Bachelor Thesis Psychology

# “Exploring the relationship between usability perception of orthopedic shoes and activity levels in people with diabetes with a high risk for foot ulcers. “

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June 2021

## Abstract

**Background.** People with diabetes often have a high risk of getting foot ulcers. These are closely related to limitations in mobility and high treatment costs due to hospitalization or amputation. To minimize the risk of getting foot ulcers, it is important actually to wear orthopedic shoes by people with diabetes at high risk of foot ulcers. The willingness of wearing orthopedic shoes is closely related to the usability perception of these shoes. Moreover, it is crucial to walk in orthopedic shoes daily to see improvements in factors like wound healing and minimize the risk of foot ulcers.

**Objective.** The study aimed to assess the relationship between the three domains of usability perception namely effectiveness, efficiency, and satisfaction determined by the questionnaire "Monitor Orthopedic Shoes" (MOS) and the activity level of patients with diabetes with a high risk for foot ulcers.

**Method.** The sample of this study consisted of 56 participants. The participants' mean age was 66.78 and consisted of 14 females and 42 males. All participants were Dutch. The usability perception of orthopedic shoes was measured using the MOS questionnaire. Lastly, the steps taken per day were measured with the activity monitor "Misfit shine 2". Frequency analysis and a post hoc analysis have been conducted to investigate the differences between the groups of step count while looking at the aspects of usability perception.

**Results.** The main findings of this research were that reduction of pain in the muscles, high satisfaction of donning and doffing orthopedic shoes, and satisfaction about communication with the orthopedic shoe technician are related to higher activity levels measured in steps made per day.

**Discussion.** It was surprising that significance was found in only one aspect out of all three usability domains because some aspects like change in pain in the muscle, sprain, and skin can be expected to be related to each other. For future research, it can be suggested to integrate activity sensors insight the orthopedic shoes in order to determine if participants have worn their orthopedic shoes while making steps. This would give insights if the current findings can be associated with the use of orthopedic shoes or might be based on other factors.

## Introduction

Due to the rising numbers of people that suffer from diabetes mellitus studies investigating the disease's side effects are getting more and more important nowadays (Yazdanpanah et al., 2015).

Diabetes mellitus can be defined as a metabolic disorder (Kerner & Brückel, 2014). Within the metabolism, the uptake of glucose from the blood in the cells is disrupted which leads to higher blood glucose levels. Many years of high blood glucose levels can cause damage to blood cells and different organs (Kerner & Brückel, 2014). Standl et al. (2019) indicate that 8.8 percent (425 million people) of the world population are affected by diabetes. Due to 2045, an increase of 9.9 percent is predicted because of the rising prevalence of obesity which is caused by unbalanced nutrition and low physical activity (Standl et al., 2019). In general, diabetes can be separated into diabetes type 1 and type 2. Diabetes type 1 is caused by the destruction of beta cells which are responsible for the production of insulin. The blood beta cells will be attacked and destroyed by the body itself. Therefore, it can be reasoned that diabetes type 1 is an autoimmune disease where affected people need insulin in order to balance the insulin deficit (Bullard et al., 2018). Diabetes type 2 is mainly caused by obesity and an unhealthy lifestyle. Over time the body builds up an insulin resistance in which insulin will still be produced but loses its effect. Therefore, diabetes type 2 will be diagnosed in adulthood most of the time (Rawshani et al., 2017).

Diabetes mellitus type 1 and 2 can cause apart from the main disease other side effects that impair the affected people even more in their daily life. Coronary heart disease and cerebrovascular disease can be named as examples of long consequences caused by diabetes (Morgan et al., 2000). Another long-term consequence are foot ulcers which can appear in both types of diabetes. According to Yazdanpanah et al. (2018), 15-25% of people with diabetes develop foot ulcers during their course of the disease. Foot ulcers can develop due to nerve injuries, circulatory disturbances, or too high blood glucose levels (Syafril, 2018). According to Noor et al. (2015), peripheral neuropathy and peripheral vascular disease can be named as the main causes of foot ulcers. More precisely, peripheral neuropathy which is caused by metabolic abnormalities leads to impairments of the nerve system. Deficits in motor, sensory and autonomic

functions favor the development of infections and foot ulcers (Noor et al., 2015). Peripheral vascular disease can cause the blockage of medium and large-sized arteries resulting in ischemia. Ischemia has a bad impact on the healing process (National Diabetes Advisory Board, 1983). Moreover, symptoms like infections, poor wound healing can lead to loss of mobility in the form of amputation and strong pain development (Syafril, 2018). Under consideration of all these aspects, it can be argued that foot ulcers can harm the patients` quality of life.

However, many patients with diabetes are not aware of the consequences and risks that can be caused by foot ulcers. Lack of research, clinical practice and the prioritizing of ulcer prevention can be named as related risks (Lim et al., 2017). Moreover, in an advanced stage of peripheral neuropathy, people with diabetes lose the sense of pain in their lower extremities (Noor et al., 2015). As a result of this people with diabetes are not aware of the importance of an adequate treatment of foot ulcers. (Amin, & Doupis, 2016). Therefore, patients, as well as the health care sector, have to become more sensitive in detecting possible risks of diabetic foot ulcers and take this problem more seriously. A research report in 2020 described that a combination of foot care, therapeutic footwear, self-management, and patients education can prevent 75% of foot ulcers (van Netten et al., 2020). The factor self-management is especially crucial because patients need to understand the importance of foot ulcer prevention. Jones et al. (2019) found that non-orthopedic shoes, which do not fit properly, cause a break in skins in 20.6% of all participants. It is clear that awareness of patients for foot problems in combination with the use of orthopedic shoes is essential (Jones et al., 2019).

However, a study in the Netherlands showed that just 46-49% of the participants wear their orthopedic shoes at least 80% a day (Waaijman et al., 2013). According to Waaijman et al. adherence at home (22%) was lower than away from home (69%). Results showed that the activity level at home was even higher than compared of away from home (Waaijman et al., 2013). Moreover, it is important that people with diabetes use their orthopedic shoes all the time. Indoor walking can be seen as problematic since people wear other shoes in these situations (Kooiman et al., 2018). Besides this, Kooiman et al. (2018) suggest making at least 7500 steps per day in order to increase the physical activity of people with diabetes and simultaneously minimize potential health risks like foot ulcers. However, research by Mueller (2020) showed

that people with diabetes with a high risk for foot ulcers only take about 2000 steps per day. While, on the other hand, research has shown that patients, which had a high activity level (13 000 steps per day) were less vulnerable for symptoms like skin break (Mueller, 2020). Mueller, (2020) recommended also that the step count made per day should increase in certain time intervals in order to develop a feeling of self-awareness in relation to diabetic foot problems.

In order to motivate people with diabetes to make a lot of steps per day in orthopedic shoes, it is important that they are confident with their shoes. The “Monitor Orthopedic Shoes” (MOS) questionnaire helps to determine the use and usability of orthopedic shoes from a patient's perspective. The questionnaire was developed by a Dutch research team in 2009 (van Netten et al., 2009). Insights into the patients' perception make it easier to identify individual and general problems with orthopedic shoes. The International Organization for Standardization defines usability as, “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction, in a specified context of use“ (Bevan, Carter, Earthy, Geis, & Harker, 2016). These three domains of usability are also represented within the MOS questionnaire (van Netten et al., 2009). The domain's effectiveness and efficiency need to be positively accomplished in order to reach satisfaction (van Netten et al., 2009). Effectiveness determines to what extent a goal for example using OS (orthopedic shoes) frequently is reached. The amount of energy it takes to reach the defined goal is described by efficiency. Lastly, satisfaction contains the acceptance of the product in order to achieve the goal. Moreover, all three domains can be identified in form of different factors like an increase in stability (effectiveness) due to better fit of orthopedic shoes (efficiency) may lead to an increase of using time per day. Factors like cosmetic appearance or communication with medical specialists belong to the domain satisfaction. An investigation in 2010 found that the three domains and their factors of usability were associated with the frequency of using orthopedic shoes (van Netten et al., 2010).

In order to prevent people with diabetes from getting foot ulcers and keep or gain a stable physical activity level, it would be interesting to investigate if the domains of usability are related to the activity level measured in steps made per day. Therefore, the study aimed to assess the relationship between the three domains of usability perception namely effectiveness, efficiency,

and satisfaction determined by the questionnaire “Monitor Orthopedic Shoes“ and the activity level of people with diabetes with a high risk for foot ulcers. It is hypothesized that positive effects reported in the MOS like wound healing, change in pain (effectiveness domain), ease of walking with OS,  the weight of OS (efficiency domain), or cosmetic appearance of OS (satisfaction domain) are related to higher activity levels measured in form of steps made per day.

## Methods

### Design

This research is part of a larger study executed by Jongebloed - Westra et al. (2021, submitted). The longitudinal study called “Using motivational interviewing combined with digital shoe-fitting to improve adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration“ investigates how the adherence of orthopedic shoes within people with diabetes can be improved. Within this main study also other measurements were taken which are not important to the current study and will not further be discussed. Moreover, with the permission of the author, all relevant materials from the main study were used in order to answer the research question. The research was approved by the University of Twente BMS Ethics Committee (EC) (approval code: 190141) and by the METC (NL 68567.091.19.).

The current study examined whether there is a significant relationship between usability perception of orthopedic shoes reported by patients with diabetes and their activity levels. Therefore, this investigation is an exploratory quantitative research. In contrast to the main study the current study employs a cross-sectional study design that involves data collection and analysis at a specific point in time. In addition, the data collection was executed on a within-person level since each participant was measured in the same condition.

### Participants

The participants of the main study executed by Jongebloed - Westra et al. (2021, submitted) were recruited from Voetencentrum Wender and Voetmax Orthopedie in the Netherlands. The foot care

was reimbursed by the Dutch health care system. People had to fulfill the following inclusion criteria in order to be eligible for the main study: a clinical diagnosis of diabetes mellitus type 1 or 2, being 18 years or older, with or without previous callus and/or ulcers, identified with risk profiles 2, 3 or 4, according to the 'zorgmodule preventie diabetische voetulcera 2014' (van Loghum, 2014), and the participants had to be eligible for a prescription of orthopedic shoes (Jongebloed - Westra et al., 2021, submitted). In order to be eligible for the current study, participants had to meet the inclusion criteria of sharing their personal data in the case report form, filling out the MOS questionnaire (6 months after inclusion), and be part of the activity monitoring (6 months after inclusion).

The available data at 06.05.2021 consisted of 140 participants within the main study. Based on the available data of the main study, 84 participants had to be excluded from the sample, which results in the current study in a final sample size of 56 participants. The participants consisted of 14 females and 42 males. The age ranged from 48 to 88 years (Mean= 66.87; SD= 9.19). All people were Dutch and participated voluntarily in the study. Before their participation, people were asked to sign a consent form (appendix A).

## Materials

### Case Report Form (Appendix B)

The case report form was used to get a first picture of the participants and their state of disease at the beginning of the main study. For example, it contains questions regarding demographics, type of diabetes, physical characteristics, and current footwear. For the current study, the first three questions were used in order to determine the patient's gender, age and nationality.

### Monitor Orthopedic Shoes (MOS) (appendix C)

The "Monitor Orthopedic Shoes" questionnaire measures the patient's usability perception of orthopedic shoes (van Netten et al., 2009). It was developed by van Netten and colleagues in 2009 (van Netten et al., 2009). The MOS can be used to gain information about the patient's expectations (pre-part) as well as the experiences after wearing the orthopedic shoes (post-part).

For the purpose of this investigation, only the post-part has been used. In general, the questionnaire contains 39 items with a variety of multiple-choice-, open-, visual analog scale- and picture-based questions. In order to measure the most relevant factors of usability of orthopedic shoes from a participant's perspective, 20 items have been used. The other items were excluded from the dataset because they were not relevant for the purpose of the current study. The usability of orthopedic shoes has been determined through three different domains called “effectiveness“, “efficiency“ and “satisfaction“ (van Netten et al., 2009). These measured the following aspects: change in walking capacity (Item B), wound healing (Item 10), change in pain in the skin (Items 1,7) and muscles (Items 2,8), and change in sprains (Items 4,9) (domain effectiveness); donning and doffing OS (Item 19), fit of OS (Items 13,14), ease of walking with OS (Items 15,16), and weight of OS (Items 17,18) (domain efficiency); cosmetic appearance in patients (Items 11,27) and others (Item 12), and communication with medical specialist and orthopedic shoe technician (Items 25, 26) (domain satisfaction).

The three items walking capacity wound healing and the cosmetic appearance perceived from others were measured through multiple choice questions with six different options to answer. For example, did the question “Have your orthopedic shoes caused a change to the wounds on your feet and/or ankles?“, contains answer options ranking from “that doesn’t apply to me“ to “more wounds“. The other 17 items were determined through the “Visual Analog Scale“. The VAS is a psychometric scale where the participants have to mark their perception on the scale somewhere between two different extremes (Crichton, 2001). Participants for example had the option to answer between “very ugly“ and “very beautiful“ when they were asked about the shoes’ appearance. Higher scores reflect a more positive usability perception by the participants like a higher reduction in the pain in the muscles.

**Misfit shine 2**

The “Misfit shine 2“ (Misfit Wearable, Burlingame, California, USA) has been used in order to gain insights into the peoples’ activity parameter “steps taken per day“. The device is a small tri-axial accelerometer that was carried at the wrist and is able to measure certain physical parameters like steps, distance, activity types, or duration. In the current study, just the steps

taken per day have been reported. The data capacity during the wearing period was sufficient because the Misfit shine 2 can hold up to 30 days of data. The Windows version of the MisFit app was used in order to transfer the data to the computer. The app generates graphs of the physical activities which makes it possible to get values appointed. These data can be imported into Excel where the number of steps per half-hour and the number of steps per day will be calculated. In the current study, data from number of steps per day were taken in order to get insights into the physical activity in diabetes patients with a high risk of foot ulcers.

**Procedure**

During a multidisciplinary consultation with the pedorthist and medical specialist, patients that meet the inclusion criteria were asked if they would like to participate within the main study. The pedorthist informed the investigator about potential participants and shared their information. Moreover, patients that showed interest became the chance to discuss open questions with the investigator and get precise information about the study. All patients that decided to participate were asked to sign a consent form. Participants were asked about their demographics. One of the researchers filled out these informations in the case report form at the moment the participant started in the study.

For the clarification of the chronological context, it has to be mentioned that the relevant measurements for the current study were taken approximately six months after the inclusion of a participant of the main study. The date of the meetings with the investigator varied between the participants. First, the participants received instructions about the activity monitor (Misfit Shine 2™) during a control consultation with the investigator. From the day after the consultation, they had to wear the Misfit Shine 2 for a whole week 24 hours per day. Afterwards the researcher transferred the gained data towards a secured server of the University of Twente. The MOS was filled out at home after the appointment with the investigator and the completion of the questionnaire took approximately 20 minutes.

**Data Analysis**

The statistical program IBM SPSS version 26 was used to analyze the data. The aim of the study was to investigate the relationship between the three domains of usability namely effectiveness, efficiency, and satisfaction determined by the questionnaire “Monitor Orthopedic Shoes" and the activity level of diabetes patients with a high risk for foot ulcers. The steps taken per day were divided into three categories: few steps (0- 2750 steps), moderate steps (2750- 5500 steps), many steps (5500 and more steps). Regarding the data of the Misfit shine 2, the mean scores were calculated in Microsoft Exel. Moreover, the standard deviation of every participant was calculated in SPSS. The data was used in order to determine the belonging category of steps taken per day. Participants were only included in the analyses if at least four weekdays and one weekend day of activity data, were available (Waaijman et al., 2013).

First, data screening helped to exclude all non-relevant data and missing values from the data set. Furthermore, descriptive statistics were used to analyze the participants' age and gender. Before analyzing the domains of usability perception the following items (1,2,4,7,8,9,17 and 18) had to be recoded so that the score 100 was the most positive score in all aspects. This made the data analysis much easier because all items were coded in the same direction. Moreover, items belonging to one aspect of one usability domain were summed up to one single scale score. Therefore, the mean score of both items was calculated. More precisely the items of the aspects change in pain in the skin (Items 1,7) change in sprains (Items 4,9) fit of OS (Items 13,14), ease of walking with OS (Items 15,16), the weight of OS (Items 17,18) cosmetic appearance in patients (Items 11,27) and communication with medical specialist and orthopedic shoe technician (Items 25, 26) were summed up into one single score of each aspect. Next, frequencies within the categories of step count were calculated in order to determine how these differ between the different aspects. Frequencies of categorical variables were calculated in percentages and data from scale scores was shown by the median. Because of the non-normal distributed data a Kruskal-Wallis test was used in order to see if there exists a difference between the categories of step count while looking at the different aspects of usability perception. The level for significant p-value was set at 0.05. All aspects that showed a significant difference in the categories of step count were further analyzed in form of a post hoc analysis. This was done in order to assess the

differences between the usability domains and the step count categories. For categorical variables, a Chi-square test and Cramér's V were used. Additionally, a Mann-Whitney U-test was used for scale measures with a non-normal distribution of the data. The effect size was calculated with $r = (z / \sqrt{n})$ (Karadimitriou et al., 2018).

## Results

### Descriptive statistics

Based on the available data of the main study of Jongebloed-Westra et al. (2021, submitted), 84 out of 140 participants had to be excluded from the data set for example because of not filling out the MOS questionnaire or not participating within the activity monitoring in form of the "Misfit shine 2". At the time point of collecting the step count data around 6 months after inclusion, it could be determined that 35% (n=20) of the participants made a few steps per day, 34% (n=19) had a moderate level of steps per day, and 30% (n=17) made many steps per day (Table 1). Moreover, within Table 1 it can be seen that according to the Kruskall-Wallis test no significant differences were found between the age and gender, and the frequency of steps in three categories (few, moderate, many).

**Table 1**

Participants characteristics, categorized with regard to the frequency of steps made per day six month after inclusion

| | | Few steps (35%; n = 20) | Moderate steps (34%; n = 19) | Many steps (30%; n = 17) | *p* |
|---|---|---|---|---|---|
| Age (years) | mean ± SD | 69 ± 8.5 | 66 ± 8.5 | 65 ± 10.6 | .343 |
| Gender | Male | 28% (16) | 21% (12) | 25% (14) | .293 |
| | Female | 7% (4) | 13% (7) | 5% (3) | |

*Note*. Values are % (*n*) or as indicated. Percentages may not add to 100 due to rounding. Few steps = making in the week of data collection on average between 0-2750 steps a day; Moderate steps = making between 2750-5500 steps per day; Many steps = making 5500 or more steps per day. *: The p-value determining the differences between the three groups of step count on that usability aspect is shown. The level for significant p-value was set at 0.05

## Frequency analysis of steps taken per day and the aspects of the participants' usability perception

Table 2 shows the association between the frequency of steps and the aspects of the participants' usability perception of orthopedic shoes. A significant difference between the groups was found for three of the 13 aspects of usability perception of orthopedic shoes. However, a more positive score for participants who also made many steps per day was just found in the two aspects "Communication with orthopedic shoe technician" and "Change in pain (muscles)". Hereby, a more positive score means a satisfying communication with the orthopedic shoe technician and a reduction in pain in the muscle. Within the aspect of "Donning / doffing OS" it was found that the score between the step count categories moderate steps and many steps were the same. Although, a Chi-square test was not applicable because more than 25% of the cells had an expected count of less than five. However, it could be observed that participants who made many steps per day had a larger improvement regarding their walking capacity. Even though, no differences were found regarding the aspects "Wounds after OS" and "Cosmetic appearance (others)". The frequencies of all other aspects can found in table 2. Including the ones that did not show any significant differences between the categories of step count.

**Table 2**

The association between activity monitoring in form of steps made per day and aspects of participants usability perception regarding their orthopedic shoes.

| | Few steps (35%; *n* = 20) | Moderate steps (34%; *n* = 19) | Many steps (30%; *n* = 17) | *p* |
|---|---|---|---|---|
| **Effectiveness** | | | | |
| Walking capacity | | | | NA[a] |

**Table 2 (continued)**

| | | | | |
|---|---|---|---|---|
| Improved, because of OS | 40% (8) | 54% (10) | 76% (13) | |
| Improved, not because of OS | 5% (1) | 5% (1) | 12% (2) | |
| No change | 30% (6) | 32% (6) | 12% (2) | |
| Deteriorated, not because of OS | 25% (5) | 10% (2) | - | |
| Deteriorated, because of OS | - | - | - | |
| Missing | - | - | - | |
| Wounds after OS | | | | NA[a] |
| More wounds | 5% (1) | - | | |
| Bigger wounds | - | - | | |
| No change | 15% (3) | 26% (5) | 12% (2) | |
| Less wounds | 25% (5) | 21% (4) | 24% (4) | |
| Smaller wounds | 10% (2) | 11% (2) | 18% (3) | |
| Missing | 45% (9) | 42% (8) | 47,1% (2) | |
| Change in pain (skin)[b] | 89 (71.8 ; 90.7) | 65 (53.5 ; 78,6) | 81 (68.7 ; 87.3) | .144 |
| Change in pain (muscle)[b] | 79 (65.4 ; 84.8) | 53 (44.4 ; 66.8) | 89 (73.5 ; 91.1) | .002* |
| Change in pain (sprains)[b] | 98 (92.5 ; 97.7) | 97 (72.4 ; 96.8) | 97 (81.5 ; 98) | .753 |
| **Efficiency** | | | | |
| Donning / doffing OS[b] | 45 (31.5 ; 56.8) | 79 (52.1 ; 81.2) | 79 (63.5 ; 85.5) | .004* |
| Weight of OS[b] | 55 (42.1 ; 60.4) | 52 (39.7 ; 52.4) | 53 (41.7 ; 65.8) | .345 |
| Fit of OS[b] | 85 (71.3 ; 90.3) | 75 (69.5 ; 84.6) | 84 (75.9 ; 90.5) | .409 |
| Ease of walking with OS[b] | 78 (64.7 ; 85.9) | 82 (66.1 ; 83.9) | 88 (77.36 ; 91.8) | .186 |
| **Satisfaction** | | | | |
| Cosmetic appearance (patient)[b] | 66 (58.5 ; 74.1) | 69 (58.4 ; 74.3) | 85 (64.8 ; 87.6) | .096 |

**Table 2 (continued)**

| | | | | |
|---|---|---|---|---|
| Cosmetic appearance (others) | | | | NA[a] |
| Very ugly | - | - | - | |
| Ugly | 5% (1) | - | - | |
| Neutral | 20% (4) | 26% (5) | 41% (7) | |
| Attractive | 30% (6) | 42% (8) | 24% (4) | |
| Very attractive | 25% (5) | 16% (3) | 29% (5) | |
| Missing | 20% (4) | 16% (3) | 6% (1) | |
| Communication with MS[b] | 86 (73.1 ; 90.1) | 89 (67.6 ; 93.8) | 94 (87.1 ; 96.3) | .077 |
| Communication with OST[b] | 84 (69.3 ; 87.6) | 91 (68.6 ; 74.1) | 94 (86.2 ; 96.1) | .009* |

*Note*. Values are %(*n*) or Median (IQR). Percentages may not add to 100 due to rounding. NA = Not applicable; MS = Medical specialist; OS = Custom-made orthopedic shoes; OST = Orthopedic shoe technician. Few steps = making between 0-2750 steps a day; Moderate steps = making between 2750-5500 steps per day; Many steps = making 5500 or more steps per day. *: The p-value determining the differences between the three groups of step count on that usability aspect is shown. The level for significant p-value was set at 0.05 [a]: A Chi-square test was not applicable because more than 25% of the cells had an expected count less than 5. [b]: Scores could range from 0 (most negative score possible) to 100 ( most positive score).

**Post hoc analysis for the determination of effect sizes between the different frequencies of steps taken per day in relation to the significant aspects.**

Table 3 shows all relevant results of the post hoc analysis. The aspect “Change in pain (muscles)” differed significantly between the group of participants who had a moderate level of steps and the two other groups. This means that participants with a moderate level of steps reported more reduction in pain in the muscles than participants that made a few steps per day. However, participants with a high frequency of steps reported feeling more reduction in pain in the muscles than participants that had a moderate activity level. The aspect of “Donning/doffing OS” showed differences between participants who made a few steps per day and both other groups. This means that people with a high and a moderate level of steps per day were more satisfied with the process of donning and doffing the shoes than participants that made a few steps per day. Even

though, the satisfaction between the groups, moderate and many steps did not differ. Lastly, regarding the aspect "Communication with the orthopedic shoe technician" could be observed that participants just differed between the categories few and many steps per day. So participants that make many steps are more satisfied regarding the communication with the orthopedic shoe technician than participants that make a few steps per day. The largest effect size with a moderate effect was found for the aspect "Change in pain (muscles)" between the categories moderate and many steps taken per day. The weakest effect size was found in "Donning/doffing OS" between few and moderate steps per day. However, all these aspects showed a moderate effect size. Based on Cohens suggestions the effect sizes were categorized in the following way, 0.2 as small effects, 0.5 as moderate effects, and 0.8 as large effects (McAlindon et al., 2000).

**Table 3**

Post-hoc analyses on the significant main effects of the step count categories in the domains of usability perception of orthopedic shoes

| | Few. - Mod. | | Mod. - Many. | | Few. - Many. | |
|---|---|---|---|---|---|---|
| | *p* | *ES* | *p* | *ES* | *p* | *ES* |
| **Effectiveness** | | | | | | |
| Change in pain (muscle) | .014* | .39 | .001* | .56 | .318 | .16 |
| **Efficiency** | | | | | | |
| Donning / doffing OS | .021* | .37 | .437 | .13 | .001* | .53 |
| **Satisfaction** | | | | | | |
| Communication with OST | .051 | .33 | .227 | .21 | .003* | .49 |

*Note*. ES = effect size; OS = Custom-made orthopedic shoes; OST = Orthopedic shoe technician. Few steps = making between 0-2750 steps a day; Moderate steps = making between 2750-5500 steps per day; Many steps = making 5500 or more steps per day. *: The p-value determining the differences between the three groups of step count on that usability aspect is shown; a significant difference indicates that participants who make more steps per day have a more positive opinion with regard to that aspect. The level for significant p-value was set at 0.05

## Discussion

This study aimed to investigate the relationship between the three domains of usability perception namely effectiveness, efficiency, and satisfaction determined by the questionnaire "Monitor Orthopedic Shoes" and the activity level of people with diabetes with a high risk for foot ulcers. First, the main findings of this research were that reduction of pain in the muscles, high satisfaction of donning and doffing orthopedic shoes, and satisfying communication with the orthopedic shoe technician are related to higher activity levels measured in steps made per day. Therefore, the hypothesis could be confirmed. For better understanding, it has to be mentioned that in this study it was not possible to determine if people that made many steps per day also used their orthopedic shoes a lot. Therefore, it was assumed that the participants wore their orthopedic shoes most of the time they were walking.

### Effectiveness domain

Within this study, it was found that participants that made many steps per day have a higher reduction in muscle pain than participants with a moderate step level. Moreover, the same results were found while comparing participants that made a few steps per day with participants that have a moderate level of steps. However, it could not be found that participants which made many steps per day have a higher reduction in pain in the muscles than participants that made a few steps per day. These findings can be compared to similar studies that have been conducted in the past. For instance, Mueller (2020) found that patients with a high step count per day are less vulnerable to symptoms like skin breaks. Another study found that participants with rheumatoid arthritis reported a reduction in foot pain after receiving and wearing orthopedic shoes (Dahmen et al., 2014). This is in line with the findings of the current study regarding the reduction in pain in the muscle. A study investigated by Busch & Chantelau, (2003) also showed that orthopedic shoes are effective in the reduction of foot ulcer symptoms in patients with a high risk for foot ulcers. Considering the findings of Mueller, (2020), Busch & Chantelau, (2003), and the ones of the current study it was unexpected to see that participants with a high activity level did not report a higher reduction in pain compared to participants that made a few steps per day. As

possible explanation could be argued that it is unknown if the participants in the current study have worn their orthopedic shoes or not. Armstrong, Abu-Rumman, Nixon, & Boulton, (2001) found that the number of steps increased especially insight the house when participants were less willing to wear their orthopedic shoes. In the current study, it was not possible to determine if people that made many steps per day also used their orthopedic shoes a lot. This creates a measurement bias because it could also be argued that the reduction of pain in the muscles is based on other factors which are not related to orthopedic shoes. For example, it was found that physical activities like strength training or exercises that support the muscle contradiction can lead to a reduction of pain for people with diabetes that have a high risk for foot ulcers (Crews, Schneider, Yalla, Reeves, & Vileikyte, 2016).

Another surprising finding was that participants with high activity levels reported a higher reduction in pain in the muscle but not in the skin and the sprains. Moreover, it could not be proven that the amount of steps made per day is related to wound healing. It was expected that the aspects which measure the participants' perception of change in pain show the same tendencies. However, Van Netten et al. (2010) found significant differences between participants' frequency of use and change in pain in the muscles, skin, and sprains but not in wound healing. That study focused on the relationship between the use of orthopedic shoes and the aspects of their usability within the domains effectiveness, efficiency, and satisfaction (Van Netten et al., 2010). An explanation for this contradiction could be the fact that the participants that participated in the study of van Netten et al. (2010) had to decide by themselves in which category of the variable use of orthopedic shoes they would sort themselves. The categories were frequent use, occasional use, or none use. Related to this, it can be assumed that the MOS measurements of the participants' usability perception differed due to the study setting. Participants that participated in the study of van Netten et al. (2010) received the MOS via post three months after the delivery of their orthopedic shoes. In the current study, participants were asked to fill out the MOS question at home after a meeting with the investigator approximately six months after inclusion. Therefore, it can be argued that the difference in study design between both studies may had an influence on the different outcomes of both studies. To name content-related reasons, it can be argued that participants have to get used to walk in orthopedic shoes and

do not notice effects like a reduction in pain instantly (Jannink et al., 2005). This could have the consequence that they report no significant changes of pain in the skin and the sprains. For future research, it can be suggested to investigate if a reduction of pain in the muscle automatically can be associated with a reduction of pain in the skin and sprains. Moreover, it would help to repeat this study in a way where it is possible to determine which steps were taken with orthopedic shoes and which without them. This could lead to new findings where it would be possible to determine if the reduction of pain in the muscle is based on the use of orthopedic shoes or external factors. Another recommendation is to include the item frequency of use within the data analysis of future studies. This would make it possible to compare the results of the current study with other ones like the study of van Netten et al. (2010) more in detail. Moreover, it could be investigated if the frequency of using orthopedic shoes and the activity level of people with diabetes can be associated with each other.

**Efficiency domain**

Investigation the domain efficiency we found that participants that made moderate or many steps per day were more satisfied with the process of donning and doffing the orthopedic shoes than participants that made a few steps per day. Even though, the satisfaction of the process of donning and doffing orthopedic shoes did not differ in participants that made moderate and many steps per day. These findings are supported by earlier studies. Jannink et al. (2005) and van Netten et al. (2010) found that the satisfaction of the process of donning and doffing orthopedic shoes can be associated with the frequency of use. Hereby, it can be hypothesized that people make many steps per day also more often take on and off their orthopedic shoes. Therefore, the awareness of the advantages of wearing orthopedic shoes may outweigh the possible problems of donning and doffing orthopedic shoes. Jannink et al. (2005) also reasoned that elderly people with a high risk for foot ulcers have to expend a lot of effort and coordination to take on or off their orthopedic shoes. This is also supported by the finding that aging, in general, can be associated with problems in donning and doffing shoes (Jellema et al., 2019). This can have the effect that participants are less willed to wear orthopedic shoes and report dissatisfaction with the

process of donning and doffing orthopedic shoes. Lastly, it can be assumed that the aspect of donning and doffing orthopedic shoes is not directly linked to the other aspects of the domain efficiency. This makes it reasonable that the aspect of donning and doffing orthopedic shoes was the only aspect that showed significant results within the domain efficiency. Future research could investigate if a high activity level can be associated with a higher frequency of donning and doffing orthopedic shoes. Moreover, it can be recommended to research if a higher frequency of donning and doffing orthopedic shoes is related to higher satisfaction with the process of taking on and off their shoes because participants get used to it. To improve the effectiveness of orthopedic shoes, it would be helpful to integrate participants in the process of improvement in future researches. The participants' opinion would be a help to identify certain issues concerning the efficiency of orthopedic shoes. Hereby, it could be further investigated if the improvement of weight and fit of orthopedic shoes would show other findings than the ones of the current study. Lastly, it has to be mentioned that by now very few studies are available that investigate factors that reduce the risk of foot ulcers (Bus et al., 2008). Elderly people without as well as with diseases have problems with donning and doffing their shoes. Therefore, it can be assumed that an easy process of donning and doffing shoes can be related to a positive attitude towards these shoes.

**Satisfaction domain**

The last significant finding has shown that participants that made many steps per day were more satisfied regarding the communication with the orthopedic shoe technician than participants that made a few steps per day. This finding is in line with the study of van Netten et al. (2010). Van Netten et al. (2010) found that a higher frequency of use can be associated with higher satisfaction with the communication with the orthopedic shoe technician and the medical specialist. In the current study it was surprising to see that compared to the communication with the orthopedic shoe technique, the communication with the medical specialist did not differ significantly between the groups. Ratliff et al., (2021) argued that people with diabetes with a high risk for foot ulcers are forced to visit the medical specialist a lot. This has the consequence

that these patients feel dependent on medical support by medical specialists (Crocker, Palmer, Marrero, & Tan, 2021). In addition, it was found that people with diabetes with a high risk for foot ulcers experience emotions like shame, depression, or fear which may have an impact on the adherence to treatment (Searle et al., 2005). Therefore, it can be argued that all participants may have negative associations regarding the communication with the medical specialist because these confront the participants with negative side effects of their main disease diabetes for the first time. In this case, it must also be taken into account that in the current study it was not possible to determine if the participants were wearing their orthopedic shoes while taking steps. On the one hand, it might be the case that participants that made many steps per day did not wear their orthopedic shoes and therefore reported the same experiences as participants that made a few steps per day. On the other hand, it could be argued that the satisfaction does not differ between the groups because the participants made their judgments based on the sympathetic appearance of the medical specialist without considering the quality of its medical consolation. It was found that good communication between clinicians and participants can be associated with the use of orthopedic shoes (Say et al., 2006). It can be hypothesized, that participants who are willed and use their orthopedic shoes report higher satisfaction in the communication with the orthopedic shoe technician because participants are aware that orthopedic shoes can help to minimize the risk of getting foot ulcers. Lastly, it has to be mentioned that in the current study there were found no differences between the opinion about cosmetic appearance and the number of steps made per day. These findings are not in line with studies conducted in the past. It was found that cosmetic appearance can be associated with the use of orthopedic shoes (Macfarlane, & Jensen, 2003; van Netten et al., 2010). Hereby, it can also be assumed that the findings of the current study are based on the missing determination if orthopedic shoes were worn or not. Moreover, a study indicated that a structured program including communication with medical specialists and orthopedic shoe technicians can reduce the risk of foot ulcers in people with diabetes (Rizzo et al., 2012). Research findings were able to determine that orthopedic shoes can reduce the risk of foot ulcers (Waaijman et al., 2013; Kooiman et al., 2018). In addition some studies were able to prove that orthopedic shoe technicians have an impact on the quality of the orthopedic shoe and the related reduction of foot ulcers. However, it has to be mentioned that it is

still necessary to analyze more in depth which factors contribute to the satisfaction of orthopedic shoes perceived by its users. Future research could further investigate if the communication between the orthopedic shoe technician and the medical specialist can be considered as independent from each other. Moreover, it can be suggested to ask the patients more in detail which factors of communication they appreciate or dislike. This would help to determine if their satisfaction or dissatisfaction is mainly based on the characteristics of the orthopedic shoe technician or medical specialist. Lastly, a determination of the steps taken in orthopedic shoes could lead to new findings which might not be in line with the results of the current study.

**Strengths and limitations**

A strong point of this study is that it was found that higher satisfaction with the process of donning and doffing orthopedic shoes and the communication with the orthopedic shoe technician can be associated with a higher activity level. Therefore, it can be said that the domains efficiency and satisfaction can be considered as equally important as the domain effectiveness while studying the use and usability of orthopedic shoes (Jannink et al., 2005). The disease diabetes in combination with a high risk for foot ulcers is an issue which is not investigated in research for a long time. Therefore, all findings help to gain more knowledge about the participants' usability perception of orthopedic shoes in order to improve these.

Secondly, the number of participants within the three different step categories was nearly equally distributed. This is a strength because it shows that enough participants out of every step category filled out the MOS questionnaire in order to show a representative picture of the results.

The current study did have several limitations which are important to be discussed in order to improve future studies. As already mentioned one limitation is the fact that in the current study it was not possible to determine whether the participants were wearing their orthopedic shoes or not. This has implications for the validity of the study because it could be the case that participants did not use their orthopedic shoes while making many steps in normal shoes. Moreover, the MOS was designed to measure the usability of orthopedic shoes which presupposes that the participant wears the orthopedic shoes for at least a certain period of time.

Therefore, in this study, it was assumed that the participants wore their orthopedic shoes most of the time they were walking. Van Netten et al. (2009) criticizes that studies that investigate the use and usability of orthopedic shoes define the use of orthopedic shoes differently. For future research, it can be recommended that researchers determine when participants are wearing their orthopedic shoes while walking and when not. This could be done in form of a small sensor that will be added to the orthopedic shoe in order to count the steps made in the orthopedic shoes (Li et al., 2016). Simultaneously, the participant could be instructed to wear an activity monitor, measuring step counts to determine the total steps taken per day and compare them with the steps taken in the orthopedic shoes.

Another limitation is the time period of data collection with the "Misfit Shin 2". People that suffer from diabetes and have a high risk for foot ulcers experience periods where they are restricted in their daily life because of their disease (Jannink et al., 2005; Syafril, 2018). This restriction might also influence their daily walking abilities. Therefore, the minimum wearing time of 4 workdays and one weekend day cannot be seen as a realistic representation of the average step duration of people with diabetes and a high risk of foot ulcers. Considering the sample size of 56 participants it can be recommended to expand the wearing time of the activity monitor in order to get a more detailed picture of the average wearing time of the participants.

Another limitation is the sample size. The study of van Netten et al. (2010) included 339 participants and showed except for two in every aspect except significant results. Moreover, the study of Jongebloed-Westra et al. (2021, submitted) measured the participants' activity and the participants' usability perception in two different periods. Analyzing the data of two different periods would give a broader picture of the participants walking behavior and their usability perception of orthopedic shoes. In the current study, based on the frequency of steps the sample got divided into three different subgroups. This had the consequence that the sample size within the different groups became too small in order to use the data of both periods. Taking van Netten et al. (2010) as an example and increase the sample size could help to find more meaningful results. Lastly, it has to be mentioned that data analysis was not sufficient. In future studies, it can be recommended to include statistical tests like Bonferroni in order to minimize the risk of incorrectly reporting correlations as significant.

## Conclusion

In conclusion, the current study provides evidence that a high activity level can be associated with a reduction in pain in the muscles, higher satisfaction with the process of donning and doffing orthopedic shoes and a higher satisfaction regarding the communication with the orthopedic shoe technician perceived by people with diabetes with a high risk of getting foot ulcers. Investigating the three domains effectiveness, efficiency, and satisfaction more in detail could help to improve orthopedic shoes and make them even more usable. In future research, it can be assumed that the use of an activity sensor insight of orthopedic shoes which measure the steps taken per day might lead to more interesting findings. Moreover, the use of a reliable activity monitor in orthopedic shoe makes future studies that investigate the use and usability of orthopedic shoes more comparable. Lastly, it can be suggested to investigate if and which aspects of usability are related to each other in order to make further explanations about the current results and improve the validity of the MOS. In general, it can be concluded that this study demonstrates the connection between the sector of psychology and healthcare. Literature as well as the findings of the current study have shown that psychological factors are important to consider in order to develop methods that improve the treatment of certain diseases in the health care sector. In addition, it can be stated that the findings like the ones of the current study contribute to the enlightenment within the society that psychology has to be considered as crucial factor in order to help people to deal with their diseases.

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# Appendix

## Appendix A - Informed Consent

Proefpersoneninformatie

**Proefpersoneninformatie voor deelname aan medisch-wetenschappelijk onderzoek**

**Betere zorg via motiverende gespreksvoering in combinatie met het digitaal aanmeten van orthopedische schoenen**
*Het effect van motiverende gespreksvoering in combinatie met het digitaal aanmeten van schoenen op therapietrouw aan orthopedische schoenen*

Geachte heer/mevrouw,

Wij vragen u om mee te doen aan een medisch-wetenschappelijk onderzoek. Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig. U ontvangt deze brief omdat u diabetes mellitus (suikerziekte) heeft en problemen heeft met uw voeten, waarvoor orthopedische schoenen zijn voorgeschreven.

Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de coördinerend onderzoeker om verdere uitleg als u vragen heeft. U kunt ook de onafhankelijk deskundige, die aan het eind van deze brief genoemd wordt, om aanvullende informatie vragen. U kunt er ook over praten met uw partner, vrienden of familie. Verdere informatie over meedoen aan zo'n onderzoek staat in de bijgevoegde brochure 'Medisch-wetenschappelijk onderzoek'.

### 1. Algemene informatie

Voor dit onderzoek zijn 220 proefpersonen nodig. Het onderzoek is opgezet door de Universiteit Twente en wordt gedaan in samenwerking met Voetencentrum Wender en Voetmax Orthopedie. De Ethische Commissie van de faculteit BMS van de Universiteit Twente heeft dit onderzoek goedgekeurd. Algemene informatie over de toetsing van onderzoek vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'.

### 2. Achtergrond en doel van het onderzoek

Diabetische voetwonden zijn een belangrijke oorzaak van ziekenhuisopnames en amputaties, en dragen bij aan hoge behandelingskosten. Op maat gemaakte orthopedische schoenen helpen om nieuwe wonden te voorkomen. Om dat te bereiken is het belangrijk dat deze schoenen gedragen

worden. Echter, orthopedische schoenen worden geregeld te weinig gedragen. Er is nog beperkt kennis over hoe dat verbeterd kan worden. Wij stellen een nieuwe zorgaanpak voor: motiverende gespreksvoering en een digitale procedure voor het aanmeten van de orthopedische schoenen. Met deze nieuwe aanpak willen we het dragen van orthopedische schoenen verbeteren.





Het doel van deze studie is om deze nieuwe zorgaanpak (motiverende gespreksvoering gecombineerd met digitaal aanmeten) te onderzoeken in vergelijking met de standaardzorg (geen motiverende gespreksvoering en traditionele manier van aanmeten) met betrekking tot de therapietrouw van orthopedische schoenen en de voorkoming van diabetische voetwonden.

## 3. Wat meedoen inhoudt

### Behandeling

Als u meedoet aan het onderzoek zult u de nieuwe zorgaanpak of standaardzorg krijgen. De nieuwe zorgaanpak zal bestaan uit motiverende gespreksvoering door de podotherapeut gecombineerd met het digitaal aanmeten van uw orthopedische schoenen door de orthopedisch schoenmaker. Bij de standaardzorg vindt geen motiverende gespreksvoering plaats en worden uw orthopedische schoenen door middel van gipsen aangemeten. Welke zorgaanpak, de nieuwe of de standaardzorg, het meest effectief is, is dus nog niet bekend en onderzoeken we door middel van dit onderzoek.

Als u meedoet aan het onderzoek, zal het onderzoek voor u duren tot één jaar na het ontvangen van het eerste paar orthopedische schoenen. Gedurende deze periode zullen er verschillende afspraken zijn met uw podotherapeut, de orthopedisch schoenmaker en de onderzoeker.

### Gebruik producten

Bij deelname aan het onderzoek wordt in de zool van één van uw orthopedische schoenen een sensor geplaatst. Deze is niet te zien of te voelen. Wanneer u ook een tweede paar schoenen krijgt, zal ook in dit paar schoenen een sensor geplaatst worden. Deze sensoren meten de draagtijd. Na het ontvangen van uw schoenen, moeten de sensoren elke 3 maanden uitgelezen worden.

Ook vragen wij aan u twee keer om één week lang 24 uur per dag een activiteitenmeter te dragen om uw loop/wandelactiviteit bij te houden. Op deze manier kunnen we de draagtijd van uw schoenen koppelen aan uw activiteiten.

### Bezoeken en metingen

Om de sensoren elke 3 maanden uit te lezen is het van belang dat we u na 3, 6, 9 en 12 maanden na het ontvangen van de schoenen zien. Dit kan op verschillende locaties (zoals de Kievit te Hengelo en het ZGT te Almelo), bij u thuis, of gecombineerd met een afspraak bij bijvoorbeeld een podotherapeut van Voetencentrum Wender. Op verschillende momenten tijdens het onderzoek zullen vragenlijsten afgenomen worden. Deze vragenlijsten gaan over uw kwaliteit van leven, het gebruik van medische zorg, de invloed van complicaties op uw dagelijks leven, hoe u het gebruik van uw orthopedische schoenen ervaart en wat het effect is van uw orthopedische schoenen.

Een aantal van u, in totaal 30 deelnemers, zal ook telefonisch benaderd worden voor twee diepte-interviews. Deze deelnemers zullen willekeurig gekozen worden.





**Anders dan bij gebruikelijke zorg**

In verband met het onderzoek zult u wanneer u de nieuwe zorgaanpak krijgt twee extra afspraken hebben. Eén afspraak waarbij de podotherapeut uw ervaringen wil bespreken rondom de orthopedische schoenen en één afspraak voor het uitlezen van de sensoren. Zit u in de groep die standaardzorg krijgt dan heeft u één extra afspraak ten opzichte van de gebruikelijke zorg. Eén afspraken voor het uitlezen van de sensoren. Voor beide groepen zijn ook de twee diepte-interviews extra ten opzichte van de gebruikelijke zorg.

**4. Wat wordt van u verwacht**

Om het onderzoek goed te laten verlopen is het belangrijk dat u zich aan de volgende afspraken houdt:

- Afspraken voor bezoeken nakomt;
- De activiteitenmeter gebruikt volgens de uitleg;
- Niet aan een ander medisch-wetenschappelijk onderzoek meedoen dat onderzoek doet naar uw voeten of onderbenen.

Het is belangrijk dat u contact opneemt met de coördinerend onderzoeker:

- Als u in een ziekenhuis wordt opgenomen of behandeld, zoals bijv. op de diabetische voetenpoli;
- Als u plotseling gezondheidsklachten krijgt;
- Als u niet meer wilt meedoen aan het onderzoek;
- Als uw contactgegevens wijzigen.

**5. Mogelijke ongemakken en risico's**

Er zijn voor u geen extra risico's wanneer u meedoet aan het onderzoek, ten opzichte van wanneer u niet mee zou doen. Het dragen van de activiteitenmeter gedurende 24 uur per dag voor tweemaal één week zou mogelijk als onprettig ervaren kunnen worden. De activiteitenmeter heeft het formaat van een gemiddeld horloge en is 3cm groot en 8mm dik. De activiteitenmeter zal door middel van een klittenband aan uw onderbeen bevestigd worden.

**6. Mogelijke voor- en nadelen**

Het is belangrijk dat u de mogelijke voor- en nadelen goed afweegt voordat u besluit mee te doen. Als u meedoet aan dit onderzoek levert dit mogelijk geen voordelen voor u op. Maar u draagt wel direct bij aan meer kennis over de behandeling van diabetische voeten en het voorkomen van voetwonden en amputaties. Deze kennis kan de zorg rondom diabetische voetwonden verbeteren, en daar kunnen nieuwe patiënten, en wellicht uzelf, in de toekomst voordeel van hebben.

Nadelen van meedoen aan het onderzoek kunnen zijn:

- - Dat u afspraken heeft waaraan u zich moet houden;
- - Dat u mogelijk een onprettig gevoel van het dragen van de activiteitenmeter ervaart;
- - Dat u extra tijd kwijt bent. De afspraken zullen over het algemeen langer duren dan wanneer u niet deelneemt;
- - Dat u extra afspraken heeft.



**7. Als u niet wilt meedoen of wilt stoppen met het onderzoek**

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig. Als u niet wilt meedoen, wordt u op de gebruikelijke manier behandeld.
Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen, ook tijdens het onderzoek. U wordt dan weer op de gebruikelijke manier behandeld. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de coördinerend onderzoeker of behandelaar. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

Als er nieuwe informatie over het onderzoek is die belangrijk voor u is, laat de coördinerend onderzoeker dit aan u weten. U wordt dan gevraagd of u blijft meedoen.

**8. Einde van het onderzoek**

Uw deelname aan het onderzoek stopt als

- Alle bezoeken zoals beschreven onder punt 3 voorbij zijn

- U zelf kiest om te stoppen

- De coördinerend onderzoeker of uw arts het beter voor u vindt om te stoppen

- Universiteit Twente, de overheid of de beoordelende medisch-ethische toetsingscommissie, besluit om het onderzoek te stoppen.
  Het hele onderzoek is afgelopen wanner alle onderzoeksgegevens van alle deelnemers verzameld zijn en de resultaten zijn gerapporteerd.
  Na het verwerken van alle gegevens informeert de coördinerend onderzoeker u over de belangrijkste uitkomsten van het onderzoek.

**9. Gebruik en bewaren van uw gegevens**

Voor dit onderzoek worden uw persoonsgegevens verzameld, gebruikt en bewaard. Het gaat om gegevens zoals uw naam, adres, geboortedatum en om gegevens over uw gezondheid. Het verzamelen, gebruiken en bewaren van uw gegevens is nodig om de vragen die in dit onderzoek worden gesteld te kunnen beantwoorden. Alle betrokken onderzoekers hebben toegang tot deze gegevens. Wij vragen voor het gebruik van uw gegevens uw toestemming.

**Vertrouwelijkheid van uw gegevens**

Om uw privacy te beschermen krijgen uw gegevens een code. Uw naam en andere gegevens die u direct kunnen identificeren worden daarbij weggelaten. Alleen met de sleutel van de code zijn gegevens tot u te herleiden. De sleutel van de code blijft veilig opgeborgen in de lokale onderzoeksinstelling. De gegevens die naar de opdrachtgever worden gestuurd bevatten alleen de code, maar niet uw naam of andere gegevens waarmee u kunt worden geïdentificeerd. Ook in rapporten en publicaties over het onderzoek zijn de gegevens niet tot u te herleiden.

**Toegang tot uw gegevens voor controle**

Sommige personen kunnen op de onderzoekslocatie toegang krijgen tot uw gegevens. Ook tot de gegevens zonder code. Dit is nodig om te kunnen controleren of het onderzoek goed en betrouwbaar is uitgevoerd. Personen die ter controle inzage krijgen in uw gegevens zijn de

commissie die de veiligheid van het onderzoek in de gaten houdt, een controleur die voor de Universiteit Twente werkt of die door de universiteit is ingehuurd, nationale en internationale toezichthoudende autoriteiten. Zij houden uw gegevens geheim. Wij vragen u voor deze inzage toestemming te geven.

**Bewaartermijn gegevens**

Uw gegevens moeten 10 jaar worden bewaard op de onderzoekslocatie.

**Intrekken toestemming**

U kunt uw toestemming voor gebruik van uw persoonsgegevens altijd weer intrekken. Dit geldt voor dit onderzoek en ook voor het bewaren en het gebruik voor het toekomstige onderzoek. De onderzoeksgegevens die zijn verzameld tot het moment dat u uw toestemming intrekt worden nog wel gebruikt in het onderzoek.

**Meer informatie over uw rechten bij verwerking van gegevens**

Voor algemene informatie over uw rechten bij verwerking van uw persoonsgegevens kunt u de website van de Autoriteit Persoonsgegevens raadplegen.
Bij vragen over uw rechten kunt u contact opnemen met de verantwoordelijke voor de verwerking van uw persoonsgegevens. Voor dit onderzoek is dat: Universiteit Twente, zie bijlage A voor contactgegevens.

Bij vragen of klachten over de verwerking van uw persoonsgegevens raden we u aan eerst contact op te nemen met de onderzoekslocatie. U kunt ook contact opnemen met de Functionaris voor de Gegevensbescherming van de instelling Universiteit Twente of de Autoriteit Persoonsgegevens.

**Registratie van het onderzoek**

Informatie over dit onderzoek is ook opgenomen in een overzicht van medisch-wetenschappelijke onderzoeken namelijk (www.trialregister.nl). Daarin zijn geen gegevens opgenomen die naar u herleidbaar zijn. Na het onderzoek kan de website een samenvatting van de resultaten van dit onderzoek tonen. U vindt dit onderzoek onder [NL7710].

**10.Verzekering voor proefpersonen**

Als u deelneemt aan het onderzoek, loopt u geen extra risico’s. De Universiteit Twente hoeft daarom van de medisch-ethische toetsingscommissie geen extra verzekering af te sluiten.

**11.Informeren behandelend specialist**

Uw podotherapeut en orthopedisch schoenmaker behandelend specialist zullen op de hoogte gebracht worden van uw deelname aan het onderzoek.

In het kader van dit onderzoek is het mogelijk dat de onderzoekers relevante gegevens opvragen uit uw medisch dossier of bij uw podotherapeut en orthopedisch schoenmaker. Door het tekenen van de toestemmingsverklaring geeft u hiervoor toestemming.





**12.Geen vergoeding voor meedoen**

U wordt niet betaald voor het meedoen aan dit onderzoek. Net als wanneer u niet deelneemt aan het onderzoek, zijn de kosten voor de eigen bijdrage voor uw orthopedische schoenen en het eigen risico voor uzelf.

**13.Heeft u vragen?**

Bij vragen kunt u contact opnemen met de coördinerend onderzoeker. Voor onafhankelijk advies over meedoen aan dit onderzoek kunt u terecht bij de onafhankelijke arts. Hij weet veel over het onderzoek, maar heeft niets te maken met dit onderzoek.
Indien u klachten heeft over het onderzoek, kunt u dit bespreken met de coördinerend onderzoeker of uw behandelend arts. Wilt u dit liever niet, dan kunt u zich wenden tot de onafhankelijke arts. Alle gegevens vindt u in bijlage A: Contactgegevens.

**14.Ondertekening toestemmingsformulier**

Wanneer u voldoende bedenktijd heeft gehad, wordt u gevraagd te beslissen over deelname aan dit onderzoek. Indien u toestemming geeft, zullen wij u vragen deze op de bijbehorende toestemmingsverklaring schriftelijk te bevestigen. Door uw schriftelijke toestemming geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.

Zowel uzelf als de coördinerend onderzoeker ontvangen een getekende versie van deze toestemmingsverklaring.

Dank voor uw aandacht.





**Bijlagen bij deze informatie**

A. Contactgegevens
B. Toestemmingsformulieren
C. Brochure ‘Medisch-wetenschappelijk onderzoek. Algemene informatie voor de

proefpersoon’ (versie 01-03-2017)





**Bijlage A: Contactgegevens**

**Onderzoekers**

De betrokken onderzoekers aan dit onderzoek zijn
Drs. M. Jongebloed-Westra – Coördinerend onderzoeker (T: 053-4896209) Drs. B.E. Bente – Onderzoeker (T: 053-4899660)
Prof. Dr. J.E.W.C. van Gemert-Pijnen – Hoofdonderzoeker

Universiteit Twente
Faculteit Gedrags-, management- en sociale wetenschappen Vakgroep Psychologie, Gezondheid en Technologie
Postbus 217
7500 AE Enschede

**Functionaris voor de Gegevensbescherming**

Functionaris UT: Mevr. R. te Brake Telefoonnummer: 053-4891282
Contact Persoon BMS: Mevr. L. Kamphuis-Blikman Telefoonnummer: 053-4893399
Postbus 217
7500 AE Enschede

**Onafhankelijk arts**

Dr. R.R. Kruse - Vaatchirurg Ziekenhuisgroep Twente Telefoonnummer: 088-7083436 Postbus 7600

7600 SZ Almelo

**Deelnemende centra**

Voetencentrum Wender Sabina Klinkhamerweg 10 7555 SK Hengelo

Voetmax Orthopedie Sabina Klinkhamerweg 10 7555 SK Hengelo

Proefpersoneninformatie

**Bijlage B: Toestemmingsformulier proefpersoon**

**Betere zorg via motiverende gespreksvoering in combinatie met het digitaal aanmeten van orthopedische schoenen**

- Ik wil meedoen aan dit onderzoek en heb de informatie hieronder gelezen.

- Ikgeef □**wel** □ **geen**

toestemming om mijn gegevens langer te bewaren en te gebruiken voor toekomstig onderzoek op het gebied van therapietrouw.

Naam proefpersoon:
Handtekening: Datum : __ / __ / __ ---------- ---------- Ik verklaar dat ik de deelnemer volledig heb geïnformeerd over het onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):
Handtekening: Datum: __ / __ / __
---

*De deelnemer krijgt een volledige informatiebrief mee, samen met een getekende versie van het toestemmingsformulier.*

*Toelichting*
*- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende*

*beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.*
*- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.*
*- Ik geef toestemming voor het informeren van mijn podotherapeut en orthopedisch schoenmaker dat ik meedoe aan dit onderzoek.*
*- Ik geef toestemming voor het anoniem verzamelen en gebruiken van mijn gegevens voor de beantwoording van de onderzoeksvraag in dit onderzoek. Ook wanneer deze opgevraagd dienen te worden uit mijn medisch dossier.*
*- Ik weet dat voor de controle van het onderzoek enkele personen toegang tot mijn gegevens kunnen krijgen. De personen die ter controle inzage kunnen krijgen in uw gegevens zijn leden van de onderzoeksgroep en een controleur die voor de Universiteit Twente werkt. Ik geef toestemming voor die inzage door deze personen.*

*- Ik geef toestemming voor het informeren van mijn podotherapeut en orthopedisch schoenmaker over onverwachte bevindingen die van belang (kunnen) zijn voor mijn gezondheid.*
*- Ik geef toestemming voor het opnemen van één van mijn gesprekken met de podotherapeut.*





**Bijlage C: Brochure 'Medisch-wetenschappelijk onderzoek. Algemene informatie voor de proefpersoon' (versie 01-03-2017)**



**Appendix B - Case Report Form**

1. Age: ……
2. Gender: Men / Woman

**Appendix C - Monitor Orthopedic Shoes - Questionnaire**

1. (Item B) Compared with the period before you received your orthopedic shoes, your walking capacity ...

... is improved, because of the orthopedic shoes

... is improved, but not because of the orthopedic shoes

... has not changed

... has deteriorated, but not because of the orthopedic shoes

... has deteriorated, because of the orthopedic shoes

2. (Item 1) Indicate the amount of pain you feel in the skin of your feet and/ or ankles during activities like standing and / or walking.

none |————————————————————————————————-| very much

3. (Item 2) Indicate the amount of pain you feel in the muscles and joints of your feet and/or ankles during activities like standing and / or walking.

none |————————————————————————————————————-| very much

4. (Item 7) Indicate the amount of trouble you have with spraining of your ankles.

none |————————————————————————————————————-| very much

5. (Item 8) With your orthopedic shoes, do you have less or more pain in the skin of your feet and / or ankles, during activities like standing and / or walking? Indicate the amount of change in pain.

much less |————————————————————————————————————-| much more

not applicable

6. (Item 4) With your orthopedic shoes, do you have less or more pain in the muscles and joints of your feet and / or ankles, during activities like standing and / or walking? Indicate the amount of change in pain.

much less |————————————————————————————————————-| much more

not applicable

7. (Item 9) With your orthopedic shoes, do you have less or more trouble with spraining of your ankles? Indicate the amount of change in trouble with spraining.

much less |————————————————————————————————————-| much more

not applicable

8. (Item 10) Have your orthopedic shoes caused a change to the wounds on your feet and / or ankles? (multiple answers are possible)

…more wounds

…bigger wounds

…no difference

…less wounds

…smaller wounds

…this is for me not applicable

9. (Item11) Indicate how ugly or attractive your orthopedic shoes are.

very ugly |——————————————————————————————-| very attractive

10. (Item 12) What do others think of the cosmetic appearance of your orthopaedic shoes?

…very ugly

…ugly

…neutral

…attractive

…very attractive

…I do not know what others think of the cosmetic appearance of my shoes.

11. (Item 13) Indicate how poor or how well your shoes fit.

very poor |——————————————————————————————-| very well

12. (Item 14) Indicate if your orthopedic shoes fit worse or fit better than you expected.

much worse |——————————————————————————————-| much better

13. (Item 15) Indicate how poor or how well you can walk in your orthopedic shoes.

very poor |——————————————————————————————-| very well

14. (Item 16) Indicate if you can walk worse or better than you expected in your orthopedic shoes.

much worse |————————————————————————————-| much better

15. (Item 17) Indicate what you think of the weight of your orthopedic shoes.

too light |————————————————————————————-| too heavy

16. (Item 18) Indicate if your orthopedic shoes lighter or heavier than you expected.

much lighter |————————————————————————————-| much heavier

17. (Item 19) Indicate how difficult it is to put on and take off your orthopedic shoes.

very difficult |————————————————————————————-| very easy

18. (Item 25) Indicate how well the doctor listened to you when your orthopedic shoes were reviewed.

very bad |————————————————————————————-| very well

19. (Item 26) Indicate how well the shoe technician listened to you when your orthopedic shoes were delivered and reviewed?

very bad |————————————————————————————-| very well

20. (Item 12) Indicate what you think is more important: that your orthopedic shoes look good or that your orthopedic shoes solve your foot problems.

that they look good |———————————————————————————-| that they solve my foot problems