FOREFOOT PROBLEMS IN OLDER ADULTS
Forefoot problems in older adults

ACADEMISCH PROEFSCHRIFT

VRIJE UNIVERSITEIT

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General introduction

FOOT PAIN

It has been shown that 22-25% of the adult population has some form of foot pain\(^1,2\). In about two thirds of these individuals the foot pain leads to functional limitations of foot related activities like standing and walking\(^2,3\). And one third of these people have chronic foot pain lasting two years or longer\(^4\). As a consequence, foot pain has been related to a decreased ability to carry out some daily activities\(^5, 6, 7\). For instance, the chance of having difficulties while climbing stairs or walking more than one kilometre is three times higher for people with foot pain. Both balance and gait are negatively influenced by having foot pain\(^6, 8, 9\). One study with women aged 65 or over shows that chronic and severe foot pain almost doubled the chance of walking difficulties\(^8\). As a consequence of walking difficulties, people with foot pain have more falls and fall related fractures than individuals without pain\(^9, 10\). Foot pain and the resulting impaired mobility can lead to a decrease in health related quality of life\(^5, 11-15\).

The chance of suffering foot pain increases with age\(^1, 2, 16\) and more women than men have foot pain\(^6, 7, 17\). The only proven risk factor for developing foot pain is obesity\(^8, 18\). An assumed risk factor is wearing shoes that are too small or of improper quality. Even though this assumption is expressed by multiple authors\(^19, 20\) its contribution to foot pain has yet to be established.

FOREFOOT

A Dutch survey showed that the forefoot is affected in 60% of the individuals who reported foot pain\(^7\), compared to 27-32% in the hind foot\(^21\) and 24-33% in the arch\(^22\). Affected areas in the forefoot can be the nails and toes, the dorsal side of the forefoot and the plantar side, also known as the ball of the foot (figure 1). Forefoot pain and forefoot prob-
HEALTHCARE SEEKING
A population based survey in the Netherlands showed that 56% of the individuals who reported foot pain sought (para-) medical attention for their foot problem. The largest proportion of people (46%) consulted their general practitioner (GP) and 36% a medical specialist; mainly orthopaedic surgeons. Paramedical care, which mainly comprised of podiatrists, was sought by 18% of the individuals. In a comparable cross-sectional study in Australia 17.7% of people with foot pain consulted a podiatrist. It is unknown if any of the participants in this study sought any other form of medical attention. Having foot pain that results in the limitation of foot related activities has been shown to increase the chance of consultation by a three-fold. As mentioned before, prevalence's of foot pain are higher in women than in men, so understandably the number of women seeking medical attention for foot pain is higher than in men. One study shows that individuals with forefoot pain consult less often than people with pain in other parts of the foot.

TREATMENT OPTIONS
TREATMENT IN GENERAL PRACTICE
Treatments provided by GPs is obviously diagnosis dependent, but the most common is a prescription of paracetamol or non-steroidal anti-inflammatory drugs (NSAID’s). Another treatment option is a referral to a (para-)medical specialist like a podiatrist, chiropodist or orthopaedic surgeon. A third option is to provide lifestyle advice: loose weight, wear better shoes or try to relax more. GPs in the Netherlands, like in the UK and Scandinavia, have a gatekeeper’s role; i.e. they are the first medical contact many patients have. It could very well be that treatment

FIGURE 1 Specific prevalence of forefoot problems per area

FOREFOOT PROBLEMS IN OLDER ADULTS

GENERAL INTRODUCTION
NVvP provides “how to” advice; e.g. take your time buying shoes, buy shoes at the end of the day, tie shoes when trying them on, etc.

**TABLE 1. Characteristics of ‘proper’ footwear according to GP and Podiatrist**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>GP1</th>
<th>Podiatrist2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustable fixation</td>
<td>Fixation over the instep; preferably laces</td>
<td></td>
</tr>
<tr>
<td>Flexible upper</td>
<td>Breathing (leather) upper</td>
<td></td>
</tr>
<tr>
<td>Sturdy upper around toes</td>
<td>Sturdy heel counter</td>
<td></td>
</tr>
<tr>
<td>Sturdy heel counter</td>
<td>Flexible sole</td>
<td></td>
</tr>
<tr>
<td>Longitudinal sole rigidity</td>
<td>Preferably rubber</td>
<td></td>
</tr>
<tr>
<td>Sole: leather or synthetic</td>
<td>Heel height: so that the calf muscles are relaxed</td>
<td></td>
</tr>
<tr>
<td>Heel height &lt; 3 cm</td>
<td>Heel flexion point: under metatarsal heads</td>
<td></td>
</tr>
<tr>
<td>Heel surface: &gt; 9 cm^2</td>
<td>No seams over painful area</td>
<td></td>
</tr>
<tr>
<td>length/width/toebox: sufficient room</td>
<td>length/width/toebox: sufficient room</td>
<td></td>
</tr>
</tbody>
</table>

1. Information derived from the book “Diagnosing common complaints”.
2. Information derived from the internet site of the NVvP.

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**FOOTWEAR**

Both the GP and the podiatrist provide shoe advice. Currently only a few elements of shoe advice have been scientifically evaluated and thus most of advice is not evidence based. In neither profession recommendations for providing shoe advice are standardized. An overview of the elements that shoe advice may address is presented in Table 1. Characteristics of ‘proper’ footwear according to GPs is based on the Chapter of “foot problems” in the book for GPs: “Diagnosing common complaints”. The information presented by podiatrists is based on the information provided on the previously mentioned homepage of the NVvP.

Additional to the advice on footwear characteristics from Table 1, the

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**OBJECTIVE AND OUTLINE OF THIS THESIS**

The main goal of this thesis was to evaluate the treatment of forefoot pain and subsequent functional limitations, in primary care, by comparing the effectiveness of two common treatment options in a randomised controlled trial: Podiatric care and footwear advice by means of an information leaflet. In Chapter 2 we describe the protocol of the RCT and the results of the RCT are reported in Chapter 3.

We performed process analyses of both treatment options from the RCT. The results of the study of the podiatric treatment process are reported in Chapter 4. Shoe advice provided to participants in the RCT is done so by providing a shoe advice leaflet. In Chapter 5 we provide a description of the development of the content and the results of a RCT.
that evaluates if women asked to select shoes with the developed leaflet are able to choose better footwear than women who do not have the leaflet.

In Chapter 6 we report on the Dutch translation and the full evaluation of measurement properties of the Manchester Foot Pain and Disability Index. We used this instrument in the RCT to measure foot pain and its related dysfunction.

As described in Chapter 5, there is a lack of evidence concerning appropriateness of several shoe characteristics that are currently recommended. Therefore, in Chapter 7 we evaluate one of these characteristics on planter loading during gait: the sole flexion point.

Finally, in Chapter 8 we provide a summary and a methodological reflection on the preceding results. At the end of this chapter we give recommendation for clinical practice and future research.

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Treatment of forefoot problems in older people: study protocol for a randomised clinical trial comparing podiatric treatment to standardised shoe advice

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BACKGROUND

Pain and discomfort due to foot problems are common and increase with age. Population-based surveys have estimated the prevalence of foot problems between 14.9 and 41.9% for people aged 50 years and older. The prevalence of foot problems was found to be higher in women than in men. Not all foot problems or foot deformities lead to pain or functional limitations but people with disabling foot pain have been shown to experience a lower degree of well-being and to have a higher risk of a decrease in mobility and falling 9,10.

Forefoot problems including metatarsalgia, hallux valgus and hallux rigidus are the most common foot problems in older people. A community-based study among 5689 older people in the Dutch area of Apeldoorn (a mixed urban-rural area) showed a prevalence rate of forefoot problems of 60% within the group of people reporting non-traumatic foot problems (n=1130). In an English population survey among 3417 adults, more than one-third indicated to have pain in the great toe or in the first metatarsophalangeal joint (MTP-joint), and 9.5% indicated to be disabled by their foot problem.

Underreporting of foot problems is an acknowledged phenomenon in healthcare. The community-based survey among older people in The Netherlands showed that only 56% of the respondents sought health care, by consulting their general practitioner (GP) (46%), a medical specialist (36%) (mainly orthopaedic surgeons) or an allied health care professional (18%) (mainly podiatrists). A GP will commonly refer non-traumatic foot problems to a podiatrist or will treat the patient him or herself. Dutch podiatric care starts with an assessment which includes medical history, detailed analysis of the anatomical relationships within the foot and both a postural and a gait analysis. Treatment may consist of (or a combination of) construction of full length podiatric insoles, silicone toe devices, (shoe) advice or basic foot and nail care. The treatment by the GP usually consists of prescribing pain medication (simple analgesic or non-steroidal inflammatory drugs [NSAIDs]) or by giving lifestyle advice (e.g. try to lose weight, improve shoe wear).

ABSTRACT

Background: Foot problems in general and forefoot problems in particular can lead to a decrease in mobility and a higher risk of falling. Forefoot problems increase with age and are more common in women than in men. Around 20% of people over 65 suffer from non-traumatic foot problems and 60% of these problems are localised in the forefoot. Little is known about the best way to treat forefoot problems in older people. The aim of this study is to compare the effects of two common modes of treatment in the Netherlands: shoe advice and podiatric treatment. This paper describes the design of this study.

Methods: The study is designed as a pragmatic randomised clinical trial (RCT) with 2 parallel intervention groups. People aged 50 years and over who have visited their general practitioner (GP) with non traumatic pain in the forefoot in the preceding year and those who will visit their GP during the recruitment period with a similar complaint will be recruited for this study. Participants must be able to walk unaided for 7 metres and be able to fill in questionnaires. Exclusion criteria are: rheumatoid arthritis, neuropathy of the foot or pain caused by skin problems (e.g. warts, eczema). Inclusion and exclusion criteria will be assessed by a screening questionnaire and baseline assessment. Those consenting to participation will be randomly assigned to either a group receiving a standardised shoe advice leaflet (n=100) or a group receiving podiatric treatment (n=100). Primary outcomes will be the severity of forefoot pain (0-10 on a numerical rating scale) and foot function (Foot Function 5-pts Index and Manchester Foot Pain and Disability Index). Treatment adherence, social participation and quality of life will be the secondary outcomes. All outcomes will be obtained through self-administered questionnaires at the start of the study and after 3, 6, 9 and 12 months. Data will be analysed according to the “intention-to-treat” principle using multilevel level analysis.

Discussion: Strength of this study is the comparison between two common primary care treatments for forefoot problems, ensuring a high external validity of this trial.

The trial registration number with the ‘Nederlands Trial Register’ (NTR) is 2212.
The primary cause of non-traumatic forefoot problems can be very diverse and includes the possible influence of ill-fitting shoes. Some evidence exists that ill-fitting footwear is associated with foot problems such as corns, calluses, hallux valgus and lesser toe deformities. Both the advice to buy well-fitting shoes and referral to a podiatrist are common treatment modalities of Dutch GPs. Whether these treatments actually lead to improvement of non-traumatic forefoot problems is not known, nor is it known if one treatment is more effective than the other.

The aim of this article is to describe the protocol of a pragmatic randomised clinical trial to compare the effectiveness of two common treatments for forefoot problems in older people and to discuss (or comment on) the choices made in the design. The primary objective of the trial is to investigate the effectiveness of podiatric treatment versus standardised shoe advice in people aged 50 years and older with disabling forefoot pain. The secondary objective is to conduct a process evaluation of the podiatric treatment provided for forefoot pain in this trial.

**METHOD**

**Trial design**

This study is designed as a pragmatic open randomised clinical trial with 12 months follow-up. Participants will be recruited via general practice clinics (Figure 1); those who are eligible and give written consent to participation will be randomly assigned to either the intervention group or the control group. The Medical Ethics Committee of the VU University Medical Centre in Amsterdam has approved the design of this study (No. 2009/267).

**Participants**

General practice clinics affiliated with the Academic Network for GPs of the VU University Medical Centre in Amsterdam will partake in this study. Recruitment of participants will be from patients who have visited their GP with non-traumatic pain in the forefoot in the preceding year and those who will visit their GP during the recruitment period with a similar complaint. Participants, aged 50 or over, will have non-traumatic pain.

![Figure 1: Design of the RCT](image-url)
around the MTP-joints (Figure 2) or further distally of at least one month’s duration. The pain will be due to a musculoskeletal forefoot problem and the participants indicate to be functionally disabled because of this ailment. Participants will be excluded if they have received treatment for this problem in the previous six months or if the pain is caused by rheumatoid arthritis, a recent trauma, an operation, or by a non musculoskeletal problem (e.g. warts or a fungal infection of the foot). Additionally, patients with diabetic neuropathy of the feet or with foot problems that are deemed to be too serious by either the GP or by the study team to be treated in primary care will be excluded. Patients with rheumatoid arthritis or diabetic neuropathy are excluded from this trial because Dutch medical guidelines indicate that these patients should be referred for podiatric care in all cases. Participants who are not able to walk 7 meters without a walking aid are also excluded, as they will not be able to perform the foot pressure measurements.

Inclusion procedure
Potential participants will be recruited by three different methods. First, in all participating practices a retrospective search of the medical records will be carried out to identify all people aged 50 and over who have consulted their GP for a forefoot problem in the year preceding the start of the study. Second, all older people who consult their GP for forefoot problems during a period of 12 months following the start of the study will be considered for participation (prospective recruitment). Finally, all people visiting the general practice (for any reason) will be informed about the study by putting up posters in the waiting area of the GP clinics inviting patients to contact their GP if they have forefoot pain.

All potentially eligible patients will be invited to participate in the study and will receive comprehensive information about the study, a screening questionnaire and a pre-paid envelope to return the consent form and the questionnaire. Non-responders will receive a reminder after 2 weeks.

In addition to the assessment by the GP, inclusion and exclusion criteria will be assessed using self-report information from the screening questionnaire. Forefoot pain intensity is scored using a 0–10 point numerical rating scale and the location of pain is indicated on a foot manikin. The area that will lead to inclusion in the study is shown in Figure 2. Foot disability is assessed by the Foot Pain and Disability Index (FPDI).

All patients who are potentially eligible for the study based on the screening questionnaire will be invited for a foot examination details of which will be discussed below (see Foot examination). The purpose of the foot examination is to measure baseline foot and pressure characteristics and to assess eligibility to participate in the trial. If the foot problem of the patient is considered to be too severe, and neither podiatric treatment nor shoe advice is considered adequate treatment, or if there are signs of any of the exclusion criteria like diabetic neuropathy, the patient will be referred back to their GP. If patients meet all eligibility criteria, written consent to participation in the trial will be obtained and a unique study number will be allocated to the participant.

**Figure 2** Foot manikin screenings questionnaire. "I" is the inclusion area.

Foot examination
A foot examination will be performed at baseline before randomisation to assess eligibility. Additionally, 25 participants from the podiatry group will be asked to attend a second foot examination after three months to
enable the process evaluation (see process evaluation of podiatric treatment). The presence of diabetic neuropathy in the forefoot will be ruled out based on tests using a 10 gram Weinstein monofilament and a 64 Hz tuning-fork. With the participant having his or her eyes closed, the skin on the plantar skin of the hallux and the MTP joints of I and V will be touched with the monofilament, and two out of three touches must be perceived. The vibrating tuning-fork is placed on the medial side of MTP1 and on the lateral side of MTP5; the vibration must be perceived for more than 5 seconds. Digital photographs of the ventral, lateral and medial side of the foot and shoes will be taken on a surface containing measurement lines in centimetres. Participants will be asked to bring the shoes they wear most often for this assessment and for the pressure measurements. Next, the Foot Posture Index will be assessed and scored according to Redmond et al. To assess pressure distribution patterns during barefoot and shod gait Emed-X (Novel gmbh, München, Germany) and Pedar-X (Novel gmbh, München, Germany) will be used. The Emed platform (4 sensors per cm², sample frequency 100 Hz) is imbedded in a polyethylene walkway. A two-step protocol will be used for the barefoot pressure measurements, and each foot will be measured 3 times. Each participant will be asked to walk at their preferred speed and with their preferred step length, in other words “as normally as possible”. Everyone will have at least two practice runs per foot before the actual measurements are made. Participants are asked to look straight ahead to prevent targeting; if targeting is suspected, the measurement will be discarded and a new run will be executed. For the in-shoe pressure measurements an adequate size sensor-insole will be placed in the shoe (99 sensors/insole, 100Hz). Participants will be asked to walk back and forth until twelve steps per foot are obtained. First steps, final steps and steps while turning will be excluded from the measurements.

**Podiatric treatment**

The participants (n =100; see Sample size) in the intervention group will be referred to a podiatrist to receive usual podiatric care. The treatment may consist of shoe advice, a silicone toe orthotic or corrective orthotics by means of an insole. Podiatrists are asked to follow the treatment protocol recommended by podiatric department of Fontys University of Applied Sciences. Each participant will be advised to contact the podiatrist if there are any problems with the treatment and an appointment will be made with each participant to examine progress and response to treatment after six to eight weeks. If needed, the treatment will be adjusted. The podiatrist will register details regarding the assessment of the forefoot problem, the diagnosis and treatment decisions on a standardised form.

**Control condition**

Participants (n=100; see Sample size) in the control group will receive a leaflet with shoe advice. The leaflet has been developed in cooperation with the GPs of the Academic Network of the VU University medical centre, the podiatric school of Fontys University of Applied Sciences and 8 podiatrists in the region. Shoe advice is part of the lifestyle advice that is frequently given by GPs to patients with foot problems. Discussions with GPs prior to the trial indicated that this reflects a common minimal and first treatment option; general advice is given to wear well-fitting shoes of good quality and sometimes the patient's shoes are checked and commented on. Some GPs give more specific advice to adapt the shoe or to buy custom made shoe inlays or orthoses. In order to reflect usual care while ensuring optimal contrast between the two treatment groups, we will ask the GPs to refrain from specific individual advice. The participants will be advised to compare their shoes with recommended shoe wear presented in the leaflet and to purchase better fitting shoes if their shoes are not compatible with these recommendations. A reimbursement of € 25,- is given as an encouragement. All patients are invited to contact the research group or their GP for questions regarding the information leaflet. All participating GPs will receive a brief training session on how to provide information based on the leaflet and how to perform a shoe assessment.
Primary and secondary outcome measures
The primary outcome measures will be forefoot pain intensity scored by the participant on an 11-point pain numerical rating scale (PI-NRS, where 0=no pain and 10=worst possible pain), foot function using the 5 point Foot Function Index (FFI-5pts) and foot disability using the FPD1. The FFI-5pts has been translated into Dutch and validated for similar participants as an interview schedule. The FPD1 has been validated for participants with foot problems but was not yet available in Dutch. Within the scope of this trial the FPD1 has been translated into Dutch and will be validated according to methods proposed by Beaton et al. Secondary outcomes include social participation (Keele Assessment of Participation) and Quality of Life (SF-12). Both primary and secondary outcome measures will be collected at baseline and after 3, 6, 9, and 12 months. Data on personal education and work history, shoe history and co-morbidity are collected at baseline as possible effect modifiers or confounders.

Process evaluation of podiatric treatment
Descriptive statistics will be used to describe the extent to which assessment of the forefoot problem and podiatric treatment decisions concur with the protocol, and if deviations (if any) can be explained.

For each patient in the podiatry treatment group, an expert panel of a podiatrist, a lecturer of the podiatry department of Fontys University for Applied Sciences and a human movement scientist will evaluate whether the diagnoses of the podiatrists are in accordance with the results of their assessment, and whether adequate decisions are made regarding treatment. For this evaluation, the notes of the podiatrists and the results of the entrance examination will be made available to the expert panel.

Sample size
There are no evidence-based estimates for clinically important change in assessing forefoot pain or for clinically relevant differences between interventions for chronic foot pain. In a previous study it was estimated that a reduction of approximately two points on an 11-point pain intensity numerical rating scale represents a clinically important improvement. We assume that the improvement in the podiatric treatment group will be one point larger than the improvement in the control group (a mean improvement of approximately 2 versus 1 point on the 0-11 point NRS, with an estimated standard deviation of 2.5). In this design the main question is “whether the podiatric treatment is more effective than the control treatment viz. a standardised shoe advice”. Therefore we will perform a one-sided statistical test with the null hypothesis that podiatric treatment has either an equal outcome or a worse outcome as compared to standardised shoe advice, both outcomes having an equal clinical consequence.

In order to detect a 1 point difference in improvement between the groups after 12 months with a one-sided significance level of 0.05, and assuming a power of 0.8, an ICC between podiatrists and GPs of 0.05, a correlation of 0.50 between repeated measurements and a minimum of 5 patients per care provider, we would need complete data of 75 participants in each study group. We will enrol 2 x 100 patients to allow for a drop-out rate during follow-up of 25%. If every podiatrist will treat a minimum of 5 patients, 15 podiatrists will be needed to deliver the treatment in the entire intervention group.

In 17 practices of the Academic Network, with a total of n=23,231 patients of 50 years or older, the diagnosis “foot problems” (ICPC 17) or free text words indicating foot problems were noted in the GP records of n =497 patients within this age group. This incidence (21/1000) is in accordance with a previous estimate of 17/1000). We expect that about one third of all consulters presenting with foot problems have forefoot problems that meet our criteria, and assuming about 50% of these patients are eligible and willing to participate, a practice with a population of average age distribution can generate a minimum of 5 participants per year. This means that we will need to recruit at least 40 practices to participate in the trial to achieve the required number of patients.
Discussion

In this paper we have described the design of a randomised clinical trial to compare the effects of two common treatments for forefoot pain in older people. During the design of this trial we had to make some decisions which could potentially influence the trial results. In order to explore the effectiveness of podiatric treatment on forefoot problems, it would be optimal to compare the podiatric treatment to a placebo treatment. However, we aim to enrol patients who consult their GP with a need for care of their forefoot problem. Consequently, including a no-treatment arm would not be an option in view of ethical reasons. GPs frequently only provide lifestyle advice for foot problems including the advice to wear well-fitting shoes. By implementing a standardised minimal intervention strategy by means of a shoe leaflet we will reflect usual GP care for forefoot problems and not deny the participants a treatment for their forefoot problem. Participants allocated to this control treatment may be disappointed and we therefore decided to offer partial reimbursement of the costs of new shoes. We expect that this will reduce potential contamination between the control and intervention group and enhance treatment adherence in the control group. We will investigate treatment adherence and contamination in our process evaluation, perform a per protocol analysis as a secondary analysis.

It is conceivable that wearing better fitting shoes has a positive result on both foot function and foot pain. Nevertheless, in this study we are mainly interested to see if referral to podiatric treatment provides a better outcome than merely shoe advice. A problem we cannot resolve is that all subjects will be aware of how they are being treated, either by receiving standardised shoe advice or podiatric treatment. The GPs will be instructed to stimulate adherence to treatment whenever possible. If the foot pain of participants in either group does not respond to treatment after 3 months, the GPs are instructed to proceed with providing an alternative treatment. Possible changes of treatment are thoroughly documented.

Treatment allocation and adherence

After providing informed consent, randomisation will be performed based on an allocation schedule that is generated before the start of the trial by a computerised random number generator using block randomisation with blocks of 8 or 4 with pre-stratification for gender and age (<75, 75). Since the age group 75 is expected to be smaller, a block of 4 has been chosen to increase the likelihood of equal distribution over the control and intervention groups. An independent research assistant will prepare coded sealed envelopes containing the treatment allocation. After baseline measurements the correct allocation envelope is opened by the participant. The foot examiner will be blinded for the random sequence and will not be informed of the block size ensuring concealed allocation of treatment. All GPs will be notified about the participants’ allocated treatment, and will be asked to stimulate adherence to treatment whenever the participant contacts the GP during the intervention period. If symptoms do not improve despite adherence to treatment during the 3 months following randomisation, or with deterioration of the foot problem, the GP is free to provide another treatment or refer the participant for further treatment elsewhere.

Data analysis

Multilevel analysis will be used to estimate the overall effect of podiatric treatment as compared to standardised shoe advice on the three primary outcome measures (PI-NTR, FFI-5pt and FPDI). Both clustering due to participants being treated by podiatrists and clustering due to repeated measurements within the same individuals will be taken into account. Results will be adjusted for differences in baseline similarity, if these occur. The effect of interest is the treatment x time interaction where the primary focus will be on the primary outcome measures at 3 and 12 months’ follow-up. Differences in secondary outcome will be estimated using similar statistical methods. All data will be analysed using an intention-to-treat approach. In all cases, a significance level of 5% is pre-stipulated.
Furthermore, although the podiatrists will be requested to adhere to treatment protocol, it is evident that podiatric treatment will be carried out by different therapists. In this design a maximum of 5 or 6 patients will be treated by a single podiatrist. This reduces the possible influence of a therapist effect on the outcome of the study, although the GPs would then need to refer to more podiatrists than they normally do. A multilevel analysis method will be used to estimate the ‘therapist effect’ (variation in treatment effect due to differences in podiatrists). Forefoot problems are very heterogeneous, and the various problems may respond differently to treatment. Although this will be analysed, the study sample will prove too small to provide conclusive evidence on any subgroup effects.

The strength of this study is that we created the design for a pragmatic trial which will compare two treatments that are most often advised by GPs: the advice to wear well-fitting shoes and podiatric treatment. Therefore, the results will contribute to clinical decision making by primary care professionals in patients with forefoot problems and it will provide information on the potential benefits of a referral for podiatric care.

COMPETING INTERESTS
The author(s) declare that they have no competing interests.

AUTHORS’ CONTRIBUTION
BvdZ will be responsible for data-collection and wrote, together with PE, the manuscript. DK has carried out the power analysis and helped to write the statistical paragraph. PE, KG, LP, DvdW and HH developed the original concept of the study and commented on the manuscript. The study design was further developed by BvdZ, PE, KG, LP, DvdW and HH. All authors have read and approved the final manuscript.

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Treatments of forefoot problems in older people; a randomised clinical trial comparing podiatric treatment to standardised shoe advice

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ABSTRACT

Purpose: Consultations for forefoot pain are frequent in primary care but scientific underpinning of treatment options is scarce. The purpose of this study is to investigate the effect of podiatric treatment versus standardised advice on proper shoe characteristics and fit of shoes in people aged 50 years and older with hindering forefoot pain in primary care.

Methods: In this RCT 205 participants aged 50 and over with hindering non-traumatic forefoot pain have been recruited at their general practitioner (GP) office. Exclusion criteria: treatment of forefoot problem less than 6 months prior to inclusion, rheumatoid arthritis, a diabetic neuropathy or having pain considered to be non-musculoskeletal (e.g. warts). Participants received shoe advice by means of an information leaflet or podiatric care. Foot pain, foot related (dys)function, general health and social participation were assessed by means of questionnaires. Results were analysed using multi-level analysis with levels: (i) outcome measures, (ii) individual, (iii) GP.

Results: No differences were found between the two treatment groups. Both intervention groups showed an improvement over time in foot pain and foot related dysfunction.

Conclusion: This study showed that providing shoe advice to people consulting their GP for forefoot pain is just as effective as referring them to a podiatrist. Based on these results primary care providers should be reserved in referring to a podiatrist and should start by providing advice on proper characteristics and fit of shoes.

INTRODUCTION

Having foot pain is a common occurrence and increases with age. Epidemiologic research found a prevalence of 22-25% in the adult general population\(^1,2\). Per every 10,000 registered patients in the Netherlands and the UK a GP will have an average of 249-290 consultations a year in which foot and ankle problems are presented, most of which are non-traumatic\(^1,3\). This comprises 8% of all musculoskeletal\(^1\) or 17.6% of all lower extremity consultations\(^3\). Patients in the Netherlands and the UK who seek medical attention for foot pain primarily visit their general practitioner (GP).

Women have foot pain more often than men\(^2\) and consult their GP for it more often\(^1\). The location where most foot pain occurs is the forefoot\(^4,5\). More specifically, 53.7% of foot pain is located in the toes (including ingrown toenails)\(^6\), 32.5-37.2% on the dorsal side of the forefoot\(^6,7\) and 24.3-37.2% on the plantar side or the ball of foot\(^7\). Metatarsalgia, hallux valgus, hallux limitus and lesser toe deformities are some of the diagnoses related to forefoot pain\(^4,8,9\). Foot pain in general has been associated with an increased risk of falling and therefore fractures\(^10,11\), a decrease in mobility\(^4,12\) and decreased sense of well-being\(^5,13-15\).

In the Netherlands the GP will most often prescribe anti-inflammatory medication for people with foot pain\(^16\). Other possibilities are referral to (para)medical specialist (e.g. podiatrist, chiropodist, orthopaedic surgeon) or to provide lifestyle advice (e.g. wear better shoes, loose weight). Currently, only a reduction of pain intensity after surgical treatment of painful hallux valgus has been scientifically established\(^17\). However, none of the other alternatives of managing (fore)foot pain have ever been evaluated. The most common choice for the GP is referral to a podiatrist and providing shoe advice is a simple and low cost form of treatment. Wearing improper shoes is assumed to have a negative influence foot problems even though a causal relationships has not been studied\(^18-21\). The purpose of this study is to investigate the effect of podiatric treatment versus standardised shoe advice on foot pain, foot disability, quality of life and social participation in people aged 50 years and older with hindering forefoot pain in primary care.
METHODS

Trial design
The design of this study was published in detail elsewhere\(^2\). In short, we performed a pragmatic RCT in the setting of general practices in which referral of patients with forefoot problems to a podiatrist was compared to a standardised advice to wear shoes of good quality and fit by means of a shoe advice leaflet over a follow up period of one year. The medical ethical committee of the VU medical centre has approved the study (2009/267).

Participants
Twenty-four GP practices comprising of approximately 79,000 patients participated in the study. Prospective participants were invited to participate by either their GP during a consultation, by a letter if a search in the electronical medical information system had indicated that the patient had consulted the GP for forefoot pain in a 12 month period before March 2010 or by posters in the waiting area in the GP offices. The inclusion lasted from March 2010 until April 2012. Inclusion criteria were: age 50 years or older, having non-traumatic forefoot pain >3 months causing a functional impediment and willing to be randomised. Exclusion criteria were: treatment for the forefoot pain less than 6 months prior to inclusion, rheumatoid arthritis, a diabetic neuropathy or having pain that was considered non-musculoskeletal (e.g. warts). People who were interested in the study received a screening form (exclusion criterion questions, pain location on a foot manikin, Manchester Foot Pain and Disability Index). Patients who met the inclusion criteria according to the screening form were invited for an examination prior to final inclusion. The physical examination consisted of: neuropathy screening, photographs of feet and shoes, assessing foot posture, barefoot and in-shoe pressure assessment and footwear assessment.

Interventions
Participants were randomly allocated to either receive shoe advice or to be referred to a podiatrist. The participants referred to a podiatrist received the address and phone number of a podiatrist located near their home. By allocating participants to a specific podiatrist, we were able to refer participants as evenly as possible over the 17 participating podiatrists. Except for one, all podiatrists located near the participating GPs consented to treat patients in our trial.

Those provided with shoe advice acquired a leaflet containing advice on shoe characteristics and proper fit\(^23\). The content of the leaflet was explained to participants by BvdZ, who used their current footwear to illustrate the content.

Outcomes
Participants received a questionnaire at baseline and every 3 months after inclusion until 12 months. Primary outcome measures were foot pain and foot function. Both constructs have been measured with several questionnaires as the measurement properties of these instruments had not been completely established and using multiple outcome measures increases the reliability of the conclusion, provided that the different instruments agree on the changes in outcome. Foot pain was measured using: an 11-point pain intensity numerical rating scale (PI-NRS)\(^24\), the pain subscale of the 5 point Foot Function Index (FFI-5pt)\(^25\) and the pain subscale of the Manchester Foot pain and Disability Index (MFPDI)\(^26\). Foot (dys)function was measured using the foot dysfunction subscale of the FFI-5pt and the function subscale of the MFPDI\(^26\). The seven item FFI-5pt pain scale is rated as “no pain” to “intense pain” and the 8 item dysfunction scale as “no difficulty” to “impossible” both in 5 level increments. The MFPDI is scored as “none of the time”, “on some days” and “on most/every day(s)". Secondary outcomes were general health measured with the Short Form health survey (SF-12)\(^27\) and social participation measured with the Keele Assessment of Participation (KAP)\(^28\). Adherence was also assessed in every questionnaire. If the podiatric treatment (orthotics or other) were worn >3 days a week at ≥2 time points, participants were considered to be adherent. Participants in the shoe advice group were considered to be adherent if they indicated that they had bought new shoes using the folder or had selected to wear worn shoes.
that were -in the opinion of the participant- (more) consistent with the leaflet during the first six months after inclusion.

**Sample Size**

Data analysis was performed blinded. First all participants were analysed in the original group whether or not they received the allocated treatment (intention to treat principle). We tested for normality using visual evaluation Q-Q plots and skewness. A distribution skewed less than 1.0 was considered a normal distribution. Baseline values for both study groups were compared using a T-test for independent measures (p<0.05). Data was analysed with multilevel analyses using MLwiN. Fixed effects were time (baseline, 3, 6, 9 and 12 months) and the group (shoe advice, podiatrist) × time interaction. The group × time interaction is the effect of interest\(^\text{30}\). Level one were the different outcome measures, level two the individuals and the general practitioners were the highest level in the model. A random intercept was assumed for the level-3 (between GP) variances, and an unstructured covariance matrix was assumed for the repeated measurements of patients at the different time points. Subsequently, the same analysis was repeated after exclusion of all non-adherent participants using the definitions as previously described (per protocol analysis).

**Randomisation**

Gender and age were pre-stratified during randomisation: \(<\geq 75\) years of age: 8 per stratum, \(\geq 75\) years of age: 4 per stratum. Sequence was generated with random allocation software. Participants received a sequenced allocation envelope after the physical examination.

**Statistical methods**

Data analysis was performed blinded. First all participants were analysed in the original group whether or not they received the allocated treatment (intention to treat principle). Tested for normality using visual evaluation Q-Q plots and skewness \(<1.0\) is considered a normal distribution. Baseline values for both study groups were compared using a Chi squared test (p<0.05). Data was analysed with multilevel analyses using MLwiN. Fixed effects were time (baseline, 3, 6, 9 and 12 months) and the group (shoe advice, podiatrist) × time interaction. The group × time interaction is the effect of interest\(^\text{30}\). Level one were the different outcome measures, level two the individuals and the general practitioners were the highest level in the model. A random intercept was assumed for the level-3 (between GP) variances and an unstructured covariance matrix was assumed for the repeated measurements of patients at the different time points. Subsequently, the same analysis was repeated after exclusion of all non-adherent participants using the definitions as previously described (per protocol analysis).

**RESULTS**

**Participants**

Of the 286 individuals who declared to be interested in the study n=213 were invited for the screening examination (figure 1). A total of 205 participants were included in the trial; 103 in the shoe advice group and 102 in the podiatry group. Recruitment ceased when the desired sample size of a 100 participants per group was attained. The participants’ characteristics at baseline are reported in table 1 and the locations of the foot pain at baseline are depicted in figure 2. The outcome measures’ baseline scores for the entire population and the subgroups separately are reported in table 2. The means of both groups were tested for all outcome measures and none were found to differ statistically significant.
Patient characteristics at baseline for the whole population and divided over the intervention groups. No significant differences found between the shoe and podiatry group using a Chi squared test.
As for treatment adherence, 64 participants adhered to the podiatric care and 71 participants to the footwear advice. In the per-protocol analysis, no differences were observed between the two intervention groups (Table 2).

We found no differences between the study groups (Table 2). Both intervention groups decreased significantly in foot-related pain and foot-related dysfunction over the course of a year (Table 3). Foot pain measured using the PI-PI-NRS, FFI-5pt, and MFPDI decreased with approximately 20% (p<0.001) after 3 months and roughly 35% after 12 months. Both general health and social participation did not change.

Treatment adherence and per-protocol analysis.

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### Table 2: Intention to treat analyses

<table>
<thead>
<tr>
<th>Foot pain</th>
<th>3 months Difference (p-value)</th>
<th>6 months Difference (p-value)</th>
<th>9 months Difference (p-value)</th>
<th>12 months Difference (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS (0-10)</td>
<td>0.32 (0.37)</td>
<td>0.42 (0.24)</td>
<td>-0.04 (0.91)</td>
<td>0.49 (0.26)</td>
</tr>
<tr>
<td>FFI-5pts (0-100)</td>
<td>0.20 (0.76)</td>
<td>-0.31 (0.67)</td>
<td>-0.28 (0.72)</td>
<td>-0.04 (0.96)</td>
</tr>
<tr>
<td>MFPDI (0-10)</td>
<td>0.06 (0.86)</td>
<td>-0.04 (0.90)</td>
<td>-0.14 (0.69)</td>
<td>-0.05 (0.89)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Foot function</th>
<th>3 months Difference (p-value)</th>
<th>6 months Difference (p-value)</th>
<th>9 months Difference (p-value)</th>
<th>12 months Difference (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFI-5pts (0-100)</td>
<td>0.05 (0.94)</td>
<td>-0.01 (0.99)</td>
<td>-0.14 (0.63)</td>
<td>0.22 (0.75)</td>
</tr>
<tr>
<td>MFPDI (0-18)</td>
<td>0.65 (0.18)</td>
<td>0.17 (0.73)</td>
<td>0.18 (0.73)</td>
<td>0.36 (0.45)</td>
</tr>
</tbody>
</table>

### Table 2: Per-Protocol analyses

<table>
<thead>
<tr>
<th>Foot pain</th>
<th>3 months Difference (p-value)</th>
<th>6 months Difference (p-value)</th>
<th>9 months Difference (p-value)</th>
<th>12 months Difference (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS (0-10)</td>
<td>-0.32 (0.37)</td>
<td>0.65 (0.07)</td>
<td>0.23 (0.54)</td>
<td>-0.58 (0.14)</td>
</tr>
<tr>
<td>FFI-5pts (0-100)</td>
<td>0.20 (0.76)</td>
<td>-0.31 (0.67)</td>
<td>-0.28 (0.72)</td>
<td>0.04 (0.96)</td>
</tr>
<tr>
<td>MFPDI (0-10)</td>
<td>-0.35 (0.40)</td>
<td>0.25 (0.53)</td>
<td>0.23 (0.61)</td>
<td>-0.01 (0.98)</td>
</tr>
</tbody>
</table>

### Foot function

<table>
<thead>
<tr>
<th>Foot function</th>
<th>3 months Difference (p-value)</th>
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<th>9 months Difference (p-value)</th>
<th>12 months Difference (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFI-5pts (0-100)</td>
<td>0.09 (0.91)</td>
<td>0.37 (0.67)</td>
<td>0.39 (0.68)</td>
<td>-0.47 (0.58)</td>
</tr>
<tr>
<td>MFPDI (0-18)</td>
<td>-0.04 (0.95)</td>
<td>0.28 (0.64)</td>
<td>0.29 (0.65)</td>
<td>-0.19 (0.78)</td>
</tr>
</tbody>
</table>

The differences are calculated as: effect podiatric treatment minus effect footwear advice. A positive difference signifies a larger effect of the podiatric treatment; a negative difference signifies a larger effect of the footwear advice.
The purpose of this study was to compare the effectiveness of podiatric treatment to standardised shoe advice in people aged 50 years and older with pain related forefoot dysfunction in primary care. No differences in outcomes were found between participants who received shoe advice and those who were treated by a podiatrist. This means that in this study referral to a podiatrist was not superior to the provision of shoe advice. Both treatment groups improved over time; a clinically important change (>30%) of the PI-PI-NRS at 24, 31 after three and twelve months. Several explanations are to be considered. The first explanation is that both treatments have a similar positive effect. Another possibility is the occurrence of regression towards the mean. Due to pragmatic arguments this study lacked a control group receiving no treatment at all. Therefore, we cannot exclude that the improvement can be explained by regression towards the mean. The level of forefoot pain (29.4 pts) and dysfunction (24.3 pts) measured with the FFI-5pt in our trial was higher than that measured in a cross-sectional study in the Netherlands (respectively 21.4 pts and 13.1 pts). Another possible explanation is that the improvement in both groups is due to spontaneous improvement. A longitudinal study in which the presence of musculoskeletal pain is evaluated with a year follow-up showed that 23% had pain at least one more point during the follow-up. Around 40% of our participants had pain for more than 2 years prior to inclusion. These findings do not allow us to draw any conclusions on the previous cross sectional study in women aged 50 or older, we have shown that the fact that the effectiveness of the shoe leaflet was tested in a different population, and did not bear on foot pain and better fitting shoes reduces forefoot pain and its related dysfunction. However, we are aware of the fact that the effectiveness of the shoe leaflet was tested in a different population, and did not bear on foot pain.

### Table 3 Results Intention to treat and Per protocol analyses

<table>
<thead>
<tr>
<th>Baseline</th>
<th>3 months</th>
<th>6 months</th>
<th>9 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot Pain</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI) % difference*</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI) % difference*</td>
</tr>
<tr>
<td>NRS</td>
<td>4.6 (1.4-8)</td>
<td>2.9 (2.9-4.7)**</td>
<td>-30.4%</td>
<td>-34.6%</td>
</tr>
<tr>
<td>(0-10)</td>
<td>29.3 (21.0-25.9)**</td>
<td>-32.5%</td>
<td></td>
<td></td>
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<tr>
<td>FFI-Spts</td>
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<td>MFPDI</td>
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<td>-29.9%</td>
<td></td>
</tr>
<tr>
<td>(0-10)</td>
<td>3.5 (2.9-4.3)**</td>
<td>-29.9%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Foot function (a lower score is better functioning)

<table>
<thead>
<tr>
<th>Baseline</th>
<th>3 months</th>
<th>6 months</th>
<th>9 months</th>
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<tbody>
<tr>
<td>Foot Pain</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI) % difference*</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI) % difference*</td>
</tr>
<tr>
<td>NRS</td>
<td>4.1 (1.4-8)</td>
<td>2.9 (2.9-4.7)**</td>
<td>-30.4%</td>
<td>-34.6%</td>
</tr>
<tr>
<td>(0-10)</td>
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</table>
In light of our results we would advise, with some reservation, a GP to provide shoe advice to a patient with forefoot pain before referring to a podiatrist. Our study results also suggest that a podiatrist possibly should provide a patient with a choice of shoe advice instead of manufacturing an orthotic and thus provide a patient a choice between different levels of expense. When a patient is unwilling to accept shoe advice as a therapy, referral to the podiatrist is an alternative that is as effective as a shoe advice, but more expensive.

ACKNOWLEDGEMENTS
This study is funded by the Netherlands Organisation for Health Research and Development (ZonMw; dossier number: 42011003). We would like to thank all our participants for their time and willingness to fill out the questionnaires. And we would like to thank dr. Thielke for providing us with additional information about his interesting longitudinal study.

COMPETING INTERESTS
The authors declare that they have no competing interests.

REFERENCE LIST
(5) Menz HB, Tiedemann A, Kwan MMS, Plumb K, Lord SR. Foot pain in community-dwelling older people: an evaluation of the
FOREFOOT PROBLEMS IN OLDER ADULTS


Process evaluation of podiatric treatment of patients with forefoot pain

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Petra JM Elders

ABSTRACT

Background: Foot pain is a common problem for people aged 50 and over and occurs more often in woman than in men. About 60% of the foot problems are forefoot problems and slightly more than half of these patients seek medical help, mainly in the form of podiatric care. Podiatric treatment of forefoot problems is known to be heterogeneous. The aims of the present study are to describe the podiatric treatment of patients with forefoot pain and to evaluate the podiatric examination and treatment using an expert panel.

Method: We invited twenty-five randomly selected subjects with forefoot problems who had received podiatric treatment in a pragmatic randomised clinical trial to participate in an analysis of their treatment by an expert panel. The panel retrospectively established the cause of the foot problem as well as the therapeutic goals and evaluated the treatment. These findings were compared to those reported by the treating podiatrist.

Results: Two fundamentally different approaches were found in approach of podiatric examination; a functional approach (n=13) and a non-functional approach (n=12). In five other cases the expert panel agreed with the cause recorded by the podiatrist. In five other cases the expert panel concluded that the treatment of the podiatrist was not consistent with the cause of the problem recorded by the podiatrist. Of the 10 patients for whom the podiatrist had recorded to have given shoe advice, only two were able to recollect the proper advice. Three patients did not remember receiving advice at all.

Conclusion: In this study almost half of the podiatrists worked according to a non-functional approach where the other half (like the expert panel) chose a functional strategy that analyses the underlying problem. Fundamental differences in treatment plans and thus heterogeneous treatments could be a consequence.

BACKGROUND

Foot pain and subsequent functional limitations are common in aging people. Prevalence figures between 15% and 42% have been reported in people over 50\(^1\)\(^-\)\(^6\). Foot pain occurs more often in women than in men\(^1\)\(^-\)\(^2\) and the forefoot is affected more often than any other part of the foot\(^1\)\(^-\)\(^7\). In some cases foot pain is known to lead to decreased mobility\(^2\)\(^,\)\(^5\)\(^-\)\(^10\), increased risk of falling\(^6\)\(^-\)\(^11\) and a lower experience of well-being\(^2\)\(^,\)\(^8\).

According to a Dutch survey, 56% of people with foot complaints or pain sought medical help, mostly with a podiatrist (46%) or with a general practitioner (GP) (36%)\(^7\). Dutch GPs treat foot problems by prescribing NSAIDs, providing life-style advice (e.g. lose weight, wear other shoes), referring to a paramedical professional or referring to a medical specialist\(^12\). When referred, most patients are referred to a podiatrist\(^12\). Podiatric treatment in the Netherlands may consist of skin and nail care, providing information on footwear or providing an insole or foot orthotics\(^13\).

Podiatric treatment is heterogeneous between different countries because the treatment can be based on theoretical concepts like that of Root et al\(^14\)\(^,\)\(^15\) or the concept of Lavigne et al\(^16\). Both concepts are similar in the approach in which foot pain is related to an anatomical or kinematic impediment and in which treatment is aimed at correcting or reducing the effect of the underlying impediment (i.e. analysing the kinetic chain). The main difference between these concepts is the way the orthotic is fabricated. Besides these possible differences, even within countries in which a same treatment concept is used patients receive different treatments for similar problems\(^12\)\(^,\)\(^17\)\(^-\)\(^19\) and inter-practitioner variability is known to exist\(^19\). Most of the podiatrists in the Netherlands have received their formal education at the Fontys University of Applied Sciences whose curriculum is mainly based on the concept of Lavigne. The heterogeneity of the treatments could partly be due to the lack of reliability of important components that are part of the physical examination\(^19\).

Both the treatment and physical examination are components of the entire treatment process. The procedures and routines of podiatrists and the choices they make during the different stages of diagnosis and treat-
ment are currently unidentified. The aims of the present study are: (i) to describe general podiatric treatment of patients with forefoot pain and (ii) to evaluate the entire treatment process using an expert panel.

**METHOD**

**Participants**
Twenty-five patients who had been treated by a podiatrist for forefoot pain as part of a larger intervention study were randomly selected and invited to participate in this process-analysis of podiatric treatment. These participants had visited their GP with a functional impeding forefoot pain between March 2010 and May 2012 and were randomly allocated to be treated by a podiatrist. The medical ethics committee of the Vrije Universiteit medical centre has approved the study (2009/267).

**Podiatric treatment**
Thirteen podiatrists provided the podiatric treatment. All podiatrists received instructions about the treatment framework (Figure 1). They filled in a standardised form with the aetiology of the foot problem, the aim of their treatment and the content of the delivered treatment immediately after they had completed their treatment. If treatment by means of orthotic devices was chosen the specific elements of the orthotic device was to be recorded by the podiatrist.

**Diagnostic and therapeutic framework**
Evidence on treating forefoot problems is currently lacking. A method was needed for this trial that enabled us to describe the podiatric treatment process in a standardised manner without losing the ability to incorporate individual patient-driven attributes. Together with Fontys University of Applied Sciences a podiatric diagnostic and treatment framework was developed (Figure 1). We asked five podiatrists to use the framework and provide suggestions for improvement. All of them indicated that they could work with the framework and did not have any suggestions for changes.

**Expert panel**
In order to evaluate the entire podiatric treatment process an expert panel was formed. The panel consisted of three experts: two lecturers and an orthopaedic surgeon. Both lecturers are affiliated with the podiatry course of the Fontys University of Applied sciences. The first lecturer is a practising podiatrist and the second lecturer is a human movement specialist in anatomy, biomechanics and gait analysis. We asked the orthopaedic surgeon to state if he would have proposed an operation if he saw the patients in his office. A practising GP was asked alongside the expert panel to provide information regarding the GP perspective on treatment choices.

**Data collection**
As previously stated, the participants in this study were randomly selected from a pragmatic RCT. During the inclusion for this RCT, fouryear podiatry students performed several examinations on all patients as part of their final project supervised by the lead researcher (BvdZ). These
examinations consisted of the following elements: patient-reported area of foot problem on a foot manikin; diabetic neuropathy screening; photographs of the medial, lateral and dorsum of both feet and shoes; the Foot Posture Index; an evaluation of the shoes (function and fit); bare-foot pressure during gait. These examinations were prospectively established to facilitate the process evaluation of the podiatric treatment and were made available to the expert panel together with information about age, gender, weight and height of the subjects, and the completed treatment form by the treating podiatrist.

The expert panel also collected data. One of the lecturers from the expert panel carried out a physical examination of every participant in this trial while the other lecturer was observing. Both performed a visual gait analysis. A ‘thinking out loud’ method was used during all examinations and everything was recorded. Consensus between the members of the expert panel was reached during the examinations. Examinations were repeated if needed to reach a consensus. The number of discussions and re-examinations was scored by evaluating the recordings afterwards.

All participants were interviewed by BvdZ to establish if the situation of the foot pain had been altered since the commencement of the treatment. If changes had occurred, the expert panel attempted to acquire information from the patient about the foot pain preceding the treatment. The expert team used all the collected data to reconstruct the situation comparable to the one prior to podiatric treatment.

Interviews established whether patients remembered and understood the information provided by the podiatrists.

Expert team evaluation procedure
First, the expert panel reviewed the data collected during the inclusion measurements then carried out the interviews and physical examinations. Next, the expert panel evaluated the podiatric treatment reported by the podiatrist. A total of eight sessions were needed to evaluate all patients. The orthopaedic surgeon did not physically attend these sessions but provided his opinion prospectively and retrospectively both in person and via e-mail to one of the lecturers. The same lecturer met with the GP on three occasions.

The evaluation consisted of three elements: first, the possible cause of the foot problem(s) and the corresponding therapeutic goal(s) reported by the podiatrist were evaluated by comparing them to those established by the expert panel (element 1). The probable cause of the foot problem and the subsequent treatment goals and therapeutic choices were discussed within the expert panel until consensus was reached. Both the GP as well as the orthopaedic surgeon added information about the treatment choices they would make when treating the patient. Secondly, the expert panel evaluated the therapeutic consistency of the podiatrist using the diagnostic and therapeutic framework (figure 1) until consensus was reached (element 2). The third and last element consisted of using the information derived from the interviews. The recollection and comprehension of information by the patient was compared to the provided information as reported by the podiatrist (element 3).

RESULTS
Study population
We contacted thirty-eight randomly selected participants who had been seen by the podiatrist. Thirteen patients declined to participate in this part of the study. This was due to health related causes in four cases; nine patients could not come on the days of the examination or were too busy in that period. Finally, twenty-five participants aged 66 years (SD 9.1) were examined by the expert panel. Examinations took place on average three months (SD 2.4) after the first visit to the podiatrist. In 56.5% of the cases, symptoms had been experienced for more than two years, while in 21.7%, between one and two years. Patient characteristics are shown in Table 1. The two most affected locations of the foot were the plantar side underneath metatarsophalangeal joint 1 (52%) and 2-5 (48%). Bilateral pain was reported by 61% of the participants.

A total of thirteen podiatrists treated the twenty-five patients. Two podiatrists (five patients) neglected to return the framework form. In these
cases the expert panel tried to derive the cause and therapeutic goal of the podiatrist by analysing the fabricated insole. This was deemed possible because in all these cases an insole-element was used that solely redistributes and divides the plantar pressure underneath the MTP joints. These five patients were excluded for therapeutic consistency (element 2) or information comprehension of the evaluation (element 3).

**TABLE 1** Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Age (years)</th>
<th>Period since treatment (months)</th>
<th>Duration of the symptoms (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>1-3</td>
</tr>
<tr>
<td>Male</td>
<td>69 (4)</td>
<td>3 (2.3)</td>
<td>0</td>
</tr>
<tr>
<td>Female</td>
<td>64 (12)</td>
<td>3 (2.4)</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>65 (9)</td>
<td>3 (2.4)</td>
<td>2</td>
</tr>
</tbody>
</table>

**Expert panel evaluation process**

In seven cases, after the evaluation of the data of the inclusion examination, the members of the expert panel did not agree on the possible cause of the symptoms. All possible causes were recorded and explicitly discussed during the ensuing physical examination using a ‘thinking out loud’ method. This consisted of the following: one lecturer (with the practical podiatrist background) performed the physical examination and expressed findings and conclusions, while the second lecturer was looking on and agreed or disagreed. For every disagreement, the examination was repeated and discussed until consensus was reached. A total of forty-one disagreements were solved in this way; ranging from zero to five per participant. All discrepancies were solved and consensus was reached for every participant.

The orthopaedic surgeon’s primary policy would normally be to have an X-ray made for all patients prior to diagnosis. Based on the photographs (and depending on the expected results of the X-rays) this surgeon would have considered operating in eight patients’ cases. These were mainly cases with Hallux Valgus deviations. The general practitioner evaluated the patients’ diagnoses established by the expert panel and also gave an opinion on the treatment options available for a GP. The array of treatment choices according to the expert panel, but also the GP and orthopaedic surgeon is shown in Table 2.

**Element 1: Cause and therapeutic goals**

Of the twenty-five causes established by the podiatrists, eight were considered to be correct by the expert panel (Table 2). After further analysis of the data it became evident that the approach of reaching a diagnosis differs between podiatrists. We saw two approaches. First we identified the functional approach that was consistent with the approach of the expert panel. This is an approach in which the kinetic chain is evaluated in order to find underlying (kinematic) impediment of the foot problem or when external influences like foot wear are evaluated as a possible cause of the problem. Secondly we identified another approach in which the podiatrist described local symptoms as a diagnosis without evaluating possible impediments beyond the area of the symptoms; a non-functional approach. Examples of these approaches are shown in Box 1. Differences in approach during the analysis of the cause of the foot pain led to establishing different therapeutic goals. A summary of these findings is shown in Figure 2. In twelve of the cases, the expert panel concluded that the podiatrist merely identified non-functional causes.

Wearing shoes a size too small was found to be the sole cause of the forefoot pain in five cases according to the expert panel. In another eight cases the size was evaluated to be part of the cause in addition to an anatomical or functional anomaly. In four of these thirteen cases, podiatrists reported to have found the shoes to be a size too small and thus of influence on the development and continuation of the forefoot pain. In five other cases the podiatrist described the shoes to be too unsupportive (n=3), too old (n=1) and too stiff (n=1). The expert panel agreed with only the latter to be an actual cause of the foot problem. According to the interviews, two podiatrists did not look at the shoes until the insoles were already fabricated.
“When I came back for my insole, she examined the sole to make sure it fitted the shoe well.” (Female 71yr)

**Element 2: Therapeutic consistency**

In the second step of the diagnostic and therapeutic framework (Figure 1), podiatrists were asked to select a therapy based on the probable cause of the symptoms. The expert panel analysed whether the cause of the problem as recorded by the podiatrist was consistent with the chosen therapy. Two podiatrists (five patients) did not fill in the form with therapeutic goals therefore the expert panel could not evaluate the therapeutic consistency of these therapies. In four of the remaining twenty cases, the chosen therapy was not consistent with the stated cause. Sixteen therapies were in-line with the recorded cause of the symptoms, (Table 2) although in five of these sixteen patients the cause recorded by the podiatrist did not correspond with the cause found by the expert panel (Figure 2).

**Element 3: Information comprehension**

The expert panel evaluated if information provided by the podiatrist was comprehended by the participants who were treated, on average, 3 months prior to the interview (Table 1). Twelve podiatrists reported that they provided shoe advice to the patients as they deemed inadequate shoes to be part of the cause of the problem. Two of these patients stated that they did not remember receiving any shoe advice, while five remembered only parts of the advice or interpreted the advice incorrectly. Only five patients were able to reproduce the entire advice (Table 2).

“I received a piece of paper which contained all sorts of information. She told me that I had to wear other shoes and if I were to buy shoes I should get shoes with laces and not to buy loafers.” (Man 72yrs; remembers the entire advice)

“A bit higher heel was better than no heel at all, he told me, and it should be a bit close-fitting and supporting, that’s what I remember.” (Female 56yrs; remembers part of the advice)

**EXAMPLE 1**

**Patient 16: Female (age 64)**

**Pain** (≥ 24 months) under MTP 1, 2& 3.

**FUNCTIONAL APPROACH**

Aetiology:
Elevated pressure under MTP 1, 2 & 3.
Functional hallux limitus due to the calcaneovalgus position, in-toeing during gait.
No external rotation ability in hip joint.

Therapeutic goal:
No correction of valgus position calcaneus; it is probably a compensatory position of the inability in the hip for external rotation. Compensate the functional hallux limitus by providing advice to wear a shoe with a toe rocker and that allows for the in-toeing.

**NON-FUNCTIONAL APPROACH**

Aetiology:
Elevated pressure under MTP 1, 2 & 3 and pes transversus.

Therapeutic goal:
Decrease the pressure underneath metatarsal heads by elevating the pressure under the surrounding area’s. Correct calcaneovalgus position.

**EXAMPLE 1**

**Patient 14: Female (age 61)**

**Pain** (≥ 24 months) under MTP 2& 3.

**FUNCTIONAL APPROACH**

Aetiology:
Elevated pressure under MTP 2 & 3 due to a hallux rigidus and thus limited ROM in MTP 1. As compensation during gait MTP 2 & 3 are used excessive.

Therapeutic goal:
Realign the gait to use MTP 2 & 3 less by providing advise to wear shoes that contain a toe rocker. The toe rocker shoe might influence the gait line by reducing the amount of dorsal flexion needed in the MTP joints and thus advances the rolling over MTP 1 and less over 2&3.

**NON-FUNCTIONAL APPROACH**

Aetiology:
Elevated pressure under MTP 2 & 3. Calcaneovalgus.

Therapeutic goal:
Distribute pressure over bigger area to obtain less peak pressure under MTP 2 and 3 by means of insole with retrocapital support. Correct calcaneovalgus position by means of insole with medial support calcaneus.

**BOX 1** Two examples of the non-functional and functional approach.
“I had a pair of boots which looked quite elegant but were still comfortable, with a high heel, which would also be good, as long as the sole fitted the shoe. I brought my Archer (shoe brand – ed.) with me and this pair of Nike-air shoes. No, those were good, those shoes.” (Female 61yrs; remembers the advice incorrectly)

**FIGURE 2** Overview of different approaches to establish aetiology. TPM = treatment plan missing.

<table>
<thead>
<tr>
<th>ID</th>
<th>Cause</th>
<th>Agreement PT and EP on cause</th>
<th>Chosen therapy: insole elements</th>
<th>Shoe advice regarding</th>
<th>Lifestyle advice</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>TPM (NF)</td>
<td>No</td>
<td>d, e</td>
<td>d</td>
<td>EP</td>
</tr>
<tr>
<td>2</td>
<td>NF</td>
<td>No</td>
<td>a, b</td>
<td>g, (a)</td>
<td>EP*</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>Partial</td>
<td>a, b, c, f</td>
<td>(a)</td>
<td>PT</td>
</tr>
<tr>
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<td>NF</td>
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<td>a, b</td>
<td></td>
<td>EP*</td>
</tr>
<tr>
<td>5</td>
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<td></td>
<td></td>
<td>EP*</td>
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<td></td>
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<td></td>
<td>EP*</td>
</tr>
<tr>
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<td>Ep*</td>
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<td>F</td>
<td>Yes</td>
<td>a, b, c, f</td>
<td></td>
<td>PT, EP</td>
</tr>
</tbody>
</table>

I: NF = Non-Functional strategy, F = Functional strategy, TPM = Treatment Plan Missing: Did not receive a treatment plan from the PT.

II: Dutch orthotic devices are generally custom made insoles using the ‘Lavigne’ method [6]. Elements are divided in: retrocapital support (a); arch support (b); stabilisation of the calcaneus (c); element to raise single or multiple MTP joints (d); rear foot pronator (e); rear foot supinator (f); heel lift (g).

III: Shoes primary cause of foot problem.

IV GP (General Practitioner); OS (orthopaedic surgeon): NSAID’s (a); salicylic (10%) salve (b); night splint (c); shoe advice (d); lifestyle advice (e); referral insole fabrication (f); steroid injection (g); referral orthopaedic surgeon (h); referral neurologist (i); referral back to GP (j); operation (type depending on X-ray) (k)

<table>
<thead>
<tr>
<th>Foot pain at time of EP examination compared to time of inclusion</th>
<th>Information comprehension and collection shoe advice</th>
<th>Chosen therapy(^a) GP</th>
<th>Chosen therapy(^a) OS</th>
<th>Consistency cause and treatment PT according to EP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less pain</td>
<td>TPM</td>
<td>d</td>
<td>c, possibly f</td>
<td>TPM</td>
</tr>
<tr>
<td>More pain</td>
<td>None provided</td>
<td>d</td>
<td>d</td>
<td>Yes</td>
</tr>
<tr>
<td>Unchanged</td>
<td>Partial comprehr.</td>
<td>g, h</td>
<td>c, f</td>
<td>Yes</td>
</tr>
<tr>
<td>Less pain</td>
<td>None provided</td>
<td>f</td>
<td>f, i</td>
<td>Yes</td>
</tr>
<tr>
<td>Unchanged</td>
<td>TPM</td>
<td>g, d, possibly b</td>
<td>f, possibly k</td>
<td>TPM</td>
</tr>
<tr>
<td>Less pain</td>
<td>None provided</td>
<td>f, d, g</td>
<td>j</td>
<td>Yes</td>
</tr>
<tr>
<td>Less pain</td>
<td>None provided</td>
<td>f, d</td>
<td>f</td>
<td>Yes</td>
</tr>
<tr>
<td>Less pain</td>
<td>TPM</td>
<td>f or possibly h</td>
<td>f</td>
<td>TPM</td>
</tr>
<tr>
<td>Less pain</td>
<td>Comprehended</td>
<td>d, h</td>
<td>k</td>
<td>Yes</td>
</tr>
<tr>
<td>More pain</td>
<td>No recollection</td>
<td>f, d, discuss: h</td>
<td>k</td>
<td>No</td>
</tr>
<tr>
<td>Less pain</td>
<td>None provided</td>
<td>f</td>
<td>k</td>
<td>Yes</td>
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<td>t, b</td>
<td>f, possibly k</td>
<td>Yes</td>
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<td>d, if persisting: f</td>
<td></td>
<td></td>
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<td>f, possibly h</td>
<td>k</td>
<td>Yes</td>
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<tr>
<td>More pain</td>
<td>No recollection</td>
<td>g, d, e (dietary)</td>
<td>k, c</td>
<td>No</td>
</tr>
<tr>
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<td>None provided</td>
<td>f (foot), (hip)</td>
<td>X-ray hip and go from there</td>
<td>No</td>
</tr>
<tr>
<td>More pain</td>
<td>Partial comprehr.</td>
<td>t, d</td>
<td>c, f</td>
<td>No</td>
</tr>
<tr>
<td>Less pain</td>
<td>TPM</td>
<td>h</td>
<td>f, possibly l</td>
<td>TPM</td>
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<td>Unchanged</td>
<td>TPM</td>
<td>f</td>
<td>f, possibly k</td>
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<tr>
<td>Less pain</td>
<td>None provided</td>
<td>f</td>
<td>f</td>
<td>Yes</td>
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<td>Unchanged</td>
<td>Partial comprehr.</td>
<td>d, f, (dietary)</td>
<td>f</td>
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<tr>
<td>Less pain</td>
<td>Partial comprehr.</td>
<td>a, g, f</td>
<td>f, possibly k</td>
<td>Yes</td>
</tr>
<tr>
<td>More pain</td>
<td>None provided</td>
<td>f, d</td>
<td>f</td>
<td>Yes</td>
</tr>
<tr>
<td>Less pain</td>
<td>Comprehended</td>
<td>f, possibly g</td>
<td>f</td>
<td>Yes</td>
</tr>
<tr>
<td>Less pain</td>
<td>Comprehended</td>
<td>d, f, possibly g</td>
<td>f</td>
<td>Yes</td>
</tr>
</tbody>
</table>
fined as a search for the underlying (kinetic) cause of a symptom or looking at external factors like footwear. Most scientific research to do with foot related problems is based on a functional approach. This indicates that it is the preferred approach to establish aetiology, even though its validity has neither been studied nor the approach proven to be the best approach in the treatment of forefoot problems.

When different aetiologies are established due to differences in approach it is apparent that the therapeutic goals and treatments may differ. Literature shows that podiatric treatments are heterogeneous and that the effects of the treatments are heterogeneous as well. It is possible that the poor reliability of clinical assessments as well as the different approaches we identified provide an explanation to these reported differences. The difference in the approach to analyse a forefoot problem that has emerged from our study is noteworthy. Even though the sample of twenty-five participants is small, our study showed that almost half of the podiatrists do not adhere to the concepts taught during their training. In future studies it is advisable to allocate or ascertain the chosen approach when reporting findings, but more importantly, prospective research should be carried out to definitively establish which approach is more efficacious in problem reduction.

It has been shown that foot problems like lesser toe deformities and hallux valgus could be related to wearing shoes that are too small or of inadequate quality. A causal relationship however, has never been established. We found that the podiatrist mentioned footwear less often as a possible and/or partial cause of forefoot pain than the expert panel (15 vs. 23). This can once more be partly explained by the differences in approach. It appears that many podiatrists in our study did not look beyond the problem area of the symptoms, as required when evaluating shoes. In only four of the thirteen cases established by the expert panel did the podiatrist report to have found the shoes the patient wore prior to visiting the podiatrist, to be a size too small or lacking in appropriate quality and thus of influence on the development and continuation of the forefoot pain. Therefore most podiatrists in this study manufactured a podiatric

![FIGURE 2 Overview of different approaches to establish aetiology. TPM = treatment plan missing.](image)
insole instead of merely providing shoe advice. Another reason could be that the financial stimulant of manufacturing an insole is bigger than that of merely providing advice. Most Dutch health insurance companies provide a separate reimbursement for the inspection and physical examination of the patient and for the insoles. The fee for the latter is usually higher than for the physical examination and it could be possible that podiatrists prescribe a treatment by means of insoles more often than necessary. Lastly, the influence of the patient should not be underestimated. A patient with the expectation of receiving insoles could influence the podiatrist in providing insoles.

A marked difference in preferred treatment choices within the expert panel is the treatment choice of the orthopaedic surgeon compared to the rest of the panel for patients with a hallux valgus. The other members would mainly treat the hallux valgus conservatively with an orthotic and/or shoe advice, or a night splint. In contrast the orthopaedic surgeon would operate on seven of the twenty-five patients if an X-ray would confirm deviation of the first metatarsal. According to the orthopaedic surgeon in the expert panel, the majority of his patients have already tried most or all conservative treatment possibilities. However, GPs and podiatrists see patients prior to the point that they have tried all options and visit the orthopaedic surgeon. For the orthopaedic surgeon the most important criterion to operate is to reduce the amount of pain or to stop progression of the hallux valgus. The limited number of studies available has shown that in contrast to an operation an insole is incapable of correcting an already existing hallux valgus, however, related symptoms have been shown to decrease when treating with a custom manufactured insole.

According to the expert panel, in four cases the therapy chosen by the podiatrist was not adequate for the cause of the foot problem recorded by the podiatrist. In all of these four cases the reported aetiology on the form was in accordance with a functional approach, but the chosen treatment was symptom driven. Therewith the provided treatment (insole) did not provide the patient with a therapy that was aimed at correction of or compensation for the cause of the foot problem as established by the podiatrist, possibly rendering the treatment less effective. In the interviews, none of these patients indicated improvement of their complaints after the treatment.

The Gorter et al. study on the management of common foot problems by GPs shows that life-style advice (e.g. wear better shoes, lose weight) was provided to patients alongside other treatments. Although there is no evidence that providing such life-style advice will actually help, some evidence shows that people with a higher fat-mass are at higher risk of developing foot problems.

In this study, the podiatrists reported to have provided the patient with shoe advice in ten cases. However, it became apparent from the interviews that not all patients remembered the information correctly (n=5) or even remembered receiving any information at all (n=3). This could be explained in several ways. It could be that the podiatrists don't provide shoe advice as much as they report they do or the patients don't remember receiving advice when it is provided. The latter is a known problem in health care and it is proposed that health care providers should be aware of this problem in order to communicate more effectively. It is also possible that the average time of three months that elapsed between the podiatrist providing the advice and this study is responsible for a diminished information recollection by the patient. Some patients mentioned that they would have preferred to have some form of written advice in addition to the verbal communication. An information leaflet might be a recommendation. We also suggest that the provision of shoe and/or life-style advice should be done in a separate session, in order not to overwhelm patients with information.

Our process evaluation of podiatric treatment has to be interpreted in context of the strengths and limitations of the study. One might consider the focus on forefoot problems a limitation. The results seen in this study should therefore only be applied to patients with similar problems. On the other hand, this restriction to forefoot problems ensures a homoge-
nous population could be viewed as a strength. The diversity in backgrounds of the expert panel is an asset to the study. This way the aetiology and treatment has been analysed from several medical angles. In contrast, the size of the expert panel, small for pragmatic reasons, is a limitation of the study. In light of the striking findings of this study we would recommend a replication of this study with a prospective design. Two members of the expert panel examined the patients and did not base their evaluation merely on the data provided. The method of examination could also be seen as a limiting factor. The members did not examine the patient separately but simultaneously and discussed differences of opinion during the examination. This could have influenced the objectivity of the members. Nonetheless, forty-one discussions were conducted showing that the panel members did state differences in opinion. Another limiting factor is the fact that out of twenty-five participants two podiatrists treating five patients did not return any form (even after two reminders). We deduced the cause found by the podiatrists for these five patients by analysing the elements used in the insole and these findings are less reliable than is desirable. The evaluation of the consistency between recorded cause and executed therapy was impossible for these participants, so that analysis is based on 20 participants. Furthermore, the expert panel was not blinded for the current status of the patients, which could have influenced the evaluation.

This study indicates that the approach to reach a conclusion on aetiology of forefoot pain is heterogeneous amongst podiatrists. It could also explain part of the variability found between podiatric treatments as mentioned in other studies. Half of the podiatrists followed a non-functional approach that was inconsistent with usual treatment concepts and inconsistent with the functional approach of the expert panel. Most insole or foot orthotic related studies follow a functional approach however the superiority of a functional approach over a non-functional approach has not yet been established. It is possible that some but not all foot problems fare well with a non-functional approach. It is advisable that future podiatric effect studies analyse the approach as an additional variable. Third, the orally provided advice could be more effective. We suggest extending the oral advice with a written/photo supplement to enhance understanding and adherence or provide advice in a separate session.

COMPETING INTERESTS
The authors declare that they have no competing interests.

AUTHORS’ CONTRIBUTION
BvdZ was responsible for data-collection and wrote the manuscript, together with PE. WS assisted during data-collection and created the tables and figure 2. HH commented on several drafts of the manuscript. WS, BV and KG commented on the first and last draft of the manuscript. All authors have read and approved the final manuscript.

ACKNOWLEDGEMENTS
This study is funded by the Netherlands Organisation for Health Research and Development (ZonMw: 42011003). We would like to sincerely thank the contributions of Anika van Hout, Gerald Kraan and Lucas Viruly as members of the expert panel for sharing their time and knowledge. And we also want to thank Marja Schrama who assisted with processing the interviews as part of her Bachelor thesis.

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Development and evaluation of a leaflet containing shoe advice: a randomised controlled trial

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Accepted: Family Practise December 2nd
**ABSTRACT**

**Background** Providing advice to wear good quality shoes with appropriate fit is one of the possibilities general practitioners have when treating patients with foot problems. The aims of this study are to (i) determine which shoe characteristics are important when providing shoe advice, (ii) develop a shoe advice leaflet and (iii) evaluate if women choose better shoes with the aid of the leaflet.

**Method** We performed a literature search on the effect of separate shoe characteristics on foot pathologies and kinematics and developed an information leaflet with the aid of multidisciplinary experts. The leaflet was tested in a group of women aged 50 years or over who did not receive podiatric treatment or shoe advice in the year prior to the study. The women were asked to select shoes; half of them were provided with the leaflet. Shoe characteristics were scored blinded for the condition by two podiatrists. Data was analysed using a T-test for independent measures.

**Results** The developed leaflet contains nine shoe characteristics. A total of 57 women ranging from 54 to 86 years old (average 69) consented to participate in testing the efficacy of the leaflet. Women using the leaflet (n=29) selected better shoes than without (p=0.049).

**Conclusion** Based on a literature search and expert opinion, we have developed an information leaflet for GPs to provide as a supplement to oral shoe advice. Women using this leaflet were able to select shoes of better quality and better fit than women selecting shoes without using the leaflet.

**BACKGROUND**

Both podiatrists and doctors assume, that wearing appropriate footwear can prevent or reduce many feet or walking related problems. Poor quality and ill fitting shoes are associated with several foot problems such as foot pain, hallux valgus, corns, plantar calluses, ulceration, and lesser toe deformity. Furthermore inappropriate shoes are associated with a higher risk of falling and thus risk of fractures. However, a large proportion of the elderly is wearing shoes of poor quality or fit. Moreover Burns et al showed that 72% of the elderly in a rehabilitation centre (n=56) were wearing poorly fitting shoes. It is believed that the high prevalence of inappropriate footwear is at least partly explained by little knowledge about footwear. In a survey of 652 people aged 65 years and older 47% felt that their regular shoes were fine, although they were not classified as appropriate. Foot problems are more prevalent in women than men.

The literature about gender differences in the choice of footwear is scarce. One study shows that, on average, women have a bigger discrepancy between shoe and foot length, width and plantar surface than men. Two other studies merely evaluate women’s footwear and foot health. The preponderance of foot-shoe discrepancy in women suggests that shoe related problems in women may be a bigger problem than in men.

For a randomised controlled trial on the treatment of forefoot problems by GPs a low cost and common method was sought as a comparator to referral for podiatric treatment. Providing advice on shoe characteristics and proper fit is a part of the treatment array for common foot problems by general practitioners (GPs). The use of information leaflets, when providing advice or information is common practice for Dutch GPs. Therefore an advice leaflet containing information on beneficial shoe characteristics and proper fit was chosen as intervention. It has been shown that supplementing oral advice with an information leaflet has a positive effect on patients’ education and comprehension. No validated footwear information leaflets are available up to now. Additionally, shoe characteristics and proper fit characteristics are only partially evidence based. It is therefore unclear what the content of an information leaflet should be.

The aims of this study are: (i) to determine which shoe characteristics should be included when providing information about footwear for patients with foot pain, (ii) to develop an information leaflet, (iii) to evaluate if women asked to select shoes with the developed leaflet are able to choose better footwear than women who do not have the leaflet.
METHOD

This study is comprised of two phases. During the first phase we developed a footwear information leaflet. The content was determined by doing a literature search and consulting experts. Subsequently, we tested the developed leaflet in a randomised controlled trial.

Development of the shoe advice leaflet.
The process of determining which shoe characteristics should be included when providing footwear information to patients with foot pain, consisted of several stages and is summarised in Figure 1. In short: we searched the literature for evidence about influences of footwear on feet. Subsequently, we consulted experts to supplement the gaps in consisting evidence. We tested a preliminary version of an advice leaflet and the Dutch association of Podiatrists (‘Nederlandse Vereniging van Podotherapeuten’ or ‘NVVP’) and thirty GPs provided feedback. This resulted in a final version of the leaflet. Intelligibility of the final version was assessed by 90 people with forefoot pain participating in a RCT\textsuperscript{8}.

Trial design
We allocated participants randomly to either the intervention or control group. Both groups were asked to find shoes which were aesthetically to their liking and which each participant considered appropriate for standing and walking for longer periods of time. The intervention group did so with the assistance of the developed shoe information leaflet. Two podiatrists assessed the characteristics and fit of the chosen shoes. The medical ethical committee of the VUmc has approved the trial (addendum to: No. 2009/267).

Participants
Participants were actively recruited in a community centre in Rotterdam by means of invitational posters, word of mouth and in GP practices in Amsterdam by sending invitation letters to women aged 50 years and over. Women with diabetes mellitus or rheumatoid arthritis were excluded. Additional exclusion factors were: recent foot injury or foot surgery and podiatric treatment in the year prior to the study.

Intervention
Researcher BvdZ provided the participants in the intervention group the information leaflet and explained the items in the leaflet. Participants could ask for clarification. Those in the control group did not receive information. All participants were asked to visit a shoe shop and asked to
choose a pair of shoes that you would wear and with which you can walk for a longer period (at least four hours) for several consecutive days." The participants in Rotterdam and Amsterdam could visit respectively three and four predetermined stores in the shopping centre and choose any pair of shoes they deemed appropriate. They brought these shoes to the podiatrists to allow assessment of the shoes.

**Outcome measures**
Concurrent to the development of the advice leaflet we created an assessment form (Appendix 1). Two podiatrists assessed the characteristics of the shoes. We calculated both the total score as the separate sub-scores for functional characteristics and fit characteristics. A higher score reflects better characteristics.

**Sample size**
Since the shoe assessment form was developed for this study, there are no evidence-based estimates for minimal important difference or standard deviation (SD). To obtain estimates of the SD we executed a pilot study with 16 participants with 8 participants per group. The SD was found to be 1.8 for the control group and 1.9 for the intervention group. We set the minimal important difference at 2 points; an improvement of at least one shoe characteristic. With a two-sided significance level of 0.05, and assuming a power of 0.95, a minimum of 52 patients had to be included for this trial; 26 per group.

**Randomisation**
Using random allocation software we generated the randomisation sequence. During the pilot study it was found that participants preferred to shop in pairs even if they did not know the other participant. To ensure no cross contamination would take place, participants were randomly allocated to the control or intervention group in sets of two.

**Blinding**
When assessing the shoes, the podiatrists were blinded for all relevant participant characteristics. Both participants and podiatrists were asked not to communicate about any foot or shoe related issues until after the assessment of the shoe.

**Statistical method**
We checked the data for normality prior to data analysis. Differences in total scores and scores for each category (function and fit) between the two different groups were analysed using T-test for independent measures. We set the confidence interval at 95%. Based on our experience we assumed that it is impossible to find a high heeled shoe (> 6 cm) with proper fit characteristics (length, width and sufficient toe box); i.e. wearing a high-heeled shoe with adequate room in front of and around the toes, one will slide forward off of the heel and during walking the shoe will slip. Therefore we decided to perform a secondary analysis excluding high-heeled shoes, if necessary.

**RESULTS**
**Content of leaflet and assessment form**
We incorporated nine characteristics in the leaflet after different stages (Figure 2). Functional (quality) characteristics were: heel height < 4 cm, adjustable fixation over the instep, high friction outer sole material, stiff heel counter, longitudinal sole rigidity and a sole flexion point under MTP 1. Fit characteristics in the leaflet are: shoe length 1-2 cm bigger than longest toe, graspable upper at the level of the metatarsals and room between the dorsum and the toes and upper (toe box). The fit characteristics should all be evaluated in a standing position. Detailed information on findings in the literature, the opinion of the expert panel, the content of the information leaflet and the content of the assessment form can be found in Appendix 1. The leaflet itself is shown in Appendix 2.

**Participants**
A total of 59 women participated, 34 in Rotterdam (between February and May 2012), and 25 in Amsterdam (between April and May 2013). The mean age of the participants was 69 (range 54-86). The 59 participants
were randomly allocated to the control group (n=29) and the intervention group (n=30). Two participants were unable to find shoes during the trial: one person in the control group (unable to find shoes that were comfortable and pretty) and one person in the intervention group (unable to find shoes she liked in combination with size (EU 42, US 10, UK 7.5)). Both were excluded for further analysis. We excluded two participants (both in the intervention group) who had chosen high-heeled shoes (i.e. > 6 cm) from the secondary analysis.

**Outcome measures**

Using the information leaflet resulted in a significantly better choice of shoes (total score $p=0.05$). The separate subscales (i.e. functional characteristics and fit characteristics) did not change significantly (Table 1). Excluding shoes with high heels (>6cm) from the analysis, led to a significant increase of the total score and the subscale scores in the intervention group (total score $p=0.01$, functional characteristics $p=0.03$, fit characteristics $p=0.04$) (Table 1). The distribution of the (sub-) scores is presented in Figure 3.

**TABLE 1** Results RCT. Regular analysis contains all participants, the secondary analysis excluded high heeled shoes (>6cm).

<table>
<thead>
<tr>
<th></th>
<th>Control group (n=28) Mean (95% CI)</th>
<th>Intervention group (n=29) Mean (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total score</strong></td>
<td>10.2 (9.0-11.5)</td>
<td>11.9 (10.2-13.7)</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Function score</strong></td>
<td>7.3 (6.6-8.1)</td>
<td>8.3 (7.2-9.4)</td>
<td>0.08</td>
</tr>
<tr>
<td><strong>Fit score</strong></td>
<td>2.8 (2.2-3.6)</td>
<td>3.6 (2.6-4.5)</td>
<td>0.11</td>
</tr>
<tr>
<td><strong>Secondary analysis</strong></td>
<td>Control group (n=28) Mean (95% CI)</td>
<td>Intervention group (n=27) Mean (95% CI)</td>
<td></td>
</tr>
<tr>
<td><strong>Total score</strong></td>
<td>10.2 (9.0-11.4)</td>
<td>12.4 (10.7-14.1)</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>Function score</strong></td>
<td>7.3 (6.6-8.1)</td>
<td>8.5 (7.4-9.6)</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Fit score</strong></td>
<td>2.9 (2.2-3.5)</td>
<td>3.9 (3.0-4.8)</td>
<td>0.04</td>
</tr>
</tbody>
</table>
D I S C U S S I O N

Although causality between ill fitting shoes and foot problems has not yet been proven, podiatrists and doctors assume that shoes can have a detrimental effect on foot health and that footwear can be the cause of forefoot problems such as corns, hallux valgus and lesser toe deformities. The aims of this study were to determine which shoe characteristics should be included when providing information about footwear in an information leaflet; to produce such a leaflet and subsequently evaluate if using the developed folder results in a better choice of footwear for women aged 50 years and over.

Based on the available scientific evidence, we could select 4 shoe characteristics. Another 5 items were selected using experts’ opinions. This study shows that women who were motivated to participate in the study were able to choose shoes with more appropriate characteristics when using the leaflet than women who did not receive the leaflet. The study thus implies that the leaflet is efficacious, but its effectiveness in general use is not yet known.

We found that shoes selected with the developed leaflet scored 1.7 points higher in the primary analysis and 2.2 points higher in the secondary analysis compared to the shoes that were selected without a leaflet. A priori we set the minimal important change at 2 points. However whether this effect is clinically relevant on foot pain remains unclear. Additionally, due to the lack of evidence it is unknown which shoe characteristics have the largest influence on the development or reduction of foot pain. As a result, we deemed all characteristics to be equal during the assessment of the appropriateness of the shoes. Future knowledge and understanding of the kinetic and kinematic influences of different characteristics might result in weighted scores. Similarly, during the study we found that the height of the heel is not merely a characteristic in itself. We observed that the fit characteristics chosen to be ‘good’ are incompatible with wearing a high-heeled shoe. The fit around the forefoot was found to be snug in order for the foot not to ‘slide forward off of the heel’. Consequently shoes with a heel >6cm were excluded for a secondary analysis. Our results show that the difference between the intervention group and the control group was larger if only the selected shoes with normal heels were taken into account. This indicates that the height of the heel is not only a separate characteristic of the shoe, but has an important influence on other characteristics as well.

We expect that the leaflet will be primarily used by GPs to advise a patient who consults with foot problems. The main limitation of the study is that we did not specifically include participants with foot problems for

FIGURE 3 Distribution of (sub)scores per condition.
this RCT. It is conceivable that someone with foot pain is differently motivated to find appropriate shoes using the information leaflet or might select different shoes than people without foot problems. Another limitation is that during the development of the leaflet we did not use a complete Delphi method. We carried out a single round with several groups of experts (GPs, podiatrists and the Dutch association of podiatry) without providing them with feedback. And lastly, the participants of this RCT were only women and not men. However the prevalence of foot problems in women is higher than in men. We are unable to calculate the response rate as we do not know how many women were aware of the study and chose not to participate. A strength of the study is that the podiatrists evaluating the footwear were unaware of the status of the participants. In previous studies where shoe characteristics were assessed, the assessors had knowledge of the health status of the participants. Thus far the described leaflet is the only published tool for GPs or other specialists providing advice on footwear. The current knowledge about the relationship between foot problems and characteristics of shoes is rudimentary. Consequently, the advice to be provided to patients with foot pain is not fully based on scientific evidence. The developed information leaflet is shown in this study to improve the choice of shoes according to expert opinion. The content of the leaflet is principally composed of pictures and the text supports the pictures. Furthermore, it is comprised of shoe characteristics and not shoe stores or brands. Thus, it is likely that a translated leaflet may have similar effects outside of the Netherlands. Further research is needed to demonstrate if the recommendations in the leaflet can reduce the occurrence of foot problems. Currently we are studying the effectiveness of the leaflet compared to podiatric treatment in patients with forefoot problems.

DECLARATIONS / ACKNOWLEDGEMENTS - The medical ethical committee of the VUmc has approved the trial (addendum to: No. 2009/267). This study is funded by the Netherlands Organisation for Health Research and Development (ZonMw; dossier number: 42011003). The authors declare that they have no competing interests.

REFERENCE LIST

### Appendix 1

<table>
<thead>
<tr>
<th>Shoe characteristic</th>
<th>Literature</th>
<th>Expert opinion</th>
<th>Leaflet</th>
<th>Assessment form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heel height</td>
<td>Association with presence: hallux valgus and plantar callus (heel height &gt; 2.5 cm) [4]</td>
<td>Plantar calluses due to increased plantar pressure forefoot.</td>
<td>The height of a heel should not exceed the width of two fingers.</td>
<td>(&lt; 4 \text{ cm} = 2 \text{ points} ) (4-6 \text{ cm} = 1 \text{ point} ) (&gt; 6 \text{ cm} = 0 \text{ points} )</td>
</tr>
<tr>
<td></td>
<td>(functional characteristic) A shift of peak pressure to the medial forefoot (7.6 cm versus 3.6 cm) [2]</td>
<td>Ingrown toenails and toe deformities: the foot 'slips' off of the heel into the front of the shoe.</td>
<td>Comment it might be hard for a leaflet user to know what exactly 4 cm is. We thus used the width of two fingers, the average width of an index finger is 1.6 cm (SD 0.17 cm) [8]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increased chance of lateral ankle sprain (&gt; 2 cm) [3]</td>
<td>Decrease the muscle pump function lower leg (&gt; 6 cm) [4]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decrease the muscle pump function lower leg (&gt; 7 cm) [5]</td>
<td>Impair balance (&gt; 4.5 cm) [6]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increase the risk of falling (&gt; 2.5 cm) [7]</td>
<td>Assumption: heel &lt; 4 cm does not alter walking patterns [7]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strapping / Fixation</td>
<td>Observational study: 63% of people with fall related hip fractures wore shoes without fixation at the time of the accident [9]. Unfortunately the percentage of shoes without fixation of non-fallers is unknown.</td>
<td>Expected a relationship between wearing shoes that are considered too small and the absence of an adjustable strap over the instep.</td>
<td>Adjustable fixation over instep like laces, Velcro or clasp</td>
<td>Adjustable fixation over instep like laces, Velcro or clasp = 2 points Adjustable fixation not over instep/ non adjustable fixation = 1 point No fixation = 0 points</td>
</tr>
</tbody>
</table>

#### Heel height

<table>
<thead>
<tr>
<th>Shoe characteristic</th>
<th>Literature</th>
<th>Expert opinion</th>
<th>Leaflet</th>
<th>Assessment form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer sole material</td>
<td>Leather outer soles or soles without a tread pattern have a lower friction coefficient.</td>
<td>Hypothesis: a shoe advice leaflet would be primarily used for older people who have an increased risk of slipping and falling [10].</td>
<td>(\text{Rubber, non slippery, outer sole} = 2 \text{ points} ) (\text{Rubber sole forefoot and heel} = 1 \text{ point} ) (\text{Leather sole} = 0 \text{ points} )</td>
<td></td>
</tr>
<tr>
<td>Heel counter rigidity</td>
<td>A shoe containing a stiff heel counter reduces the stress on the fat pad of the heel [11].</td>
<td>The absence of a stiff heel counter increases instability on uneven terrain and thus the risk of inversion trauma or falling.</td>
<td>The back of the heel cannot be pushed down into the shoe.</td>
<td>(&lt; 45^\circ \text{ flexibility} = 2 \text{ points} ) (&gt; 45^\circ \text{ flexibility} = 0 \text{ points} )</td>
</tr>
<tr>
<td>Sole flexion point</td>
<td>The sole flexion point should be in accordance with the anatomy of the foot: Underneath the metatarsophalangeal joints (MTP joints).</td>
<td>The sole flexes where the toes do too.</td>
<td>Underneath MTP 1 = 2 points Proximal or distal to MTP 1 = 0 points</td>
<td></td>
</tr>
<tr>
<td>Longitudinal sole rigidity</td>
<td>-</td>
<td>The sole is rigid.</td>
<td>Twisting &lt;45° = 2 points Twisting &gt;45° = 0 points</td>
<td></td>
</tr>
</tbody>
</table>
### DEVELOPMENT AND EVALUATION OF A LEAFLET CONTAINING SHOE ADVICE

**Shoe characteristic** | **Literature** | **Expert opinion** | **Leaflet** | **Assessment form**
--- | --- | --- | --- | ---
Length | Association between wearing shoes that are too small and ulcers, foot pain and lesser toe deformities [1,2]. Prevalence’s: 10.2%-88% of size mismatches in which the foot was found to be bigger than the shoe size [1,3,4]. An existing assessment form [5,6] and a Dutch GP book [7] state that a shoe needs to be 1-2 cm bigger than the foot. | A very flexible shoe would increase the activity of the intrinsic and extrinsic foot musculature. Such increased activity could be out of the range of possibilities for older people who possess foot pain or foot related disability. | A shoe should be 1-2 cm bigger than the foot while standing. | Shoe length - foot length: 1-2 cm = 2 points

(1T characteristic)

Width | Association between wearing shoes that are too narrow and the presence of corns on toes, hallux valgus deformity and foot pain [1]. Prevalence’s: 43-81.4% of participants wear shoes that are narrower then the feet [1,2,8] | A shoe should be a thumbs’ width bigger than the longest toe while standing. Hypothesis: it might be hard for a leaflet user to know what exactly 1-2 cm is. We thus used the width of a thumb, the average width of a thumb is 2cm [8] | The upper should be graspable while standing. | Graspable upper = 2 points

(1T characteristic)

**Search terms:** Footwear, shoe, biomechanics foot, gait, falling, footwear assessment, NOT running.

**Databases searched:** Medline and reference lists related articles published until December 2010.

**Study selection:** Due to the limited quantity of related articles we included all publications.

#### REFERENCE LIST

Schoenfolder
Evaluation of the measurement properties of the Manchester Foot Pain and Disability Index.

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Berend Terluin
Henriette E. van der Horst
Petra J.M. Elders

Status: Submitted BMC Musculoskeletal disorders
ABSTRACT

Background: The Manchester Foot Pain and Disability Index (MFPDI, 19 items) was developed to measure functional limitations, pain and appearance for patients with foot pain and is frequently used in both observational studies and randomised controlled trials. A Dutch version of the MFPDI was developed. The aims of this study were to evaluate all the measurement properties for the Dutch version of the MFPDI and to evaluate comparability to the original version.

Method: The MFPDI was translated into Dutch using a forward/backward translation process. The dimensionality was evaluated using exploratory and confirmatory factor analysis. Measurement properties were evaluated per subscale according to the COSMIN taxonomy consisting of: reliability (internal consistency, test-retest reliability and measurement error), validity (structural validity, content validity and cross-cultural validity comparing the Dutch version to the English version) responsiveness and interpretation.

Results: The questionnaire consists of three scales, measuring foot function, foot pain and perception. The reliability of the foot function scale is acceptable (Cronbach’s $\alpha > 0.7$, ICC = 0.7, SEM = 2.2 on 0-18 scale). The construct validity of the function and pain scale was confirmed and only the pain scale contains one item with differential item functioning (DIF). The responsiveness of the function and pain scale is moderate when compared to anchor questions.

Conclusion: Results using the Dutch MFPDI version can be compared to results using the original version. The foot function sub-scale (items 1-9) is a reliable and valid sub-scale. Use of the MFPDI as a longitudinal instrument could be problematic due to moderate responsiveness.

BACKGROUND

Foot pain is common in older people and is associated with functional limitations in foot related activities; prevalences between 14.9 and 41.9% have been reported in people over 50 years old. The Manchester Foot Pain and Disability Index (MFPDI) is a 19 item tool developed to measure foot pain and foot related function in patients with foot pain. It intends to measure 3 constructs: functional limitation, pain and personal appearance. Statements relating to the 3 constructs can be answered in terms of frequencies: ‘none of the time’, ‘on some days’ and ‘on most/every day(s).’ Previous studies have evaluated some of the measurement properties of the questionnaire. Internal consistency (IC) is the most evaluated property although some studies evaluated it over the entire questionnaire instead of over the three constructs (i.e. sub-scales). The studies that did evaluate each sub-scale separately have found the scales to be internal consistent. Test-retest reliability has been analysed by Roddy et al. and found to be moderate for the pain and the appearance scale and both moderate and acceptable for the functional limitations scale depending on the inclusion criterion. Construct validity has been described in previous studies although the amount of hypotheses tested was small in one study and no hypotheses were stated a priori in another. The characteristics of the items in the questionnaire have been thoroughly examined using item response theory testing (IRT). The MFPDI consists of items that allow severe cases to be distinguished from the less severe cases.

The MFPDI is not merely a diagnostic tool (e.g. in cross-sectional studies) but it is also used as a tool to measure change over time as a result of an intervention. When interpreting change scores in a randomised controlled trial (RCT) or another longitudinal study, it is vital to have knowledge about measurement properties like measurement error, responsiveness and interpretation values like minimal important change (MIC) and smallest detectable change (SDC). Currently these properties have not been assessed yet. For the purpose of a Dutch study on forefoot pain in people 50 years of age or older the MFPDI had to be translated into Dutch. The aims of the current study are, firstly, to create a Dutch version of the MFPDI. Secondly, to evaluate all measurement properties based on the Classical Test Theory (CTT), including a cross-cultural validation of the Manchester Foot Pain and Disability Index using the Dutch translated version.
**METHOD**

This study describes a complete evaluation of measurement properties of the MFPDI starting with the translation of the questionnaire into Dutch. The Medical Ethics Committee of the VU University Medical Centre in Amsterdam has approved the design of this study (No. 2009/267).

**Translation**

A forward-backward method of translation was used to obtain a Dutch version of the MFPDI. Two translators; a general practitioner and a physical education teacher, both with additional experience with English, translated the original version into Dutch. During the consensus meeting with the two translators and guided by PE and BvdZ, a consented Dutch version was established. This version was then translated back into English by two native speakers; a UK scientific researcher and a UK physician assistant. Differences between the original and the translated version were discussed by BvdZ and PE and the Dutch version was accordingly adapted. The Dutch version was then tested by 10 participants, who were asked about intelligibility and completeness of the list. Concerns identified regarding intelligibility and completeness were discussed between BvdZ and PE and adapted if required.

**Participants**

As part of an RCT that compares treatment of forefoot pain by means of podiatric care or shoe advice, participants aged 50 years and over with non-traumatic forefoot pain that lead to functional limitations were recruited. Exclusion criteria were: the presence of diabetic neuropathy, non musculoskeletal foot pain (e.g. warts) or pain caused by rheumatoid arthritis. Participants had to be able to walk un-assisted for 7 metres. These participants completed the MFPDI on multiple occasions during the trial as part of self administered questionnaires. The MFPDI was used as a screening tool; participants had to score at least one item on the MFPDI as occurring ‘on most/every day(s)’ to be considered limited functionally and thus eligible for the trial.

**Procedure and outcome measures**

Preceding inclusion the MFPDI was used as a screening tool (NL Ts). One to three weeks later the participants were included in the trial and completed a comprehensive questionnaire with the below mentioned comparator instruments and the MFPDI as a baseline measurement (NL To). Since all participants had at least 3 months of foot pain and were considered to have limited functionality indicating a stable state no additional measures were taken to assess possible changes between baseline and screening. Three months after baseline a similar questionnaire was completed again (NL T3). The lowest response in the MFPDI was marked as 0 and the highest response as 2. The COSMIN taxonomy was utilized to evaluate every measurement property of the MFPDI questionnaire.

As comparator instruments to the MFPDI several other questionnaires were completed: the Foot Function Index-5pt (FFI-5pt), SF12® and an 11 point pain intensity numeric rating scale (NRS where 0 = no pain and 10 = worst possible pain). The FFI-5pt is a questionnaire on foot function, consisting of two subscales: foot pain and foot related activities, consisting of respectively 7 and 8 items. The original FFI is more extensive (23 items), has response options using visual analogue scales (VAS) and was developed for people with rheumatoid arthritis. The FFI-5pt has been validated for use in the elderly with non rheumatic foot problems, has 5 response options (ranging from “no pain” to “intense pain” and from “no difficulty” to “impossible”) and has already been translated into Dutch. In addition to the comparator instruments and the MFPDI, two global perceived effect (GPE) questions on foot pain and foot related disability were added to the NL T3 questionnaire: “How would you judge the pain in your foot now, compared to three months ago?” and “How would you judge the performance of foot related activities now, compared to three months ago?”. These GPE questions could be answered with: “much worse, worse, no change, better or much better”.

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**FOREFOOT PROBLEMS IN OLDER ADULTS**

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**MEASUREMENT PROPERTIES OF THE MANCHESTER FOOT PAIN AND DISABILITY INDEX**

Page 106
UK sample for cross-cultural validation
For the purpose of assessing cross-cultural validity, a sub-sample of data was obtained from two phases of the North Staffordshire Osteoarthritis Project (NorSTOP)^20-22. The sampling frame consisted of all adults aged 50 years and over registered with six general practices in North Staffordshire, UK. Briefly, NorSTOP consisted of a two-stage cross-sectional questionnaire. Stage 1 consisted of a postal Health Survey questionnaire. Respondents to this questionnaire who reported experiencing foot pain in the last 12 months were sent a Regional Pain Survey questionnaire which contained the MFPDI. Respondents were also asked to provide consent for review of their medical records.

Criteria for inclusion in the sub-sample for this analysis were: having foot pain in the last 12 months, reporting at least 2 items on the MFPDI occurring on “some days” or “most/every day(s)”, and both providing consent to medical record review and consulting their GP with musculoskeletal foot problems in the 18 months prior to the baseline Health Survey. Participants who had diabetes mellitus (self-report in Health Survey questionnaire) or had consulted their GP for rheumatoid arthritis in the 18 months prior to the baseline Health Survey were excluded.

Statistical analyses
First, the dimensionality of the Dutch version of the MFPDI was investigated using an exploratory factor analysis (EFA). A confirmatory factor analysis (CFA) was used to evaluate the fit of the 3 construct conceptual model^7,11 on the Dutch data. CFA was also used to test both the 3 construct conceptual model and the EFA findings on the UK data. The last two items of the MFPDI (“I am unable to carry out my previous work” and “I no longer do all my previous activities”) were not applicable for a large number of participants (39%) and were thus not used for either analyses. Model fit was evaluated by comparing Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI) and Tucker-Lewis fit Index (TLI) from the two different models. RMSEA ≤0.06 indicated good model fit and for CFI and TLI a cut off value of 0.95 was chosen^23,24.

RELIABILITY
Internal consistency (IC)
IC was evaluated per sub-scale of the NL To data using Cronbach’s α. An outcome between 0.7-0.95 was considered acceptable^25.

Test-retest reliability
To evaluate test-retest reliability, the intra class correlation (ICC agreement) was calculated comparing the NL Ts to the NL To data. Variance components were estimated using the VARCOMP tool in SPSS. The ICC agreement was calculated by dividing the variance between patients by the sum of the variance between patients (\( \sigma_p^2 \)), the variance due to systematic differences between observations (\( \sigma_0^2 \)) and the residual variance (\( \sigma_{residual}^2 \)) (equation 1)^26. An ICC of 0.7 or higher was deemed acceptable^25.

\[
\text{ICC}_{\text{agreement}} = \frac{\sigma_p^2}{\sigma_p^2 + \sigma_0^2 + \sigma_{residual}^2}
\]

Measurement error
The standard error of measurement (SEM agreement) was calculated using the same variance components used for the ICCagreement calculation (equation 2)^26, comparing the NL To with the NL Ts data.

\[
\text{SEM}_{\text{agreement}} = \sqrt{\left(\sigma_0^2 + \sigma_{residual}^2\right)}
\]

VALIDITY
Construct validity
In order to evaluate construct validity the ‘hypotheses testing’ method was chosen in absence of a gold standard^27. Hypotheses were formu-
variable) significantly affects the response. An item displays DIF when patients with the same estimated theta on the sub-scale do not have the same probability of endorsing that item. There are two kinds of possible DIF: uniform and non-uniform. Uniform DIF means that in one population an item is endorsed less (or more) often at all values of the construct, compared to the other population. Non-uniform DIF means that in one population an item is endorsed less (or more) often at some values of the construct, but more (or less) often at other values of the construct, compared to the other population. Non-uniform and uniform DIF are comparable to respectively effect modification and confounding in epidemiology. A significant effect was present if more than 2% of the variance (R²) was due to country of origin. A uni-dimensional construct could only be tested if the sub-scale consists of at least five items, sub-scales with less items were not analysed.

Responsiveness
In order to evaluate if the MFPDI was responsive to change a construct approach was chosen by absence of a gold standard. Change scores between the NL To and NL T3 data were calculated. The following seven hypotheses comparing the change scores of the functional limitation and pain sub-scales of the MFPDI to the change scores of FFI-5pts, SF12 and the NRS and to the GPE questions using Pearsons correlation (p<0.05):

1. The change score of the MFPDI- function items (MFPDI-f) correlates with the change score of the FFI-5pts function items (FFI-f) with R>0.5;
2. The change score of the MFPDI-f correlates with the change score of the SF12 physical function items (SF-12phys) with R>0.3;
3. R hypotheses 1 > R hypotheses 2;
4. The change score of the MFPDI- pain items (MFPDI-p) correlates with the change score of the FFI-5pts pain items (FFI-p) with R>0.5;
5. The change score of the MFPDI-p correlates with the change score of the Pain Numeric Rating Scale (NRS-p) with R>0.5;
6. R of the MFPDI-f - SF-12phys > R of the MFPDI-f - the SF12 mental function items (SF-12ment);
7. R of the MFPDI-f - SF-12phys > R of the MFPDI-p - SF-12phys.

The construct was deemed valid if 5 out of 7 hypotheses were confirmed.

Cross-cultural validity
Differential Item Functioning Analyses (DIF analyses) between NL To and UK NorStOP data using ordinal logistic regression based on IRT was used to test cross-cultural validity. An IRT based model does not use observed sub-scale scores but incorporates item difficulty with sub-scale score providing an estimated score of the latent trait (e.g. foot function, foot related pain); theta. A negative theta implied a low dysfunction, a positive theta more foot dysfunction. The responses to each item (dependent variables) by Dutch and UK participants with similar foot dysfunction were compared to evaluate if country of origin (independent variable) significantly affects the response. An item displays DIF when patients with the same estimated theta on the sub-scale do not have the same probability of endorsing that item. There are two kinds of possible DIF: uniform and non-uniform. Uniform DIF means that in one population an item is endorsed less (or more) often at all values of the construct, compared to the other population. Non-uniform DIF means that in one population an item is endorsed less (or more) often at some values of the construct, but more (or less) often at other values of the construct, compared to the other population. Non-uniform and uniform DIF are comparable to respectively effect modification and confounding in epidemiology. A significant effect was present if more than 2% of the variance (R²) was due to country of origin. A uni-dimensional construct could only be tested if the sub-scale consists of at least five items, sub-scales with less items were not analysed.

1. The change score of the MFPDI- function items (MFPDI-f) correlates with the change score of the FFI-5pts function items (FFI-f) with R>0.5;
2. The change score of the MFPDI-f correlates with the change score of the SF12 physical function items (SF-12phys) with R>0.3;
3. The change score of the MFPDI-f correlates with the change score of the SF12 mental function items (SF-12ment);
4. R hypotheses 1 > R hypotheses 2;
5. The change score of the MFPDI- pain items (MFPDI-p) correlates with the change score of the FFI-5pts pain items (FFI-p) with R>0.5;
to evaluate the remaining measurement properties. All measurement properties were evaluated for every uni-dimensional sub-scale derived from the previous mentioned EFA and CFA.

**RESULTS**

**Translation**

Comparison of Dutch version of the questionnaire to the original English version demonstrated four differences that needed attention. The original item one states “I avoid walking outside at all”, the “at all” was missing in the Dutch and back translated version, and therefore ‘geheel’ was added to the statement. Item 2 (“I avoid walking long distances”) was re-translated to: “I avoid walking longer distances” (“Ik vermijd het lopen over lange afstand”). After back translation this was changed into: “Ik vermijd het lopen over lange afstanden” which back translates better into the original version. The original item 10 states: “I still do everything but with more pain or discomfort.” After back translation “still” was missing; “nog steeds” was added to the Dutch version. And finally questions 12 and 13: there is no literal Dutch word for “self-conscious”; “negatief bewust” was our first choice which means: “negatively aware”. After discussion during the back translation we opted for: “verlegen” (“shy”) which in Dutch language is closer to the original although it will be impossible to get an exact translation. After pilot testing (n=10) no more changes where made to the Dutch version of the MFPDI.

**Participants**

The characteristics of the participants at screening, baseline and three months for the Dutch (NL Ts, NL T0 and NL T3) and the UK (UK NOrStOP; n=370) participants are presented in Table 1. The UK participants scored significantly higher (p<0.001) compared to the Dutch participants on the severity of foot related disability and foot pain (higher score indicates more disability or pain). The Dutch participants scored significantly lower on both the physical and mental components of the SF12 questionnaire (lower score indicates lower well-being). Characteristics of participants remaining in the NL T3 (n=178) and NL Ts (n=195)
do not differ significantly from those in the NL To (n=205). Ten NL Ts were not used since the screening form was completed on the same or previous day as completion of NL To.

**TABLE 1** Participant characteristics and item responses.

<table>
<thead>
<tr>
<th></th>
<th>NLT</th>
<th>NLT0</th>
<th>NLT1</th>
<th>UK NOSHIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: mean (SD)</td>
<td>-64.1(9.4)</td>
<td>-65.3(9.4)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gender (% Female)</td>
<td>77.6%</td>
<td>74.4%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MFPDI sub-scale scores:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional limitation</td>
<td>5.9 (3.8)</td>
<td>6.2 (4.2)</td>
<td>5.0 (4.4)</td>
<td>7.1 (5.8)</td>
</tr>
<tr>
<td>Pain</td>
<td>5.1 (2.0)</td>
<td>5.8 (2.4)</td>
<td>3.6 (2.5)</td>
<td>7.5 (2.6)</td>
</tr>
<tr>
<td>Appearance</td>
<td>3.6 (1.5)</td>
<td>3.0 (1.3)</td>
<td>0.9 (1.2)</td>
<td>3.3 (1.4)</td>
</tr>
<tr>
<td>General Health mean (SD)</td>
<td>-43.8 (8.6)</td>
<td>-46.9 (2.4)</td>
<td>-47.5 (11.6)</td>
<td>-</td>
</tr>
<tr>
<td>SF 12 physical wellbeing</td>
<td>-</td>
<td>-30.8 (9.7)</td>
<td>-33.8 (4.6)</td>
<td>-36.0 (11.9)</td>
</tr>
<tr>
<td>SF 12 mental wellbeing</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

- data was not assessed or not applicable at this point in time.
* Significant difference p<0.001 Chi square test comparing UK NOSHIP to NL T0.
** Significant difference p<0.001 T-test comparing UK NOSHIP to NL T0.
*** Significant difference p<0.05 T-test comparing UK NOSHIP to NL T0.

**Missing values**

The highest percentage of missing values per item of the MFPDI is 2.4% (items 2, 13, 16). Combining the UK and Dutch data for the DIF analyses for the cross cultural validity item 3 had the highest percentage of missing values: 2.8%. One participant in the UK data had more than 50% missing values and this participant was excluded from further analyses.

**Factor analysis**

Using EFA three sub-scales were found in NLT0 data: A foot function scale (items 1-9), a pain scale (items 10, 14-17) and a perception scale (items 11-13). Our factor structure differed from the previously reported factor structure by the location of item 11 (“I get irritable when my feet hurt”). In our analysis it was included in the perception scale whereas in previous studies it was included in the functional limitations scale. Our factor structure demonstrated the best fit in both data sets (Table 3).

**RELIABILITY**

**Internal consistency**

The functional limitation sub-scale was deemed to be internal consistent (Cronbach’s > 0.7). The internal consistency of the pain and perception sub-scales were moderate (Table 2).

**Test-retest reliability**

None of the ICC values reached the generally accepted limit of 0.7 although the ICC for the foot function sub-scale was 0.69 (Table 2).

**Measurement error**

The SEM of the perception sub-scale was large (36% of the maximum scale score). Both the foot function and the foot pain scale contained a smaller SEM; respectively 12% and 16% of the maximum scale score.

**VALIDITY**

**Construct validity**

All a priori stated hypotheses about correlations of the MFPDI function and pain scales to the FFI-5pt, SF12 and NRS were confirmed (Table 3).
### TABLE 3 Results of measurement properties related to: Validity.

<table>
<thead>
<tr>
<th>Measurement property</th>
<th>Research question</th>
<th>Method</th>
<th>Dataset(s)</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural validity</td>
<td>Do the Dutch MFPDI and the NorSPOP MFPDI consist of the same factor structure (sub-scales) as the original?</td>
<td>ECA CFA</td>
<td>NL T0 n=205&lt;br&gt;UK NorSPOP n=365</td>
<td>Factors found: Functional construct: 1-9&lt;br&gt;Pain construct: 10-14&lt;br&gt;Perception construct: 15-13</td>
<td>A slightly different factor structure fitted better in both data sets than the previously reported factor structure. The previously reported factor structure fitted acceptable in the UK dataset, but not in the Dutch dataset.</td>
</tr>
<tr>
<td>Cross cultural validity</td>
<td>Assuming a similar ‘true value’ for foot related disability, does the Dutch population has the same probability of endorsing a certain response option on the items of the MFPDI as compared to the UK population?</td>
<td>DIF analysis using ordinal regression analyses.</td>
<td>NL T0 n=205&lt;br&gt;UK NorSPOP n=365</td>
<td>Foot function sub-scales: no DIF; Foot pain sub-scale: Item 17 has DIF; $R^2 = 0.048$</td>
<td>Assuming a similar ‘true value’ for foot related disability, the Dutch population has a higher probability of endorsing the response option “none of the time” or “on some days” on item 17 as compared to the UK population.</td>
</tr>
<tr>
<td>Construct validity (hypotheses testing)</td>
<td>Does the MFPDI relate to other instruments as expected, based on the study of Garrow et al. [9]</td>
<td>Pearson Correlation*&lt;br&gt;Testing 7 a priori defined hypotheses: 1. Correlation MFPDI-I and FFI-I (R=0.5).&lt;br&gt;2. Correlation MFPDI-I and SF12-phys (R=0.5).&lt;br&gt;3. Correlation MFPDI-I and SF12-ment. (R=0.5).&lt;br&gt;4. Correlation MFPDI-I and NRS (R=0.5).&lt;br&gt;5. Correlation MFPDI-I and pain NRS (R=0.5).&lt;br&gt;6. R MFPDI-I - SF12 phys &gt; R MFPDI-I - SF12 ment.&lt;br&gt;7. R MFPDI-I - SF12 phys &gt; R MFPDI-I - SF12 phys.</td>
<td>Comparator instruments: FFI-I, FFI-II, NRS, SF12phys, SF12ment.</td>
<td>Pearson Correlations: 1. R = 0.66 (p&lt;0.0001)<em>&lt;br&gt;2. R = 0.31 (p&lt;0.0001)</em>&lt;br&gt;3. R = 0.66 &gt; 0.31*&lt;br&gt;4. R = 0.60 (p&lt;0.0001)<em>&lt;br&gt;5. R = 0.53 (p&lt;0.0001)</em>&lt;br&gt;6. R = 0.33 &gt; 0.14 (p=0.045)<em>&lt;br&gt;7. R = 0.33 &gt; R = 0.22 (p=0.002)</em></td>
<td>Construct validity is accepted; all hypotheses were confirmed.</td>
</tr>
</tbody>
</table>

*MFPDI-I = MFPDI- function items, FFI-I = FFI-I function items, SF12-phys = SF12 physical function items, GPE-F = GPE-function question, MFPDI-p = MFPDI- pain items, FFI-p = FFI-I samples pain items, NRS-p = Pain Numeric Rating Scale, GPE-p = GPE-pain.

### TABLE 4 Results of measurement properties related to: Responsiveness and Interpretability.

<table>
<thead>
<tr>
<th>Measurement property</th>
<th>Research question</th>
<th>Method</th>
<th>Dataset(s)</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsiveness</td>
<td>Do change scores on the MFPDI relate to change scores on other instruments as expected?</td>
<td>Pearson Correlation*&lt;br&gt;Testing 7 a priori defined hypotheses: 1. Correlation change MFPDI-I and FFI-I (R=0.5).&lt;br&gt;2. Correlation change MFPDI-I and SF12 phys (R=0.5).&lt;br&gt;3. Correlation change MFPDI-I and GPE-I (R=0.5).&lt;br&gt;4. R hypothesis 1 &gt; R hypothesis 2. 5. Correlation change MFPDI-I and pain NRS (R=0.5).&lt;br&gt;6. Correlation change MFPDI-I and pain NRS (R=0.5).&lt;br&gt;7. Correlation change MFPDI-I and pain NRS (R=0.5).</td>
<td>Comparator instruments: FFI-I, NRS, SF12phys, SF12ment, GPE-I</td>
<td>Pearson Correlations: 1. R = 0.31 (p&lt;0.0001)&lt;br&gt;2. R = 0.03 (p=0.747)&lt;br&gt;3. -0.46 (p=0.0001)&lt;br&gt;4. R = 0.31 &gt; R = 0.03*&lt;br&gt;5. R = 0.37 (p=0.0001)&lt;br&gt;6. R = 0.42 (p&lt;0.0001)&lt;br&gt;7. R &gt; 0.47 (p=0.0001)</td>
<td>The responsiveness of the MFPDI is moderate; only 1 out of 7 hypotheses was confirmed and the correlation with the GPE question is &lt; 0.2.</td>
</tr>
<tr>
<td>Interpretability</td>
<td>What is the Minimal Important Change (MIC)?</td>
<td>MUC: smallest cut-off change score (1-specificity)*&lt;br&gt;(1-specificity)</td>
<td>MIC: NLT0, NLT3 n=178</td>
<td>The correlation coefficient between the GPE and change score is too low to calculate a MIC (R=0.5).&lt;br&gt;The MFPDI is not responsive enough to calculate a MIC.</td>
<td>The MIC for the perception subscale is too large; the SOC is equal to the maximum possible score.</td>
</tr>
<tr>
<td></td>
<td>What is the Smallest Detectable Change (SDC)? And is the MIC higher than the SDC?</td>
<td>SDC</td>
<td>SDC : NLT0 n=200</td>
<td>SDC: Function: 6.1 (min-max score: 0-18)&lt;br&gt;Pain: 4.4 (0-10)&lt;br&gt;Perception: 5.8 (0-6)</td>
<td>The SDC for the perception subscale exhibits a large floor effect.</td>
</tr>
<tr>
<td></td>
<td>Is a floor and or ceiling effect present?</td>
<td>Floor / ceiling effect: % of participants who scored the two lowest possible scores (0 or 1) per subscale.</td>
<td>Floor / ceiling effect: NLT0 n=200</td>
<td>Floor / ceiling effect: Function: 8.8%&lt;br&gt;Pain: 7.4%&lt;br&gt;Perception: 76.5%</td>
<td>The floor of the SDC is not a floor effect.</td>
</tr>
</tbody>
</table>

*MFPDI-I = MFPDI- function items, FFI-I = FFI-I function items, SF12-phys = SF12 physical function items, GPE-I = GPE-function question, MFPDI-p = MFPDI- pain items, FFI-p = FFI-I samples pain items, NRS-p = Pain Numeric Rating Scale, GPE-p = GPE-pain.
Several studies have investigated the presence of sub-scales within the MFPDI using either EFA and/or CFA. Although differences have been found in the number of sub-scales: 2, 3 or 4; close inspection shows several similarities between the different outcomes. The main difference between the various factor structures is the placement of item 11 (“I get irritable when my feet hurt”). Previous analyses have placed this item in the foot function scale, in the foot pain scale and in a combined pain and appearance scale. In our opinion item 11 is related to emotion due to foot pain and therefore should not be part of the foot function scale. In our data it fits best with items 12 and 13 which were previously labelled as appearance items. These two items are actually about feeling self-conscious about the appearance of feet and shoes and do not mention the appearance itself of feet and shoes. Adding item 11 to these two and naming it “perception scale” adds to the face-validity of the scale in our opinion.

Reliability
Although internal consistency has been evaluated in every MFPDI validation study published, only two studies evaluated the IC per individual sub-scale. Both studies found acceptable internal consistencies (0.7) for all tested sub-scales in contrast to our findings. Our findings suggest that the functional scale is internally consistent (0.8), the pain scale is just below acceptable (0.67) and the internal consistency of the perception sub-scale is moderate (0.60). The differences between our results and those found by Cook et al (IC of the pain and appearance scale: 0.75) could be explained by the differences in the number of items; respectively 3 and 7 items. The test-retest reliability of the foot function sub-scale is almost acceptable (ICC = 0.69) but the reliability of the pain sub-scale is moderate (0.49) and the reliability of the perception sub-scale is poor (0.10). All participants scored at least one item of the entire MFfPDI as: “on most/every day(s)” and our findings are consistent with those reported by Roddy et al. A measurement error has not been established before. Our findings suggest that the SEM for the perception scale is too large; 36% of the possible maximum score.

Cross cultural validity
Due to the limited amount of items (<5) in the perception sub-scale, DIF analysis was not performed on this sub-scale. DIF analysis on the foot function sub-scale showed that there was no DIF between the UK and a Dutch population (Table 3). Item 17 in the foot pain sub-scale (“I get shooting pain in my feet”) showed uniform DIF. Having a similar level of foot pain (theta), the Dutch population has a higher probability of answering this item with: “none of the time” or “on some days” than the UK population.

Responsiveness
One of the 7 a priori stated hypotheses about correlations between different change scores (change score = the difference between the scale score at NL T0 and NL T3) was confirmed (Table 4). Neither the function scale nor the pain scale change scores correlated to the corresponding GPE questions at an acceptable level (respectively R=0.46 and R=0.47). These correlations were considered too low to calculate a MIC.

Interpretability
The perception sub-scale showed an extreme floor effect; 86.2% of the participants obtained the minimum possible scale score. The other subscales do not exhibit a floor or ceiling effect (Table 4).

The SDC of the perception sub-scale is as large as the maximum obtainable score of 6 points (Table 4). Due to the inability to calculate a MIC, comparison of SDC and MIC is not possible.

Discussion
Evaluation of the MFPDI measurement properties produced new useful information. Of the 3 uni-dimensional sub-scales found in the NL T0 data only the functional limitation sub-scale has an acceptable level of reliability. Scores from the Dutch and UK version can be interpreted similarly; only the pain subscale possesses one DIF item but the differences in item responses and thus sub-scale responses are smaller than the measurement error. The responsiveness of the questionnaire is moderate.
Validity
The UK and Dutch participants differ on baseline on the amount of foot related pain and dysfunction. However, these differences are not of influence on the cross-cultural validity analyses because item responses of UK and Dutch patients with similar ‘true values’ are compared to each other.

Assessment of the cross cultural validity by means of DIF analysis showed that Dutch and UK participants with a similar level of foot dysfunction complete the foot function sub-scale in a similar manner. A small difference was found in the completion of the foot pain sub-scale. Assuming a similar ‘true value’ for foot related disability, the Dutch population has a higher probability of endorsing the response option “none of the time” or “on some days” on item 17 as compared to the UK population. We expect that the DIF of item 17 is due to the difference in location of the foot pain. The UK population was included if they had pain in any part of the foot whereas the Dutch population was selected when having pain in the forefoot or toes. It is plausible that the characteristics of forefoot pain might differ from the characteristics of general foot pain explaining the difference between the Dutch and UK population.

The seven a priori stated hypotheses were all confirmed and thus the foot function and the pain scales seem to be valid. Due to absence of a comparator instruments the validity of the perception scale has not been assessed. In a previous study by Menz et al. the MFPDI scores were compared to other patient reported outcomes like the GADS depression sub-scale and the SF-36 mental health and general health sub-scale. These correlation coefficients were lower than those in our results; their highest correlation was R=0.34. This is probably due to the fact that the comparator instruments differ in both studies and that the instruments used in this study are more foot related. Even though the construct validity is acceptable based on these findings, we are hesitant about the face validity of the foot pain scale. Previous authors have described this scale as measuring pain intensity. The items mainly ask about when the foot pain is worse and about the kind of pain. This scale also contains several opposing statements. Item 15 states: “My feet are worse in the morning” whilst item 16 states: “My feet are more painful in the evening”. Items 14 and 17 are somewhat opposing as well: “I have constant pain in my feet” versus I have shooting pain in my feet”. We are hesitant to use this sub-scale if pain intensity is the construct of interest.

Responsiveness and interpretation
Neither responsiveness nor a MIC have previously been established. Comparing the change scores of the foot function and the pain sub-scale to changes in comparator instruments like the foot function index-5pt (foot related activities and pain sub-scales), the SF12 physical component and the pain NRS, only moderate correlations were found. But most importantly, the correlation between the change scores and anchor question (GPE question) were only moderate (R= 0.43-0.47). We considered these correlation coefficients too low (below 0.5) to calculate a MIC. There are multiple possible explanations for the moderate responsiveness. With regard to the entire questionnaire, it could be that the response options (none of the time, on some days and on most/every day(s)) are too widely spaced to be able to measure small changes over time. With regard to the foot function sub-scale; the questionnaire uses items that clearly begin with: ‘because of the pain in my feet...’. Even so, the activities stated could very likely be influenced by other variables like loss of muscle strength or pain in other joints, especially within an older population. It could possibly be hard to distinguish the inability to do something because of foot pain or other pains and therefore it might not respond to change if only one of the problems improves. The SDC is calculated based on the SEM and so the perception scale has an extreme high SDC; 5.8 points on a scale that has a 6 point maximum. This sub-scale also has a large floor effect; 76.5% of the participants have a score of 0 or 1 point. Combining these two findings, it will be improbable to find a change within this scale.
The main strength of this study is that the full array of measurement properties based on CTT has been evaluated. Nevertheless, the results of this study should be interpreted in light of its limitations. The group of participants used for this evaluation of the MFPDI (NL T0) is very homogeneous; >50 years of age, visited their GP with forefoot pain not due to rheumatoid arthritis or skin lesions and no diabetic neuropathy. Particularly the attribute of having forefoot pain is different compared to other studies. Even though our results do not seem to differ a lot from previously published work, measurement properties like responsiveness, MIC, SDC and SEM have not been assessed before. And thus it is unsure if, for instance, the moderate responsiveness the MFPDI holds for populations with other kinds of foot pain as well.

Although foot pain in general is more common in woman than in man\textsuperscript{2,3}. The percentage of women in this study (77.6\%) differ from both gender distributions reported by Garrow et al.\textsuperscript{2} (59.6\%) or the UK NORStO\textsuperscript{P} data (63\%). These studies contain people with foot pain in general. It could be that women are, more so than men, predisposed to have forefoot problems, compared to pain anywhere in the foot. Nevertheless, most outcomes in this study are comparable to those of other studies\textsuperscript{9-12}. We therefore assume that the difference in gender distribution does not affect the outcome of this study.

Results using the Dutch version of the MFPDI are not different from those using the English version since the function scale has no DIF and the pain scale only a small amount. Due to the limited reliability, moderate responsiveness, floor effect and large measurement error of both the pain and most of all the perception scale, it is advisable that the items in these scales (item 10-17) are no longer used. Quantifying pain by the use of a NRS or VAS can be an alternative. The reliability of the function scale (items 1-9) is acceptable as is its construct validity. The moderate responsiveness of the MFPDI function scale should be taken into consideration when using it in a longitudinal study. It is unclear if these results would be different for participants with foot pain other than the forefoot or if the results are influenced by problems in the entire lower extremity.

**LIST OF ABBREVIATIONS**

- CFA: Confirmatory Factor Analysis
- CTT: Classical Test Theory
- DIF: Differential Item Functioning
- EFA: Exploratory Factor Analysis
- FFI: Foot Function Index
- GPE: Global Perceived Effect (also known as anchor question)
- IC: Internal Consistency
- ICC: Intraclass Correlation
- IRT: Item Response Theory
- MFPDI: Manchester Foot Pain and Disability Index
- MIC: Minimal Important Change
- NL Ts, T0, T3: Dutch datasets respectively just prior to baseline, baseline and after 3 months
- NRS: Numeric Rating Scale
- SEM: Standard Error of Measurement
- SDC: Smallest Detectable Change

**COMPETING INTERESTS**
The authors declare that they have no competing interests.

**AUTHORS’ CONTRIBUTION**
BvdZ was responsible for data-collection and wrote the manuscript. CT assisted with the statistical analysis, BT assisted with the DIF analysis, PE commented on several drafts of the manuscript. CT, ER, BT and HH commented on the first and last draft of the manuscript. All authors have read and approved the final manuscript.

**ACKNOWLEDGEMENTS**
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REFERENCES


Variation in the location of the shoe sole flexion point influences plantar loading patterns during gait.

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Hylton B Menz

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**INTRODUCTION**

Wearing shoes is an inherent part of our daily lives; however research suggests that some footwear characteristics such as high heels and ill-fitting shoes can have detrimental effects on our feet. Wearing high-heeled shoes has been shown to increase plantar pressure and ground reaction force, increase the risk of falling and change spatial gait characteristics. Wearing ill-fitting shoes has been shown to be associated with foot pain, hallux valgus, deformities of the lesser toes, calluses, corns and ulceration. Shoes have also been shown to restrict the range of motion of the foot in both adults and children although the long term effects of these changes are unclear.

In recognition of the association between footwear characteristics and foot problems, several footwear assessment forms have been developed to assist with the optimum selection of footwear. Although these tools are based on available evidence, they also recommend shoe characteristics based on clinical experience that are currently unverified. One of these characteristics is the position of the sole flexion point in the sagittal plane relative to the metatarsophalangeal joints (MTPJs). It is assumed that the sole flexion point should ideally be located directly underneath the MTPJs and that more proximally-located sole flexion points are detrimental; however this assumption has not yet been evaluated. Therefore, the aim of this study was to evaluate the effects of three different positions of the sole flexion point on plantar loading during gait: a sole flexion point right underneath the MTPJs (control), one proximal to the MTPJs and one underneath the tarsometatarsal joints. We hypothesised that the more proximally-located sole flexion points would (i) increase the pressure-time integral of the forefoot due to premature heel elevation, and (ii) cause a lateral shift in loading across the MTPJs due to changes in the windlass mechanism during propulsion.

**VARIATION IN LOCATION OF SHOE SOLE FLEXION POINT INFLUENCES PLANTAR LOADING PATTERNS**
METHOD

Participants
Female staff and students between the age of 20 and 40 were recruited at the for Applied Sciences via e-mail. All participants had to have a shoe size between 38 and 41. Participants were excluded if they (i) had a Foot Posture Index outside the normal range (<0 - >6) \textsuperscript{13,14}, (ii) had rheumatoid arthritis, (iii) had diabetic neuropathy or (iv) were wearing custom made orthotic devices. The medical ethics committee of the Vrije Universiteit medical centre has approved the study (2009/267) and informed consent was obtained from all participants.

Footwear conditions
Three shoes (Bata Industrials\textsuperscript{©} type EVA: laced work shoes, nubuck leather upper, PU-sole) with different positions of the sole flexion point were worn by all participants. To create differences in sole flexion point, the outer soles of the shoes were incised over the full width of the shoe up to the inner sole. One shoe was incised directly underneath the MTPJs (hereafter referred to as sub-MTPJ); one (depending on the shoe size) 2- proximal to the MTPJs (hereafter referred to as prox-MTPJ) and one at the level of the tarso-metatarsal joints (hereafter referred to as mid-foot) (figure 1). Prior to the study, the shoe size of the right foot was established by means of a shoe size caliper (heel to longest toe), and this size was used for both feet. The corresponding size insoles for the plantar pressure assessment were placed in the shoe. All shoes were tied by the same researcher in order to diminish the influence of the lace tightness on the outcome as much as possible. Participants were asked to walk in the shoes for two minutes prior to data collection. During data collection participants walked over an eight metre walkway at their own comfortable speed. The order of presentation of the three shoe conditions was randomised.

Plantar pressure assessment
In-shoe plantar pressures were measured using the Pedar-X system (Novel gmbh, München, Germany), which consists of 99 capacitive sensors arranged in a grid and embedded within a thin flexible insole approximately thick. A previous study has demonstrated acceptable reliability of this system with the exception of the area under the toes \textsuperscript{15}. Data of twelve steps were obtained after excluding initiation, termination and turning steps \textsuperscript{16}. Previous findings of Pataky et al \textsuperscript{17} highlighted the importance of choosing borders of masks that are congruent with plantar anatomy. Based on an average peak pressure template of 104 ‘normal and healthy’ feet \textsuperscript{18}, anatomically correct masks were therefore created to evaluate the pressure-related outcome measures to reflect the more proximal location of MTPJs 4 and 5 and the 4\textsuperscript{th} and 5\textsuperscript{th} toes (figure 2).
Statistical analysis
All data were tested for normalcy; the data was defined to be normal distributed when skewness > 1.0 (IBM© SPSS© statistics version 20.0.0). Skewed data were log transformed. For each mask all variables were compared across the three different shoe conditions using multilevel model linear regression (MLwiNversion 2.26©). The different outcome measures were set as level 1, the participants were set as level 2©. Random intercepts and random slopes were added to the basic model and changes of the -2log likelihood ratio were used to evaluate the best model. The confidence interval was set at 95%.

RESULTS
Twenty-one participants were included for this trial; the participants’ characteristics are shown in Table 1. Both walking speed and BMI were not found to be confounding in any of the data. All results shown (Table 2) are derived from a random intercept model; the addition of a random slope did not improve the model.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Participant characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average (SD)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>27.5 (6.1)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>171 (6.8)</td>
</tr>
<tr>
<td>BMI</td>
<td>22.9 (3.4)</td>
</tr>
</tbody>
</table>

Peak pressure
Walking with the prox-MTPJ versus the sub-MTPJ sole flexion point produced changes in PP for two masks (figure 3). The PP increased in the MTPJ 4-5 mask (avg 154.2kPa from 145.2kPa p= 0.028) and decreased in the medial midfoot mask (avg. 91.5kPa from 99.9kPa p= 0.008) (table 1). No other changes were found between these two sole flexion points for any of the other variables. Several differences were found when walking in the shoe with a midfoot flexion point. Significant decreases were found in PP medial midfoot (94 kPa p=0.023), medial hindfoot (227 kPa

Outcome measures
Five pressure-related variables were selected a priori for analysis: peak pressure (PP), contact time (CT), pressure-time integral (PTI) and the ratio PP and PTI between masks MTPJ1 and MTPJ2-3 (PP and PTI ratio). PP and CT were derived directly from the software. PTI was calculated according the method described by Melai et al©:

\[ FTI + CA \]  
\[ (FTI = \text{Force Time Integral, CA = Contact Area}) \]

The PP and PTI ratio were determined by dividing the PP or PTI of the MTPJ2-3 mask by the PP or PTI of the MTPJ1 mask, to provide an indication of lateral shift in forefoot loading. Walking speed and BMI were measured to test for confounding.
p=0.023) and lateral hindfoot (231 kPa P=0.01) when walking with a midfoot sole flexion point versus the sub-MTPJ sole flexion point (resp. 99.9, 237, 243.3kPa). No significant changes were found comparing the midfoot to the prox-MTPJ flexion point.

Contact time
Contact time was found to decrease in the midfoot (medial: 591ms p=0.013 and lateral 607.2ms p<0.000) wearing the midfoot sole flexion point shoe versus both other flexion points (sub-MTPJ resp. 608.4 and 628.7ms; prox-MTPJ resp. 606.7 and 624.1ms). The lateral hindfoot was found to have a lower CT (415.4ms p=0.025) in the midfoot shoe versus the sub-MTPJ shoe (444.8ms).

Pressure time integral
Reduction of the PTI in the medial midfoot (0.957 Ns/cm² p=0.003), lateral midfoot (1.252 Ns/cm² p=0.046), medial hindfoot (3.628 Ns/cm² p=0.003) and lateral hindfoot (3.633 Ns/cm² P=0.006) were found in the midfoot flexion point versus the sub-MTPJ sole flexion point (resp. 1.09, 1.514; 3.895 and 3.852 Ns/cm²) and the prox-MTPJ (resp. 1.09, 1.628; 3.809 and 3.914 Ns/cm²).

Peak pressure and pressure-time integral ratio
Walking in the midfoot sole flexion point shoe showed a trend towards a lateral shift in forefoot loading (PTI MTP2-3/MTP1=1.09) compared to the sub-MTPJ (PTI MTP2-3/MTP1=1.03) but this trend was not significant (p=0.056).

FIGURE 3 Percentage change in each mask compared to the sub-MTPJ sole flexion point.
### Table 2

Peak pressure, contact time, pressure-time integral and ratio of MTPl/MTPj peak pressure results for each of the three sole flexion points.

<table>
<thead>
<tr>
<th></th>
<th>Sub-MTPJ</th>
<th>Prox-MTPJ</th>
<th>Midfoot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(kPa)</td>
<td>(95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>Hallux</td>
<td>278.3 (239.7-316.9)</td>
<td>266.2 (247.4-285.0)</td>
<td>0.208</td>
</tr>
<tr>
<td>Lesser toes</td>
<td>112.4 (97.9-126.9)</td>
<td>115 (107.4-122.6)</td>
<td>0.505</td>
</tr>
<tr>
<td>MTP 1</td>
<td>244.4 (224.2-264.6)</td>
<td>239.8 (228.2-251.4)</td>
<td>0.436</td>
</tr>
<tr>
<td>MTP 2&amp;3</td>
<td>226 (207.4-244.6)</td>
<td>229.9 (222.3-237.5)</td>
<td>0.317</td>
</tr>
<tr>
<td>MTP 4&amp;5</td>
<td>145.2 (132.9-157.5)</td>
<td>154.2 (146.2-162.2)</td>
<td>0.028*</td>
</tr>
<tr>
<td>Medial midfoot</td>
<td>99.9 (92.8-107.2)</td>
<td>91.5 (86.6-96.4)</td>
<td>0.008*</td>
</tr>
<tr>
<td>Lateral midfoot</td>
<td>108 (94.5-121.5)</td>
<td>116.2 (101.3-131.1)</td>
<td>0.281</td>
</tr>
<tr>
<td>Medial hindfoot</td>
<td>237 (222.5-251.5)</td>
<td>232.9 (224.3-241.5)</td>
<td>0.351</td>
</tr>
<tr>
<td>Lateral hindfoot</td>
<td>243.3 (228.6-258.0)</td>
<td>239.6 (230.2-249.0)</td>
<td>0.441</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Sub-MTPJ</th>
<th>Prox-MTPJ</th>
<th>Midfoot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(ms)</td>
<td>(95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>Hallux</td>
<td>492.5 (461.1-523.9)</td>
<td>495.6 (471.1-520.1)</td>
<td>0.804</td>
</tr>
<tr>
<td>Lesser toes</td>
<td>471.8 (440.4-503.2)</td>
<td>497.9 (471.6-524.2)</td>
<td>0.052</td>
</tr>
<tr>
<td>MTP 1</td>
<td>511.3 (487.4-535.2)</td>
<td>514.3 (494.7-533.9)</td>
<td>0.764</td>
</tr>
<tr>
<td>MTP 2&amp;3</td>
<td>560.3 (538.5-582.1)</td>
<td>570.9 (559.5-582.3)</td>
<td>0.068</td>
</tr>
<tr>
<td>MTP 4&amp;5</td>
<td>581.8 (562.0-601.6)</td>
<td>587.7 (577.3-598.1)</td>
<td>0.266</td>
</tr>
<tr>
<td>Medial midfoot</td>
<td>608.4 (590.8-626.0)</td>
<td>606.7 (591.0-620.4)</td>
<td>0.808</td>
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<tr>
<td>Lateral midfoot</td>
<td>628.7 (611.5-645.9)</td>
<td>624.1 (613.5-634.7)</td>
<td>0.394</td>
</tr>
<tr>
<td>Medial hindfoot</td>
<td>485.7 (449.6-521.8)</td>
<td>472 (439.3-504.7)</td>
<td>0.412</td>
</tr>
<tr>
<td>Lateral hindfoot</td>
<td>444.8 (415.0-474.6)</td>
<td>426.5 (400.8-452.2)</td>
<td>0.162</td>
</tr>
</tbody>
</table>

### Table 2 Continued

<table>
<thead>
<tr>
<th></th>
<th>Sub-MTPJ</th>
<th>Prox-MTPJ</th>
<th>Midfoot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N/cm²)</td>
<td>(95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>Hallux</td>
<td>3.243 (2.735-3.751)</td>
<td>3.238 (3.058-3.418)</td>
<td>0.957</td>
</tr>
<tr>
<td>Lesser toes</td>
<td>1.262 (1.021-1.503)</td>
<td>1.252 (1.152-1.352)</td>
<td>0.845</td>
</tr>
<tr>
<td>MTP 1</td>
<td>4.5 (4.035-4.965)</td>
<td>4.452 (4.252-4.652)</td>
<td>0.638</td>
</tr>
<tr>
<td>MTP 2&amp;3</td>
<td>4.476 (4.002-4.950)</td>
<td>4.338 (4.171-4.505)</td>
<td>0.105</td>
</tr>
<tr>
<td>MTP 4&amp;5</td>
<td>3.181 (2.762-3.600)</td>
<td>3.367 (3.136-3.598)</td>
<td>0.115</td>
</tr>
<tr>
<td>Medial midfoot</td>
<td>1.09 (0.955-1.225)</td>
<td>1.09 (1.004-1.176)</td>
<td>0.957</td>
</tr>
<tr>
<td>Lateral midfoot</td>
<td>1.514 (1.255-1.773)</td>
<td>1.628 (1.371-1.885)</td>
<td>0.384</td>
</tr>
<tr>
<td>Medial hindfoot</td>
<td>3.895 (3.560-4.230)</td>
<td>3.809 (3.631-3.987)</td>
<td>0.345</td>
</tr>
<tr>
<td>Lateral hindfoot</td>
<td>3.852 (3.497-4.207)</td>
<td>3.914 (3.759-4.069)</td>
<td>0.433</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Sub-MTPJ</th>
<th>Prox-MTPJ</th>
<th>Midfoot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(95% CI)</td>
<td>(95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>PP MTP2&amp;3 / MTP 1</td>
<td>0.952 (0.834-1.070)</td>
<td>1 (0.949-1.051)</td>
<td>0.065</td>
</tr>
<tr>
<td>PTI MTP2&amp;3 / MTP 1</td>
<td>1.033 (0.898-1.168)</td>
<td>1.081 (1.022-1.140)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

* p-value < 0.05 compared to sub-MTPJ condition
** p-value < 0.05 compared to sub-MTPJ condition and prox-MTPJ condition
We hypothesized that a proximally-located sole flexion point would transfer the load of the forefoot more laterally (i.e. more towards MTPJs 2 and 3 and less on MTPJ1). We theorized that when wearing footwear with a sole flexion point located in the midfoot, the arch would flatten more than a sole flexion point located around the MTPJs. A decrease in arch height would lengthen the distance between forefoot and hindfoot and therefore tension the plantar fascia, leading to decreased mobility of MTPJ1 joint due to the windlass mechanism 22 and a corresponding increase in-lateral loading of the MTPJs. This is described by Bojsen-Møller 23 as a “low gear” push off. Although the ratio of PTI MTP2-3/MTP1 was not significant, the p-value of 0.056 does suggest a trend towards a lateral shift with a midfoot flexion point. It has been shown that a reduction in PTI under MTPJ2 is correlated to subjective pain improvement 24 and therefore this trend could be very important for patients with pain in that region of the foot.

The strength of this study is that we used the same type, make and size of shoe and merely incised the sole at different locations to create sole flexion points. As such, any differences observed between the shoes can be confidently attributed to the variation in sole flexion point. However, there are also several limitations to this study. Firstly, we used pressure measurements to assess the changes in load on the foot. Although increased pressure is an important variable in relation to diabetic foot ulceration 25, the relationship between plantar pressures and pain is inconsistent 26. Secondly we have not assed kinematics of the foot using motion analysis. In our opinion a pressure displacement is not possible without motion; however, this has not been validated. Thirdly, the sample population in this study were homogenous; females between 20 and 40, normal foot posture and no foot pain or deformities. Therefore, the results should be interpreted in light of this limitation.

In summary, this study has shown that the location of the sole flexion point of the shoe influences plantar loading patterns. Based on our findings, it would be advisable to change the current footwear assessment
structures to include a flexion point located just proximal to the MTPJs as optimal, but a flexion point more proximal to this should still be considered to be potentially detrimental.

**ACKNOWLEDGEMENTS**
This study is funded by the Netherlands Organisation for Health Research and Development (ZonMw: 42011003). HBM is currently a National Health and Medical Research Council Senior Research Fellow (ID: 1020925). All shoes were donated by Bata Industrials.

**CONFLICT OF INTEREST STATEMENT**
HBM is Editor-in-Chief of Journal of Foot and Ankle Research. It is journal policy that editors are removed from the peer review and editorial decision making processes for papers they have co-authored. The other authors declare that they have no competing interests.

**REFERENCE LIST**

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General discussion

The main goal of this thesis was to evaluate the treatment of forefoot pain and subsequent functional limitations in primary care, by comparing the effectiveness of two commonly used treatment options in a randomised controlled trial: Podiatric care and footwear advice. In order to enable a more in-depth interpretation of these results we also evaluated the process of podiatric treatment and we performed an RCT to measure the efficacy of the footwear advice leaflet that was used in the main trial. Prior to the RCT such a leaflet did not exist and therefore we developed it. We also evaluated the measurement properties of the Manchester Foot and Pain Disability Index (MFPDI) which is one of the primary outcome measures of this study, because this had only been partially done previously. And lastly we have assessed the effect of one of the shoe characteristics from the advice leaflet; the sole flexion point on plantar loading. In the current chapter we will discuss the main findings and interpret them in the light of existing knowledge. We will also address some methodological issues. Finally recommendations for clinical practice and future research will be provided.

COMPARISON OF SHOE ADVICE WITH LEAFLET TO PODIATRIST

The results of the main study of this thesis show that providing shoe advice by handing out a leaflet and explaining the content of the leaflet has the same effect on all outcome measures in people of 50 years of age and older with forefoot pain as treatment by a podiatrist. Although we found no differences between the study groups, both foot pain and foot dysfunction measured with different tools did decrease over time. Since the study did not have a control group without any treatment, this result can indicate that either both treatments have an equal effect or neither treatment have an effect.
cause of the forefoot pain in 12 out of the 25 patients participating in the process evaluation, while podiatrists considered this to be the case in only two participants. Although 12 out of 25 patients received some form of footwear advice by the podiatrist, almost everyone (24/25) also received insoles. In the opinion of the expert panel, 10 of these patients should just have received shoe advice; i.e. more insoles are fabricated by the podiatrists than deemed necessary by the expert panel. A partial explanation is that the expert panel is of the opinion that patients with a hallux limitus or hallux rigidus do not benefit as much from an insole as they would from wearing a shoe containing a toe rocker. A toe rocker could relieve part of the toe extension needed for walking, in the opinion of the expert panel. This would enable the foot to progress over the hallux instead of over digits 2 and 3 and thus alleviate the pressure underneath the second and third metatarsal heads. Nonetheless, this hypothesis has yet to be addressed in an experimental study.

But the hypothesis that a toe rocker has a beneficial effect on the progression over the hallux can not be the only reason for the difference between expert panel and podiatrists. It is my experience that both podiatrists and other medical professionals report/state that the patients’ demands are leading in their choice of treatment. In our main RCT (Chapter 3) we noticed that some people did not want to participate in the study because they did not perceive shoe advice as treatment. However, all the participants agreed to be randomised and therefore agreed to be potentially randomised into the shoe advice treatment group. Hence, it is not very likely that participants did not regard shoe advice as treatment, and asked for insoles, thus explaining the high percentage of insoles. A last potential reason for the difference is that the monetary reward for an insole is higher than that of providing advice only. Some Dutch health insurance companies compensate podiatric treatment in sections: a small fee for the assessment and a larger fee for the orthotic device separately. This and the higher gain on orthotic devices could also attribute to the discrepancy between the expert panel and the podiatrists.

Little is known about spontaneous improvement of foot pain or musculoskeletal pain. Personal communication with the author of an observational study in older adults indicated that about one third of musculoskeletal foot and ankle pain is chronic with a duration of more than two years. Based on the scant available knowledge of the course of forefoot problems, spontaneous improvement can not be dismissed nor accepted.

We did not perform a cost effectiveness analysis. However in our study most podiatrists fabricated insoles. Since insoles usually cost more than a pair of new shoes and one usually has to buy new shoes to accommodate insoles, we expect that a podiatric treatment is more expensive than a shoe advice. We therefore conclude that shoe advice is to be preferred over referral to a podiatrist. Supplementary to the RCT a process analysis of podiatric treatment and an RCT to measure efficacy of the leaflet have been performed. In the next paragraphs we will discuss the findings of these analyses and their relevance to the outcomes of our main RCT.

PODIATRIC TREATMENT

In chapter 4 we reported the process evaluation of podiatric treatment for 25 participants of the main RCT. We found that methods of assessment of the aetiology fundamentally differ between podiatrists. We have distinguished a functional and a non-functional approach. The evaluation of the kinetic chain and external influences is central to the functional approach in contrast to the more localised assessment characterising the non-functional approach. The scant literature available on the effect of podiatric treatment shows heterogeneous effects with large standard deviations. It is conceivable that the fundamental differences in approach of foot problems such as we found in our study contribute to the observed treatment differences reported elsewhere.

Evaluating footwear as possible external influence on the possible cause of a forefoot problem or as perpetuating factor is consistent with working according to a functional approach. In the opinion of the expert panel wearing ill fitting shoes or shoes of poor quality were the main cause of the forefoot pain in 12 out of the 25 patients participating in the process evaluation, while podiatrists considered this to be the case in only two participants. Although 12 out of 25 patients received some form of footwear advice by the podiatrist, almost everyone (24/25) also received insoles. In the opinion of the expert panel, 10 of these patients should just have received shoe advice; i.e. more insoles are fabricated by the podiatrists than deemed necessary by the expert panel. A partial explanation is that the expert panel is of the opinion that patients with a hallux limitus or hallux rigidus do not benefit as much from an insole as they would from wearing a shoe containing a toe rocker. A toe rocker could relieve part of the toe extension needed for walking, in the opinion of the expert panel. This would enable the foot to progress over the hallux in stead of over digits 2 and 3 and thus alleviate the pressure underneath the second and third metatarsal heads. Nonetheless, this hypothesis has yet to be addressed in an experimental study.

But the hypothesis that a toe rocker has a beneficial effect on the progression over the hallux can not be the only reason for the difference between expert panel and podiatrists. It is my experience that both podiatrists and other medical professionals report/state that the patients’ demands are leading in their choice of treatment. In our main RCT (Chapter 3) we noticed that some people did not want to participate in the study because they did not perceive shoe advice as treatment. However, all the participants agreed to be randomised and therefore agreed to be potentially randomised into the shoe advice treatment group. Hence, it is not very likely that participants did not regard shoe advice as treatment, and asked for insoles, thus explaining the high percentage of insoles. A last potential reason for the difference is that the monetary reward for an insole is higher than that of providing advice only. Some Dutch health insurance companies compensate podiatric treatment in sections: a small fee for the assessment and a larger fee for the orthotic device separately. This and the higher gain on orthotic devices could also attribute to the discrepancy between the expert panel and the podiatrists.
and perception should not be used anymore as confirmed by the two other studies that assessed reliability for subscales separately\textsuperscript{9, 13, 14}. We compared the change scores of the MFPDI functional limitation scale to similar questionnaires (PI-NRS, FFI-5pt) and to the corresponding global perceived effect (GPE) question. The observed low correlations (R < 0.5) indicate poor responsiveness of this remaining subscale. Because the correlation was lower than 0.5 between the MFPDI functional limitations and pain scale and the corresponding GPE questions, we could not define the MIC. Several interpretations of our findings are possible. First of all it is possible that the questionnaire is unresponsive in reality. This might be explained by the choice of foot related activities items in the MFPDI. Statements like: ‘I avoid walking long distances,’ ‘I walk slowly,’ ‘I need help with housework/shopping’; could very well be influenced by other problems than those of the foot. Even though the statements start with: ‘Because of pain in my feet:’ it might be hard to distinguish the influence of foot pain on these general activities. Thus changes in the current state of foot pain might not influence the statements as much if they are also influenced by, for instance, reduced muscular strength in the legs.

Another possibility is that the instruments used as comparison are just as unresponsive and therefore less appropriate to assess responsiveness of the MFPDI. In our study we compared the foot function scale of the MFPDI with the pain and activity restriction subscales of the 5 point Foot Function Index (FFI-5pt)\textsuperscript{15} and the mentioned GPE question (“How would you judge the performance of foot related activities now, compared to three months ago?”). Currently no evidence exists about the responsiveness of the FFI-5pt questionnaire, so it could very well be that the comparator instrument is inadequate. One study shows that a GPE question is more correlated with the current state (of foot dysfunction) than with the change of it over the period in question\textsuperscript{16}.

When searching literature for responsiveness of questionnaires it is evident that this is not a measurement property that is assessed often\textsuperscript{17, 18}, even studies reviewing measurement properties of questionnaires some-
times completely ignore responsiveness^{19,20}. Until a questionnaire is created that is more responsive to change, using several questionnaires that measure the same construct might be the best solution.

**ELEMENT SHOE ADVICE: SOLE FLEXION POINT**

As previously mentioned, the content of the shoe advice in the leaflet is only partly based on evidence (Chapter 5). One of the characteristics mentioned in the leaflet and in other literature^{12,21,22} is the placement of the sole flexion point compared to the position of the first metatarsalphalangeal joints (MTPJ-I). It has always been assumed that the flexion point should be positioned underneath MTPJ-I so that the anatomical point of flexion is congruent with that of the shoe. The results in Chapter 7 do not substantiate this assumption. They indicate that only a sole flexion point underneath the midfoot is less favourable for the foot. Thus a next version of the shoe advice leaflet might be adjusted to this result. The effects on foot mechanics of most of the other characteristics are still unknown and thus its importance for footwear advice in general.

**EXTERNAL VALIDITY OF THE RESULTS**

We were not able to record the number of eligible people who did not want to participate in our study. One reason frequently mentioned was that they specifically wanted an insole and did not perceive shoe advice as a treatment. Due to the number of ways one could receive information about the study (GP, GP’s assistant, research assistant, information leaflet) it was impossible to record the amount of people that asked for information and then decided not to participate. Based on retrospective general inquiries among the GPs and the research assistant, on my own recollection and the amount of participants who provided this reason at a later stage we estimate that this happened at least three dozen times. This indicates a considerable inclusion bias. Besides indicating that footwear advice is not always perceived as treatment, it could also mean that the equal effectiveness of the shoe leaflet compared to podiatric treatment only applies for patients who are willing to try both treatments. Since podiatric treatment results in similar treatment effects, the specific wish of the patient can be adhered, the main difference being the cost of the treatment.

The participants of the study underwent a small physical examination to check for exclusion criteria by a group of fourth year podiatry students and myself. Due to practical considerations, the handing out and explanation of the footwear advice leaflet was executed during this session. We chose to provide the advice right after allocation instead of referring the patients back to the GP in order to minimise both the burden of the participant and the burden of the GP and to reduce the amount of dropout. In theory it is possible that the content of the explanation of the leaflet by the research team is different from that of the GP’s. However, during the workshop in which we tested the leaflet we had the impression that the GP’s were comfortable with the content of the advice leaflet.

About 40% of our participants indicated that their forefoot pain existed for two years or more, which could be seen as a chronic condition. Another large group (23.9%) had a much shorter duration of their problem (3-6 months). It is conceivable that a chronic impediment reacts differently to the treatments provided in our studies than problems that have occurred more recently. However, supplementary analysis of the RCT data showed that both more current (3-6 months) and chronic (>24 months) impediments do not benefit differently from either receiving shoe advice or podiatric treatment. But the amount of participants does not enable us to perform this supplementary analysis with sufficient statistical power to exclude such a possibility.

The data used for the process evaluation (Chapter 5) have been gathered from the participants of the main RCT (Chapter 4) and thus from the podiatrists that are currently working in the Amsterdam and Haarlem area. We do not know if the 14 podiatrists of the process analysis and the 17 podiatrists of the main RCT are representative for podiatrists in the Netherlands. A variable that could be of influence might be the time
since they received their training. The podiatry course in the Netherlands has changed from a 2-year duration when it commenced in the 1980’s to a 3-year and to the current 4-year course. It is plausible that the content of the course has changed over time. These changes in the training of podiatrists could have lead to changes in method of working. However, we think we have a representative group of podiatrists; the oldest podiatrist was part of one of the first cohorts of certified podiatrists, the youngest had 4 years of experience and an even spread of experience in between. Furthermore, one of the participating podiatrists was a Saxion university of applied science alumnus, while the others were Fontys university of applied science alumni. This is in accordance with expectations since Fontys has been sole educator for the last 3 decades and Saxion has only opened its doors in the last decade.

RECOMMENDATIONS FOR FUTURE RESEARCH

A great challenge will be to assess the influence of wearing ill fitting shoes or shoes with less desirable characteristics on the development of (fore)foot pain, (fore)foot dysfunction or toe deformities. Circumstantial evidence indicates that such a relation exists.²³-²⁵ The existence of such a causal relationship can however also be disputed and will be very difficult to assess. Since foot pain and related dysfunction are very common, such a study is very important in my opinion. A cohort that can be easily followed over multiple decades (like medical students) might enable us to study possible causal relationships between footwear characteristics and the development of foot pain.

There is no evidence underpinning other treatments for patients who do not benefit from the shoe advice with leaflet nor is it known which people will benefit from the shoe advice. Further research could focus on distinguishing variables that would predict improvement of forefoot pain by means of general shoe advice.

Podiatric treatment of foot problems has been shown to be heterogeneous and our study has shown that this could be due to differences in the assessment of the aetiology. Since this is the first study to have evaluated this part of podiatric practice and the study was a retrospective one, we still do not know if one approach is better than the other. If the approach to establish aetiology would be more homogeneous, it could very well be possible that the treatment would be as well. But before performing more studies on the effect of podiatric treatment it should be established which method is preferred. I for one, am very curious if a purely functional podiatric approach could lead to a different effect when comparing it to shoe advice and I expect that it will have more effect than the effect we observed in the main RCT.

The current content of the shoe advice leaflet has been shown to improve the selection of shoes in women who were prepared to use the leaflet. Nonetheless, additional research should be commenced to eval-
uate the separate items of the leaflet on plantar loading and foot biomechanics so that future versions can be adjusted accordingly. The hypothesis of the expert panel that a toe rocker will aid patients with a hallux limitus or rigidus by reducing the load of the second and third metatarsal heads should be studied. Based on my experience as a woman buying shoes, my experience of advising other women on shoe fit and the lack of literature, the additional length of the shoe compared to the foot should be one of the first characteristics that should be evaluated. If an addition of 1 cm between foot and shoe is advocated than it has to be possible to do so for women. Indications are that this is at least very difficult. Some literature shows that footwear designed for women is fabricated using shoe lasts that are downsized from the lasts that were developed for men. However, a female foot is not comparable to a downsized men’s foot. An important difference is the width of the calcaneus which is narrower in women. This would imply that the shoes presently designed for women are too wide at the calcaneus which would induce slipping during walking. And slipping will probably lead to choosing a shoe that is a size smaller, which has been related to other foot problems.

A future full of possibilities for both foot related research and its clinical practice awaits us. I am happy to have been part of it and hope to be so in the future.

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Foot pain and related functional limitations are common and the chance of developing foot pain increases with age. Approximately 1 in 4 women and 1 in 7 men older than 50, have foot pain, of which 60% is located in the forefoot. Having foot pain and possibly a subsequent functional limitation can affect mobility, increase the chance of falling and affect general sense of well being. The cause of developing forefoot pain is neither known nor previously studied. Nevertheless, wearing ill-fitting shoes or shoes of poor quality has been related to the existence of Hallux valgus, lesser toe deformities and foot pain.

Most patients with foot pain that seek medical attention consult their GP. GPs can treat the pain by prescribing pain relief medication, by providing advice (wear better shoes or lose weight) or by referring to other (para)medical specialists like podiatrists or orthopaedic surgeons.

The aim of the main study described in this thesis is to investigate the effect of podiatric treatment versus standardised shoe advice on foot pain, foot disability, quality of life and social participation in people aged 50 years and older with hindering forefoot pain in primary care.

**CHAPTER 2 AND CHAPTER 3**

A total of 205 patients with forefoot pain who indicated to also have a functional limitation of foot related activities were included for this study. They were randomly allocated to receive podiatric treatment or shoe advice by means of an information leaflet. During a follow-up of 12 months, every 3 months foot pain, foot dysfunction, general health and social participation were assessed with questionnaires.

No difference between the groups was observed in any of the out-
come measures. Both groups decreased in foot pain and foot dysfunction equally but did not change in general health or social participation. The results of this study indicate that providing shoe advice and podiatric treatment are equal beneficial for patients who consult their GP with functional limiting forefoot pain. Therefore a GP could start by providing a less costly shoe advice first or ask the podiatrist to do so before fabricating an insole.

CHAPTER 4
The aims of this study are: (i) to describe general podiatric treatment of patients with forefoot pain and (ii) to evaluate the entire treatment process using an expert panel. Twenty-five participants of the main study (Chapters 2 and 3) participated in this study. A group of experts (a podiatrist, a human movement scientist and an orthopaedic surgeon) evaluated the baseline data and the findings described by the podiatrist and performed a physical examination, on average, 3 months after inclusion. The expert panel identified two different approaches in establishing aetiology of the podiatrists. Firstly they defined a functional approach in which the podiatrist looks for the cause of the problems by evaluating the kinetic chain and other external factors that might influence the foot pathology. And secondly, a non-functional approach in which the podiatrist evaluates at a more local manner. The heterogeneousness of assessing aetiology may be related to the heterogeneous results established in other studies and may have had an effect on the lack of difference between the interventions described in Chapters 2 and 3.

CHAPTER 5
The aims of this study are: (i) to determine which shoe characteristics should be included when providing information about footwear for patients with foot pain, (ii) to develop an information leaflet, (iii) to evaluate if women asked to select shoes with the developed leaflet are able to choose better footwear than women who do not have the leaflet.

The content of the information leaflet was based on evidence and professional opinion due to the lack of evidence on the influence of shoe characteristics on foot pain and dysfunction. A leaflet was developed with 9 characteristics; 6 functional and 3 fit characteristics. A total of 59 women with an average age of 69 (range 54-86) were asked to find shoes in a shopping mall that they liked and thought appropriate to walk on for several consecutive hours. Twenty-nine randomised women did so with the help of the information leaflet. The shoes were assessed by two podiatrists who were not aware whether the women had made use of the leaflet. The women using the leaflet were able to choose shoes that were more appropriate according to the leaflet than those without. Thus the leaflet seems to be efficacious.

CHAPTER 6
The aims of the study described in this chapter are (i) to create a Dutch version of the Manchester Foot Pain and Disability Index (MFPDI) and (ii) to evaluate all measurement properties based on the Classical Test Theory (CTT), including a cross-cultural validation of the Manchester Foot Pain and Disability Index using the Dutch translated version. Foot pain and related dysfunction as described in Chapters 2 and 3 were measured using this questionnaire together with two others. Using the data from this study we assessed measurement properties.

The questionnaire is comprised of 3 factors and we concluded that the functional limitations factor is the only factor that is reliable. In the functional limitations sub-scale, no differences have been found that can attributed to language or culture between the Dutch and the UK version of the questionnaire and the scale is valid. Responsiveness is moderate. Based on these findings and other studies the other sub-scales should not be used henceforth and using the functional limitation scale for longitudinal studies should be done with caution.

CHAPTER 7
The aim of this study was to evaluate the effects of three different positions of the sole flexion point on plantar loading during gait: a sole flexion point right underneath the metatarsalphalangeal joints MTPJs (control), one proximal to the MTRJs and one underneath the tarso-metatarsal joints.
For every conditions the same brand and make shoes were used of which the outer sole was incised until the inner sole was reached. Peak pressure (PP), pressure time integral (PTI) and contact time (CT) were assessed during walking.

We did not observe an increase of the variables as hypothesized. However, a decrease of PP, PTI and CT underneath the hindfoot and midfoot was observed with the midfoot sole flexion point. This could indicate that the foot is slipping within the shoe and therefore increasing shear force behind the calcaneus. This study indicates that the location of the sole flexion point does not have to be underneath the MTRJs as previously assumed.

CHAPTER 8

Based on the studies described in this thesis and the current heterogeneous state of podiatry as seen in our study, providing shoe advice by means of a shoe advice leaflet is an acceptable treatment for forefoot pain in primary care. In a future version of the leaflet the position of the sole flexion point does not have to be as stringently positioned as it is in the current leaflet. Furthermore, use of the MFPDI in future longitudinal studies should be done with caution or an alternative should be developed that is more responsive to change.

Samenvatting

Pijn in de voet(en) komt veel voor en ouder worden vergroot de kans op het ontwikkelen ervan. Ongeveer 1 op de 4 vrouwen en 1 op de 7 mannen boven de 50 jaar heeft pijn in de voet(en). Van deze mensen heeft 60% pijn in de voorvoet. Het hebben van pijn in de voet(en) kan leiden tot verminderde mobiliteit, verminderd gevoel van welbevinden en een vergrote kans op vallen. Het dragen van niet passend schoeisel of schoenen met minder goede eigenschappen is in verband gebracht met de aanwezigheid van hallux valgus, teenafwijkingen en pijn in de voet(en). De oorzaak van het ontwikkelen van pijn in de voet(en) is echter tot op heden nog niet wetenschappelijk onderzocht.

De meeste mensen in Nederland met pijn in de voet(en) consulteren hun huisarts voor medisch advies. Huisartsen gebruiken meerdere therapeutische opties: het advies om betere schoenen te dragen of af te vallen, een behandeling met pijnstillende medicijnen, verwijzen naar paramedische specialisten zoals een podotherapeut of verwijzing naar een orthopedisch chirurg.

Het doel van het hoofdonderzoek zoals beschreven in dit proefschrift is om het effect van een podotherapeutische behandeling te vergelijken met het effect van een gestandaardiseerd schoenadvies op pijn in de voorvoet(en), het functioneren van de voet, de algemene gezondheid en sociale participatie bij mensen van 50 jaar of ouder die hun huisarts consulteren in verband met pijn in de voorvoet(en).

HOOFDSTUK 2 EN 3

Aan het hoofdonderzoek hebben 205 patiënten deelgenomen die pijn hadden in de voorvoet en hierdoor functioneel belemmerd waren. Middels
door een probleem op lokaal niveau. Deze twee zeer verschillende manieren van benadering zijn mogelijk gerelateerd aan de heterogene resultaten van podotherapie die in andere studies worden gevonden. Daarnaast heeft het mogelijk invloed op het uitslijten van een verschil in de interventies zoals beschreven in hoofdstuk 2 en 3.

**HOOFDSTUK 5**

De doelstellingen van dit onderzoek zijn: (i) vaststellen welke schoeneigenschappen en welke aspecten van de pasvorm onderdeel zouden moeten zijn van een schoenadvies voor mensen met pijn in de voet(en), (ii) een schoenadviesfolder ontwerpen en (iii) evalueren of vrouwen met behulp van de folder betere schoenen uit kunnen zoeken dan vrouwen die de folder niet gebruiken. Er is weinig wetenschappelijke literatuur over de invloed van schoenen op voetpijn en het functioneren van de voet. Omdat de inhoud van de adviesfolder zowel gebaseerd op wetenschappelijk onderzoek als opvattingen uit de praktijk. De ontwikkelde schoenadviesfolder bestaat uit 9 onderdelen: 6 functionele eigenschappen en 3 eigenschappen over pasvorm. Negenvijftig vrouwen van 50 jaar en ouder hebben deelgenomen aan dit onderzoek. Zij werden gevraagd om in een winkelcentrum schoenen uit te zoeken waarop ze naarminder of meer onder elkaar zouden kunnen lopen en staan. Van deze groep werden 29 vrouwen middels loting geselecteerd om zich bij de schoenkeuze te laten ondersteunen door de informatie uit de ontwikkelde folder. De eigenschappen van de uitgekozen schoenen werden vervolgens beoordeeld door twee podotherapeuten. Zij waren niet op de hoogte wie er een folder had gebruikt. De door de vrouwen die de folder gebruikten uitgekozen schoenen kwamen beter overeen met de adviezen in de folder dan de schoenen die zonder folder waren uitgekozen. Derhalve lijkt de folder werkezaam.

**HOOFDSTUK 6**

De doelstellingen van dit onderzoek zijn: (i) het ontwikkelen van een Nederlandse versie van de ‘Manchester Foot Pain and Disability Index’ (MFPDI) en (ii) de klinimetrische eigenschappen van de
MFPDI bepalen gebaseerd op de ‘Classical Test Theory’. Een cross-culturele validatie van de Nederlandse versie ten opzichte van de originele versie is hier een onderdeel van. Voetpijn en voetfunctie zoals beschreven in hoofdstuk 2 en 3 zijn gemeten met behulp van de MFPDI en twee andere vragenlijsten. Deze data zijn gebruikt om de klinimetrische eigenschappen van de MFPDI te bepalen. De MFPDI bestaat uit 3 factoren en we hebben vastgesteld dat alleen de factor die voetfunctie meet betrouwbaar is. Uit de cross-culturele validatie blijkt dat uitkomsten van de Nederlandse versie van deze factor hetzelfde geïnterpreteerd kunnen worden als de resultaten gemeten met de originele Engelse versie. Daarnaast blijkt deze voetfunctiefactor valide te zijn. De responsiviteit van deze factor is echter matig. Gebaseerd op deze resultaten en die van andere studies zouden de andere factoren niet meer gebruikt moeten worden. Tevens is voorzichtigheid geboden bij het gebruik van de voetfunctiefactor in longitudinale studies of moet er een nieuwe lijst ontwikkeld worden die gevoeliger is voor verandering.

HOOFDSTUK 7
Dit laatste deelonderzoek had als doel om de effecten te bepalen van drie verschillende posities van het buigpunt van de schoen op de plantaire belasting tijdens het lopen. Wij onderzochten een buigpunt direct onder de metatarsophalangeale gewrichten (MTP gewrichten) met zowel een buigpunt proximaal van de MTP gewrichten als een buigpunt onder de tarsometatarsale gewrichten (middenvoet). Tijdens dit onderzoek werd één model schoenen van hetzelfde merk gebruikt. Het buigpunt werd opgelegd door de buitenzool tot aan de binnenzool in te snijden. Tijdens het lopen op een zelf gekozen snelheid zijn piekdruk (Peak Pressure; PP), druk tijd integraal (Pressure Time Integral; PTI) en contact tijd (CT) gemeten.

Voorafgaand aan de studie verwachten we een toenem van de PTI onder de voorvoet bij schoenen met een buigpunt dat niet direct onder de MTP gewrichten ligt. Echter, dit werd niet waargenomen. Bij het dragen van de schoen met een buigpunt onder de middenvoet werd een afname van de PP, PTI en CT aan de achterzijde van voet vastgesteld. Dit zou kunnen betekenen dat de hiel binnen in de schoen slipt. Hierdoor zou er een wrijvingskracht kunnen ontstaan tussen de hiel en het binnenwerk van de schoen. Deze resultaten duiden erop dat het buigpunt van de schoen niet direct onder de MTP gewrichten hoeft te liggen zoals eerder aangenomen. Een ligging van het buigpunt onder de middenvoet lijkt minder acceptabel.

HOOFDSTUK 8
Op basis van de onderzoeken beschreven in dit proefschrift en de geobserveerde niet-uniforme werkwijze van de podotherapeuten is het geven van schoenadvies met behulp van een folder een acceptabele behandeling voor mensen met pijn in de voorvoet(en) in de eerste lijn. Voor toekomstig schoenadvies hoeft de ligging van het buigpunt van een schoen niet meer beschreven te worden als: “direct onder de MTP gewrichten”. Voorzichtigheid is geboden voor het gebruik van de MFPDI in longitudinale studies.
Dankwoord

De afgelopen jaren heb ik met veel plezier aan dit onderzoek en proefschrift gewerkt. Er zijn veel mensen die mijn pad hebben gekruist waar ik wat van geleerd heb of die mijn pad een stuk mooier hebben gemaakt. Een aantal mensen wil ik in het bijzonder noemen.

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2001  Dissection lab assistant Anatomy lab; VU medical centre
2003  Lecturer; European School for Physiotherapy University of Amsterdam for
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2005  Lecturer; podiatry Fontys University for Applied Sciences.
      (Anatomy, Biomechanics, Motion analysis, Gait analysis, coordination of
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2007  Project leader Development and Administrator Part time course Podiatry,
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2009  PhD candidate; department of General practice and elderly care medicine VU
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2012  Research Internship; Musculo-Skeletal Research Centre La Trobe University
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LIST OF PUBLICATIONS
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2013 van der Zwaard BC, Poppe E, Vanwanseele B, van der Horst HE, Elders PJ; Development and evaluation of a leaflet containing shoe advice: a randomised controlled trial. Family Practice. 2013 Accepted December 2nd; in print.


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International presentations

November 2013
Oral presentation Treatment of forefoot problems in older people; a randomised clinical trial comparing podiatric treatment to standardised shoe advice. Conference: North American Primary Care Research Group annual meeting 2013 (Ottawa, Canada), Organisation: North American Primary Care Research Group

October 2013
Oral presentation Variation in the location of the shoe sole flexion point influences plantar loading patterns during gait: A randomised controlled trial. Conference: World Congress of Podiatry (Rome Italy), Organisation: Fédération Internationale des Podologues

November 2009
Poster presentation Treatment of forefoot problems in older people; study protocol for a randomised clinical trial comparing podiatric treatment to standardised shoe advice. Conference: World Congress Orthopaedic Shoe Technology (the Hague, Netherlands) Organisation: NVOS-Orthobanda

Dutch Non Peer Reviewed Publications

2011 van der Zwaard BC; “Falling and getting up again: decreased proprioception enhances the risk of falling with the elderly(1).” Medische voet 2011 Feb; 4(1): 4-7

van der Zwaard BC; “Falling and getting up again: decreased proprioception enhances the risk of falling with the elderly(2).” Medische voet 2011 Apr; 4(2): 12-14

van der Zwaard BC; “Getting older balanced: Keep moving is good for body and mind.” Medische voet 2011 Okt; 4(5): 30-31

van der Zwaard BC; “Childerns’ shoes; what to look for as a parent?” Medische voet 2011 dec; 4(6): 4-7
Invited lectures

2013  Forefoot problems in older adults: provide shoe advice or podiatric treatment?  
Meeting: Research meeting department of General Practice and Elderly care medicine Organisation: VU medical centre.

2010-current
Foot 101; understanding foot mechanics and treatments. Meeting: GP specialisation training; Organisation: VU medical centre.

2012  Key note presentation: The relationships between foot motion and motion of the lower extremity. Conference: The day of the Foot in Brussels; Organisation: De Medische Voet

Research proposal: Does an information leaflet containing shoe advice enable women to wear better fitting shoes? Meeting: Research meeting department of General Practice and Elderly care medicine Organisation: VU medical centre.

Provide shoe advice as a GP. Meeting: Bi-annual meeting Academic Network of General Practitioners Organisation: VU medical centre.

The plantar fat pad. Conference: Mechanical stress; Organisation: Provoet  