (Pod08)
		"I did pick my things up, I won't say I made a 100% copy of every I learned. But I just took out the details that I thought I can apply myself and I can work with" (Pod01)
3.8.	**Added value of MI**	
3.8.1.	Change talk	"You also have to be able to argue it [wearing orthopaedic shoes] very well, I think, and be able to substantiate it. So I do think it is an added value, but then especially for the people who have difficulty with that" (Pod01)
		"It is of added value for a lot of patients who are still just a bit in doubt…and thus show themselves that they can change themselves instead of that I [the podiatrist] am always the one for them to say to do this and adjust to that, and then it'll be fine" (Pod10)
		"That the patient chooses: I choose this, or don't choose it" (Pod08)
		"The behavioural changes is actually seen in the patient who, through the last [MI-] conversation I had with him, was actually suddenly willing to make an appointment with an pedorthist, which he never wanted in the past…" (Pod14)
3.8.2.	Patient dependent	"Because this is a group that is sometimes difficult to motive, and that was also our first feeling, how should we motivate those people. But I think if that's the feeling you have about something, that is also the best target group to motivated in this way. I do think it is the right target group [to apply MI on]" (Pod04)
		"I think that the patients who are open to it, that they really see the benefit of it" (Pod07)
		"He's motivated, I know him too, it's not that you haven't seen him enough, you know where you started, then I really think this is so useless" (Pod05)
		"No, I've no idea whether the shoes fit well, whether they are worn…on the one hand you also shouldn't have patients that you know too well or that you know they are adherent, but when only seeing a patient for the very first time, and never seeing that patient again after such a conversation, I question the added value" (Pod05)
3.9.	**Dealing with resistance to orthopaedic shoes**	"You also accept that they feel that resistance. At least, you indicate that you think it is logical that they experience it that way" (Pod15)
		"You first explain what is going on, what the problem and diagnosis is, what a solution could be, and what concessions they have to make in functionality, and how the shoes look like. And I always explain that scale in function and how it looks like…if you make it negotiable you don't actually get a problem or a weird reaction from them" (Pod08)

4. Patient's experiences observed and mentioned by the podiatrist	
4.1. Partnership	"…People always like to be flexible themselves and that you [as podiatrist] think on the wish of the patient, that that wish is heard and you [the podiatrist] not just sit there as a listener. That is what all people like I think" (Pod17)
	"I think it takes time of getting used to [the application of MI], especially for patients… because they come to you to solve their complaint, or arch support or whatever. And then you suddenly turn it around, by letting them do things themselves, and…they probably didn't expect that either. Some do, some don't" (Pod09)
	"Especially because he received the confirmation from me that he was doing well…I got the feeling that he liked to get the confirmation…" (Pod13)
	"That you notice that as the conversation progresses, their attitude becomes more open, that their hands are no longer crossed and that they have a different facial expression" (Pod16)
	"I notice that especially the new way of reporting, we now have a different way of reporting for diabetes patients, ensures that they really have the idea of what a lot of questions. We now really have to tackle many things step by step, so ask a lot of questions about how things are going with the pedicure, but also other questions. That it is a bit too much for some [patients], and then they have the feeling is that all necessary?" (Pod10)
4.2. Change talk	"Because I had patients who said at the end [of the conversation] said for example: 'okay…so I can do something about it myself'" (Pod12)
	"Two or three weeks ago I had a conversation with someone, and he came in and he said that he was so glad that I started such a conversation with him, that it really made him think. And that was actually going a lot better, even noticed that his walking was getting better" (Pod07)
	"Sometimes I've the impression that the moment you start talking about the shoes by patient with diabetes, they find it whining or an obligation. Then you may also elicit something that it feels confrontational [for the patient] and that that is experienced as negative" (Pod15)
4.3. Other aspects	"But I think it took some time getting used to it [the application of MI] for the patient, because they just come [to us] with an expectation [about the appointment] and when we don't meet that expectation, it will be different for them" (Pod09)
	"I also had a patient with diabetes, who really thought it was all nonsense that I asked those question. Therefore the conversation was really uncomfortable" (Pod12)
5. Recommendations	
5.1. Application MI by all podiatrists	
5.1.1. Partnership	"…A patient comes to you [the podiatrist] with something [a problem], and wants to go somewhere [a solution], then you [the podiatrist] are there to guide that patient there. I don't think it will work if I just say: 'you have to do this and that', patients already have to do so much. I think it works better if you [the podiatrist] just listen very carefully to what the patient needs, and that you work with the patient to find a solution, and not because you are convinced that there is only one way that works" (Pod11)
	"…when applying it [MI] in practice that simply allows patients to get very different insights, which actually increases patients' adherence…" (Pod13)
	"It [the application of MI] improves insights from the patients themselves. It's not that I'm as podiatrists going to fix it for you, but I'm the podiatrists and I can help you, so that we can do together the best for you…" (Pod04)
5.1.2. Change talk	"…eliciting those questions from people themselves, so that you let them think for themselves. And I have the idea that by thinking they also give a different answer than they would in the first place [without thinking about it themselves first]…" (Pod03)

5.1.3.	Other aspects	"It is indeed because I think that you also become very aware of the way you conduct a conversation in the first place. You really don't' know that [what you are doing], you just do what you think is right. Because of the training I really found out in what way I conduct conversations, and in what way I could improve them" (Pod12)
		"I think that it [the MI-training] is an added value for everyone to have a bit of background knowledge [about conversation techniques]…" (Pod05)
		"It is a very valuable addition about how you deal with patients…to be able to have better conversations with a patient…" (Pod17)
		"… it [the application of MI] also gives you insights about a piece of self-knowledge, but also about the knowledge of others. So you can quickly see from others whether they apply only sustain talk or also want to change…" (Pod10)
		"If I at least think for myself, I also have several [conversation] techniques that I find interesting. Now [in this training] it was really just motivational interviewing, but I believe… that there are more options. So I personally think that not one option is the right one, sing you also have to deal with many different types of people" (Pod10)
5.2.	**Include MI in the primary podiatry education**	"When I think back to the beginning of my career, I recognise that I often had problems with patients…I feel like I had those kinds of situations more in the beginning than in recent years. And I think that has a lot to do with the fact that I do indeed think more along with the wishes of the patient…So get the expectations [from your patient] very clear" (Pod17)
		"If I look at the podiatry training, it should have been included in three…then you can make it come back more often" (Pod03)
		"I do think that, imagine if it [the MI-training] was really a one-year course, that would be even more effective" (Pod10)
		"I don't know if it [MI] should be in the podiatry training…maybe you should do it one or two years afterwards, so that you have rest in the treatment room, that you know what to do, and that you also have time to apply motivational interviewing...It is the most desirable situation and you should definitely to it, but I don't know whether that will work, or whether that it is feasible. They [the students] are happy if they can ask a question about the correct diagnosis, and I wonder when I see the fourth-year students start working, I don't think it is feasible to apply motivational interviewing complete correctly, but of course they can already get tips" (Pod08)
		"I especially think about the podiatrist who are already familiar in practice, because when you are just starting and you are still looking how does everything work…they actually thought that it was a lot [already they had to think about]…after six months of working, than I think it is actually a very good moment to get that course, because then you are just a bit in your rhythm…then you can train your conversation techniques very nicely" (Pod07)

Chapter 5

The effectiveness of motivational interviewing on adherence to wearing orthopedic shoes in people with diabetes at low-to-high risk of foot ulceration: a multicenter cluster-randomized controlled trial

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ABSTRACT

Aim: To evaluate the effectiveness of motivational interviewing (MI) performed by MI-trained podiatrists in improving adherence to wearing orthopedic shoes in comparison to usual care in people with diabetes at low-to-high risk of ulceration.

Methods: People with diabetes with loss of protective sensation and/or peripheral artery disease, and with orthopedic shoes prescription were allocated to receive one MI-consultation by a podiatrist randomized to MI training (N=53) or usual care only (N=68). Adherence was measured as the percentage of steps taken while wearing orthopedic shoes, determined using an insole temperature microsensor and wrist-worn activity tracker during one week at 3 and 6 months.

Results: The proportion of participants ≥80% adherent to wearing their orthopedic shoes was higher in the control group than in the MI-intervention group at 3 months (30.9% versus 15.1%; p=0.044), and not significantly different at 6 months (22.1% versus 13.2%; p=0.210). Average adherence was also higher in the control group than the intervention group at both 3 months (60.9% versus 50.9%; p=0.029) and 6 months (59.9% versus 49.5%; p=0.025).

Conclusions: One podiatrist-led MI-consultation in its current form did not result in higher adherence to wearing orthopedic shoes in people with diabetes 3 and 6 months after inclusion.

Trial registration: Netherlands Trial Register NL7710 (available on the International Clinical Trials Registry Platform).

INTRODUCTION

With a lifetime prevalence of 19-34% foot ulceration is a common complication in people with diabetes mellitus (1, 2). Diabetic foot ulcers can lead to infection, hospitalization, and amputation (1) and are associated with immobility and reduced quality of life (3). To prevent re-ulceration, self-management for early risk detection and protective footwear such as orthopedic shoes are considered essential (4-6). People with diabetes who are adherent to these strategies have significantly better outcomes than those who are not (7). However, research has shown that adherence to wearing orthopedic shoes is rather low, with only 46-49% of people with diabetes wearing their orthopedic shoes ≥80% of their daily total steps (5, 8). Since it's a challenge to achieve better adherence, new interventions are needed to improve adherence (9).

Previous studies have shown that communication with the healthcare provider is essential to influence someone's decision to use orthopedic shoes and is associated with increased long-term use of orthopedic shoes (10, 11). Regarding good communication, it is important to patients that they feel being listened to and that they are involved in the prescription process of orthopedic shoes, to be able to make their own choices during that process (i.e., establish a partnership) (10). As such, it is thought that good communication can improve adherence to wearing orthopedic shoes (10, 12).

Motivational interviewing (MI), defined as a collaborative, goal-oriented style of communication of the healthcare worker with particular attention to the language of change (13), may stimulate a satisfactory working alliance and, as a result, positively influence adherence. MI is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's reasons for change within an atmosphere of acceptance and compassion (14). Recently, a small explorative study showed that MI had clinically relevant short-term positive effects on adherence to wearing orthopedic shoes in people with diabetes 1 week after the intervention (4). However, adherence returned to baseline levels 3 months after the intervention. Besides, in this study MI was performed by investigators who had no direct clinical experience in treating people with diabetic foot problems.

Because podiatrists work at the frontline of diabetic foot care, MI may be an opportunity for podiatrists to increase adherence to recommended self-care behavior (15). Previous research already showed that podiatrists can be trained to apply MI in daily clinical practice (16, 17). However, adequately powered randomized controlled trials (RCTs) with longer-term follow-ups (e.g. six months or more) are needed to establish the efficacy of MI in improving adherence to wearing orthopedic shoes (4, 16, 17). Therefore, this RCT aimed to evaluate the effectiveness of MI performed by an MI-trained podiatrist, in improving objectively measured 3- and 6-months adherence to wearing orthopedic shoes and 1-year ulcer prevention in comparison to usual care in people with diabetes at low-to-high risk of foot ulceration. Additionally, the participants experiences on the use and usability of their orthopedic shoes and health-related quality of life (HRQoL) were assessed.

METHODS

Study design

This study was designed as a multicenter, cluster-randomized controlled trial. The study was exempted from the requirement of full medical ethical approval by the CMO region Arnhem – Nijmegen (NL 68567.091.19). The CMO judged that the participants were not subjected to (such) actions or no (such) behavior was imposed on them to fall under the Dutch Medical Research Involving Human Subjects Act (WMO), and as such the study was exempt from full medical ethical approval under Dutch law. Subsequent ethical approval for the study protocol was obtained from the Ethical Committee of the BMS faculty of the University of Twente (190141). The protocol for this RCT has been published elsewhere (18). All participants gave written informed consent before taking part in this study.

Study participants

People with diabetes, for whom foot care was reimbursed in the Dutch healthcare system, were recruited at different locations of Voetencentrum Wender and Voetmax Orthopedie, located in the east of the Netherlands. Inclusion criteria were: a clinical diagnosis of diabetes type 1 or 2; aged ≥18 years, classified with risk profiles 1-3 according to the International Working Group on Diabetic Foot (IWGDF) (19), and prescribed with orthopedic shoes. Exclusion criteria were having a foot ulcer, as a result of which no orthopedic shoes could be worn at the time of inclusion, active Charcot's neuro-arthropathy or foot infection, being unable to walk, or being unable to read and understand the study instructions.

Randomization

The randomization process is described in detail in our published protocol (18). Randomization was performed at the level of the podiatrist, so that the background assignment of the participant's regular podiatrist (being trained in MI or not) determined the treatment allocation of the participants to either the intervention or control group. The randomization was done centrally by an independent researcher using www.sealedenvelope.com (18).

Interventions

Usual care consisted of: (a) foot screening and professional foot care by a podiatrist once every 1-12 months, depending on the IWGDF risk classification; (b) structured education about appropriate foot self-care for preventing a foot ulcer; (c) orthopedic shoes fitted by a pedorthist, if indicated based on foot condition and ulcer risk, as provided in standard clinical practice in the Netherlands in accordance with evidence-based guidelines (9).

The intervention consisted of usual care plus MI. A certified MI-trainer trained the podiatrists assigned to the MI-group in the principles of MI during a three-day (21 hours) basic training (17). After their basic MI-training the podiatrists were able to apply MI in daily clinical practice at a solid beginner level and did this significantly better than untrained podiatrists, as we have described in a previous publication (17). During the MI-consultations the podiatrist focused on improving acceptance of and adherence to orthopedic shoes.

In both groups, all consultations with the podiatrist were planned as much as possible with the participant's regular podiatrist or with one of the other podiatrists belonging to the

same randomized group as the regular podiatrist (being trained in MI or not) during the 12-month follow-up period.

Procedures and assessments

All participants were followed for 12 months. At inclusion, after providing informed consent and receiving their new pair of orthopedic shoes, the investigator embedded a validated temperature microsensor (Orthotimer®) in the custom-made insole of every pair of orthopedic shoes possessed and used at study entry (i.e. earlier prescriptions) or that was prescribed during follow up for determining wearing time of the orthopedic shoes. The sensor was placed in the medial arch of one of the shoe insoles, because of sufficient place in the insole, relatively low pressure from the foot, and its previous validation at this location (20). Participants allocated to the intervention group had an extra consultation with an MI-trained podiatrist for a single MI-consultation. This consultation occurred around the time the participants received their orthopedic shoes.

During the 12-month follow-up period, the participants had, besides their regular consultations with their podiatrist and pedorthist, a consultation with one of the investigators at 3, 6, 9, and 12 months after inclusion. During these consultations, the temperature microsensors were read out with the Orthotimer® reading device. Additionally, the participants received a reliable wearable wrist activity monitor (Misfit Shine 2™) (21) at 3 and 6 months to continuously register their steps taken, and were instructed to wear this activity monitor for one whole week starting the day after the consultation (24 hours per day).

Additionally, we assessed the proportion of participants (re-)experiencing ulceration based on self-report, asked during the consultations with the investigators, and clinical data, up to 1 year after inclusion. Clinical data (including notes and photos) from all participants were obtained from the digital patient file of the podiatrist. Besides, if the participant self-reported that they experienced an ulcer up to 1 year that resulted in hospital treatment, the clinical data from the relevant hospital was obtained. For validation, we also checked if there was clinical hospital data available from 20% of randomly chosen participants who self-reported that they experienced an ulcer during the 1-year follow-up, but did not indicate that they had been to a hospital for treatment. Only one participant was treated in the hospital while they indicated that this was not the case. In addition, the total number of ulcer-days from both the intervention and the control group were determined. An ulcer-day was defined as a day on which a participant had one or more foot wounds at one or both feet.

The participants were also asked to fill in the RAND-36 item Health Survey V2.0 (RAND-36 V2.0) at inclusion, 6 and 12 months, and the Monitor Orthopedic Shoes post-part (MOS) (22) at 6 and 12 months. The RAND-36 V2.0 is the validated Dutch version of the 36-item Short Form Health Survey (SF-36) and assesses experienced health status and health related-quality of life (HRQoL) (23, 24). The MOS post-part was designed to measure the use and the most relevant factors of usability of orthopedic shoes from a participant's perspective through multiple choice and visual analog scale (VAS) questions (22).

Outcomes

Primary outcome

In line with the IWGDF guidelines and previous studies, adherence was objectively measured (6, 20, 22, 25). The level of adherence to wearing orthopedic shoes was determined by the percentage of total steps taken during the two 1-week periods that the step counts were registered by the activity monitor and were calculated separately for these two measurements as follows:

$$Week\ adherence = \frac{\sum steps\ wearing\ orthopaedic\ shoes}{\sum steps} \times 100\%$$

Total steps wearing orthopedic shoes were calculated using the continuous log data from temperature microsensors fitted in the orthopedic shoes of all participants (18). Total steps were calculated using data from activity monitors over the 1-week period (18). The primary outcome for this study was the proportion of participants who sufficiently adhered to wearing their orthopedic shoes at 3 months (short-term) and 6 months (longer-term) after inclusion, defined as minimally 80% of steps taken in their orthopedic shoes (5, 8).

Raw data from the temperature microsensors were analyzed using the validated Groningen algorithm, version 2, to determine shoe use (20, 26). Wearing times of orthopedic shoes and daily step counts from the activity monitor were processed in MATLAB (The MathWorks Inc., Natick, MA, USA). Adherence to wearing orthopedic shoes was only calculated for participants if at least four complete days of step count recordings, including one weekend day, were available (8). Data could be missing due to delayed sensor readings or drop-outs. Besides this data was considered invalid when data showed inactivity ≥3 hours between 07.00–22.00h. For the participants for whom it was not possible to calculate adherence due to missing or invalid data, adherence was imputed using single-imputation with linear regression with residual estimation adjustment based on the available data of the wearing time of their orthopedic shoes. However, missing or invalid activity data were not imputed and included in the analysis. The correlation between observed wearing time and adherence in the current sample was strong at r=0.65 (N=85) and 0.76 (N=80) at 3 and 6 months after inclusion, respectively and similar to correlations observed in previous studies (8, 27).

Secondary outcomes

Secondary outcomes were: 1) level of adherence (as a percentage) to wearing orthopedic shoes during one week at 3 and 6 months after inclusion; 2) change in adherence between 3 and 6 months after inclusion; 3) total wearing time during 1-year follow-up, 4) the proportion of participants (re-)experiencing ulceration up to 12 months after inclusion; 5) the participant experiences on the use and usability of their orthopedic shoes measured with the MOS at 6 and 12 months after inclusion; and 6) the participant-perceived HRQoL measured with the RAND-36 V2.0 at inclusion, 6 and 12 months after inclusion.

Sample size calculation

The original a-priori sample size calculation indicated that 220 participants would be needed for this study to provide 80% power to detect the anticipated proportional difference of

20% in adherent participants at 12 months in favor of the MI intervention group (18). The target sample size could not be achieved, due to several logistic reasons and the outbreak of COVID-19 (18). After incorporating some changes to the original study protocol, as described in our published protocol, and an extension of the planned inclusion period for 1 year, a total of 121 participants had been allocated. A post-hoc multilevel power analysis using the same assertions as the a priori sample size calculation indicated that the estimated power of the study to detect a 20% difference between both groups was reduced to 59%.

Statistical analysis

Statistical analysis was performed using SPSS statistical software version 28 (IBM, New York, USA). All tests of between- and within-group differences were two-sided and used a significance level of $p<0.05$. Differences in the baseline characteristics between the intervention and control group were tested with t-tests, Mann-Whitney U tests, chi-square tests, or Fisher's exact tests, depending on the type and distribution of variables.

The primary outcome was analyzed both on an intention-to-treat (ITT) basis including all randomized participants and on an as-treated per-protocol (PP) basis including only those participants in the intervention group that had received the extra MI-consultation with an MI-trained podiatrist and those participants in the control group that did not receive an extra MI-consultation. A binary logistic mixed model with a random effect for podiatrist was originally planned for the primary outcome analysis (18). However, such a model could not be adequately fitted because the clustering of participants per podiatrist was unbalanced, as several podiatrists had treated only one or two participants. Therefore, the between-group difference in the proportion of adherent participants at 3 and 6 months was tested using simple chi-square tests.

All secondary outcomes were analyzed on an ITT basis and missing data for secondary outcomes at the different time points were not imputed. Differences in the percentage of adherence, the differences in change in adherence, and the differences in total wearing time were tested using independent t-tests. Differences in the analyses for (re)ulceration were tested with t-tests or Mann-Whitney U tests for continuous, or chi-square tests for categorical variables. Between-group differences in the participant experiences on the use and usability of their orthopedic shoes as measured with the MOS at 6 and 12 months were tested with Mann-Whitney U tests for continuous or chi-square tests for categorical variables. Within-group changes between 6 and 12 months after inclusion in both groups were tested with Wilcoxon tests or Marginal Homogeneity tests. Finally, scores on participant-perceived health-related quality of life as measured with the RAND-36 V2.0 at inclusion, 6, and 12 months were analyzed using repeated measures linear mixed models with group, time, and group x time interaction as fixed factors. A compound symmetry covariance structure was used to model the repeated measurements for all eight domains.

RESULTS

Baseline characteristics

The study flow diagram is shown in Figure 1. Participants were recruited between November 14, 2019, and April 7, 2021, and the last follow-up of the last participant ended

on April 6, 2022. A total of 121 participants were included of whom 53 were allocated to the intervention group and 68 to the control group. In total, 34 podiatrists were involved in the study of which 18 were randomized to the intervention group. However, the number of participants was disproportionately distributed over the podiatrists; 49% of the participants of the control group were treated by one podiatrist, while most MI-trained and untrained podiatrists had treated only one or two participants.

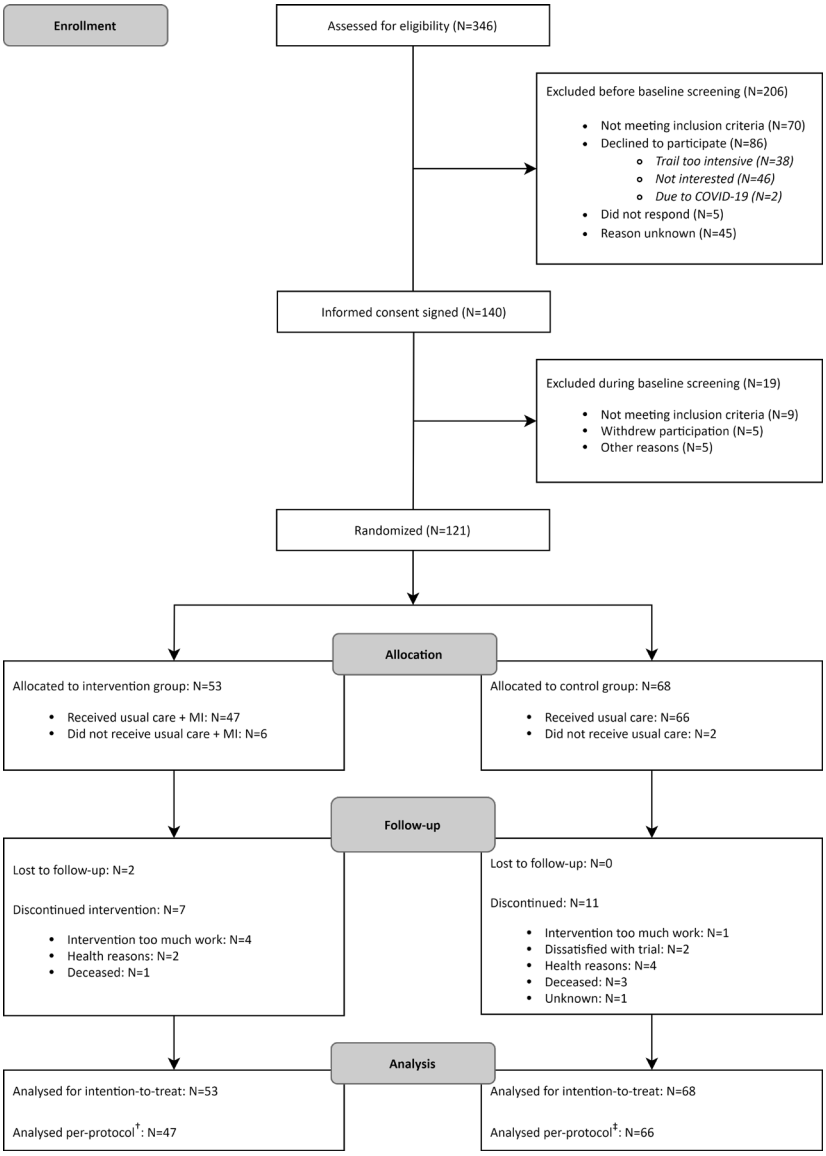

Figure 1. Flow diagram for this study (CONSORT).

†Per-protocol analysis in which for the intervention group only the participants who had an MI-consultation with an MI-trained podiatrist were included.
‡Per-protocol analysis in which for the control group only the participants who only received usual care were included. Participants in the control group who had an MI-consultation with an MI-trained podiatrist were excluded.

Table 1. Baseline characteristics of the intention-to-treat population

Characteristic	All	Usual care + MI % (N)	Usual care % (N)	Missing values N (%)	p-values*
No. participants	121	44% (53)	56% (68)		
Age (years)	68.5±8.3	68.8±9.5	68.2±7.2		0.743
Sex					0.888
Male	69% (83)	68% (36)	69% (57)		
Female	31% (38)	32% (17)	31% (21)		
Ethnic origin: Caucasian	99% (120)	98% (52)	100% (68)		0.442
Living alone	33% (40)	38% (20)	29% (20)	1 (1%)	0.363
Education				1 (1%)	0.150
Low	41% (49)	34% (18)	46% (31)		
Medium	33% (40)	30% (16)	35% (24)		
High	26% (31)	34%(18)	19% (13)		
Employed	25% (30)	25% (13)	25% (17)		0.952
Diabetes type					0.875
Type 1	10% (12)	9% (5)	10% (7)		
Type 2	90% (109)	91% (49)	90% (61)		
Diabetes duration (years)	17.8±12.4	17.9±13.8	17.7±11.3	1 (1%)	0.587
BMI (kg/m^2)	30.7±5.2	30.7±4.8	30.7±5.6		0.738
Loss of protective sensation†	97% (117)	98% (52)	96% (65)		NA††
Peripheral artery disease‡	23% (28)	17% (9)	28% (19)		0.156
IWGDF Risk category§					NA††
Category 1	3% (4)	2% (1)	4% (3)		
Category 2	36% (44)	28% (15)	43% (29)		
Category 3	60% (73)	70% (37)	53% (36)		
Foot deformity¶				4 (3%)	NA††
Mild	7% (9)	8% (4)	7% (5)		
Moderate	82% (99)	83% (44)	81% (55)		
Severe	7% (9)	4% (2)	10% (7)		
Amputation				1 (1%)	NA††
No amputation	84% (102)	83% (44)	85% (58)		
Lesser toe(s)	4% (5)	8% (4)	2% (1)		
Hallux or ray	9% (11)	8% (4)	10% (7)		
Forefoot	1% (1)		2% (1)		
Major	1% (1)		2% (1)		
Health related quality of life					
Physical functioning	54.0±29.9	52.0±30.1	55.6±29.8	13 (11%)	0.534
Social functioning	68.5±26.2	65.6±27.3	70.6±25.4	13 (11%)	0.353
Role functioning (physical)	47.8±30.0	44.2±30.1	50.5±29.9	14 (12%)	0.217
Role functioning (emotional)	76.2±27.9	71.6±30.1	79.6±25.9	13 (11%)	0.260
Mental health	73.6±16.8	69.8±18.8	76.5±14.6	14 (12%)	0.095
Vitality	55.3±20.5	52.0±20.1	57.8±20.6	14 (12%)	0.166
Pain	61.6±25.4	59.1±24.6	63.4±26.0	12 (10%)	0.305
General health	48.7±19.7	45.3±19.2	51.2±19.8	16 (13%)	0.139

Data are expressed as % (number) or mean±SD. LOPS: loss of protective sensation, PAD: peripheral artery disease.
[†]Loss of protective sensation was confirmed present in both feet by the inability to sense the pressure of a 10-g Semmes-Weinstein monofilament at any of three plantar foot sites (hallux, first and third metatarsal head) or a vibration of 25 volts at the hallux from a biothesiometer by the attending podiatrist.
[‡]Peripheral arterial disease was confirmed present when pedal pulses were nonpalpable and the ankle-brachial index was <0.9 in the foot with the most recent episode of ulceration according to the PEDIS classification by the attending podiatrist (28).
[§]IWGDF Risk 1-3 (19) for eligible participants; IWFDF Risk category 1: moderate ulcer risk + LOPS + PAD; IWFDF Risk category 2: moderate ulcer risk + LOPS or PAD + foot deformity; IWFDF Risk category 3: high ulcer risk + LOPS or PAD, and one or more of the following: history of a foot ulcer, a lower-extremity amputation, end-stage renal disease.
[¶]The foot (left or right) with the most severe deformity determined classification per patient. Foot deformity was classified as "absent", "mild" (i.e. pes planus, pes cavus, hallux valgus or limitus, hammer toes, and lesser toe amputation), "moderate" (i.e. hallux rigidus, hallux or ray amputation, prominent metatarsal heads, claw toes), or "severe" (i.e. Charcot deformity, (fore)foot amputation and pes equines).
[††]A Chi-square test was not applicable because more than 25% of the cells had an expected count of less than 5.

Baseline participant characteristics are shown in Table 1. No significant baseline differences were observed between the two groups.

Primary outcome

A significantly higher proportion of participants in the control group (30.9%) than in the intervention group (15.1%) wore their orthopedic shoes ≥80% of their steps taken 3 months after inclusion in the ITT analysis (Table 2). Although still numerically higher in the control group, the proportion of adherent participants was no longer significantly different between the intervention and control groups after 6 months (Table 2).

The PP analysis showed similar results. However, the difference in the proportions of adherent participants between the groups at 3 months did not reach statistical significance (Table 2).

Table 2. Proportion of participants who sufficiently adhered[†] to wearing their orthopedic shoes

	Intervention group (N=53)	Control group (N=68)	p-values
Adherence 3 months after inclusion (ITT)	15.1%	30.9%	0.044[*]
Adherence 6 months after inclusion (ITT)	13.2%	22.1%	0.210
Adherence 3 months after inclusion (PP)	17.0%	31.8%	0.076
Adherence 6 months after inclusion (PP)	14.9%	21.2%	0.395

[†]Adherent is defined as minimally 80% of steps taken in their orthopedic shoes.
[*]Significantly different between groups, p<0.05.

Secondary outcomes

Level of adherence

The level of adherence to wearing orthopedic shoes was significantly higher in the control group on both the 3- and 6-month assessments (Table 3). The mean change in adherence between 3 and 6 months after inclusion was 1.4 percent point (pp) for the intervention group and 1.0 pp for the control group and did not change significantly in either the intervention group (p=0.666) or control group (p=0.666).

Table 3. Adherence in % of steps taken in orthopedic shoes (ITT)

	Intervention group		Control group		p-values
	Mean	**95% CI**	**Mean**	**95% CI**	
3 months after inclusion	50.9	43.8 to 57.9	60.9	55.0 to 66.8	0.029[*]
6 months after inclusion	49.5	42.2 to 56.9	59.9	54.3 to 65.6	0.025*

[*]Significantly different between groups, p<0.05.

(Re)ulceration

During the 1-year follow-up in the entire study population, 37 unique participants developed 43 ulcers; 18 participants of the intervention group developed 22 ulcers and 19 participants of the control group developed 21 ulcers. The proportion of participants who developed one or more ulcers during the 1-year follow-up was not significantly different between both groups (resp. 34% and 28%; p=0.476). The mean (SD) number of ulcer-days in the intervention group was 52.7 (106.4) and 24.0 (59.7) days for the control group and did not significantly differ between the groups (p=0.312). Mean (SD) time to first ulceration was 16.0 (18.6) versus 17.2 (17.2) weeks in the intervention versus control group, respectively (p=0.837). In the total sample, mean adherence was not significantly different between those participants with at least one ulcer (60.1%, SD=26.0) versus those without an ulcer (54.9%, SD=25.0) 3 months after inclusion (p=0.297). Six months after inclusion the results were similar (58.3% (28.2) and 54.1% (24.0) in those without an ulcer; p=0.434).

Use and usability of orthopedic shoes

With respect to the self-reported use and usability of their orthopedic shoes, no clear differences were observed between the intervention and control groups at 6 and 12 months after inclusion (Table 4). The participants of the intervention group did experience the weight of their orthopedic shoes as heavier 6 months after inclusion compared to the participants of the control group (p<0.001), but no longer at 12 months (p=0.759).

In the intervention group, the participants experienced significantly less pain in their muscles due to their orthopedic shoes 12 months after inclusion compared to 6 months after inclusion (p=0.020). In the control group, the participants experienced the weight of their orthopedic shoes as heavier at 12 months compared to 6 months after inclusion (p=0.022). Besides, the participants of the control group were less satisfied with the communication by both the medical specialist and pedorthist/orthopedic shoe technician 12 months after inclusion compared with 6 months after inclusion (resp. p=0.003, p=0.049).

Participant-perceived health-related quality of life (HRQoL)

HRQoL scores were quite comparable between and stable within both groups at the different time points (Table 5). For all eight aspects of HRQoL, no significant effects were found for group, time, or the interaction between group and time. This indicates that mean HRQoL scores were not significantly different over time between the intervention and control group, did not significantly change over time in the entire study population, nor changed significantly differently over time between the two groups.

Table 4. Participant experiences on the use and usability of their orthopedic shoes

	Intervention			Control			p-values between-group*	
	6 months	12 months	p-value within-group*	6 months	12 months	p-value within-group*	6 months	12 months
Effectiveness								
Change in pain (skin)† (N=25, 23; 35, 34)‡	84 (57-97)	86 (75-96)	0.552	76 (63-96)	87 (69-94)	0.137	0.392	0.738
Change in pain (muscles)† (N=27, 22; 35, 33)‡	79 (51-93)	87 (56-93)	0.020*	80 (64-95)	83 (61-95)	0.445	0.306	0.857
Change in sprains† (N=23, 17; 21, 24)‡	97 (81-98)	92 (65-98)	0.656	92 (80-99)	89 (72-97)	0.432	0.733	0.916
Efficiency								
Donning/doffing OS†	75 (51-92)	75 (47-93)	0.768	75 (49-87)	70 (49-93)	0.542	0.802	0.666
Fit of OS†	89 (76-97)	90 (78-96)	0.962	90 (77-98)	85 (75-95)	0.120	0.075	0.433
Ease of walking with OS†	89 (71-69)	89 (70-96)	0.387	88 (72-97)	85 (71-96)	0.265	0.698	0.813
Weight of OS†	46 (26-52)	49 (31-53)	0.468	52 (46-60)	47 (25-55)	0.022*	<0.001*	0.759
Satisfaction								
Cosmetic appearance (patient)†	75 (56-94)	76 (50-93)	0.771	77 (51-91)	76 (66-93)	0.067	0.805	0.457
Cosmetic appearance (others)§			0.631			0.789	NA¶	NA¶
Very ugly or ugly	1 (2%)	1 (2%)		2 (3%)	4 (6%)			
Neutral	11 (21%)	16 (30%)		17 (25%)	13 (19%)			
Attractive or very attractive	25 (47%)	18 (34%)		29 (43%)	29 (43%)			
Do not know or missing	16 (30%)	18 (34%)		20 (29%)	22 (32%)			
Communication with MS†	90 (74-95)	85 (55-93)	0.393	90 (78-97)	84 (74-96)	0.003*	0.576	0.183
Communication with OST†	89 (81-96)	93 (78-95)	0.986	92 (79-97)	88 (75-97)	0.049*	0.847	0.495

Data are expressed as median (IQR), or N (%), or as indicated. MS = Medical Specialist; OS = orthopedic shoes; OST = orthopedic shoe technician.
*Significantly different, p<0.05.
†Scores could range from 0 (lowest score possible) to 100 (highest score possible).
‡Not all participants had wounds, pain or sprains, therefore the number of participants for these questions is indicated, for each group respectively.
§Participants' answer on the question what others think about the cosmetic appearance of their OS.
¶A Chi-square test was not applicable because more than 25% of the cells had an expected count less than 5.

Table 5. Participant-perceived health-related quality of life

Domain	Month	Intervention group		Control group		Fixed effects estimates (95% CI)		
		Mean	95% CI	Mean	95%CI	Group	Time	Group x Time
Physical functioning	0	52.3	44.2 to 60.4	56.0	48.8 to 63.2	2.9 (-7.8 to 13.6)	-0.4 (-1.2 to 0.5)	0.2 (-0.3 to 0.7)
	6	51.4	43.3 to 59.6	53.6	46.4 to 60.9			
	12	50.1	41.8 to 58.3	56.3	48.9 to 63.7			
Social functioning	0	65.6	58.1 to 73.2	70.2	63.6 to 76.7	1.6 (-8.2 to 11.3)	-0.1 (-1.5 to 1.3)	0.0 (-0.8 to 0.8)
	6	72.4	64.8 to 80.1	68.0	61.2 to 74.7			
	12	64.0	56.0 to 72.0	69.0	62.0 to 76.1			
Role functioning (physical)	0	44.5	36.1 to 52.8	50.9	43.5 to 58.3	6.0 (-4.9 to16.9)	-0.3 (-1.6 to 1.1)	0.1 (-0.7 to 0.9)
	6	44.6	36.1 to 53.1	50.3	42.7 to 57.9			
	12	42.2	33.5 to 51.0	49.7	41.8 to 57.5			
Role functioning (emotional)	0	70.8	62.4 to 79.2	78.9	71.5 to 86.2	8.9 (-1.9 to 19.6)	-0.4 (-1.9 to 1.1)	-0.2 (-1.1 to 0.7)
	6	63.6	55.1 to 72.0	72.8	65.0 to 80.5			
	12	63.6	54.8 to 72.4	69.5	61.6 to 77.3			
Mental health	0	69.9	65.0 to 74.8	76.1	71.8 to 80.4	5.4 (-1.0 to 11.8)	0.5 (-0.3 to 1.2)	-0.3 (-0.7 to 0.2)
	6	74.2	69.5 to 79.4	76.7	72.3 to 81.2			
	12	72.2	67.1 to 77.4	75.3	70.8 to 79.9			
Vitality	0	51.9	46.0 to 57.8	57.2	51.9 to 62.4	5.2 (-2.4 to 13.0)	-0.1 (-1.0 to 0.8)	0.1 (-0.5 to 0.6)
	6	52.3	46.3 to 58.3	58.3	52.9 to 63.7			
	12	51.7	45.5 to 57.9	58.1	52.5 to 63.6			
Pain	0	59.0	51.7 to 66.4	63.5	57.1 to 69.9	3.5 (-6.0 to 13.0)	0.4 (-0.8 to 1.6)	-0.2 (-0.9 to 0.5)
	6	60.3	52.8 to 67.7	60.4	53.8 to 67.0			
	12	61.5	53.8 to 69.1	63.8	57.0 to 70.6			
General health	0	45.5	39.7 to 51.3	50.7	45.5 to 55.8	4.5 (-3.1 to 12.1)	0.3 (-0.5 to 1.1)	-0.1 (-0.6 to 0.4)
	6	46.8	40.9 to 52.6	49.5	44.0 to 54.8			
	12	48.1	42.1 to 54.0	52.6	47.2 to 58.0			

DISCUSSION

People with diabetes at low-to-high risk of foot ulceration who received usual care plus MI focused on improving adherence to orthopedic shoes by a trained podiatrist were not significantly more or less adherent to wearing orthopedic shoes compared to participants who received usual care. Three months after inclusion, the proportion of adherent participants was even significantly higher in those that received usual care than in those who received usual care plus MI. This outcome suggests that the MI-intervention as implemented in its current form does not contribute to improving adherence to wearing orthopedic shoes in daily practice. Besides, no significant differences were found between the intervention and control group in the proportion of participants (re-)experiencing ulceration 12 months after inclusion, the participant experiences' on the use and usability of their orthopedic shoes, or the participant-perceived HRQoL.

Overall, the proportion of adherent participants in the current study was similar to those reported in previous studies (8, 29-31). In these studies, 22-36% of people with diabetes at risk for ulceration wore their orthopedic shoes all day or at least >80% of daytime. However, with respect to the level of adherence, Waaijman et al. showed that people with diabetes at high risk for ulcer recurrence wore their orthopedic shoes on average in 71% of the steps taken (8). In the current study, the mean level of adherence was 61% in the control group and 51% in the intervention group 3 months after inclusion and this level was stable 6 months after inclusion. One possible explanation for this lower level of adherence is that all participants in the study of Waaijman and colleagues were at high risk of foot re-ulceration, because of their recently healed plantar ulcer, making the importance of wearing orthopedic shoes much higher compared to our population that also included people at low or moderate risk of ulceration (8).

Secondly, the current study mostly took place during the COVID-19 pandemic. Due to the pandemic, many people were forced to work more from home and likely stayed more at home indoors in general. In their study, Waaijman et al. (8) showed that adherence to orthopedic shoes was much lower indoors than outdoors. This may partly explain the lower level of adherence in the current study, as only a few participants owned custom-made indoor shoes, which may have limited the use of orthopedic shoes indoors. Keukenkamp et al. recently showed that custom-made indoor shoes increased adherence to wearing orthopedic shoes in both the short-term and long-term in people at risk of diabetic foot ulceration (32). In the current study we did not assess whether participants were indoors or outdoors when wearing their shoes, something that we do recommend registering in future research. Finally, the satisfaction of the participants with the communication with their podiatrist was not measured. It is possible that the application of MI by the podiatrist had a negative effect on the adherence to wearing orthopedic shoes, because most participants have been seeing a podiatrist already for years and are likely to be unfamiliar with this way of communicating with their podiatrist (17). Perhaps not only the podiatrist has to get used to applying MI, but the participant may also have to get used to the podiatrist using MI. By encouraging MI to be included already in primary podiatrist training, it is likely that future patients already become accustomed to this way of communicating early on in their treatment.

The lower adherence in the intervention group compared to the usual care group was surprising and the reason for this remains unclear, also because no significant differences were found between the baseline characteristics of both groups. This difference in adherence may be caused by some limitations of the study. First of all, it is unknown whether the intervention and control group differed from each other at inclusion regarding adherence to wearing orthopedic shoes, as no baseline adherence measurement was performed. No baseline adherence measurement was done, because clinical practice experience showed that only 3 months after receiving the orthopedic shoes the majority of the patient could wear the shoes all day long, because they had to get used to the shoes and adjustments had to be made. However, for future research we recommend to do a baseline measurement if possible Secondly, the results of this study may be limited by the implementation of the MI-intervention in its current dose and form. In this study, the participants had only one MI-consultation with an MI-trained podiatrist, who applied MI in daily clinical practice at a solid beginner level. Previous research showed that the number of brief MI-consultations was unrelated to the outcome, which suggests that longer time in a single MI-visit combined with booster-sessions may promote better outcomes (33). This is in line with Keukenkamp et al, who suggested based on their study that booster MI-sessions may improve the outcome (4). Besides, Keeley and colleagues showed that to realize the full benefits of MI healthcare providers may need to invest slightly more time in each visit (34). In their systematic review and meta-analysis Lundahl et al. showed that just a small amount of extra time with a patient per consultation to build a relationship and evoke change talk resulted in a 10-15% improvement (35). Therefore, more research is needed on the application and required dose of MI to better inform clinical practice how to improve adherence to wearing orthopedic shoes. Thirdly, as the purpose of the current study was to evaluate the effectiveness of one MI-consultation in daily practice settings, the importance of highly external valid outcomes overrode aspects of internal validity, such as equal and normal distribution of the participants over the podiatrists. As a result, the number of participants was disproportionately distributed over the podiatrists, with almost half of the participants of the control group being treated by one and the same podiatrist. Therefore, it is possible that the characteristics and the patient-healthcare provider relationship of this specific podiatrist disproportionately influenced the level of adherence of the control group and possibly thereby also the results of the comparison with the intervention group on the level of adherence. As multilevel analyses were not possible to take these differences between podiatrists into account, this may have led to confounding. In addition, the current study concerns research in daily clinical practice where the aim was to investigate something that could also be implemented in that clinical practice. Multiple MI-consultations are much more difficult to implement in practice and would not have been necessary if the current study showed that one MI-consultation was effective. Follow-up research, such as qualitative interviews with the podiatrists and/or participants, could shed more light on the reasons for both the overall low adherence rate and the even lower adherence in MI intervention group.

Regarding the perceived use and usability of orthopedic shoes, the results of the current study did show that the participants of the intervention group experienced the weight of their orthopedic shoes as significantly heavier than the participants of the control group 6 months after inclusion. This result is in line with previous research, in which van Netten

et al. found a significant difference regarding the weight of orthopedic shoes between frequent and occasionally users (11). However, it is unlikely that this difference 6 months after inclusion alone would explain the difference in the level of adherence between the two groups in the current study. Besides, Arts et al. showed that comfort (ease of walking with OS in the current study) and the appearance/style of the shoe were perceived as the most important aspects for wearing orthopedic shoes (36), while van Netten et al. found the communication with the medical specialist and pedorthist to be essential to influence a patient's decision to use orthopedic shoes (10, 11). Even though the participants in the current study were satisfied with the communication with the medical specialist and pedorthist, adherence to wearing orthopedic shoes was low.

In comparison to previous studies, the HRQoL scores of the participants in the current study were clearly worse than those of the general Dutch population (37) and people with diabetes (38). However the scores were similar to people with diabetes and high risk of ulceration (39, 40), and better than in people with a current ulcer (40-42). Therefore, the HRQoL of participants included in the current study appears to be representative of the population of people with diabetes at risk of ulceration.

In conclusion, the current implementation of MI by an MI-trained podiatrist in addition to usual care did not improve adherence to wearing orthopedic shoes 3 and 6 months after inclusion nor 1-year outcomes in ulcer prevention. The relation between effectiveness of MI and adherence to wearing orthopedic shoes may be more complex than expected. It may also be affected by other variables as shown in previous studies and limited due to implementation complexities in clinical practice settings, such as the reimbursement of an appointment with the podiatrists by the health insurance. Therefore, although MI may have the potential to increase adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration, it does not seem a simple standalone solution. A higher dose of MI or podiatrists applying MI at a higher level may be required to substantially improve the level of adherence to wearing orthopedic shoes and should be investigated in future trials.

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Chapter 6

Effect of different casting design characteristics on offloading the diabetic foot

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ABSTRACT

Background: Non-removable knee-high devices, such as a total contact cast (TCC), are recommended for offloading diabetic plantar forefoot ulcers. However, it is insufficiently known how each of the different design characteristics of these devices contribute to offloading the diabetic foot.

Research question: What is the offloading effect of the different design characteristics that make up a non-removable knee-high cast for people with diabetes and active or previous plantar forefoot ulcers?

Methods: Sixteen persons with diabetes, peripheral neuropathy and a healed or active plantar forefoot ulcer had their plantar pressures measured during walking in a non-removable knee-high device (TCC), in that device made removable (BTCC), in that device made below-ankle (cast shoe), in that cast shoe worn with a different walking sole and in a newly made cast shoe without a custom-moulded foot-device interface. Peak pressures, force-time integral, and perceived walking comfort were assessed.

Results: Compared with the BTCC, peak pressures in the TCC were 47% ($p=0.028$), 26% ($p=0.003$) and 15% ($p=0.050$) lower at the hallux, midfoot and (previous) ulcer location, respectively. Compared to the cast shoe, peak pressures in the BTCC were 39-43% and 47% (both $p<0.001$) lower in the forefoot regions and (previous) ulcer location, respectively. The total force-time integral was 21% and 11% ($p<0.007$) lower in the TCC and BTCC compared to the cast shoe. Perceived walking comfort was 5.6 in the TCC and 6.5 in the BTCC ($p=0.037$). Effects of the other design characteristics (i.e. walking sole and plantar moulding) were non-significant.

Significance: The TCC gives superior offloading, mostly because of being a knee-high and non-removable device, providing an optimal 'shaft effect'. The TCC does, however, negatively affect walking comfort. These results aid decision-making in offloading diabetic plantar forefoot ulcers.

INTRODUCTION

Among people with diabetes mellitus and peripheral neuropathy, foot ulcers are a serious and debilitating long term complication that significantly increases the risk of infection, hospitalization and lower limb amputation (1). Yearly incidence of developing a foot ulcer in diabetic patients is 2-4%, and lifelong incidence 19-34% (2). Most ulcers occur on the plantar side of the foot, in the forefoot and toe regions (3). In the presence of neuropathy, elevated plantar pressure is one of the most important risk factors for foot ulcer formation and maintenance (4, 5).

Offloading areas of high plantar pressure is a cornerstone of treating plantar diabetic foot ulcers, and is achieved by redistributing plantar pressure to other areas (4, 6-9). Different devices are available for ulcer offloading, such as a total contact cast (TCC), a knee-high walker or specially designed shoes (10). International guidelines recommend the use of non-removable knee-high devices as first option of treatment (1, 10), as meta-analyses and health technology assessment shows that these devices have higher healing rates than other devices (4, 6, 8, 9). Removable devices and special shoes are only recommended when non-removable knee-high devices are contraindicated or not tolerated by the patient (10). However, these latter do represent 'standard of care' in offloading plantar foot ulcers, as non-removable devices are underused in clinical practice (3, 11-15).

The design characteristics differ between these devices: e.g. knee-high vs. ankle-high, non-removable vs. removable, and custom-made vs. prefabricated. Furthermore, the plantar foot-device interface can be individualized, and different walking soles can be attached to the device. While healing outcomes of these devices have been widely studied (4, 6, 8, 9), these different design characteristics all contribute to the offloading effect of such a device. However, the (relative) contribution of these design characteristics on offloading itself is insufficiently studied. Knee-high devices are more effective in reducing plantar pressure than below-the-ankle devices, mostly because the shaft of a knee-high device can pick up a significant portion of the load on the lower-extremity (16-18). The knee-high devices in these studies were either removable or non-removable (16-18), and it can be questioned whether the removability influences the offloading capacity. Furthermore, other design characteristics mentioned have not been investigated in a controlled study setting. Such an investigation is needed, to better understand the design characteristics, to drive the development of standardized casting protocols, and to improve clinical decision-making in the offloading treatment of diabetic plantar forefoot ulcers.

The aim of this study was to investigate the offloading effect of the different design characteristics that make up a non-removable knee-high cast for people with diabetes and active or previous plantar forefoot ulcers. We hypothesized that the total contact shaft portion of the knee-high cast, its non-removability, the custom-moulding of the foot-device interface, and the type of walking sole attached, all significantly contribute to the offloading effect.

METHODS

Participants

Sixteen persons with diabetes mellitus, peripheral neuropathy, an active or healed plantar forefoot ulcer and who were treated with a casting device participated in this study (Table 1). Peripheral neuropathy was defined as "loss of protective sensation" and confirmed in each participant by the inability to sense a 10-g Semmes-Weinstein monofilament (1). Participants who were unable to walk a distance of 20m repeatedly without walking aid, whose previous ulcer location had been amputated, or who had a Charcot deformity, equines foot deformity, or treatment for serious medical conditions or injuries other than diabetes that may interfere with lower limb function (walking) were excluded. An earlier study testing similar devices (19), showed a mean peak pressure differences of 50kPa (SD 40kPa) between knee-high and ankle-high devices. Using this data and a power of 0.8 and α=0.05, seven subjects would be required for the current study. We included 16 subjects to increase statistical robustness, considering that more than two devices are compared. All participants gave their written informed consent before the start of the study, which was approved by the Medical Ethics Committee Twente (P15-005; NL52480.044.15). The study was prospectively registered in the Dutch Trial Registration (NTR5137).

Table 1. Participant characteristics (N=16).

Gender (male/female)	13 / 3
Age (years)	52.7 (13.2)
Body height (cm)	186.1 (8.5)
Body mass (kg)	102.8 (18.9)
Body-mass index (kg/m2)	29.7 (5.2)
Type of diabetes (type 1/type 2)	6 / 10
Years with diabetes	17.7 (13.7)
Participants with active foot ulcer	7
Location of the (previous) ulcer	
Hallux	8 (50%)
MTH1	6 (38%)
MTH4	1 (6%)
MTH5	1 (6%)

Note: Values are presented as N or as the mean (standard deviation). Abbreviations: MTH: metatarsal head

Casting devices

Each participant's ulcerated leg was first fitted with a TCC (Fig. 1a). This protocol was applied by an experienced (>20 years) technician (HM): participants were positioned supine with the ankle bent at neutral position. One 5mm layer of felt padding (Cellona® Polster, Lohmann&Rauscher, Vienna, Austria) was fitted around the (previous) plantar ulcer surface. The pressure-measuring insole (see "*Protocol*") was wrapped in foil and positioned against the plantar foot surface. The foot was wrapped with synthetic cast padding (Delta-Rol®-S, BSN-Medical, Hamburg, Germany). A 'terry stockinet' (Delta® Terry-Net-S, BSN-Medical, Hamburg, Germany) was pulled over foot, insole and leg, and taped at the toes. An opening was made in the stockinet, at the ankle, for the insole-connector. The plantar surface was covered with 8-10 layers rigid fiberglass (Cellacast® Xtra, Lohmann&Rauscher,

Vienna, Austria). Subsequently, 1-3 rolls rigid fiberglass (depending on leg/foot size=) were wrapped around forefoot, rear foot and lower leg (mid-tibia), leaving the insole connector free. The not yet rigid fiberglass of the plantar surface was custom-moulded, effectively applying pressure proximal to the metatarsal heads (13). The nose of the device was casted with semi-rigid fiberglass (Cellacast® Soft, Lohmann&Rauscher, Vienna, Austria).

After completing the pressure measurements in the TCC, the TCC was made removable by bi-valving it anteromedially and anterolaterally into two valves with a plaster saw (BTCC; Fig. 1b, 1f). The cut was partially U-shaped to ensure exact fit of the two parts of the cast. The pressure measurement insole was positioned against the foot and a cotton stockinet (Specialist® Stockinette, BSN Medical, Hamburg, Germany) was pulled over the foot and leg and was taped at the toes. At the ankle, an opening was made in the cotton stockinet for the insole connector. The cast wall was wrapped with cohesive bandage (Elastomull® haft, BSN Medical, Hamburg, Germany) for closure, similar to what is done with an “instant-TCC” (20).

After completing the pressure measurements in the BTCC, the cast wall of the BTCC was cut just below ankle level to create a ‘cast shoe’ (Fig. 1c). The cut was again U-shaped and was wrapped with cohesive bandage for closure of the cast shoe. The three devices were fitted with a Solo® sole (BSN Medical, Hamburg, Germany), a vinyl walking sole with a rocker outsole (Fig 1.).

A fourth device was created by replacing the Solo® sole of the cast shoe with a flat (non-rockered) Cellona® sole (Lohmann & Rauscher, Vienna, Austria) (Fig. 1d). As fifth device, a new cast shoe was created using the same casting protocol as described above, but without custom-moulding the foot-device interface. The rigid fiberglass was simply wrapped around the foot to mimic a casting device created by a technician with no experience in the custom-moulding (Fig. 1e).

In all devices tested, participants wore their own shoe on the contralateral foot. The possible height difference between the cast and the participant’s shoe was not compensated.

(a) Total Contact Cast (TCC)

(b) Bivalved Total Contact Cast (BTCC)

(c) Cast shoe

(d) Cast shoe flat sole

(e) Cast shoe without custom-moulded foot device interface

(f) Creating a BTCC from a TCC

Figure 2. The five different cast devices tested in the study (a-e). Bivalving of the TCC (f).

Protocol
Each participant visited our outpatient clinic once for casting and measurements. Data were recorded on health history, foot deformities, and previous foot ulcers, and photographs of the foot were taken. The five casting devices were tested in the following order: TCC, BTCC, cast shoe, cast shoe with flat sole, and cast shoe without custom-moulded foot-device interface. This was the only order possible, to investigate these devices while keeping the foot-device interface identical, because the changes from TCC to BTCC to cast shoe are irreversible.

Participants walked in a natural manner, without specific instructions, at their own preferred speed across a 20-meter-long walkway. In each device, participants walked approximately 120m before pressure-measurements started, to become accustomed to walking with the device (21). Walking speed was calculated from the stopwatch recorded time it took to complete 20 meters, and was standardized for the BTCC and cast shoe based on the speed measured in the TCC (maximum 5% deviation allowed). Walking speed was also standardized between the three cast shoe conditions tested. In-device plantar pressures during walking were measured at 50Hz sampling rate using the Pedar-X system (Novel, Munich, Germany). A minimum of 12 midgait steps for each foot, during one or more walking trial(s), were collected per condition (22). Comfort of walking was assessed after completion of data collection in each device using a visual analogue scale (VAS) with outcome scores ranging from 0 (most uncomfortable) to 10 (most comfortable).

Data analysis
In-device plantar pressure data were analysed using Novel multimask software. Using a standard masking procedure, each foot was divided into six anatomical regions: hallux, lesser toes, metatarsal head (MTH) 1, MTH 2-5, midfoot and heel. Additionally, the (previous) ulcer location was masked separately. For each region and the total foot, the mean peak pressure was calculated (7, 23) and for both feet the total foot FTI.

Statistical analysis was carried out with SPSS, version 23.0. The differences in peak pressure, FTI, and perceived walking comfort between casting devices were tested with a repeated measures analysis of variance (ANOVA). Normality of the data was tested with the Shapiro-Wilk test. Because most variables were not normally distributed, all plantar pressure and FTI data were log-transformed before statistical analysis. Bonferroni post-hoc testing was used for multiple pairwise comparisons between TCC-BTCC; BTCC-cast shoe; cast shoe with rocker-sole vs. cast shoe with flat-sole; cast shoe with vs. without custom-moulded foot-device interface. The FTI between the ipsi- and contralateral foot was compared between devices with an ANOVA (when normally distributed data) or a Wilcoxon signed-rank test (when not normally distributed). For all analyses a significance level of $p<0.05$ was used.

RESULTS

Outcomes per casting device are shown in Table 2. Walking speed was standardized within 5% between the TCC, BTCC and cast shoe devices, but nevertheless participants walked significantly faster in the BTCC compared to the TCC (4% difference, p=0.011).

Compared with BTCC, peak pressures in TCC were 26% lower at the midfoot (p=0.003), 47% at the hallux (p=0.028) and 15% at the (previous) ulcer location (p=0.050). Total foot FTI was significantly lower in TCC than in BTCC (11.3%, p<0.001). No significant differences between these devices were found for the other foot regions (Table 2).

Compared with the cast shoe, walking in the BTCC showed significantly lower peak pressures at MTH1 (43.0%, p<0.001), MTH2-5 (39.4%, p<0.001), hallux (42.7%, p=0.022), lesser toes (35.0%, p=0.007), and (previous) ulcer location (46.8%, p<0.001). Total foot FTI was significantly lower in BTCC compared to cast shoe (10.9%, p=0.007). No significant differences between these devices were found for the other foot regions (Table 2).

Table 2. Results for walking speed, plantar pressure data and walking comfort (N=16, casted foot only)

Variable	Cast devices					
	TCC (a)	BTCC (b)	Cast shoe (standardized speed) (c)	Cast shoe (preferred speed) (d)	Cast shoe flat sole (e)	Non-moulded cast shoe (f)
Walking speed (m/s)	0.95 (0.29)[b*]	0.99 (0.29)[a*]	0.98 (0.29)	1.03 (0.28)	1.03 (0.29)	1.03 (0.30)
Peak Pressure (kPa)						
Total foot	225 (61)	239 (75)[c*]	299 (65)[b*]	295 (63)	303 (58)	298 (71)
Heel	199 (76)	200 (83)	226 (81)	228 (80)	235 (87)	234 (93)
Midfoot	77 (36)[b*]	104 (43)[a*]	129 (76)	127 (76)	112 (52)	108 (45)
Metatarsal head 1	111 (80)	116 (76)[c**]	204 (90)[b]	202 (87)	220 (86)	208 (94)
Metatarsal head 2-5	121 (65)	137 (60)[c**]	227 (74)[b]	226 (76)	228 (70)	229 (95)
Hallux	57 (56)[b*]	108 (89)[ac*]	188 (90)[b]	183 (87)	202 (87)	143 (83)[d]
Lesser toes	32 (26)	58 (28)[c*]	89 (32)[b]	85 (33)	89 (42)	73 (22)
(Previous) ulcer location	97 (63)	114 (52)[c**]	215 (88)[b]	210 (85)	205 (101)	180 (82)
Force-time integral (N/cm.s)						
Total foot	470.3 (107.1)[b*]	530.2 (129.9)[ac*]	595.1 (150.7)[b]	570.3 (112.3)	582.4 (122.9)	549.0 (112.6)
Peceived walking comfort (VAS)	5.6 (2.8)[b*]	6.5 (2.5)[a*]	6.9 (2.2)	6.9 (2.2)[c]	6.1 (2.5)[d]	7.0 (2.3)

Data are expressed as mean (SD). Significant differences in pairwise comparisons [a]TCC, [b]BTCC, [c]Cast shoe (standardized speed), [d]Cast shoe (preferred speed), [e]Cast shoe flat sole, or [f]Non-moulded cast shoe.

Between the cast shoe worn with a rocker sole or with the flat sole, none of the foot regions showed a significant difference in peak pressure, with differences ranging from 1.2%-13.5% (p-values: 0.093-1.000). The cast shoe without custom-moulded foot-device interface showed a significantly lower hallux peak pressure (21.5%, p=0.008) compared to the cast shoe with custom-moulded foot-device interface. No significant differences were found for any of the other regions.

Perceived walking comfort (Table 2) was significantly lower in the TCC than in the BTCC (5.6 vs. 6.5, p=0.037). The cast shoe with rocker walking sole scored significantly higher on walking comfort compared to the cast shoe with flat walking sole (6.9 vs. 6.1, p=0.024). Differences in the total FTI between the casted (ipsilateral) and non-casted (contralateral) foot were significantly greater for walking with the TCC (192.6 (75.9) N/cm.s) than with the BTCC (140.6 (63.6) N/cm.s, difference 27.0%, p=0.002) and for walking with the BTCC (140.6 (63.6) N/cm.s) than with the cast shoe (82.6 (47.7) N/cm.s, difference 41.3%, p=0.006).

DISCUSSION

For the first time, the effect of different design characteristics of total contact casting on offloading the plantar diabetic foot was studied in a controlled setting. The differences in peak pressure found between the TCC and BTCC and between the BTCC and cast shoe showed that a knee-high and non-removable cast device has superior offloading effects compared to these other modalities. A knee-high and non-removable shaft portion are key design characteristics of the TCC. Other design characteristics that were expected to also have a significant effect on offloading, including the custom-moulding of the foot-device interface and the walking sole used, had relatively small and non-significant contributions to offloading. The findings of this study confirm the important contribution of the shaft and the non-removability of a knee-high cast device in offloading the foot (16, 17), and support from an offloading perspective the recommendations from the International Working Group on the Diabetic Foot (10).

The importance of the shaft design of the TCC in offloading has been described before (16, 17). Shaw and colleagues measured the offloading effect of a TCC in comparison with a cast shoe in healthy participants and found 30% of the total load on the foot to be taken up by the cast wall (16). This was 47% in our study. However, Shaw and colleagues did not control the foot-device interface, contrary to our study, so it is unknown whether their offloading effect was entirely the result of the shaft effect (16). Begg and colleagues compared a TCC and cast shoe while controlling the foot-device interface, similar to our study, and found a 30% offloading effect in the TCC (17). However, in order to accommodate the capacitance sensors for pressure measurement, they had to bivalve the TCC before the measurements (17). Our study shows that such bi-valving can have a pressure-increasing effect, probably because the snug total contact fit is lost after doing so. Clinically, the better healing rates found for non-removable knee-high devices in comparison to removable knee-high devices (9, 24-28), may therefore not only be explained by the factor of forced adherence, but also by the more effective offloading through a snuggly fit shaft portion of the knee-high cast.

An additional offloading effect found in the knee-high devices compared to the below-ankle cast shoe was the redistribution of pressure from the forefoot to more proximal regions. This also corresponds with previous data in healthy participants (16). These differences may be explained by changes in the patient's gait, where immobilization of the ankle in a knee-high device reduces forefoot pressures. This may have also affected the redistribution of load to the contralateral foot in the knee-high devices, as shown by their significantly greater FTI-difference between the ipsi- and contralateral foot, compared to the cast shoe. Such redistribution, however, comes with increased asymmetry in walking and potentially an increased contralateral foot ulcer risk, necessitating adequate attention during treatment.

Minimal effects on plantar pressure were found with the use of different walking soles, although walking in the cast shoe with rocker sole was rated as significantly more comfortable than walking with a cast shoe with flat sole. Within the limits of this study, this suggests that the type of walking sole used is of limited relevance for plantar pressure reduction and can be chosen based on other preferences, such as walking comfort, effect on leg-length discrepancy, or costs. The minimal, and where present even negative, effects on plantar

pressure from custom-moulding the foot-device interface of the cast shoe was another outcome that did not correspond with our hypothesis. We expected custom-moulding to improve pressure redistribution, as shown for custom orthoses and custom-made insoles in diabetic footwear (29). It is unclear why this effect was not present in casting the foot; maybe the degree of customization achieved in casting the foot-device interface was not large enough to gain further significant effects, because total contact with the foot, and therefore some form of customization, is already created in casting the foot. Alternatively, the experienced casting technician who made the casts and who normally moulds the foot-device interface of the cast may unconsciously have applied some moulding in the cast without custom-moulded foot-device interface. Future research should better test these effects using multiple casting technicians with different levels of experience.

With regard to walking comfort, the TCC was perceived as significantly less comfortable compared to the BTCC. This may have to do with the looser fit of the BTCC and resultant greater ankle joint movement possible in the device, but it may also be an inevitable order effect in the study, with participants getting used to walking in the knee-high device and therefore preferring the BTCC. This was an inevitable limitation of the study design of modifying one TCC per patient to allow investigation of different design characteristics. This study design, however, was an important strength regarding our primary aim, as it allowed us to control multiple design characteristics while not changing the foot-device interface.

Our biomechanical findings underline the IWGDF recommendations that a knee-high non-removable offloading device is the recommended offloading for healing neuropathic plantar forefoot ulcers, in favour of using a non-removable knee-high, ankle-high or below-the-ankle offloading device (10). However, the use of offloading in clinical practice is often not in line with the IWGDF recommendations and large differences exist between centres and countries, with removable ankle-high devices being preferred by clinicians and patients (11, 12, 14, 15). We stress again, and demonstrate in the current study, that an ankle-high device is inferior in offloading compared to a knee-high device. As a result, the use of an ankle-high device will likely delay ulcer healing, causing an increased risk of infection and hospitalization, and higher treatment costs.

Conclusion

We provided an analysis of different design characteristics applied when casting for offloading the diabetic foot. The offloading effect of a TCC is mainly attributable to the cast wall (or shaft) effect, being knee-high and non-removable, and the transfer of load to the contralateral foot. The added offloading effect of a specific walking sole or custom-moulding of the foot-device interface seem from our analyses to have only small and non-significant effects. The superior offloading effect of the TCC comes at some expense of walking comfort, which should be considered when using a TCC. The outcomes support from a biomechanical perspective the IWGDF recommendation of using a knee-high non-removable device as first treatment option for offloading a neuropathic plantar forefoot ulcer in persons with diabetes.

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Chapter 7

General discussion

As mentioned before was this thesis part of one of the calls of the program "Goed Gebruik Hulpmiddelenzorg thuis" of ZonMw. Therefore, the overall aim of this thesis is to expand our knowledge and understanding of objectively measured long-term adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration, the potential of the application of motivational interviewing by podiatrists to change adherence behavior and to prevent (re)ulcerations, and the value of different offloading devices for healing of diabetes-related foot ulcers in (clinical) daily practice. The following four specific objectives were addressed: 1) to objectively assess long-term wearing patterns and identify factors associated with wearing of orthopedic shoes in a large group of people with diabetes at moderate-to-high risk of ulceration; 2) to analyze the application of MI in consultations carried out by MI-trained podiatrists and the way of communication of the non-MI-trained podiatrists in daily clinical practice, and to explore the podiatrists' attitudes and experiences towards the use of MI and the implementation of the MI-techniques in their work with people with diabetes at high-risk of foot ulcers; 3) to evaluate the effectiveness of MI performed by an MI-trained podiatrist, in improving objectively measured 3- and 6-months adherence to wearing orthopedic shoes and 1-year ulcer prevention in comparison to usual care in people with diabetes at low-to-high risk of foot ulceration; and 4) to investigate the offloading effect of the different design characteristics that make up a non-removable knee-high cast for people with diabetes and active or previous plantar forefoot ulcers.

In this final chapter, the main findings of the thesis are summarized and discussed, a reflection on the used methodologies is given, implications for clinical practice and future research are described, and finally a general conclusion is provided.

MAIN FINDINGS

Chapter 1 described that literature abundantly indicates that diabetes related foot ulcers have a high impact on mobility and daily functioning and lead to high treatment costs. To prevent (re)ulceration, custom-made orthopedic shoes are considered essential. To be effective in preventing diabetes-related foot ulcers these orthopedic shoes need to be worn as much as possible during walking. However, robust data on long-term wearing time of orthopedic shoes was not yet available, and more insights into wearing patterns and associated factors were needed. In **chapter 2** it was shown that objectively measured adherence to wearing orthopedic shoes, based on temperature measurements inside the orthopedic shoes, is suboptimal in most participants at moderate-to-high risk of foot ulceration. Participants with a consistent wearing pattern showed higher daily wearing times than participants with an inconsistent pattern. Besides, orthopedic shoes were worn less during weekend days compared to weekdays. Of all explored potential predictors, only the person's satisfaction with their orthopedic shoes wear was uniquely associated with wearing time.

As adherence to wearing orthopedic shoes is low, and improving adherence was found to be very challenging in the past, a major aim of this thesis was to conduct a multicenter, cluster-randomized controlled trial on the effectiveness of motivational interviewing to improve objectively measured adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration. The study protocol of this trial was described in **chapter 3**. This trial

was aimed at generating novel insights into the effectiveness of motivational interviewing on adherence to wearing orthopedic shoes, prevention of (re)ulcerations, participants' experiences on the use and usability of their orthopedic shoes and their perceived health-related quality of life. From November 2019 to April 2021, 121 participants were included in this trial and followed for 12 months.

Podiatrists are key professionals in promoting adequate foot self-care for people with diabetes at high-risk of developing foot ulcers. However, to realize behavioral change merely informing these patients about the advantages of foot self-care was insufficient. Despite training the podiatrists in motivational interviewing seemed to be beneficial, the podiatrists' attitudes and experience towards the use of MI and the implementation of the MI-techniques in their work with people with diabetes at risk of foot ulcers were unknown. In **chapter 4**, showed the mixed-methods observation and analysis of the application of MI in consultations carried out by MI-trained podiatrists and the way of communication of the non-MI-trained podiatrists in the trial, that the MI-trained podiatrists used the principles of MI at a solid beginner proficiency level in their clinical practice in comparison to the non-MI-trained podiatrists, who did not reach this level. The MI-trained podiatrists scored significantly better on establishing partnership and cultivating change talk. These were also the specific MI-related skills that the podiatrists themselves described in relation to their attitudes and experiences of using MI in practice. That they were not able to apply all MI-related skills that were covered in the training, corresponds to the podiatrists' own reports that they learned and realized that MI is not a trick to be applied, but is a new communication technique to acquire which takes time to apply correctly and fully in practice. However, these results indicated that podiatrists can be effectively trained in applying MI in daily clinical practice.

In **chapter 5** the trial results on the effectiveness of motivational interviewing on improving adherence to wearing orthopedic shoes are reported. These results showed that the participants who received usual care plus MI were not significantly more or less adherent to wearing orthopedic shoes compared to the participants who received only usual care after six months. Three months after baseline, the proportion of adherent participants was even significantly higher in the participants who received usual care than in those who received usual care plus MI. Besides, no significant differences were found between the intervention and control group in the proportion of participants (re-)experiencing ulceration 12 months after baseline. There were also no significant differences found between both groups with regard to the participants experiences on the use and usability of their orthopedic shoes, or the participant-perceived health-related quality of life.

Next to improving adherence to wearing prescribed orthopedic shoes to prevent diabetes-related foot ulcers, adequate offloading of the diabetes-related foot is essential to support healing of ulcers that do occur. Non-removable knee-high devices, such as a total contact cast (TCC), are recommended for offloading diabetes-related plantar forefoot ulcers. However, it was insufficiently known how each of the different design characteristics of these devices contribute to offloading the diabetes-related foot ulcers. In the comparative study described in **chapter 6**, peak pressures were measured during walking in five conditions. Four pairwise comparisons were made: 1) a non-removable knee-high device (TCC) vs. that

TCC made removable (bivalved-TCC; BTCC); 2) the BTCC vs. that BTCC made below-ankle (cast shoe); 3) the cast shoe with a rocker-sole vs. the same cast shoe with a flat-sole; and 4) the cast shoe vs. a newly made cast shoe without a custom-molded foot-device interface. It was shown that the TCC gives superior offloading, mostly because of being a knee-high and non-removable device, the cast wall provides an optimal 'shaft effect'.

METHODOLOGICAL CONSIDERATIONS

In this section some important methodological issues, limitations and strengths of the performed studies will be discussed. The most important methodological issues concerned the sample size, the participant randomization procedure and the novel care approach, usual care plus MI, as applied in the main trial (1).

Sample size

The a-priori determined sample size of 220 participants required for the RCT turned out to be infeasible with the initially defined criteria and study design in the intended period due to several reasons. First, the 220 participants were intended to be included in a period of 9 months throughout different footcare center locations across the Netherlands. However, for practical reasons it was not possible to include throughout the Netherlands and therefore inclusion took place only in the East of the Netherland. Second, the outbreak of the COVID-19 pandemic occurred shortly after the study had started which had a major impact on the possibilities to include new participants and perform measurements.

In order to include as many participants as possible, the inclusion period was extended with 1 year and several changes to the original study protocol were implemented. First, besides the initially included participants receiving their first pair of orthopedic shoes, also patients who already had orthopedic shoes and were eligible for a new pair of orthopedic shoes were included. Therefore, the pedorthists became also actively involved in participant recruitment. Second, an additional group of 12 podiatrists received MI-training and 16 podiatrists were added to the control group to further increase inclusion. Despite these protocol changes and extension of the inclusion period, the target sample size was not achieved, and inclusion was stopped when 121 participants were allocated.

Participant randomization

The randomization of the participants was performed at the level of the podiatrists to avoid contamination between intervention and control participants. Because the podiatrists differed widely in their number of patients seen and experience with the specific target group, stratified randomization was used for the first cohort of podiatrists. However, because the inclusion in the intervention group lagged behind the control group, the second cohort of podiatrists, who received MI-training, consisted of the podiatrists who saw most patients with diabetes in contrast to the first group of podiatrists for which stratified randomization was used.

Novel care approach

To improve adherence to wearing orthopedic shoes, initially a novel care approach was proposed that combined MI with a digital shoe-fitting procedure. The aim of this study was

to assess the (cost-)effectiveness of this novel care approach compared to usual care (no MI and casting-based shoe-fitting) in promoting footwear adherence and ulcer prevention. However, at the time of the study started, the digital shoe-fitting procedure had already become the norm. Therefore, it was no longer possible to assess the effect of digital shoe-fitting compared to casting-based shoe-fitting, and only the (cost-)effectiveness of usual care + MI compared to usual care was assessed.

The background assignment of the treating podiatrist (being trained in MI or not) no longer determined the shoe-fitting procedure by the pedorthist, because also patients who already had orthopedic shoes and were eligible for a new pair of orthopedic shoes were included. Each pedorthist used one of the following shoe-fitting procedures: the digital shoe-fitting procedure or the casting-based shoe-fitting procedure. In addition, because the existing last was also used for an extra pair of orthopedic shoes, the shoe-fitting procedure was already determined for each subsequent pair of orthopedic shoes. However, the background assignment of the treating podiatrist remained leading over the shoe-fitting procedure with regard to which group the participant belonged to (MI-intervention or control group), because most participants had been treated by the same podiatrist for years, which should not be changed for this study. The participants in the intervention group had 1 MI-consultation with their own podiatrist or with one of the other MI-trained podiatrists before or as soon as possible after they received their first or new pair of orthopedic shoes.

Taken together, these methodological issues illustrate some of the difficulties that can be encountered when trying to perform strictly designed and protocolized randomized controlled trials in the complex and fast-changing real-world healthcare settings that are often outside of the control of researchers (2).

Limitations and strengths

Several studies have been presented in this thesis, each with its own limitations and strengths. The most important limitations and strengths are discussed. The results of the main trial may be limited by the following (3): First of all, as the purpose of this trial was to evaluate the effectiveness of one MI-consultation in daily practice settings, the importance of highly valid external outcomes was given precedence over aspects of internal validity, such as equal distribution of the participants over the podiatrists, and within the podiatrist being trained in MI or not. As a result, the number of participants was disproportionately distributed over the podiatrists, with almost half of the participants of the control group being treated by a single podiatrist. Therefore, it is possible that the characteristics and the patient-healthcare provider relationship of this specific podiatrist disproportionately influenced the level of adherence of the control group and possibly thereby also the results of the comparison with the intervention group on the level of adherence. Due to this unbalanced clustering of participants per podiatrist, multilevel analyses were not possible to adequately take these differences between podiatrists into account, which may have led to confounding. Besides, the number of podiatrists in the intervention was quite different from that in the control group. This difference was unavoidable, because the current study took place in clinical practice and the number of eligible patients varied enormously per podiatrist (1). Secondly, it is unknown whether the intervention and control group differed from each other at baseline regarding adherence to wearing orthopedic shoes, as no

baseline adherence measurement was performed. Due to practical changes to the original study protocol with regard to the number of study consultations, the participants received the activity monitor three and six months after baseline instead of two to four weeks and four months after baseline (1). Because of this also an adherence measurement short after receiving the new pair of orthopedic shoes is missing. Thirdly, there is no information available of the participants being indoors or outdoors, which led to an important data gap. This was caused by many patients being forced to work more from home and likely stayed more at home indoors due to the COVID-19 pandemic and lockdowns during the study.

Nevertheless, up to now this is the largest adherence intervention trial in this target group that has objectively measured long-term adherence to orthopedic shoes (3). The strength of the main trial is the reliable and accurate method to objectively assess adherence based on temperature measurements inside the orthopedic shoes to identify (non-)wearing of these shoes (4). One of the strengths regarding the study about the application of MI is the mixed-method approach with data triangulation, which provided more comprehensive evidence than in previously performed pilot studies (5, 6). Besides, the high external validity of that same study makes the results more generalizable to health-care providers in clinical practice and therefore applicable for education and training purposes, because it matches the needs and expectations of those being trained (7).

CLINICAL IMPLICATIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

Research design in clinical settings

Doing research in real-world clinical settings with vulnerable patients and challenging circumstances requires flexibility in study design. In this context high external validity may be more relevant than high internal validity. Recognition of this priority may lead to more pragmatic real-world studies, providing generalizable and meaningful outcomes that can contribute to refining national and international guidelines. This may result in better implementation of study outcomes in clinical practice to prevent diabetes-related foot ulcers.

Mixed-methods study designs

Besides, to collect data for research in clinical practice in an efficient way, mixed-methods study designs would be very helpful to expand knowledge and understanding of the results to implement in clinical practice (8). Quantitative and qualitative research methods focus on different questions, collect other kinds of data and can result in various perspectives on a certain topic. By combining the results of quantitative and qualitative components outcomes from different perspectives can be obtained and the results can be contextualized (7, 8).

Adherence

The proportion of adherent participants in the current study was low, but similar to those reported in previous studies (9-12). In these studies, 22-36% of people with diabetes at risk for ulceration wore their orthopedic shoes all day or at least >80% of daytime. The current study mostly took place during the COVID-19 pandemic. Due to the pandemic, many patients were forced to work more from home and likely stayed more at home indoors in general. In their study, Waaijman et al. (12) showed that adherence to orthopedic shoes was much

lower indoors than outdoors. This may partly explain the lower level of adherence in the current study, as only a few participants owned custom-made indoor shoes, which may have limited the use of orthopedic shoes indoors. Keukenkamp et al. recently showed that adherence to wearing orthopedic shoes increased in both the short-term and long-term in people at risk of diabetes-related foot ulceration after providing them custom-made indoor shoes besides their usual orthopedic shoes (13). However, the results of previous studies showed that there is no simple standalone solution to increase adherence to wearing orthopedic shoes (6, 12-15). Therefore, future research should focus on a combination of strategies, for example personalized healthcare and the application of motivational interviewing in clinical practice. In addition, future research, such as qualitative interviews with the podiatrists and/or participants, could shed more light on the reasons for both the overall low adherence rate and the even lower adherence in the MI intervention group.

Personalized healthcare

One of the aims was to investigate objectively measured long-term patterns of orthopedic shoes in people with diabetes at moderate-to-high risk of ulceration. A wide range in daily wearing time was found, indicating large differences between participants. Since previous studies exploring determinants of adherence to wearing orthopedic shoes explained only a limited amount of the variance of adherence (12, 15-18), it's recommended that the influence of other factors like the individual patient's perspective with regard to the effectiveness and efficiency of, and the satisfaction with their orthopedic shoes should be investigated. As a stable wearing pattern is mostly associated with high daily wearing times, it is likely that these participants formed habits to often wear their orthopedic shoes. Therefore, taking the patient's perspective on orthopedic shoes into account to support changing the patient's wearing behavior to a more stable pattern may be a potential avenue to improve long-term adherence to wearing orthopedic shoes.

As the focus in the main trial was on the objective adherence measurement, the collected patient interview data are not published yet and only preliminary and cautious suggestions can be given. This interview data suggested that almost all participants were highly motivated to wear their orthopedic shoes, but that it is important to know what the participants understood by "always" wearing their orthopedic shoes, as there was a discrepancy between the objective and subjective adherence measurements. Besides, it is also important to identify the needs of a patient with regard to orthopedic shoes, so that the patient can be informed about suitable options of which he/she is not (always) aware, e.g., orthopedic indoor shoes or walking shoes. In this way a solution regarding the orthopedic shoes can be achieved that meets the needs of the patient as closely as possible to ensure that more orthopedic shoes are worn. Therefore, it would be a good starting point for future research to focus on the understanding and needs of the patient instead of "standard" care. Besides, future research could also focus on ecological momentary assessments of perceived adherence in addition to continuous monitoring adherence with temperature sensors.

In addition, when diabetes-related foot ulcers nevertheless occur, it is also important that their treatment is as adequate as possible. Guidelines have shown that sufficient evidence is available to support the use of non-removable knee-high offloading devices

to heal plantar forefoot ulcers, over all other offloading interventions (31-33). Only in case of contraindications or patient intolerance to non-removable offloading devices other offloading devices should be considered, because the principle advantage of non-removable devices over removable offloading devices is enforced adherence (34). If this is the case patients should be sensitized to acknowledge the benefits of adherence to using a removable offloading device during all weight-bearing activity to improve the effectiveness of the device to heal their ulcer. Future research should investigate the best way of sensitizing patients about the benefits of adherence to offloading devices to heal diabetes-related foot ulcers.

Application of MI in clinical practice

The results of this study may be limited by the implementation of the MI-intervention in its current intensity and form. In this study, the participants had only one MI-consultation with an MI-trained podiatrist, who applied MI in daily clinical practice at a solid beginner level. Previous research showed that the total amount of time (106 min) participants received MI interventions contributed to a better outcomes and not the number of MI-consultations (2.6 sessions) (19). Lundahl and colleagues suggest that just a small amount of extra time with a patient per consultation to evoke change talk and build a relationship resulted in a 10-15% improvement (19). This is in line with the results of Keeley and colleagues which showed that healthcare providers may need to invest slightly more time, 10% in each visit, to realize the full benefits of MI (20). Nevertheless, Otto and colleagues suggest to combine longer time in a single MI-visit with booster-sessions to provide better outcomes (21). This is in line with Keukenkamp et al, who suggested that booster MI-sessions may improve the outcome (6). Taken together, this suggests that in the current study having only one MI-consultation may not be the limitation, but possibly the duration of this consultation (15-30 min). Since the application of MI leads to more complex conversations, the standard duration of a consultation may no longer be sufficient. However, because patients visit the podiatrist frequently, the previous conversation can be continued at a subsequent consultation. Therefore, longer time in a single MI-consultation followed by follow-up consultations (booster sessions) may suffice to improve adherence to wearing orthopedic shoes. To confirm or deny this more research is needed on the required intensity of MI to better inform clinical practice how to improve adherence to wearing orthopedic shoes.

However, as the podiatrists in the current trial applied MI in daily clinical practice just at a solid beginner level, increasing their MI skill levels may also be beneficial. As mentioned before, the podiatrists learned and realized that MI is not a trick to be applied but is a new communication technique to acquire and takes time to apply correctly and fully in practice (22). These results are in line with previous research on MI-training for diabetes healthcare providers. Several studies showed that some MI-related skills are less complex to learn and easier to apply during clinical practice compared to some other skills (5, 23-27). For example, change talk, empathy and asking open questions are less complex MI-related skills to learn and easier to apply during clinical practice compared to complex reflections and reduction of confrontation. Therefore, future research should focus on optimizing the MI-training by paying extra attention to the more complex MI-related skills. An in-depth analysis of MI-related skills may also contribute to further optimizing the MI-training. In such an analysis the focus should be on the effect of different MI-related skills between

specific patient groups with regard to adherence to wearing orthopedic shoes.

Implementation of MI

Regarding the implementation of MI in daily practice, the current study provides some recommendations for daily practice and future research. First, it is important that daily practice allows the podiatrists to integrate MI-techniques more easily into their work. There must be sufficient time and the digital patient reporting system should not be an obstacle. The use and maintenance of new skills in routine practice should be facilitated and not hindered by contextual factors such as the current reporting system (28, 29), as also mentioned by the podiatrists. The digital patient reporting system they use already requires asking many questions to complete a patient file. This might lead to an overload of topics to discuss with a patient during one consultation when implementing MI.

Second, it's recommended to include MI within the primary podiatry education, as MI takes time and practice, and requires self-awareness and discipline from the healthcare provider (30). Including MI already within primary podiatry education is likely to promote a successful use of MI in practice, because of regular repetition of the content of the MI-training and the provision of frequent feedback. This supports the podiatrists in applying MI as their standard communication technique, which makes them MI-minded, so the application of MI does not cost extra energy but becomes automatic. In addition, the inclusion of MI in the podiatry education from the beginning of their education provides the podiatrist with insight into and focus on patients' expectations and wishes. However, before MI can be implemented in daily practice as mentioned above, future research should first focus on optimizing the MI-training for podiatrists.

In addition, the satisfaction of the patients with the way of communication with their podiatrist was not measured. It is possible that the application of MI by the podiatrist had a negative effect on the adherence to wearing orthopedic shoes, because the participants were unfamiliar with this way of communicating with their podiatrist (22). Follow-up research should also measure the satisfaction of the patients with the way of communication with their podiatrist to get insight in the effect of the use of motivational interviewing by the podiatrist on the participant.

Implications for the patient

As improving adherence to wearing orthopedic shoes is crucial in preventing diabetes-related foot ulcers, also changes, which affect the patient, should be made in clinical practice. First, in addition to the fact that the podiatrist has to get used to applying MI, the patient also has to get used to the podiatrist's application of MI during a consultation. Most participants have been seeing the podiatrist already for years and as mentioned before, are likely to be unfamiliar with this new way of communicating with their podiatrist (22). Nevertheless, it is important that they get used to it, because MI can help to strengthen personal motivations and commitment to a specific goal which is essential for patients with loss of protective sensation of the feet, who miss their natural protective system. By encouraging MI to be included already in primary podiatrist training, it is likely that future patients already become accustomed to this way of communicating early on in their treatment.

Second, the specific needs of the individual patient with regard to orthopedic shoes should

be questioned better, because if these needs are identified the patient can be better informed about suitable options of which he/she is not (always) aware. As mentioned before, in this way a solution regarding the orthopedic shoes can be achieved that meets the needs of the patient as closely as possible to ensure that orthopedic shoes are worn more often (e.g., orthopedic indoor shoes or walking shoes).

Thirdly, this is also the case for the treatment of diabetes-related foot ulcers whereby the specific needs of the individual patient should be considered. When a non-removable offloading device cannot be used due to contraindication or patient intolerance, patients should be sensitized to acknowledge the benefit of adherence to using their removable offloading device during all weight-bearing activity to improve the effectiveness of this device to heal their ulcer. If the needs of the patient are met as closely as possible this may motivate and encourage them to adhere to this recommended behavior.

Implications for health insurance

However, for personalized healthcare to succeed, the reimbursement policy of the health insurances may have to be adjusted as the current reimbursements for orthopedic shoes for people with diabetes-related foot disease are not sufficient for everyone. Therefore, it is important that future research focuses on the cost-effectiveness of personalized healthcare regarding orthopedic shoes of people with diabetic-related foot disease.

Need for multidisciplinary approach

Adherence to foot self-care, including wearing orthopedic shoes, is crucial in preventing and healing diabetes-related foot ulcers. However, there does not seem a simple standalone solution to improve adherence. As different healthcare providers, among others a diabetes and wound nurse, physician assistant, pedorthist, vascular surgeon, and rehabilitation doctor, are involved in the treatment of diabetes-related foot ulcers, it may be desirable to train not only the podiatrists in MI, but also the other healthcare providers. This would support a single uniform way of communicating of all concerned healthcare providers with the patient, building on partnership and shared decision making, with a focus on the patient's perspective, not only about wearing orthopedic shoes, but also regarding different offloading devices. Therefore, research is necessary into the effect of a multidisciplinary application of MI with regard to the care of diabetes-related feet. When this leads to positive results, MI should become part of all healthcare-related training, so that MI becomes the standard way of communicating about selfcare behaviors with patients in healthcare.

GENERAL CONCLUSION

With this thesis the knowledge and understanding of the prevention and healing of foot ulcers in people with diabetes in clinical practice are expanded. First, it was shown that adherence to wearing orthopedic shoes is suboptimal in most people at moderate-to-high risk of foot ulceration. People with a consistent wearing pattern showed higher daily wearing times than those with an inconsistent pattern. Besides, orthopedic shoes were worn less during weekend days compared to weekdays. Secondly, following the triangulation of the qualitative and quantitative results of the application of MI it can be concluded that after a basic MI-training, podiatrists can effectively apply MI in daily clinical practice at a

solid beginner level. Furthermore, the findings support implementation of MI in practice and encourage MI training in the primary podiatrist training and maintenance training for daily clinical practice. Thirdly, one podiatrist-led MI-consultation did not contribute to improving adherence to wearing orthopedic shoes in people with diabetes at low-to-high risk of foot ulceration. Finally, if a wound occurs due to low adherence or due to another reason, a knee-high and non-removable device ensures the best plantar pressure reduction. Overall, it can be concluded that there seems to be no simple standalone solution to prevent and heal diabetes-related foot ulcers and that improved communication of the whole multidisciplinary team with the patient is necessary to help patients at risk as good as possible (3). We hope that the findings of this thesis support researchers and clinicians in further investigating strategies to prevent and heal foot ulcers in people with diabetes.

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Chapter 9

Summary

Prevention and healing of diabetes-related foot ulcers
Motivational interviewing, objective adherence and offloading

Diabetes mellitus is one of the most common chronic diseases worldwide and the number of people with diabetes is still increasing. This is alarming because people with diabetes are at risk of developing numerous complications. One of the most common serious and debilitating complications is diabetes-related foot disease. Diabetes-related foot ulcers have a serious impact on the person's health and life. They significantly increase the risk of infection and amputation, are the most frequently reason for hospitalization, and can cause immobility and a reduced quality of life. In addition to these health-related effects, diabetes-related foot ulcers incur high costs due to unemployment, hospital admissions, and home care. Therefore, prevention of diabetic-related foot ulcers has high priority to reduce the burden on people with diabetes, healthcare systems and society.

To treat pre-signs of diabetes-related foot ulcers, for example hyperkeratosis, people at high-risk of developing foot ulcers are recommended to see a podiatrist once every 1-3 months, as compared to every 12 months or less for those not at high-risk. In addition, offloading areas of high plantar pressure is the cornerstone to prevent (re)ulceration through orthopedic shoes and heal foot ulcers through offloading devices. Adherence to wearing orthopedic shoes is considered essential for preventing (re)ulceration, because these shoes are optimized for high pressure reduction at locations that are at high risk for ulceration. A reliable and accurate method to objectively assess wearing time of orthopedic shoes is based on temperature measurements inside these shoes. However, previous studies that used objective temperature-based sensors to measure wearing time, had limitations regarding the short measurement period and small sample size.

Despite the fact that adherence to orthopedic shoes results in significantly better health outcomes, on average adherence is rather low. Previous studies have shown that good communication with the healthcare provider is essential to influence patients' decision to encourage to use orthopedic shoes and is associated with increased long-term use of orthopedic shoes. Regarding good communication, it is important to patients that they feel being listened to and that they are involved in the prescription process of orthopedic shoes, to be able to make their own choices. As such, it is expected that good communication can improve adherence to wearing orthopedic shoes. Motivational interviewing (MI), defined as a collaborative, goal-oriented style of communication of the healthcare provider with particular attention to the language of change, may stimulate a satisfactory working alliance and, as a result, positively influence adherence.

Besides, when a foot (re)ulceration does occur, different offloading devices are available, which differ from each other in device characteristics: knee-high vs. ankle-high, non-removable vs. removable, and custom-made vs. prefabricated. These different design characteristics all contribute to the potential offloading effect of such a device. However, the (relative) contribution of the different design characteristics of the several devices is insufficiently studied.

The overall aim of this thesis is to expand knowledge and understanding of:

1. Objectively measured long-term adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration,
2. The effects of the application of motivational interviewing by podiatrists on adherence

behavior and to prevent (re)ulcerations, and
3. The value of different offloading devices on healing of diabetes-related foot ulcers in (clinical) daily practice.

In **chapter 1**, the background of these topics is described and the research objectives are formulated.

The study in **chapter 2** objectively assessed long-term wearing patterns of orthopedic shoes during 12 months in 61 people with diabetes at moderate-to-high risk of ulceration by a temperature sensor built into their orthopedic shoes. Moreover, factors associated with wearing orthopedic shoes were evaluated, as previous studies to factors associated with adherence to wearing orthopedic shoes did not result in definitive conclusions. A wide range in daily wearing time was found, indicating large differences between participants. However, participants with a consistent wearing pattern showed higher daily wearing times than participants with an inconsistent pattern. Therefore, changing the wearing behavior of patients to a more stable pattern seems a potential avenue to improve long-term adherence to wearing orthopedic shoes. Of the investigated factors, only self-reported "satisfaction with my wear of orthopedic shoes" was positively associated with wearing time, the other factors were not associated with wearing time. Mixed-methods research is needed to combine the objectively measured wearing time with the patients' perspective through triangulation so the results can be contextualised.

In **chapter 3** the study protocol of a multicenter, cluster-randomized controlled trial on the effectiveness of motivational interviewing to improve objectively measured adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration was presented. This trial aimed to generate novel insights into the effectiveness of motivational interviewing on adherence to wearing orthopedic shoes, prevention of (re)ulcerations, participants' experiences on the used and usability of their orthopedic shoes and their perceived health-related quality of life. In total 121 participants with diabetes, were included and received usual care or usual care plus motivational interviewing (MI). The primary outcome of the study was defined as the assessment of effectiveness of MI in promoting shoe adherence and ulcer prevention.

The research described in **chapter 4** observed and analyzed the application of MI in consultations carried out by MI-trained and non-MI-trained podiatrists with their patients, and explored podiatrists' attitudes and experiences towards MI. Eighteen podiatrists followed a three-day basic MI-training and four podiatrists were not trained in MI. The main findings of this mixed-methods (qualitative and quantitative) study indicated after data triangulation that the MI-trained podiatrists used the principle of MI at a solid beginner proficiency and did this significantly better than non-MI-trained podiatrists. The MI-trained podiatrists scored better on the less complex MI-related skills, which was also described by themselves as being related to their attitudes and experiences of using MI in practice. However, they were not able to demonstrate all MI-related skills, especially the more complex MI-related skills. This corresponds to the podiatrists' comments that they have realized that MI is a new communication technique that requires further training, and that it takes time to apply MI correctly and fully in practice. To support implementation of MI

in practice, including MI training in the primary podiatrists training program and offering maintenance training for daily clinical practice are encouraged.

In **chapter 5**, the effect of MI performed by MI-trained podiatrists in improving adherence to wearing orthopedic shoes in comparison to usual care in people with diabetes at low-to-high risk ulceration was evaluated. People with diabetes with loss of protective sensation and/or peripheral artery disease, and with orthopedic shoes prescription were allocated to receive one MI-consultation by a podiatrist randomized to MI training (N=53) or usual care only (N=68). Participants with diabetes who received usual care plus MI focused on improving adherence to orthopedic shoes by a trained podiatrist were not significantly more or less adherent to wearing orthopedic shoes compare to participants who received usual care. Three months after inclusion, the proportion of adherent participants was even significantly higher in those that received usual care than in those who received usual care plus MI. This outcome suggests that the MI-intervention as implemented in its current form does not contribute to improving adherence to wearing orthopedic shoes in daily practice. Besides, no significant differences were found between the intervention and control group in the proportion of participants (re-)experiencing ulceration 12 months after inclusion, the participant experiences' on the use and usability of their orthopedic shoes, or the participant-perceived health-related quality of life.

In conclusion, the current implementation of MI by an MI-trained podiatrist in addition to usual care did not improve adherence to wearing orthopedic shoes 3 and 6 months after inclusion nor 1-year outcomes in ulcer prevention. It seems that the relation between effectiveness of MI and adherence to wearing orthopedic shoes may be more complex than expected. A higher dose of MI or podiatrists applying MI at a higher level may be required to substantially improve the level of adherence to wearing orthopedic shoes. Adherence may also be affected by other variables than MI as shown in previous studies and limited due to implementation complexities in clinical practice settings. Therefore, although MI may have the potential to increase adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration, it does not seem a standalone approach.

Chapter 6 described the offloading effect of the different design characteristics that make up a non-removable knee-high cast for people with diabetes and active or previous plantar forefoot ulcer. Sixteen people with diabetes had their plantar pressures measured during walking in 1) a non-removable knee-high device(TCC), 2) in that device made removable (BTCC), 3) in that device made below-ankle (cast shoe), 4) in that cast shoe worn with a different waling sole and 5) in a newly made cast shoe without a custom-molded foot-device interface. The TCC gave superior offloading, mostly because of being a knee-high and non-removable device, providing the optimal 'shaft' effect. However, the TCC did negatively affect walking comfort, which should be considered when using a TCC. The outcomes supported, from a biomechanical perspective, the International Working Group on the Diabetic Foot (IWGDF) recommendation of using a knee-high non-removable device as first treatment option for offloading a neuropathic plantar forefoot ulcer in people with diabetes.

In **chapter 7** the main findings of the studies in this thesis were summarized and discussed in context of currently available literature. A reflection on the used methodologies is given, implications have been identified for clinical practice and future research to prevent diabetes-related foot ulcers. Overall, it can be concluded that there seems to be no simple standalone solution to prevent and heal diabetes-related foot ulcers and that improved communication of the whole multidisciplinary team with the patient is necessary to provide optimal support to diabetes patients at risk.

Samenvatting

Het voorkomen en genezen van diabetes-relateerde voetwonden

Motiverende gespreksvoering, objectieve adherentie en drukverlaging

Diabetes mellitus is wereldwijd één van de meest voorkomende chronische ziekten en het aantal mensen met diabetes neemt nog steeds toe. Dit is alarmerend, omdat mensen met diabetes het risico lopen om tal van complicaties te ontwikkelen. Eén van de meest voorkomende, ernstige en invaliderende complicaties is diabetes-gerelateerde voetziekte. Diabetes-gerelateerde voetulcera (voetwonden) hebben een ernstige impact op iemands gezondheid en leven. Voetulcera verhogen het risico op infectie en amputatie aanzienlijk, zijn de meest voorkomende reden voor ziekenhuisopname en kunnen immobiliteit en een verminderde levenskwaliteit veroorzaken. Naast deze gevolgen voor de gezondheid brengen diabetes-gerelateerde voetulcera ook hoge kosten met zich mee door werkloosheid, ziekenhuisopnames en thuiszorg. Daarom heeft preventie van diabetes-gerelateerde voetulcera hoge prioriteit om de last voor mensen met diabetes, de gezondheidszorg en de maatschappij te verminderen.

Om de voortekenen van diabetes-gerelateerde voetulcera, bijvoorbeeld hyperkeratose, behandelen, wordt mensen met een hoog risico op het ontwikkelen van voetulcera aangeraden eens in de 1-3 maanden naar een podotherapeut te gaan, in tegenstelling tot eens in de 12 maanden of minder voor mensen zonder dit hoge risico. Daarnaast is het ontlasten van gebieden met een hoge plantaire druk, de hoeksteen om (her)ulceratie te voorkomen door middel van orthopedische schoenen en voetulcera te genezen door middel van druk ontlastende hulpmiddelen. Het dragen van orthopedische schoenen is essentieel voor het voorkomen van (her)ulceratie, omdat deze schoenen geoptimaliseerd zijn voor hoge drukverlaging op plaatsen met een hoog risico op ulceratie. Een betrouwbare en nauwkeurige methode om de draagtijd van orthopedische schoenen objectief te beoordelen is gebaseerd op temperatuurmetingen in deze schoenen. Echter, eerdere onderzoeken die objectieve temperatuursensoren gebruikten om de draagtijd te meten, hadden enkele beperkingen, zoals een korte meetperiode en kleine steekproefgrootte.

Ondanks het feit dat het dragen van orthopedische schoenen leidt tot significant betere resultaten is de therapietrouw aan het dragen van orthopedische schoenen vrij laag. Eerdere onderzoeken hebben aangetoond dat goede communicatie met de zorgverlener essentieel is voor het stimuleren van iemands beslissing om orthopedische schoenen te gaan gebruiken, en geassocieerd is met een verhoogd gebruik van orthopedische schoenen op de lange termijn. Wat betreft goede communicatie is het voor patiënten belangrijk dat ze het gevoel hebben dat er naar hen geluisterd wordt en dat zij betrokken worden bij het voorschrijfproces van orthopedische schoenen om hun eigen keuzes te kunnen maken. Daarom wordt verwacht dat goede communicatie de therapietrouw voor het dragen van orthopedische schoenen kan verbeteren. Motiverende gespreksvoering (MGV), gedefinieerd als een collaboratieve, doelgerichte communicatiestijl van de zorgverlener met bijzondere aandacht voor verandertaal, kan een bevredigende werkalliantie stimuleren en als gevolg daarvan de therapietrouw positief beïnvloeden.

Daarnaast zijn er, wanneer een voet (her)ulceratie optreedt, verschillende druk verlagende hulpmiddelen beschikbaar die wat betreft eigenschappen van elkaar verschillen, bijvoorbeeld: kniehoog vs. enkelhoog, niet- afneembaar vs. afneembaar, en op maat gemaakt vs. geprefabriceerd. Deze verschillende ontwerpkenmerken dragen allemaal bij aan het potentiële ontlastende effect van een dergelijk hulpmiddel. Echter, de (relatieve)

bijdrage van de verschillende ontwerpkenmerken van diverse hulpmiddelen is onvoldoende onderzocht.

Het doel van dit proefschrift is het vergroten van kennis en begrip van:
1. Objectief gemeten lange termijn therapietrouw aan het dragen van orthopedische schoenen bij mensen met diabetes met een risico op voetulcera,
2. De mogelijkheden van de toepassing van MGV door podotherapeuten om therapietrouw te veranderen en (her)ulceraties te voorkomen, en
3. De waarde van verschillende druk verlagende hulpmiddelen voor genezing van diabetes-gerelateerde voetulcera in de (klinische) dagelijkse praktijk.

In **hoofdstuk 1** is de achtergrond van bovengenoemde onderwerpen beschreven en zijn de onderzoeksdoelen geformuleerd.

In **hoofdstuk 2** is objectief, door middel van temperatuursensoren, het draagpatroon van orthopedische schoenen gemeten op de lange termijn gedurende 12 maanden bij 61 mensen met diabetes met een matig tot hoog risico op ulceratie. Bovendien zijn factoren geëvalueerd die samenhangen met het dragen van orthopedische schoenen. Er is een grote variatie in dagelijkse draagtijd gevonden, wat duidt op grote verschillen tussen de deelnemers. Mensen met een consistent draagpatroon vertoonden echter een hogere dagelijkse draagtijd dan mensen met een inconsistent patroon. Daarom lijkt het veranderen van het draaggedrag van mensen naar een stabieler patroon een goede mogelijkheid om het dragen van orthopedische schoenen op de lange termijn te verbeteren. Van de onderzochte factoren is alleen de zelf gerapporteerde “tevredenheid met het dragen van orthopedische schoenen” positief geassocieerd met de draagtijd, de andere factoren zijn niet geassocieerd met draagtijd. Mixed-methods onderzoek is nodig om de objectief gemeten draagtijd te combineren met het perspectief van de patiënt door middel van triangulatie, zodat de resultaten in hun context kunnen worden geplaatst.

In **hoofdstuk 3** werd het studieprotocol gepresenteerd van een multicenter, cluster gerandomiseerde gecontroleerde trial naar de effectiviteit van MGV ter verbetering van objectief gemeten therapietrouw aan het dragen van orthopedische schoenen bij mensen met diabetes die risico lopen op voetulceraties. Het doel van deze studie was om nieuwe inzichten te verkrijgen in de effectiviteit van MGV op de therapietrouw aan het dragen van orthopedische schoenen, de preventie van (her)ulceraties, de ervaringen van deelnemers over het gebruik en de bruikbaarheid van hun orthopedische schoenen en hun ervaren gezondheid gerelateerde kwaliteit van leven. In totaal zijn 121 deelnemers met diabetes geïncludeerd die gebruikelijke zorg of gebruikelijke zorg plus MGV kregen. De primaire uitkomst van het onderzoek was het evalueren van de effectiviteit van MGV in het bevorderen van therapietrouw aan orthopedische schoenen en ulcuspreventie.

Het onderzoek beschreven in **hoofdstuk 4** observeerde en analyseerde de toepassing van MGV in consulten uitgevoerd door MGV-getrainde en niet-MGV-getrainde podotherapeuten met hun patiënten, en onderzocht de houding en ervaringen van podotherapeuten ten opzichte van MGV. Achttien podotherapeuten volgden een driedaagse basistraining MGV en vier podotherapeuten werden niet getraind in MGV. De belangrijkste bevindingen van deze

mixed-methods (kwalitatieve en kwantitatieve) studie gaven na datatriangulatie aan dat de MGV-getrainde podotherapeuten het principe van MGV op een solide beginnersniveau gebruikten en dit significant beter deden dan niet-MGV-getrainde podotherapeuten. De MGV-getrainde podotherapeuten scoorden beter op de minder complexe MGV-gerelateerde vaardigheden, wat ze ook zelf beschreven als gerelateerd aan hun houding en ervaringen met het gebruik van MGV in de praktijk. Echter, ze waren niet in staat om alle MGV-gerelateerde vaardigheden te reproduceren, zoals de meer complexe MGV-gerelateerde vaardigheden. Dit komt overeen met de opmerkingen van de podotherapeuten dat ze hebben ingezien dat MGV een nieuwe communicatietechniek is die verder getraind moet worden, en dat het tijd kost om MGV correct en volledig toe te passen in de praktijk. Om de implementatie van de MGV in de praktijk te ondersteunen wordt opname van MGV-training in de primaire podotherapeuten opleiding en onderhoudstraining voor de dagelijkse klinische praktijk aangemoedigd.

In **hoofdstuk 5** werd het effect geëvalueerd van MGV uitgevoerd door MGV-getrainde podotherapeuten op het verbeteren van therapietrouw aan het dragen van orthopedische schoenen in vergelijking met gebruikelijke zorg bij mensen met diabetes met een laag tot hoog risico op ulceratie. Mensen met diabetes met verlies van beschermend gevoel en/of perifeer vaatlijden, en met orthopedische schoenen voorgeschreven, werden toegewezen aan één MGV-consultatie door een podotherapeut gerandomiseerd naar MGV-training (N=53) of alleen gebruikelijke zorg (N=68). Deelnemers met diabetes die gebruikelijke zorg plus MGV gericht op het verbeteren van het dragen van orthopedische schoenen door een getrainde podotherapeut kregen, waren niet significant meer of minder therapietrouw aan het dragen van orthopedische schoenen in vergelijking met deelnemers die gebruikelijke zorg kregen. Drie maanden na inclusie was het percentage deelnemers dat therapietrouw was zelfs significant hoger bij degenen die gebruikelijke zorg ontvingen dan bij degenen die gebruikelijke zorg plus MGV ontvingen. Deze uitkomst suggereert dat de MGV-interventie zoals die in de huidige vorm is geïmplementeerd niet bijdraagt aan het verbeteren van de therapietrouw aan het dragen van orthopedische schoenen in de dagelijkse praktijk. Daarnaast werden er geen significante verschillen gevonden tussen de interventie- en controlegroep in het percentage deelnemers dat 12 maanden na inclusie (opnieuw) ulcera kreeg, de ervaringen van deelnemers over het gebruik en de bruikbaarheid van hun orthopedische schoenen, of de door deelnemers ervaren gezondheid gerelateerde kwaliteit van leven.

Concluderend kan worden gesteld dat de huidige implementatie van MGV door een MGV-getrainde podotherapeut in aanvulling op gebruikelijke zorg de therapietrouw aan het dragen van orthopedische schoenen 3 en 6 maanden na inclusie niet verbeterde, noch de 1-jaars uitkomsten in ulcuspreventie. Het lijkt erop dat de relatie tussen effectiviteit van MGV en therapietrouw aan het dragen van orthopedische schoenen complexer is dan verwacht. Een hogere dosis MGV of podotherapeuten die MGV op een hoger niveau toepassen, kan nodig zijn om de mate van therapietrouw aan het dragen van orthopedische schoenen substantieel te verbeteren. Therapietrouw kan ook beïnvloed worden door andere variabelen dan MGV zoals aangetoond in eerdere studies en beperkt worden door de complexiteit van de implementatie in de klinische praktijk. Hoewel MGV de therapietrouw aan het dragen van orthopedische schoenen kan verhogen bij mensen met diabetes die

risico lopen op voetulceratie, lijkt het daarom geen op zichzelf staande aanpak.

In **hoofdstuk 6** is onderzocht wat het druk verlagende effect is van de verschillende ontwerpkenmerken van een niet-afneembaar kniehoog gips voor mensen met diabetes en een actief of eerder doorgemaakt plantair voorvoetulcus. Bij zestien mensen met diabetes is de plantaire druk gemeten tijdens het lopen in een niet-afneembaar kniehoog gips (TCC), in een afneembaar gips kniehoog (BTCC), in een onder de enkel gedragen gips (gipsschoen), in een gips met een andere loopzool en in een nieuw gemaakte gipsschoen zonder een gemodelleerde loopzool. De TCC gaf een superieure ontlasting, vooral omdat het een kniehoog en niet-afneembaar hulpmiddel is, dat een optimaal 'schacht'-effect geeft. De TCC heeft echter wel een negatieve invloed op het loopcomfort, waarmee rekening moet worden gehouden bij het gebruik van een TCC. De uitkomsten ondersteunen vanuit een biomechanisch perspectief de aanbeveling van de International Working Group on the Diabetic Foot (IWGDF) om een kniehoog niet-afneembaar hulpmiddel te gebruiken als eerste behandelingsoptie voor de druk ontlasting van een neuropathisch plantair voorvoetulcus bij mensen met diabetes.

In **hoofdstuk 7** zijn de belangrijkste bevindingen van de studies in dit proefschrift samengevat en besproken in de context van de huidig beschikbare literatuur. Er is een reflectie gegeven op de gebruikte methodologieën, er zijn implicaties benoemd voor de klinische praktijk en toekomstig onderzoek om diabetes-gerelateerde voetulcera te voorkomen. In het algemeen kan worden geconcludeerd dat er geen eenvoudige opzichzelfstaande oplossing lijkt te zijn om diabetes-gerelateerde voetulcera te voorkomen en te genezen en dat een verbeterde manier van communicatie van het hele multidisciplinaire team met de patiënt noodzakelijk is om optimale ondersteuning te bieden aan diabetespatiënten die risico lopen op voetulcera.

Appendices

Dankwoord
Curriculum vitae
Publications and other output

DANKWOORD

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CURRICULUM VITAE

Manon Jongebloed-Westra was born 3 January 1988 to Eddy and Maaike Westra in Hengelo (ov), the Netherlands. She grew up together with Annelie, her younger sister, in Borne. In 2006 she completed high school at CSG Het Noordik, in Almelo and began her BSc in Human Movement Sciences at the University of Groningen. After obtaining her bachelor's degree she started in 2010 at the Univeristy Utrecht to study Clinical Health Science, in particular Physiotherapy Science.

In May 2014, Manon joined Ziekenhuisgroep Twente (ZGT) in Almelo as junior researcher in the surgical department, especially the diabetic foot unit. She also worked here from September 2017 till September 2018 for Voetmax Orthopedie as orthopedic advisor in training. In October 2018 she began her PhD, researching the socio-economic impact of motivational interviewing on adherence to orthopedic shoes at the department PHT of the faculty BMS of the University of Twente under the supervision of prof. dr. J.E.W.C. Gemert-van Pijnen.

Currently Manon works again at Ziekenhuisgroep Twente (ZGT) in Almelo as research coordinator in the cardiological department.

PUBLICATIONS AND OTHER OUTPUT

Publications in peer-reviewed journals

Exterkate SH, *Jongebloed-Westra M,* ten Klooster PM, Koffijberg H, Bode C, van Gemert-Pijnen JEWC, van Baal JG, van Netten JJ. Objectively assessed long-term wearing patterns and predictors of wearing orthopaedic footwear in people with diabetes at moderate-to-high risk of foot ulceration: a 12 months observational study. J Foot Ankle Res. 2023 Sep 14;16(1):60.

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Jongebloed-Westra M, Bode C, Bente BE, de Jonge JM, ten Klooster PM, Koffijberg H, Exterkate SH, van Netten JJ and van Gemert-Pijnen JEWC. Attitudes and experiences towards the application of motivational interviewing by podiatrists working with people with diabetes at high-risk of developing foot ulcers: a mixed-methods study. Presented at 19e Symposium Diabetische voet Almelo; 2022 June 28, Almelo, The Netherlands. 2022.

Posters

Jongebloed-Westra M, Koffijberg H, Bode C, van Netten JJ, ten Klooster PM, Exterkate SH, van Gemert-Pijnen JEWC. Effect of motivational interviewing combined with digital shoe-fitting on adherence to orthopaedic shoes: study protocol. Poster presented at Supporting Health by Technology X; 2021 June 10-11; Enschede, The Netherlands. 2021.

Westra M, van Netten JJ, Manning HA, van Baal JG, Bus SA. Effect of different casting design characteristics on offloading the diabetic foot. Poster presented at 8th International Symposium on the Diabetic Foot; 2019 May 21-25; The Hague, The Netherlands. 2019.

Jongebloed-Westra M, Koffijberg H, Bode C, van Netten JJ, ten Klooster PM, Exterkate SH, van Gemert-Pijnen JEWC. Effect of motivational interviewing combined with digital shoe-fitting on adherence to orthopaedic shoes: study protocol. Poster presented at Supporting Health by Technology IX; 2019 May 16-17; Groningen, The Netherlands. 2019.

Other Output

Website: therapietrouw | BMS - Therapietrouw (utwente.nl)
Movie made by ZonMw: https://www.youtube.com/watch?v=xiT_s972C1I
Movie made by Wender: https://www.youtube.com/watch?v=BKRreM4IVH8