Bachelor thesis Psychology

# Association between the quality of life and the characteristics of age, type of diabetes, and foot deformity of people with diabetes.

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**Abstract**

Quality of life (QoL) is an important aspect of well-being that should be considered when treating patients with chronic illnesses such as diabetes mellitus, which affects 422 million people worldwide. The health consequences of diabetes impact how people with diabetes might perceive their QoL. Therefore, this study aimed to analyze the association between quality of life and characteristics of age, type of diabetes and foot deformity in people with diabetes over a period of 6 months. The study also looked into the prevalence of foot deformity and type of diabetes per age group.

The RAND-36 (SF) questionnaire was used to measure the QoL and data of 46 participants (mean age = 66; 26% women, 74% men) were analyzed. Statistical analyses used during this research were Spearman rho for calculating the association, Kruskal-Wallis for calculating differences between subgroups of the characteristics and a Mann-Whitney U test for calculating differences between domain scores over time.

The data analyses showed no association between type of diabetes and QoL and no difference between domain scores over a period of six months. There was a negative association between age and health change ($r_s(46) = -.29$, $p=.04$) and age and physical functioning ($r_s(46) = -.31$, $p=.03$), however, subgroup analysis did not reveal any significant association with the domains of the RAND-36. For foot deformities, there was a positive association between moderate foot deformity and pain ($r_s(29)=.52$, p.004) and moderate foot deformity and health change ($r_s(29)=.52$, p.004). There was also a significant difference between domain scores for those with mild and those with severe foot deformities ($p=.01$).

In conclusion, QoL on some domains was higher for people with moderate foot deformities than mild or severe foot deformities. This finding contradicts previous findings stating that those with mild foot deformities experience a higher quality of life than those with moderate or severe foot deformities.

## Introduction

Diabetes Mellitus (DM) is a disease that affects many lives across the globe. According to the World Health Organization (WHO), 422 million people were diagnosed with diabetes in 2014 and it has a global prevalence of 8.5%. According to the Dutch Public Health and Healthcare, it was estimated that in 2019 1.137.800 people in the Netherlands had diabetes (Nielen et al., 2020). Diabetes was more prevalent in males than females and when comparing the age groups, diabetes is most prevalent in the age group 65+ followed by the age group 45-64 (Nielen et al., 2020). The age group with the least amount of diabetes cases was the age group 20-44 and for the age group 0-19 a diabetes diagnosis was rare (Nielen et al., 2020). According to Spijkerman et al. (2020), these incidence rates of diabetes in the Netherlands in 2019 are a decrease in numbers compared to the incidence numbers of 2011.

Diabetes is a chronic metabolic disorder characterized by hyperglycemia which is caused by a deficiency of insulin, excessive insulin or both (American Diabetes Association, 2014). There are two main types of diabetes, namely, type 1 diabetes and type 2 diabetes. Type 1 diabetes occurs in 5-10% of patients with diabetes while type 2 diabetes is the most prevalent form of diabetes occurring in about 90-95% of people with diabetes (American Diabetes Association, 2014). Type 1 diabetes occurs when there is a lack of insulin and the body cannot produce its insulin. It often occurs in children but is also present in adults (Alam et al., 2014; Mobasseri et al., 2020). On the other hand, when people have type 2 diabetes the body does produce insulin, however, there is insulin resistance (Alam et al., 2014; World Health Organization, 2020). From the total cases of diabetes in the Netherlands in 2019, about 9% of people with diabetes had type 1 and about 91% had type 2 diabetes (Poos & Gommer, 2020). Type 1 diabetes was more prevalent in younger people than in older people. In the age group 0-9 100% of the total diabetes cases were type 1 diabetes and for the age group 65+ it was between 1.3% and 5.6% (Poos & Gommer, 2020). Thus, the diagnosis for type 1 diabetes decreases with age while the diagnosis for type 2 diabetes increases with age. Both types of diabetes share similar health consequences.

Diabetes has various health consequences such as chronic complications. Chronic complications of diabetes can be divided into two categories, namely vascular and nonvascular complications. The vascular complications consist of complications that affect the peripheral nervous system and or consist of peripheral vascular disease. According to Tripathi & Srivastava (2006), neuropathy is common in almost half of all people with diabetes. This becomes a problem when it coincides with vascular impairment seeing that it

could lead to non-healing ulcers which, in turn, could cause non-traumatic amputations (Tripathi & Srivastava, 2006). Diabetic foot ulcers affect an estimated 25% of all people with diabetes during their lifetime (Noor, Khan & Ahmad, 2017). For people with diabetes, infections in the ulcerated foot are the leading cause of morbidity, and causes “discomfort, reduced physical and mental quality of life, need for health care provider visits, wound care, antimicrobial therapy, and often surgical procedures" and it is the cause for “diabetes-associated hospitalization and lower extremity losses” (Noor, Khan & Ahmad, 2017, p. 151). Foot infections in people with diabetes cause approximately 60% of lower limb amputations (Noor, Khan & Ahmad, 2017). Therefore, diabetes can have a great impact on a patient’s quality of life.

As in any case of chronic illness, quality of life in people with diabetes is important to take into consideration. Quality of life (QoL) affects how motivated a patient is to perform their self-care activities and how it might impact their diabetes management and control (Singh & Bradley, 2006). QoL is a “subjective measure of a person’s physical and psychological well-being and represents a patient’s assessment of how a particular disease or intervention has affected their life” (Hogg et al., 2012, p553). In other words, QoL helps to give a view of how the patient is affected by their illness both psychologically and physically. Complications from disease or illness can affect a patient’s QoL and have an emotional and physical impact which causes a change in well-being, both personal and familial (Zurita-Cruz et al., 2018). Knowles et al. (2020), found that the way patients perceive their illness, their self-efficacy in managing their illness and its challenges and coping strategies are associated with QoL and psychological well-being. Factors that impact the quality of life of people with diabetes are social isolation, depression, difficulty in performing leisure or work activities and pain (Noor, Khan, Ahmad, 2017). Some studies have been done to analyze the difference between the QoL of type 1 and type 2 people with diabetes. Jacobson et al. (1994) concluded that people with type 2 diabetes, whether taking insulin or not, experienced higher QoL than those with type 1 diabetes. Other studies have concluded that low levels of QoL were evident for those with more complications, high-risk HbA1c levels or insulin use within each type of diabetes (Glasgow et al., 1997; Svedbo et al., 2019). According to Allan et al. (2016), reduced QoL is linked to people who have diabetic foot ulcers. In people with foot ulcers, QoL in aspects of physical health was lower than in people with diabetes without foot ulcers (Valensi et al., 2005). The reduced QoL is caused by leading a sedentary life due to pain due to foot problems or the health complaints tied to diabetes. Some factors can modify the QoL

of people with diabetes this includes medication adherence, longer duration of diabetes, diabetes distress, depressive symptoms, comorbidities and marital status, just to name a few (Zurita-Cruz et al., 2018). Thus, taking into consideration the QoL of people with diabetes is important not only to learn how the illness affects their daily lives but also to understand their attitude towards self-care and how to improve treatment.

Preventative care for diabetic foot infections and diabetic foot ulcers entails integrated foot care. Integrated foot care is a combination of elements that could help the prevention of foot ulcers and/or foot infections (Bus et al., 2020). According to Bus et al. (2020), there are five elements of preventative care for diabetic foot ulcers. The first two elements are identifying patients with at-risk feet, and regular checkups and inspections of at-risk feet. The third element is educating the patient, their direct social circle and health care providers on how to prevent foot ulcers with instructions on foot self-care. Guaranteeing regular wearing of custom-made footwear is the fourth element of preventative care. Custom-made footwear can be used for the prevention of ulcers, supporting foot deformities, diminishing pain and providing stability (van Netten et al., 2010). The fifth element of integrative foot care is treating foot ulcers and infections. By following these guidelines, people with diabetes can prevent and reduce foot ulcerations and decrease the chance of amputation. Custom-made footwear can support foot deformities, which is also common in people with diabetes. The way the foot is formed can influence the potential spread of an infection and foot ulcer occurrence (Ledoux, et al., 2005; Noor, Khan & Ahmad, 2017). There are different foot types and/or foot deformities that affect foot ulcers in different ways. The most prominent foot deformities in people with diabetes are pes cavus, hammertoes, claw toes, hallux limitus and hallux valgus (Perera et al., 2013; Ledoux et al., 2005) (see Appendix A for examples). These deformities can occur separately or in combination and affect the foot globally, partially, fully or with one or more toes (Perera et al., 2013). Foot deformities have various impacts on a person's mobility and limit a person's ability to perform daily activities. Each foot type and foot deformity should be taken into consideration during treatment, or prevention treatment, to prevent diabetic foot infection and, in turn, limit the chance of amputation.

Diabetic foot ulcers affect the quality of life in people with diabetes, as in any case of chronic illness and therefore, quality of life is a valuable health consequence that needs to be considered when treating people with diabetes (Allan et al., 2016). Keeping this in mind can help health care providers guide people with diabetes to better self-care and treatment adherence and help them improve their treatment. This study aims to answer the research

question: *What is the association between quality of life and the characteristics of age, type of diabetes and foot deformity in people with diabetes over a period of 6 months?* To answer this research question, there are three sub-questions namely, "How is age associated with quality of life?", "How is the type of diabetes associated with quality of life?" and "How is the type of foot deformity associated with quality of life?". The prevalence of the type of diabetes and foot deformity in the different age groups will also be analyzed. In this research the data will be compared at two points in time, namely moment of inclusion (0 months) and six months after inclusion, to investigate if the quality of life changed after inclusion.

## Method

*Design*

The present study is part of a larger study by Jongebloed-Westra et al. (2021, submitted) namely "Using motivational interviewing combined with digital shoe-fitting to improve adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration". Ethical authorization was granted by the ethical committee of the BMS faculty of the University of Twente under number 190141 and by the METC under number NL 68567.091.19. The study by Jongebloed-Westra et al. (2021, submitted) aims to improve people with diabetes' adherence to orthopedic footwear and follows participants for a year during which they have follow-up appointments every three months. The current study is a quantitative longitudinal study that looked at correlations between quality of life and patient characteristics over a period of six months. A part of the data of the main study collected from the different appointments regarding patient characteristics and quality of life were used in the present study.

*Participants*

Participants were recruited from Voetmax Orthopedie and Voetencentrum Wender in the Netherlands whose foot care was reimbursed by the Dutch healthcare system. Inclusion criteria included a clinical diagnosis of diabetes mellitus type 1 or 2, aged 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" and they must be eligible for a prescription of orthopedic shoes. Exclusion criteria include not receiving orthopedic shoes but an adaptation to confection shoes or semi-orthopedic shoes, having a foot ulcer, active

Charcot's neuro-arthropathy, and a foot infection, unable to walk and unable to read and understand the study instructions.

Inclusion criteria for the current study included filling in the RAND-36 questionnaire at both time points 0 and 6 months after inclusion. Exclusion criteria included having more than four missing values in the RAND-36 questionnaire, or missing values of the RAND-36 questionnaire which made it difficult to calculate the dimension scores at either time point.

In the main study, there were a total of 140 participants. With the added inclusion and exclusion criteria of the current study, only 46 participants remained. Therefore, in the current study, the data of 46 participants were analyzed. The participants' age varied between 48 and 88 years (M=66.0, SD=9.3). There were a total of 34 male participants and 12 female participants. The race of the participants was as follows: 45 Caucasian participants and 1 Latin American participant.

*Materials*

A *case report form* (Appendix B) was used to analyze the prevalence of the type of diabetes and foot deformity in each age group. This case report form was filled in by the investigator at the moment of inclusion of the participant. It contains questions regarding the participants demographic such as age, sex, ethnic background, educational background, marital status and living and work situation. It also includes questions regarding aspects of their diabetes, such as the type, physical characteristics, foot deformity, amputations and ulcers, and questions about the footwear they currently use.

To analyze the participant-perceived quality of life of the participants, the *RAND-36 item Health Survey V2.0* (RAND-36 V2.0) was used (van der Zee & Sanderman, 1993; "36-Item Short Form Survey (SF-36)", n.d.) (Appendix C). This questionnaire was administered at the moment that the participant started with the study, and 6 months and after inclusion. It is a self-reporting questionnaire where participants answer questions regarding their physical and mental health for four weeks before filling in the questionnaire ("36-Item Short Form Survey (SF-36)", n.d.). The RAND 36-item consists of 36 items that test the generic and coherent quality of life measures. The 36 items are divided into eight domains namely physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, pain, general health perception and energy/fatigue. Aside from these eight domains, there is an additional item regarding health change (van der Zee & Sanderman, 1993; "36-Item Short Form Survey (SF-36) Scoring

Instructions", n.d.). To analyze the nine domains of the Rand-36, some of the raw scores had to be recoded (items 1, 2, 6, 8, 11b, 11d, 9a, 9d, 9e, 9h and 7). Physical functioning entails ten items that are related to limitations in physical aspects of daily activities. People who score high on these items can be more physically active than those who have lower scores. For social functioning, there are two items regarding limits in social activities due to illness. A low score indicates that the participant was not able to attend social activities due to their illness. Role limitation due to physical and emotional problems entails problems with work or daily activity due to health problems such as having less time to work. Scoring low on the four items for physical and three items for emotional problems indicates having problems with work or daily activities while a high scorer has no limitations in this domain. The five mental health items consist of questions regarding depression and anxiety, low scorers experience some effects of depression or anxiety while high scorers did not. High scorers on the four items for the energy domain felt energetic in the last four weeks compared to low scorers. The pain domain contains two items where low scorers experience pain and limitation compared to high scorers. Lastly, the general health perception domain contains five items that evaluate the general health of the participant. A low scorer on this domain perceives their health as bad and expects it to get worse over time. A high scorer on the other hand perceives their health to be good (van der Zee & Sanderman, 1993). To get a good sense of the QoL of the participant, it was necessary to analyze all the domains in detail to fully understand which domain might have influenced their QoL. The Cronbach's alpha coefficient for the RAND-36 consisted of nine subscales $\alpha$=0.90 at time point 1 (0 months) deeming it reliable. At time point 2 (6 months), the Cronbach's alpha consisted of nine subscales $\alpha$=0.88 deeming it thus reliable (Tavakol & Dennick, 2011). Deleting any item at both time points would result in a decrease of Cronbach's alpha except for the item of health change, which would increase the Cronbach's alpha if deleted.

*Procedure*

Patients who were eligible for the study were informed about the study by the podiatrist and received the information brochure and informed consent form in Appendix D (Jongebloed-Westra et al., 2021, submitted). The podiatrist provided the investigator with the patients' information. The investigator then contacted these patients for further explanation and to answer any questions patients had about the study. Upon deciding to participate, the investigator or a representative asked the patient to sign the informed consent form.

Afterwards, the recruited participant needed to fill in various questionnaires. First, the investigator filled in the case report form, where the demographic data such as age and nationality were collected alongside the diabetes type and foot deformity. Next, various other questionnaires were given to the participants such as the participant-perceived quality of life, which were filled in at home. Six months after inclusion, the participant had another appointment with the investigator, during which they received for the second time questionnaires regarding their perceived quality of life, which were also filled in at home.

*Data analysis*

The statistical environment IBM SPSS for Macintosh, version 27.0 was used for statistical analysis of the data obtained from the main study collected up to the 6th of May 2021. The current study aimed to investigate the association between patient characteristics such as age, type of diabetes, and foot deformity with quality of life. The 3 characteristics were divided into subgroups (table 1). The four subgroups for age were 48-58, 59-68, 69-78, 79-88, which were based on the age range of the current participants. The type of diabetes was divided into type 1 and type 2. The types of foot deformity were divided into four categories: absent, mild, moderate and severe. The categories for the foot deformities were chosen based on a study by Bus et al. (2013) where they categorized foot deformities into four groups for their analyses and were adapted to the foot deformities mentioned in the case report of the current study.

Table 1

*Subgroups per characteristic*

| **Characteristic** | **Subgroups** |
|---|---|
| Age | 48-58 years<br>59-68 years<br>69-78 years<br>79-88 years |
| Type of diabetes | Type 1<br>Type 2 |
| Foot deformities | Absent: *(no amputation or foot ulcer)*<br>Mild: *(pes planus, pes cavus, hallux valgus, hallux limitus, hammertoes, rear valgus, rear varus and lesser toe amputation)*<br>Moderate: *(hallux rigidus, hallux or ray amputation, prominent metatarsal head and claw toes)*<br>Severe: *(Charcot deformity, fore/midfoot amputation and lower leg amputation)* |

First, the data were screened to exclude irrelevant data and missing values from the data set. Descriptive statistics were used to analyze the participant characteristics such as age, gender and ethnicity, duration of diabetes and marital status. The sum score for each domain was computed as well as the mean, minimum and maximum score and standard deviation for time point 1 (0 months) and time point 2 (6 months). Next, Cronbach's alpha was conducted to check the internal consistency and test-retest correlation of the RAND-36. The Cronbach's alpha must be higher than 0.7 to show good internal consistency (Tavakol & Dennick, 2011). Then, the four assumptions, namely independence, normality, equality and linearity were checked to see if the data was suitable for analysis using Shapiro Wilk's test for normality. The independence should not be met seeing that the data consists of the same participants measured over time.

Second, the prevalence of the type of diabetes and foot deformity in the different age groups was analyzed using crosstabs. After that, the mean score and range were computed per domain for each characteristic namely age, type of diabetes and foot deformity.

Next, a correlation analysis was conducted for the subgroups of the three characteristics (age, type of diabetes and foot deformities) with the domain result of the RAND-36 using the Spearman's rho test. For all the tests, a p-value of $<.05$ is significant. This was done for the first time point (0 months) to check the association between QoL and each characteristic and their subgroups. This was then repeated for time point 2 (6 months). A more detailed analysis was done using the Kruskal-Wallis test to analyze which subgroups differ from each other when there was a significant difference in the QoL between groups or within characteristics. To analyze the QoL within each characteristic in more detail, if there is a significant difference, a post-hoc Dunn-test with a Bonferroni correction was used. The post-hoc Dunn-test with a Bonferroni correction was conducted for the characteristic against the domain in which there was a significant difference to analyze which subgroups differ from each other. This test was done for relevant differences at the time point of 0 months and 6 months.

Lastly, a bar graph was used to depict the overall changes in domain scores over the two time periods per subscale of the RAND-36. To see if the QoL changes over time, a Mann-Whitney U test was conducted to see if there was a significant difference between the domain scores from time point 1 (0 months) and time point 2 (6 months). If there was a significant difference, a Kruskal-Wallis test combined with a post-hoc Dunn-test was conducted to analyze which subgroups differ from each other.

## Results

*Descriptive Statistics*

The characteristics of 46 participants and the frequency per characteristic can be found in table 2. Results of the descriptive statistics indicate that most participants were married and had diabetes for 11-20 years. Most of the participants were in the age group 59-68, were male, had type 2 diabetes and moderate foot deformities.

Table 2

*Participant characteristics with group size*

| **Characteristic** | | **Number of participants** |
|---|---|---|
| Marital status | Single | 7 |
| | Married | 30 |
| | Divorced | 2 |
| | Widowed | 4 |
| | Registered Partnership | 3 |
| Duration DM | 1-10 years | 16 |
| | 11-20 years | 17 |
| | 21-30 years | 9 |
| | 31-45 years | 4 |
| Age group | 48-58 | 10 |
| | 59-68 | 17 |
| | 69-78 | 16 |
| | 79-88 | 3 |
| Gender | Male | 34 |
| | Female | 12 |
| Type of diabetes | 1 | 6 |
| | 2 | 40 |
| Foot deformity | Absent | 0 |
| | Mild | 6 |
| | Moderate | 29 |
| | Severe | 11 |

The descriptive statistics for the nine domains and 46 participants for time point 1 (0 months) and time point 2 (6 months) can be found in table 3. From the means and standard deviation over time, some differences can be observed. The range of scores also became shorter after a period of 6 months, for example, at time point 1 the scores for health change ranged from 0-100 and at time point 2 they ranged from 25-100. The changes in the score ranges are also observed for role limitation due to emotional problems (T1: 0-100 and T2: 16.6-100), mental health (T1: 35-100 and T2: 40-100) and general health perception (T1: 5-80 and T2: 15-95).

Table 3

*Descriptive statistics per domain RAND-36 T1 and T2*

| | T1 | | | T2 | | |
|---|---|---|---|---|---|---|
| **Domain** | **Min-Max** | **Mean** | **SD** | **Min-Max** | **Mean** | **SD** |
| Physical functioning | 0-100 | 60.9 | 28.7 | 0-100 | 59.1 | 27.3 |
| Social functioning | 0-100 | 69.0 | 27.9 | 0-100 | 73.9 | 23.8 |
| Role limitation (physical) | 0-100 | 53.7 | 30.4 | 0-100 | 53.1 | 27.5 |
| Role limitation (emotional) | 0-100 | 78.8 | 28.1 | 16.6-100 | 74.3 | 25.9 |
| Mental health | 35-100 | 75.0 | 17.3 | 40-100 | 77.2 | 17.3 |
| Energy | 18-100 | 59.2 | 20.4 | 18.7-100 | 59.5 | 18.7 |
| Pain | 0-100 | 64.6 | 27.1 | 0-100 | 66.1 | 23.9 |
| General health perception | 5-80 | 48.9 | 17.9 | 15-95 | 48.9 | 20.1 |
| Health change | 0-100 | 49.5 | 25.5 | 25-100 | 53.8 | 21.7 |

When testing for the assumptions, independence, equal variance and normality was not met, therefore non-parametric tests were used to analyze the correlation and difference of QoL and the three characteristics.

*Prevalence of characteristics per age group*

The prevalence of foot deformity per age group can be found in table 4 with both the count and percentage. All the age groups had one type of foot deformity and thus none of them fell into the absent category. The most prevalent foot deformities in all age groups were moderate

foot deformities. The least prevalent foot deformity in all age groups were mild foot deformities.

Table 4

*Prevalence foot deformity per age group*

| Age | Absent | Mild | Moderate | Severe | Total |
|---|---|---|---|---|---|
| 48-58 | 0 | 0 | 6 (60.0%) | 4 (40.0%) | 10 (21.7%) |
| 59-68 | 0 | 3 (17.6%) | 11 (64.7%) | 3 (17.6%) | 17 (37.0%) |
| 69-78 | 0 | 3 (18.8%) | 9 (56.3%) | 4 (25.0%) | 16 (34.8%) |
| 79-88 | 0 | 0 | 3 (100%) | 0 | 3 (6.5%) |
| Total | 0 | 6 (13.0%) | 29 (63.0%) | 11 (24.0%) | 46 (100%) |

The prevalence of the type of diabetes per age group can be found in table 5. Type 2 diabetes was the most prevalent type of diabetes (87%) and the least prevalent was type 1 (13%).

Table 5

*Prevalence type of diabetes per age group*

| Age | Type 1 | Type 2 | Total |
|---|---|---|---|
| 48-58 | 2 (20.0%) | 8 (80.0%) | 10 (21.7%) |
| 59-68 | 3 (17.6%) | 14 (82.4%) | 17 (37.0%) |
| 69-78 | 1 (6.3%) | 15 (93.8%) | 16 (34.8%) |
| 79-88 | 0 | 3 (100%) | 3 (6.5%) |
| Total | 6 (13.0%) | 40 (87.0%) | 46 (100%) |

*Analysis of quality of life per characteristic*

**Age**

Table 6 displays the mean, standard deviation, minimum and maximum scores for the domains of the RAND-36 for each subgroup of the age characteristic at both time points.

When looking at the Spearman rho's correlation test (table 7) between age and the nine domains, the p-values were higher than .05 ($p>.05$) at time point 1. At time point 2, there was a significant negative association between physical functioning and age ($rs(46)= -.31$, $p=.03$) and a significant negative association between health change and age ($rs(46)= -.29$,

p=.04). However, when looking at the association between the age subgroups with pain and between the age subgroups and physical functioning, no significant association was indicated (p>.05). For the other domains, no significant association was found (p>.05). The Kruskal Wallis test indicated no significant difference between age for the nine domains (p>.05) at time point 1 and time point 2.

Table 6

*Mean (M), standard deviation (SD) and range (minimum-maximum) score per age group T1 and T2*

| | T1 | | | | | | | | T2 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Age(N)** | **48-58(10)** | | **59-68(17)** | | **69-78(16)** | | **79-88(3)** | | **48-58(10)** | | **59-68(17)** | | **69-78(16)** | | **79-88(3)** | |
| **Domain** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** |
| Physical functioning | 70 (22.5) | 30-100 | 63.5 (27.7) | 5-90 | 59.7 (29.9) | 5-90 | 20 (20) | 0-40 | 68.5 (26.9) | 35-100 | 63.8 (23.8) | 20-95 | 55.2 (28.2) | 0-90 | 21.7 (12.6) | 10-35 |
| Social functioning | 82.5 (20.6) | 37.5-100 | 66.9 (26.9) | 25-100 | 66.4 (27.7) | 12.5-100 | 50 (50) | 0-100 | 83.8 (14.5) | 62.5-100 | 74.3 (20) | 37.5-100 | 65.6 (29.8) | 0-100 | 83.3 (28.9) | 50-100 |
| Role limitation (physical) | 57.5 (27.5) | 31.3-100 | 55.9 (32.7) | 0-100 | 52.5 (30.1) | 0-100 | 35.4 (37.7) | 0-75 | 62.5 (26.4) | 25-100 | 56.6 (26.1) | 12.5-100 | 48.1 (28.7) | 0-93.8 | 29.2 (26) | 0-50 |
| Role limitation (emotional) | 87.5 (22.7) | 33.3-100 | 76 (28.2) | 25-100 | 81.8 (26.2) | 0-100 | 50 (46.4) | 8-100 | 80.8 (22.6) | 41.7-100 | 69.6 (28.2) | 16-100 | 76 (27.2) | 25-100 | 69.4 (29.3) | 41.7-100 |
| Mental Health | 75 (18) | 45-95 | 75.3 (19.9) | 35-100 | 78.1 (14.1) | 45-100 | 56.7 (2.9) | 55-60 | 77.5 (21.5) | 45-100 | 77.1 (16.8) | 45-100 | 76.9 (17) | 40-100 | 78.3 (15.3) | 65-95 |
| Energy | 60.6 (15.6) | 37.5-75 | 57 (24.5) | 25-100 | 63 (17.2) | 31-94 | 45.9 (28.2) | 19-75 | 56.9 (15.6) | 31-81 | 59.2 (16.8) | 45-100 | 61.3 (20.9) | 18-88 | 60.4 (14.4) | 44-69 |
| Pain | 68.4 (21.6) | 44.9-100 | 64.6 (28.4) | 10-100 | 67.5 (29.5) | 0-100 | 37.4 (13) | 22-45 | 66.1 (21.7) | 44.9-100 | 66.5 (18.9) | 22-100 | 66.1 (31.3) | 0-100 | 64 (23.2) | 45-90 |
| General health perception | 48.5 (17) | 35-75 | 43.2 (20.4) | 5-80 | 56.8 (14.1) | 20-75 | 41.7 (15.3) | 25-55 | 47.5 (21) | 20-85 | 43.2 (20.1) | 15-85 | 55 (20) | 20-95 | 53.3 (16.1) | 35-65 |
| Health change | 60 (33.8) | 0-100 | 39.7 (19.9) | 25-100 | 54.7 (24.5) | 25-100 | 41.7 (14.4) | 25-50 | 65 (21.1) | 50-100 | 51.5 (18.7) | 25-100 | 53.1 (23.9) | 25-100 | 33.3 (14.4) | 25-50 |

Table 7

*Spearman rho's correlation and p-value age and RAND-36 domains T1 and T2*

| | Age groups | | | |
|---|---|---|---|---|
| | T1 | | T2 | |
| **Domain** | **correlation** | **p-value** | **correlation** | **p-value** |
| Physical functioning | -.24 | .10 | -.30* | .03* |
| Social functioning | -.22 | .13 | -.15 | .31 |
| Role limitation (physical) | -.06 | .06 | -.21 | .14 |
| Role limitation (emotional) | -.14 | .33 | -.05 | .73 |
| Mental Health | -.07 | .62 | -.05 | .72 |
| Energy | -.01 | .94 | .08 | .55 |
| Pain | -.10 | .50 | .02 | .85 |
| General health perception | .15 | .29 | .18 | .21 |
| Health change | -.02 | .88 | -.29* | .04* |

**Foot deformity**

In table 8, the mean, standard deviation and minimum and maximum score for each domain are depicted for each subgroup of the foot deformity category at time point 1 and time point 2.

The results of the Spearman rho test can be found in table 9. At time point 1, there was a significant positive association found between the domain pain and the foot deformity categories (rs(46)= .37, p=.01) and a significant positive association between the domain health change and the foot deformity categories (rs(46)= .30, p=.04), meaning that they experience less pain and experience better health change. For the moderate foot deformities, there was a positive association with the domains pain (rs(29)=.52, p.004) and with the domains and health change (rs(29)=.52, p.004). No significant association was indicated for severe and mild foot deformities with the domain pain and health change (p>.05). For the other domains, no significant association was indicated (p>.05). Kruskal-Wallis test indicated a significant difference in the domain pain for the three foot deformity categories, H(2)= 6.34, p=.04. Participants with mild foot deformity had a lower pain score (Mdn=33.7) than those with moderate foot deformities (Mdn=67.3) and severe foot deformities (Mdn=87.7). A

post-hoc Dunn-test with a Bonferroni correction indicated a significant difference between mild and severe foot deformities ($p=.01$) for the domain pain but not between other foot deformities, namely mild and moderate, and moderate and severe.

No significant associations were found between the different domains and foot deformities at time point 2 ($p>.05$). Kruskal-Wallis test also indicated no significant difference between the different foot deformities for the different domains at time point 2 ($p>.05$).

Table 8

*Mean (M), standard deviation (SD) and range (minimum-maximum) score per foot deformity category T1 and T2*

| | T1 | | | | | | T2 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Foot Deformity (N)** | **Mild(6)** | | **Moderate(29)** | | **Severe(11)** | | **Mild(6)** | | **Moderate(29)** | | **Severe(11)** | |
| **Domain** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** |
| Physical functioning | 50.8(35.9) | 5-90 | 61(30) | 0-95 | 65.9(21.2) | 30-100 | 39.2(33.7) | 0-80 | 62(26.1) | 10-100 | 62.3(24.5) | 35-100 |
| Social functioning | 54.2(28.1) | 25-100 | 67.7(29.6) | 0-100 | 80.7(18.8) | 37.5-100 | 54.2(40.8) | 0-100 | 75(18.9) | 37.5-100 | 81.8(20.4) | 37.5-100 |
| Role limitation (physical) | 41.7(42.9) | 0-100 | 54.4(30.5) | 0-100 | 58.5(22.6) | 31.3-50 | 46.9(45) | 0-100 | 53.7(24.9) | 0-100 | 55.1(24.8) | 0-93.8 |
| Role limitation (emotional) | 83.3(30.3) | 25-100 | 75.3(30.1) | 0-100 | 85.6(21.4) | 33.3-100 | 66.7(33.3) | 25-100 | 75.6(26.4) | 16.7-100 | 75(22.1) | 25-100 |
| Mental Health | 79.2(17.4) | 50-100 | 73.9(18.2) | 35-100 | 75.5(15.9) | 50-100 | 71.7(18.4) | 40-90 | 75.5(17.8) | 45-100 | 84.6(14.2) | 55-100 |
| Energy | 57.3(17.4) | 31-87 | 57.4(22.3) | 18-100 | 64.8(14.3) | 43.8-87.5 | 43.8(15.3) | 18-56 | 60.9(17.7) | 31-87.5 | 64.2(20.4) | 25-100 |
| Pain | 40.8(36.5) | 0-87 | 63.8(23.8) | 10-100 | 79.9(21.3) | 44.9-100 | 46.9(37.4) | 0-100 | 65.9(19.2) | 22.4-100 | 76.9(22.4) | 44.9-100 |
| General health perception | 43.9(24.2) | 5-75 | 48.8(17.6) | 20-80 | 52.3(15.9) | 25-75 | 35.8(16.6) | 15-60 | 49.7(19.2) | 25-85 | 54.1(22.7) | 20-95 |
| Health change | 45.8(29.2) | 25-100 | 43.9(21.2) | 0-100 | 65.9(28) | 25-100 | 54.2(18.8) | 25-75 | 49.1(20.6) | 25-100 | 65.9(23.1) | 50-100 |

Table 9

*Spearman rho's correlation and p-value foot deformity and RAND-36 domains T1 and T2*

| | Foot deformity | | | |
|---|---|---|---|---|
| | T1 | | T2 | |
| **Domain** | **correlation** | **p-value** | **correlation** | **p-value** |
| Physical functioning | .07 | .60 | .18 | .24 |
| Social functioning | .27 | .06 | .19 | .18 |
| Role limitation (physical) | .12 | .39 | .24 | .10 |
| Role limitation (emotional) | .02 | .88 | .09 | .54 |
| Mental Health | -.05 | .74 | .02 | .87 |
| Energy | .15 | .30 | .25 | .09 |
| Pain | .37* | .01* | .25 | .09 |
| General health perception | .12 | .42 | .28 | >.05 |
| Health change | .30* | .04* | .24 | .10 |

**Type of diabetes**

In table 10, the mean, standard deviation and minimum and maximum score for each domain are depicted for each type of diabetes at time point 1 and time point 2.

Spearman rho's test (table 11) indicated no significant association between type of diabetes and the domains of QoL at time point 1 ($p>.05$). Kruskal-Wallis test also indicated no significant difference between types of diabetes for the domains of QoL at time point 1 ($p>.05$). The same results were found for time point 2.

Table 10

*Mean (M), standard deviation (SD) and range (minimum-maximum) score per type of diabetes T1 and T2*

| | T1 | | | | T2 | | | |
|---|---|---|---|---|---|---|---|---|
| **Type of Diabetes(N)** | **Type 1(6)** | | **Type 2(40)** | | **Type 1(6)** | | **Type 2(40)** | |
| **Domain** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** | **M(SD)** | **Range** |
| Physical functioning | 57.5(35.3) | 10-95 | 61.4(28.1) | 0-100 | 60.8(34.6) | 25-100 | 58.8(26.6) | 0-100 |
| Social functioning | 77.1(27.9) | 37.5-100 | 67.8(28) | 0-100 | 68.8(25.9) | 37.5-100 | 74.7(23.8) | 0-100 |
| Role limitation (physical) | 56.3(25) | 31.3-87.5 | 53.4(31.4) | 0-100 | 54.2(28.1) | 25-100 | 52.9(27.8) | 0-100 |
| Role limitation (emotional) | 76.4(28.6) | 25-100 | 79.2(28.4) | 0-100 | 68.1(26.6) | 25-100 | 75.2(26.1) | 16.7-100 |
| Mental Health | 77.5(16.9) | 50-100 | 74.6(17.5) | 35-100 | 77.5(16.6) | 60-100 | 77.1(17.6) | 40-100 |
| Energy | 61.5(19.1) | 31.3-87.5 | 58.8(20.8) | 18.7-100 | 58.3(24.9) | 31.3-100 | 59.7(18.1) | 18.7-87.5 |
| Pain | 59.9(27.6) | 34.7-100 | 65.4(27.3) | 0-100 | 56.1(18.8) | 44.9-89.8 | 67.6(24.5) | 0-100 |
| General health perception | 43.3(13.3) | 30-60 | 49.8(18.5) | 5-80 | 35(20.9) | 15-70 | 51(19.4) | 25-95 |
| Health change | 41.7(20.4) | 25-75 | 50.6(26.2) | 0-100 | 45.8(10.2) | 25-50 | 55(22.8) | 25-100 |

Table 11

*Spearman rho's correlation and p-value type of diabetes and RAND36 domains T1 and T2*

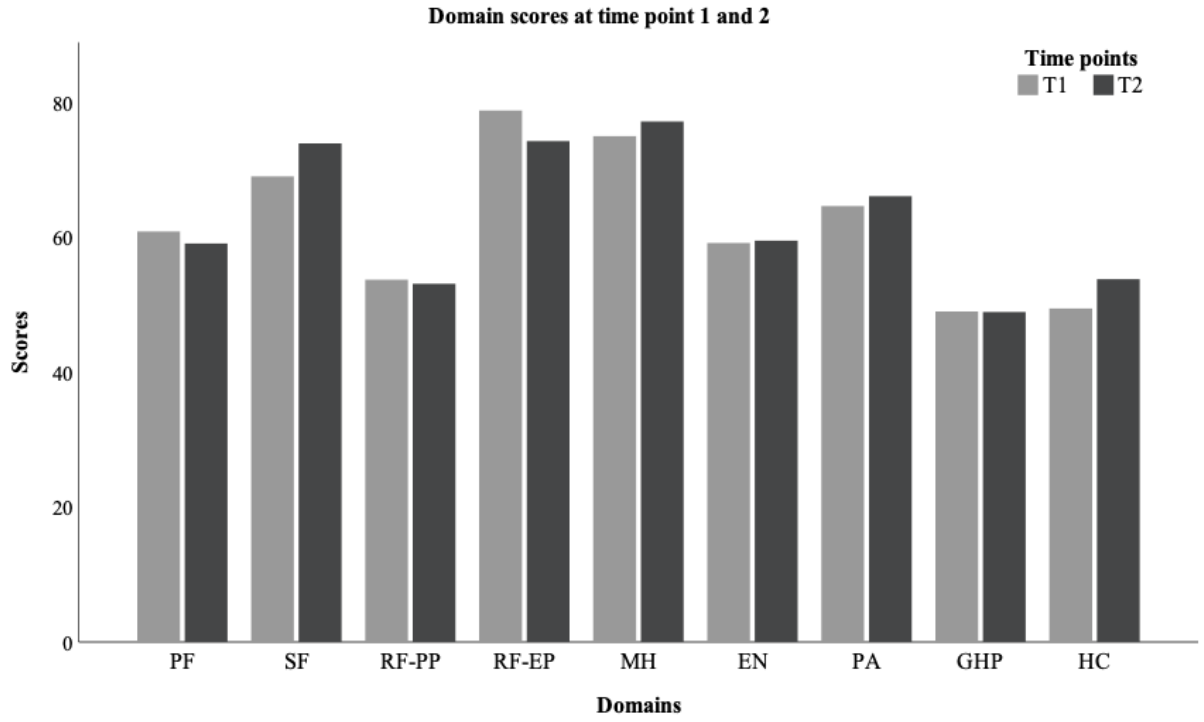
| | Type of diabetes | | | |
|---|---|---|---|---|
| | T1 | | T2 | |
| **Domain** | **correlation** | **p-value** | **correlation** | **p-value** |
| Physical functioning | -.01 | .97 | -.03 | .82 |
| Social functioning | -.12 | .41 | .12 | .40 |
| Role limitation (physical) | -.00 | .98 | .10 | .48 |
| Role limitation (emotional) | .08 | .56 | .03 | .82 |
| Mental Health | -.03 | .80 | .10 | .48 |
| Energy | -.03 | .83 | .00 | .97 |
| Pain | .11 | .46 | .06 | .65 |
| General health perception | .13 | .35 | .23 | .11 |
| Health change | .11 | .44 | .29 | >.05 |

*Analysis of quality of life over time*

Figure 1 depicts the mean scores for each domain at time point 1 and time point 2.

*Figure 1*

Mean domain scores per time point




From the bar graph, it could be observed that the mean scores of the domains social functioning, mental health, pain, health change seem to have increased over time. The mean scores for the domain physical functioning and role functioning due to emotional problems seem to have decreased over time. Mean scores for the domain role functioning due to physical problems, energy and general health perception seem to show no changes over time. However, the Mann-Whitney U test indicated no significant difference between all of the domain scores at time points 1 and 2 ($p>.05$).

## Discussion

*Association between the quality of life and patient characteristics*

The purpose of this study was to determine what the association is between the quality of life and characteristics such as age, type of diabetes and type of foot deformities in people with diabetes. The findings of this study suggest there were no associations between the type of diabetes and the nine domains of quality of life. Thus, the type of diabetes is not associated with how patients perceive their quality of life. This is in contrast to the observation of Jacobson et al. (1994) that people with type 2 diabetes experienced higher QoL than those with type 1 diabetes. Despite there being no significant difference found between the two groups in the current study, some of the domain scores showed that people with type 2 diabetes experienced higher levels of QoL than people with type 1 diabetes, which slightly coincides with the research of Jacobson et al. (1994). Possibly, the results of the current study were not significant due to the small sample size of the group of people who had type 1 diabetes.

For the age groups, a significant negative association was found between all of the age groups and physical functioning and health change. Thus, depending on a person's age, they might experience lower physical functioning and health change and, in turn, lower QoL. When looking at the differences between the age groups, younger participants scored higher on most domains, which suggests that they experienced a higher level of quality of life compared to older participants. Thus, people might experience a lower quality of life as they get older. However, the results of this study indicated that there were no significant differences between the age groups. When checking the association between age groups in more detail, no significant association was found for the subgroups of age and the physical functioning and health change domains which could be due to the small sample size. Thus, QoL was also not associated with age or specific age groups.

Lastly, for the foot deformities, the results indicated a positive association between pain and foot deformity, and health change and foot deformity. This means that patients with moderate foot deformities experienced less pain and better health change than those with mild or severe foot deformities. Taken together, patients who have moderate foot deformities thus experience a higher QoL than those with mild or severe foot deformities. A significant difference was also found between the domain scores for the pain of those with mild foot deformities and severe foot deformities. Patients who have mild foot deformities experience

more pain than those with severe foot deformities. This suggests then that patients with mild foot deformities experience lower QoL compared to patients with severe foot deformities.

As mentioned before, Allan et al. (2016) and Valensi et al. (2005) suggest that physical aspects of diabetes might cause lower quality of life. However, during this research, a positive association was found between the QoL domain regarding pain and moderate foot deformities. Those with moderate foot deformities experienced better health change and less pain and thus a higher quality of life. While this result was not expected, the result might still imply that physical aspects of foot deformities might be associated with quality of life. The same could be said for the significant difference between mild foot deformities and severe foot deformities. It was expected that those with severe foot deformities would score lower on the physical quality of life domains compared to those with mild foot deformities, however, this research found the opposite. A significant difference between foot deformity types regarding pain was also found, specifically that people with mild foot deformities experienced more pain and thus lower quality of life compared to those with severe foot deformities. Therefore, it might be interesting to further investigate this difference through a qualitative study to find out whether other factors such as duration of diabetes, physical aspects, such as neuropathy, or mental aspects such as the patients' perspective of their foot deformity might influence how they rate the pain domain. By doing this, more insight might be gained into what influences the quality of life scores and what aspects might be important to focus on in the future. However, it should be noted that this study focused on a small non-diverse sample which could have consequences on these findings.

*Prevalence of foot deformities and type of diabetes between different age groups*

The study also analyzed the prevalence of foot deformities and types of diabetes between the different age groups. The results indicated that the most prevalent foot deformity across all age groups was moderate foot deformities. This does not completely coincide with the research done by Perera et al. (2013) and Ledoux et al. (2005) which states that the most prominent foot deformities in people with diabetes are pes cavus, hammertoes, hallux limitus, hallux valgus. These foot deformities belong to the "mild category" of this study while claw toes are the only one that belongs to the "moderate category". The most prevalent type of diabetes was type 2 diabetes which coincides with previous research (American Diabetes Association, 2014; Poos & Gommer, 2020).

*Change in quality of life over a period of 6 months*

The last aim of the study was to analyze if there was a change in the quality of life six months after inclusion. From the results, it could be concluded that there was no significant difference in the domain scores of the RAND-36 over time. Thus, quality of life did not change significantly over a 6-month period for the participants in the current study. This could be due to the treatment group the participants were in, which was not addressed during this research, or due to the short time period between the two assessment points. In the main study, there were two treatment groups namely those who were in the novel care group, which received digital shoe-fitting and motivational interviewing, and those in the usual care group, who just received casting-based shoe-fitting and no motivational interviewing. The difference in treatment groups should be considered in future research to address whether different treatments might be associated with quality of life.

*Strengths, limitations and recommendations*

Some of the limitations of this study mostly involve the sample. While the sample did provide a lot of information, especially regarding the foot deformities and prevalence of the type of diabetes in the age groups, it would have been interesting to have a larger sample size. Bigger sample size would provide more diversity within the characteristic subgroups as well as more equally distributed subgroups which could lead to better inference and interpretation of the association and difference between domain scores of quality of life. It is thus recommended that future research include a more diverse sample size regarding different characteristics such as age group, including younger patients and duration time. It is also recommended to try to attain an equal distribution between the characteristics. While this recommendation might be difficult to adhere to, it should be considered as this could assure more reliable information about the differences and associations between the subgroups and the domain scores of the RAND-36.

For the comparison over time, it would have been interesting to have more time points or even a longer period in between time points to see how QoL might change over time. Lastly, missing values for some of the questionnaires also hindered the results seeing that the sample size was reduced due to participants who did not fill in the questionnaire correctly. Because of missing values, some of the domain scores per participant were also not reliable seeing that it had to be calculated which could have hindered the results in the end.

There were also some strengths to this research such as the diverse range of subgroups in the foot deformity which allowed for some significant findings and interesting results when comparing it to previous research. The sample size thus also showed some trends in how specific QoL domains might be associated with age or foot deformities which could be considered for future research. Future research could also take the treatment type and adherence into account alongside other aspects such as duration to see how this might influence the association between characteristics and quality of life over time.

*Conclusion*

In conclusion, age and type of diabetes had no direct association with a patient's quality of life. For foot deformities, on the other hand, it could be concluded that patients with severe foot deformities experienced a higher quality of life regarding pain compared to those with mild deformities. Moderate foot deformities were positively associated with quality of life domains regarding pain and health change. However, both findings contradicted previous research. The most prevalent type of foot deformity was moderate foot deformity which did not coincide with previous research while the most prevalent type of diabetes was type 2 diabetes which was expected. Finally, we can conclude that quality of life scores for people with diabetes wearing orthopedic shoes does not change drastically over a period of six months.

Future research should focus on other aspects, such as social, physical, psychological or economic aspects, that could influence the quality of life. This should be done to understand how patients perceive their own quality of life and what might influence their quality of life depending on the type of diabetes, foot deformity or age group they belong to and how this could be improved during treatment. Combining the RAND-36 questionnaire with qualitative methods such as follow up interviews regarding the quality of life or having patients keep a diary might be an option to consider. These recommendations could help make better inferences about what influences the quality of life and what could be done to ensure that patients with diabetes could cope with their illness and experience a higher level of quality of life.

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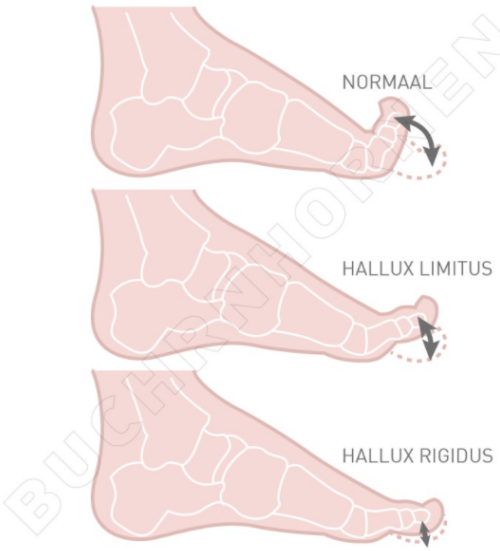
## Appendix A

## Foot deformities

**Figure 1**

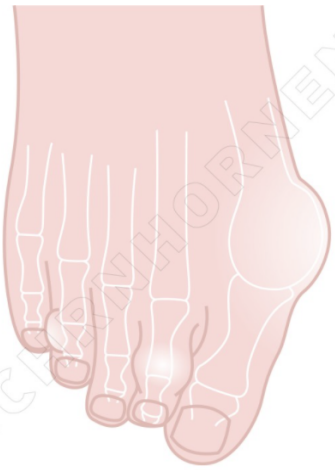
*Example hallux limitus and hallux rigidus*




*Hallux limitus / rigidus - Verminderde beweging grote teen - Buchrnhornen*. Buchrnhornen. (2021). Retrieved 22 June 2021, from https://www.buchrnhornen.nl/klachtenwijzer/hallux-limitus-rigidus/.

**Figure 2**

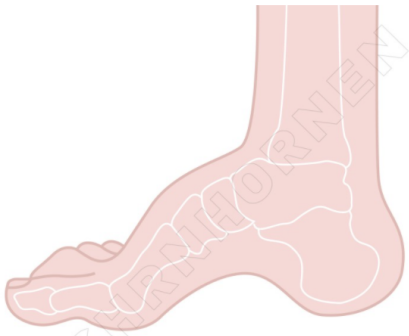
*Example hallux valgus*



*Hallux valgus - Vergroeiing grote teen - Scheve grote teen - Buchrnhornen*. Buchrnhornen. (2021). Retrieved 22 June 2021, from https://www.buchrnhornen.nl/klachtenwijzer/hallux-valgus/.

**Figure 3**

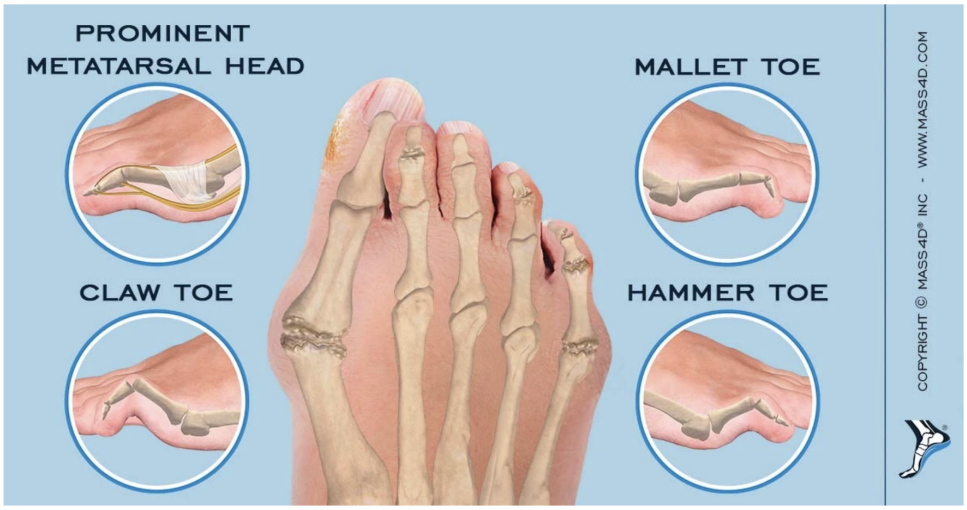
*Example pes cavus*




*Holvoet (Pes cavus) - Buchrnhornen*. Buchrnhornen. Retrieved 22 June 2021, from https://www.buchrnhornen.nl/klachtenwijzer/holvoet-pes-cavus/.

**Figure 4**

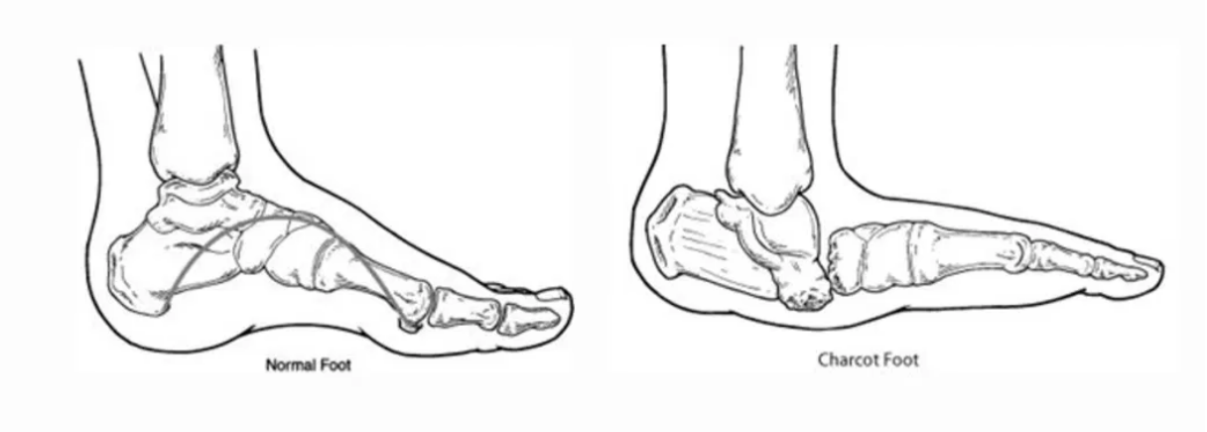
*Example toe deformities*




MASS4D Foot Orthotics.. (2018). *Types of Foot Deformities*. MASS4D® Foot Orthotics. Retrieved 22 June 2021, from https://mass4d.com/blogs/clinicians-blog/types-of-foot-deformities.

**Figure 5**

*Example Charcot foot deformity*




Whelan, C. (2018). *Charcot Foot: Causes, Symptoms, and Treatment*. Healthline. Retrieved 22 June 2021, from https://www.healthline.com/health/charcot-foot.

## Appendix B

## Case report questionnaire

*The appendix only contains the questions from the Case Report used during the research

**Demografie**

Leeftijd: .....

Geslacht: ☐ Man ☐ Vrouw

**Etnische achtergrond**

☐ Kaukasisch ☐ Afrikaans (sub-Sahara)

☐ Latijns Amerikaans ☐ Arabisch (Midden Oosten en Noord Afrika)

☐ Afro-Caribisch ☐ Indiaas/ Pakistaans/ Bangladesh

☐ Aziatisch ☐ Anders, .....

**Burgerlijke status**

☐ Alleenstaand ☐ Samenwonend

☐ Gehuwd ☐ Weduw (e)(naar)

☐ Gescheiden ☐ Anders, .....

**Diabetes**

**Type diabetes**: ☐ Type 1 ☐ Type 2 Totaal aantal jaar:.....

**Risicoprofiel:** ☐ Profiel 2 ☐ Profiel 3 ☐ Profiel 4

| Voetdeformiteiten | | | | |
|---|---|---|---|---|
| **Deformiteit** | **Rechts** | | **Links** | |
| *Klauwtenen* | ☐ Ja, 1 / 2 / 3 / 4 / 5 | ☐ Nee | ☐ Ja, 1 / 2 / 3 / 4 / 5 | ☐ Nee |
| *Hamertenen* | ☐ Ja, 1 / 2 / 3 / 4 / 5 | ☐ Nee | ☐ Ja, 1 / 2 / 3 / 4 / 5 | ☐ Nee |
| *Hallux valgus* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| *Hallux limitus* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| *Hallux rigidus* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| *Prominente MTH* | ☐ Ja, 1 / 2 / 3 / 4 / 5 | ☐ Nee | ☐ Ja, 1 / 2 / 3 / 4 / 5 | ☐ Nee |
| *Holvoet* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| *Platvoet* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| *Rear valgus* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| *Rear varus* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| *Charcot* | ☐ Ja | ☐ Nee | ☐ Ja | ☐ Nee |
| **Bent u bekend met Charcot?** | | ☐ Ja | ☐ Nee | |

***Vul het schema voetdeformiteiten samen met de orthopedisch schoenmaker in, zodat de juiste informatie genoteerd worden.***

**Amputaties**

**Rechts**

☐ Nee, geen amputaties

☐ Teen 1 / 2 / 3 / 4 / 5

☐ MTP 1 / 2 / 3 / 4 / 5

☐ Straal 1 / 2 / 3 / 4 / 5

☐ Voorvoet

☐ Midvoet

☐ Onderbeenamputatie

☐ Anders,……

**Links**

☐ Nee, geen amputaties

☐ Teen 1 / 2 / 3 / 4 / 5

☐ MTP 1 / 2 / 3 / 4 / 5

☐ Straal 1 / 2 / 3 / 4 / 5

☐ Voorvoet

☐ Midvoet

☐ Onderbeenamputatie

☐ Anders,……

## Appendix C

## RAND-36 (SF) questionnaire

**RAND-36 V2.01**

Toelichting

In deze vragenlijst wordt naar uw gezondheid gevraagd.
Wilt u elke vraag beantwoorden door het juiste hokje aan te kruisen.
Wanneer u twijfelt over het antwoord op een vraag, probeer dan het antwoord te geven dat het meest van toepassing is.

**1** Wat vindt u, over het algemeen genomen, van uw gezondheid?

| | |
|---|---|
| uitstekend | ☐ |
| zeer goed | ☐ |
| goed | ☐ |
| matig | ☐ |
| slecht | ☐ |

**2** *In vergelijking met een jaar geleden*, hoe zou u *nu* uw gezondheid in het algemeen beoordelen?

| | |
|---|---|
| veel beter dan een jaar geleden | ☐ |
| iets beter dan een jaar geleden | ☐ |
| ongeveer hetzelfde als een jaar geleden | ☐ |
| iets slechter dan een jaar geleden | ☐ |
| veel slechter dan een jaar geleden | ☐ |

**3** De volgende vragen gaan over dagelijkse bezigheden. Wordt u door **uw gezondheid** *op dit moment* beperkt bij deze bezigheden? Zo ja, in welke mate?

| | | **ja, ernstig beperkt** | **ja, een beetje beperkt** | **nee, helemaal niet beperkt** |
|---|---|---|---|---|
| a | *Forse inspanning* zoals hardlopen, zware voorwerpen tillen, inspannend sporten. | ☐ | ☐ | ☐ |
| b | *Matige inspanning* zoals het verplaatsen van een tafel, stofzuigen, fietsen. | ☐ | ☐ | ☐ |
| c | Tillen of boodschappen dragen | ☐ | ☐ | ☐ |
| d | *Een paar* trappen oplopen | ☐ | ☐ | ☐ |
| e | *Eén* trap oplopen | ☐ | ☐ | ☐ |
| f | Buigen, knielen of bukken | ☐ | ☐ | ☐ |
| g | *Meer dan een kilometer* lopen | ☐ | ☐ | ☐ |
| h | *Een halve kilometer* lopen | ☐ | ☐ | ☐ |
| i | *Honderd meter* lopen | ☐ | ☐ | ☐ |
| j | Uzelf wassen of aankleden | ☐ | ☐ | ☐ |

**4** Hoe vaak had u, ten gevolge van uw **lichamelijke gezondheid**, *de afgelopen 4 weken* één van de volgende problemen bij uw werk of andere dagelijkse bezigheden?

| | | **voortdurend** | **vaak** | **soms** | **zelden** | **nooit** |
|---|---|---|---|---|---|---|
| a | U heeft *minder tijd* kunnen besteden aan werk of andere bezigheden | ☐ | ☐ | ☐ | ☐ | ☐ |
| b | U heeft *minder bereikt* dan u zou willen | ☐ | ☐ | ☐ | ☐ | ☐ |
| c | U was beperkt in het *soort* werk of het soort bezigheden | ☐ | ☐ | ☐ | ☐ | ☐ |
| d | U had moeite met het werk of andere bezigheden (het kostte u bijvoorbeeld extra inspanning) | ☐ | ☐ | ☐ | ☐ | ☐ |

**5** Hoe vaak had u, ten gevolge van een **emotioneel probleem** (bijvoorbeeld doordat u zich depressief of angstig voelde), *de afgelopen 4 weken* één van de volgende problemen bij uw werk of andere dagelijkse bezigheden?

| | **voort-durend** | **vaak** | **soms** | **zelden** | **nooit** |
|---|---|---|---|---|---|
| a U heeft *minder tijd* kunnen besteden aan werk of andere bezigheden | ☐ | ☐ | ☐ | ☐ | ☐ |
| b U heeft *minder bereikt* dan u zou willen | ☐ | ☐ | ☐ | ☐ | ☐ |
| c U heeft het werk of andere bezigheden niet zo zorgvuldig gedaan als u gewend bent | ☐ | ☐ | ☐ | ☐ | ☐ |

**6** In hoeverre heeft uw **lichamelijke gezondheid** of hebben uw **emotionele problemen** u *de afgelopen 4 weken* belemmerd in uw normale sociale bezigheden met gezin, vrienden, buren of anderen?

helemaal niet ☐
enigszins ☐
nogal ☐
veel ☐
heel erg veel ☐

**7** Hoeveel **pijn** had u *de afgelopen 4 weken*?

geen ☐
heel licht ☐
licht ☐
nogal ☐
ernstig ☐
heel ernstig ☐

**8** In welke mate heeft **pijn** u *de afgelopen 4 weken* belemmerd bij uw normale werkzaamheden (zowel werk buitenshuis als huishoudelijk werk)?

| | |
|---|---|
| helemaal niet | ☐ |
| een klein beetje | ☐ |
| nogal | ☐ |
| veel | ☐ |
| heel erg veel | ☐ |

**9** Deze vragen gaan over hoe u zich *de afgelopen 4 weken* heeft **gevoeld**. Wilt u bij elke vraag het antwoord omcirkelen dat het beste aansluit bij hoe u zich heeft gevoeld.

Hoe vaak gedurende
*de afgelopen 4 weken*:

| | **voort-durend** | **vaak** | **soms** | **zelden** | **nooit** |
|---|---|---|---|---|---|
| a Voelde u zich levenslustig? | ☐ | ☐ | ☐ | ☐ | ☐ |
| b Voelde u zich erg zenuwachtig? | ☐ | ☐ | ☐ | ☐ | ☐ |
| c Zat u zo erg in de put dat niets u kon opvrolijken? | ☐ | ☐ | ☐ | ☐ | ☐ |
| d Voelde u zich kalm en rustig? | ☐ | ☐ | ☐ | ☐ | ☐ |
| e Voelde u zich erg energiek? | ☐ | ☐ | ☐ | ☐ | ☐ |
| f Voelde u zich neerslachtig en somber? | ☐ | ☐ | ☐ | ☐ | ☐ |
| g Voelde u zich uitgeblust? | ☐ | ☐ | ☐ | ☐ | ☐ |
| h Voelde u zich gelukkig? | ☐ | ☐ | ☐ | ☐ | ☐ |
| i Voelde u zich moe? | ☐ | ☐ | ☐ | ☐ | ☐ |

**10** *Hoe vaak* hebben uw **lichamelijke gezondheid** of **emotionele problemen** gedurende *de afgelopen 4 weken* uw sociale activiteiten (zoals bezoek aan vrienden of naaste familieleden) belemmerd?

| | |
|---|---|
| voortdurend | ☐ |
| vaak | ☐ |
| soms | ☐ |
| zelden | ☐ |
| nooit | ☐ |

**11** Wilt u het antwoord kiezen dat het beste weergeeft hoe juist of onjuist u elk van de volgende uitspraken voor uzelf vindt.

| | **volkomen juist** | **groten-deels juist** | **weet ik niet** | **groten-deel onjuist** | **volkomen onjuist** |
|---|---|---|---|---|---|
| a Ik lijk gemakkelijker ziek te worden dan andere mensen | ☐ | ☐ | ☐ | ☐ | ☐ |
| b Ik ben net zo gezond als andere mensen die ik ken | ☐ | ☐ | ☐ | ☐ | ☐ |
| c Ik verwacht dat mijn gezondheid achteruit zal gaan | ☐ | ☐ | ☐ | ☐ | ☐ |
| d Mijn gezondheid is uitstekend | ☐ | ☐ | ☐ | ☐ | ☐ |

**Appendix D**

**Information brochure and informed consent**

# 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 wanneer 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

**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.
- Ik geef □ **wel**

□ **geen**

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

Naam proefpersoon:

Handtekening: Datum : __ / __ / __

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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: __ / __ / __

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*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)**