The predictive value of quality of life and attitude towards orthopaedic shoes on number of steps a diabetes patient with foot problems takes per day

Master thesis (25EC)

Anke Scholten
S2206366

Master Health Psychology and Technology
Faculty of Behavioural, Management and Social Sciences
University of Twente

1st Supervisor: Dr. C. Bode
2nd Supervisor: B.E. Bente MSc.
Date of submission: 12-04-2021

Abstract

Introduction: Physical activity is an important aspect for management of diabetes mellitus. Unfortunately, frequency of physical activity in diabetes patients with diabetic foot problems is still low. Therefore, it is important to identify factors that potentially lead to an increase or decrease of physical activity in diabetes patients with foot problems. Based on literature it is hypothesized that quality of life and attitude towards orthopaedic shoes may both influence physical activity in diabetes patients with foot problems. However, currently there is little literature available how quality of life of diabetes patients, and attitude towards orthopaedic shoes may predict activity levels in diabetes patients with foot problems. Therefore, the main research question of this study is: *How does quality of life and attitude towards orthopaedic shoes at baseline predicts the physical activity level of diabetes patients with foot problems after 3 and 6 months?*

Method: In a longitudinal and mixed-methods design the research- and sub questions were answered, using both quantitative and qualitative data collection methods. The initial sample contains of 49 participants of which 71% is male, the mean age was 67.3, and 71% had a history with foot ulcer. The initial sample was divided into 6 different sample groups depending on combination of available data per analysis. At baseline, quality of life was examined with the RAND-36 V2, and attitude towards orthopaedic shoes was examined with in depth interviews based on the MOSpost. Physical activity was examined with an activity tracker for one week at both 3 and 6 months after baseline. Qualitative data was labelled into negative and positive codes. Quantitative data was analysed by multiple linear regression analysis and simple linear regression analysis.

Results: The results showed that three months after baseline participants on average walked 4485 steps per day, and six months after baseline participants on average walked 4085 steps per day. According the index of Tudor-Locke & Bassett, both activity levels reflect a sedentary lifestyle. Quality of life subdomain scores ranged between 49.5 and 82.7 in sample group 3 and between 46.8 and 81.9 in sample group 4. Quality of life didn't significantly explain variance in physical activity 3 months after baseline. However, 6 months after baseline quality of life subdomains physical functioning (β=33.444; t (30) =2.219; p=0.035), social functioning (β=32.704; t (30) =2.423; p=0.022) and physical role impairments (β=28.872; t (30) =3.518; p=0.021) did significantly predict variance in physical activity, in mean steps per day. The majority of the participants expressed relatively more positive than negative attitudes towards orthopaedic shoes. But, both 3 and 6 months after baseline, attitude towards orthopaedic shoes was not significantly correlated with the physical activity, expressed in mean steps per day.

Discussion: The current study has shown that, the only aspect predicting physical activity levels of diabetes patients with foot problems, is how patients value their quality of life regarding physical well-being. But only six months after baseline, and not three months after baseline. Physical activity levels of diabetes patients with foot problems were not predicted by positive or negative attitude towards orthopaedic shoes. However, in the current study adherence rates to orthopaedic shoes were not investigated. Furthermore, findings in the current study may be impaired due to small sample size and use of average steps per week. Further research is recommended to examine if this resulted in different conclusions. In order to increase physical activity, based on the results of the current study interventions should be tailored to the individual and its baseline activity level, include motivational interviewing and focus on improving physical well-being

Samenvatting

Introductie: Een belangrijk aspect in het management van diabetes mellitus is lichaamsbeweging. Helaas is therapietrouwheid van bewegingsprogramma's onder diabetespatiënten met voetcomplicaties nog steeds laag. Daarom is het belangrijk om te identificeren wat oorzaken zijn die leiden tot een stijging of daling in lichaamsbeweging van diabetespatiënten met voetcomplicaties. Gebaseerd op literatuur luidt de hypothese dat kwaliteit van leven en houding tegenover orthopedische schoenen beide mogelijk invloed hebben op lichaamsbeweging van diabetespatiënten met voetcomplicaties. Op dit moment is er weinig literatuur beschikbaar over hoe kwaliteit van leven, en houding tegenover orthopedische schoenen lichaamsbeweging in diabetespatiënten met voetproblemen beïnvloed. Daarom is de onderzoeksvraag van deze studie: *Hoe voorspellen kwaliteit van leven en houding tegenover orthopedische schoenen tijdens baseline, lichaamsbeweging in diabetespatiënten met voetcomplicaties na 3 en 6 maanden?*

Methode: De hoofd onderzoeksvraag en sub vragen werden beantwoord in een longitudinaal en mixed-method onderzoek, gebruikmakend van kwantitatieve en kwalitatieve onderzoeksmethoden. De oorspronkelijke onderzoekspopulatie bestaat uit 49 participanten, 71% man, gemiddelde leeftijd is 67.3 en 71% heeft een ulcera historie. De onderzoekspopulatie is opgedeeld in 6 verschillende sample groepen, afhankelijk van de combinatie van beschikbare data per analyse. Kwaliteit van leven werd onderzocht aan de hand van de RAND-36 V2, houding tegenover orthopedische schoenen werd onderzocht met diepte-interviews gebaseerd op de MOSpost. Lichaamsbeweging werd onderzocht aan de hand van het dragen van een activiteitenmeter voor een week op 3 en 6 maanden. Kwalitatieve data werd gecodeerd in negatieve en positieve codes. Kwantitatieve data werd geanalyseerd met meervoudige lineaire regressieanalyses en enkelvoudig lineaire regressieanalyses.

Resultaten: Drie maanden na de start van de studie liepen de participanten gemiddeld 4485 stappen per dag, na zes maanden was dit gemiddeld 4085 stappen per dag. Gebaseerd op de index of Tudor-Locke & Bassett, hadden beide groepen een sedentaire leefstijl. Scores van kwaliteit van leven varieerden in sample groep 3 per sub domein tussen 49.5 en 82.7 en in sample groep 4 tussen 46.8 en 81.9. Geen van de sub domeinen was significant voor verandering in lichaamsbeweging na drie maanden. Na zes maanden waren de sub domeinen fysiek functioneren (β=33.444; t (30) =2.219; p=0.035), sociaal functioneren (β=32.704; t (30) =2.423; p=0.022) en fysieke rolbeperkingen (β=28.872; t (30) =3.518; p=0.021) significante voorspellers voor verandering in lichaamsbeweging. Het grootste gedeelte van de participanten was overwegend meer positief dan negatief over orthopedische schoenen. Maar er zijn geen significantie correlaties gevonden tussen attitude en lichaamsbeweging na drie en zes maanden.

Discussie: De enige voorspellende factor voor lichaamsbeweging in diabetespatiënten met voetproblemen is, hoe zij kwaliteit van leven scoren op basis fysiek welbevinden, maar alleen na zes maanden en niet na 3 maanden. Houding tegenover orthopedische schoenen heeft geen effect op lichaamsbeweging van diabetespatiënten met voetcomplicaties. Maar therapietrouwheid van orthopedische schoenen is niet onderzocht. Daarnaast kunnen de resultaten verminderd betrouwbaar zijn door de kleine groepsgroottes en het gebruik van het gemiddelde aantal stappen per week in de analyses. Daarom wordt er geadviseerd om te onderzoeken of grotere onderzoekspopulaties en geen gebruik maken van een gemiddelde van lichaamsbeweging resulteert in andere resultaten. Om de hoeveelheid lichaamsbeweging te verhogen moet interventies afgestemd zijn op de individu en het activiteiten level, motiverende gespreksvoering moet worden toegepast, en er moet gefocust worden op fysiek welbevinden.

Table of contents

Introduction

Diabetes Mellitus

Over the past decade, the estimated number of diabetic patients worldwide increased substantially (Saeedi et al., 2019). In 2019, the prevalence of diabetes mellitus in the Netherlands was approximately 1.1 million (volksgezondheidenzorg.info, 2020). Diabetes mellitus, hereinafter referred to as diabetes, is a metabolic condition of which type 1 and type 2 diabetes are most common (Forouhi & Wareham, 2018). Diabetes type 2 accounts for approximately 85% of the total diabetes prevalence (Forouhi & Wareham, 2018). Diabetes is a serious long-term health condition, which can have major impact on the lives of patients, both on physical and mental well-being (Saeedi et al., 2019).

Physical well-being in diabetes patients can be impaired both on the short- and long-term. There are many early signs and symptoms of diabetes such as; unexplained weight loss, fatigue, polyuria, thirst, decreased vision, susceptibility to certain infections, bodily pain, poorly healing wounds, burning feeling, pain or numbness in feet, and so on (Ramachandran, 2014). Over time, diabetes can affect several organ systems, and lead to serious complications (Deshpande et al., 2008). Generally, long-term physical complications are classified as microvascular and macrovascular (Deshpande et al., 2008; Zheng et al., 2017). Microvascular complications include; neuropathy with risk of foot ulcers and Charcot joints, nephropathy leading to kidney failure and retinopathy with potential loss of vision. Macrovascular complications include cardiovascular disease, stroke and peripheral vascular disease (Deshpande et al., 2008).

Diabetic foot problems are the second most common complication of diabetes (Deshpande et al., 2008), and can affect a patient's life substantially (Boulton et al., 2018; Deshpande et al., 2008). The development of diabetic foot problems is affected by the presence of risk factors, such as neuropathy and peripheral vascular disease (Boulton et al., 2018; Shearman & Rawashdeh, 2016). Consequently, clawed toes, calluses, bounding foot pulses, foot ulceration, numbness and Charcot foot can occur (Howarth, 2019), Of those, foot ulceration is the most common foot complication, affecting approximately 5% of the diabetes patients each year (Shearman & Rawashdeh, 2016). In the Netherlands, diabetes patients get a so called "risk profile" based on severeness of foot problems, such as neuropathy and peripheral vascular disease. Risk profiles can vary from 0 to 4, and from risk profile 2 to 4, patients have an increased risk of developing skin defects (Nederlandse Vereniging voor Podotherapeuten [NVvP], 2014).

Besides physical consequences, living with diabetes can be psychologically challenging for diabetes patients. Patients have to adjust their life because of the disease and adhere to treatment regimen (Moran & Burson, 2017; Robinson et al., 2013). Insufficient social support, stress and a negative attitude towards diabetes can influence self-care, self-efficacy and glycaemic control negatively (Moran & Burson, 2017). Consequently, diabetes can hinder good quality of life and is a risk factor for diabetes related distress and psychiatric disorders (Robinson et al., 2013).

On the whole, diabetes can have great influence both on physical and mental well-being. Besides, diabetic foot problems are a common complication and may be related to, and interact with other aspect of diabetes, as can be seen in Figure 1. The following part of the introduction moves on to describe the variables, as displayed in Figure 1, in greater detail.

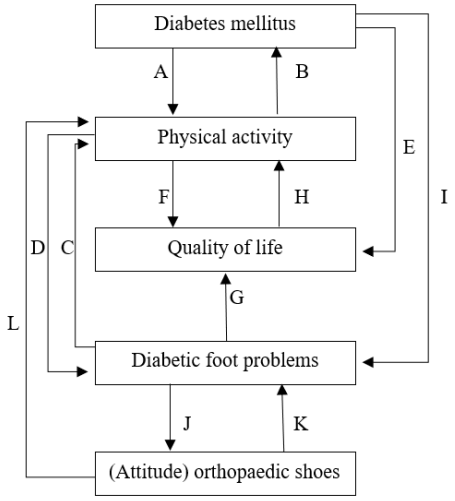

Figure 1. Overview of variables related to diabetes mellitus.

Physical activity

Physical activity is an important intervention to manage diabetes and its complications (American Diabetes Association, 2015; Qiu et al., 2012), as can be seen by arrows A and B. Regular exercise can improve blood glucose control and weight loss, reduce cardiovascular risk factors and mortality, and improve well-being and quality of life of diabetes patients (American Diabetes Association, 2015; Qiu et al., 2012). Despite the beneficial health effects, adherence to physical activity recommendations in diabetes patients is low. A study conducted by Qiu et al., (2012) has shown that only 39% of adults with diabetes reported being physical active, compared to 57% of adults without diabetes. Besides, only a few studies examined physical activity in steps per day in diabetes patients, without an intervention to increase physical activity. It was found that participants with diabetes walked an average of 4955 steps per day (Weatherall et al., 2018) and 5338 steps per day (Manjoo et al., 2012) which is less than the recommended 10.000 steps per day (Tudor-Locke & Bassett, 2004).

But physical activity may have a positive effect on diabetic foot problems (Gu et al., 2019; Matos et al., 2018). It was found that physical activity significantly improved nerve velocity, peripheral sensory function and foot peak pressure distribution (Matos et al., 2018). Furthermore, in the review of Gu et al., (2019), eleven studies reported exercise training to have beneficial effects on nerve function or neuropathy-related symptoms. Only one study reported mild adverse outcomes of exercise training (Gu et al., 2019). The potential beneficial relationship between physical activity and its influence on diabetic foot problems is displayed in Figure 1 with arrow C and the potential negative relationship with arrow D. Nonetheless, when specifically looking at diabetic foot problems and physical activity, one of the few studies that examined this topic observed that patients with peripheral neuropathy and foot ulcers rarely performed ten minutes consecutive moderate to vigorous intensive physical activity. Consequently, they rarely benefit any positive health effects of physical activity (Lee et al., 2019).

Quality of life

As can be seen in Figure 1 by arrow E, diabetes and quality of life are related to each other (Janssen et al., 2020; Robinson et al., 2013). Patients with diabetes have reported lower levels of quality of life than individuals without diabetes (Janssen et al., 2020). Recently, Jing

et al., (2018) suggested three groups of factors related to quality of life in diabetes patients namely; characteristics related to the disease, to lifestyle, and to mental factors. Besides, doing more physical exercise and regular monitoring of glucose were both associated with better quality of life (Jing et al., 2018). Adherence to physical activity recommendations can lead to better quality of life for diabetes patients in several dimensions namely; physical functioning, energy and fatigue, emotional well-being, social functioning and pain (Polikandrioti et al., 2020). The positive association between physical activity and higher quality of life can be seen in Figure 1, arrow F.

On the other hand, presence of complications, duration of diabetes, diet with more red meat, depression and anxiety were all associated with lower levels of quality of life (Jing et al., 2018). Sothornwith et al., (2018) aimed to investigate health related quality of life in patients with diabetic foot problems compared to diabetic patients with other diabetic complications and patients with no complications. Results showed that diabetic foot problems, including diabetic ulcers or amputation, had the greatest negative impact on all dimensions of health related quality of life (Sothornwit et al., 2018), as can be seen in Figure 1 arrow G. Moreover, healing of foot ulcers can result in significant improvement of quality of life (Hogg et al., 2012; Tzeravini et al., 2018)

No data has been found on how quality of life influences the activity level of diabetes patients. But based on the facts that physical activity and quality of life are both lower in diabetic patients than in individuals without diabetes it may be hypothesized that *lower quality of life in diabetes patients negatively affects their physical activity level.* This hypothetical relationship between quality of life and its influence on physical activity is displayed with arrow H in Figure 1.

Attitude towards orthopaedic shoes

As can be seen in Figure 1, arrow I displays the direct relationship of diabetes and diabetic foot problems. Foot ulceration is the most common foot problem (Shearman & Rawashdeh, 2016), but it is a preventable complication (Al-Rubeaan et al., 2015; Lundqvist & Jarl, 2016). An intervention to reduce the risk of foot ulceration are custom-made orthopaedic shoes (Bus et al., 2013; Waaijman et al., 2013), as can be seen by arrow J in Figure 1. Nevertheless, recent evidence suggest that reulceration rates are still high, what might be explained by low adherence to orthopaedic shoes (Lundqvist & Jarl, 2016; Waaijman et al., 2013). Adherence of orthopaedic shoes is influenced by several aspects such as perception of shoes' usability, appearance and perceived benefits (Van Netten et al., 2012). As can be seen in Figure 1 by arrow K, attitude towards orthopaedic shoes has an influence on adherence of the orthopaedic shoes, and therefore on diabetic foot problems.

So far, little attention has been paid to the potential role of attitude towards orthopaedic shoes and its influence on physical activity level. According to the qualitative case study of Paton et al. (2014), orthopaedic footwear may hamper activities and participation due to perceived social stigma caused by negative effects on gait and unesthetic devices (Paton et al., 2014). Furthermore, the second study Van Deursen (2008) suggested based on the gathered information, that reduced number of falls when wearing orthopaedic footwear may be contributed to the decreased level of activity when wearing orthopaedic footwear (Van Deursen, 2008). Lastly, the third study found that patients who wear orthopaedic footwear select coping strategies to boost balance confidence according to the level of fall risk associated with a certain activity. When patients are faced with a perceived high risk, they are more likely to use an

avoidance strategy and to restrict activity (Paton et al., 2013). All of the studies reviewed here support the hypothesis that *"Negative attitude towards orthopaedic shoes will negatively affect physical activity levels in diabetes patients with foot problems and positive attitudes towards orthopaedic shoes will positively affect physical activity levels in diabetes patients with foot problems."* This hypothetical relationship between attitude towards orthopaedic shoes and its influence on physical activity is displayed with arrow L in Figure 1.

Current research and research aim

Physical activity is an important aspect for management of diabetes and regular physical activity can result in beneficial health effects for diabetes patients (American Diabetes Association, 2015; Qiu et al., 2012), such as reduction of diabetic foot problems (Gu et al., 2019; Matos et al., 2018). Unfortunately, adherence rates to physical activity recommendations in diabetes patients with and without diabetic foot problems are still low (Lee et al., 2019; Qiu et al., 2012). Therefore, it is important to identify factors that potentially lead to increased or decreased physical activity rates in diabetes patients with foot problems. As can be seen in Figure 2, physical activity, (attitude towards) orthopaedic shoes, quality of life and diabetic foot problems are all related to each other.

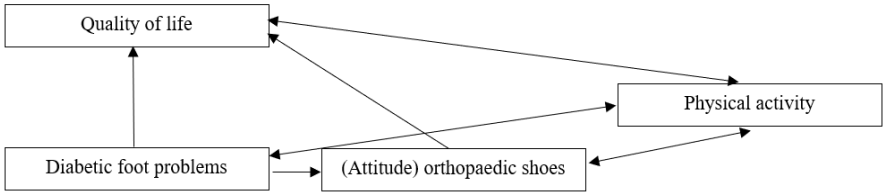

Figure 2. Overview of variables related to physical activity

So far, less is known about the role of attitude towards orthopaedic shoes, and its influence on activity level therefore remains unclear. Furthermore, no data is available on how quality of life of diabetes patients could affect their activity level. Because of the beneficial health outcomes physical activity can have on diabetes (American Diabetes Association, 2015; Matos et al., 2018; Qiu et al., 2012) and the knowledge gaps about the role of attitude towards orthopaedic shoes, and quality of life on physical activity in diabetes patients with foot problems, the main research question of this study is: *How does quality of life and attitude towards orthopaedic shoes at baseline predicts the physical activity level of diabetes patients with foot problems after 3 and 6 months?*

To answer the main research question sufficiently the following sub questions are formulated:

1. *What is the general physical activity level of diabetes patients with foot problems 3 months after baseline?*
2. *What is the general physical activity level of diabetes patients with foot problems 6 months after baseline?*
3. *What is the predictive value of quality of life at baseline on physical activity level of diabetes patients with foot problems after 3 months?*
4. *What is the predictive value of quality of life at baseline on physical activity level of diabetes patients with foot problems after 6 months?*
5. *What is the predictive value of attitude towards orthopaedic shoes at baseline on physical activity level of diabetes patients with foot problems after 3 months?*
6. *What is the predictive value of attitude towards orthopaedic shoes at baseline on physical activity level of diabetes patients with foot problems after 6 months?*

In a longitudinal and mixed-methods design the research- and sub questions will be answered. To the best of my knowledge at this moment there is no literature available on the influence quality of life has on the activity level of diabetes patients. The little available literature about the role of attitude towards orthopaedic shoes and its influence on physical activity level was measured qualitatively, correlational and with small sample sizes. The current research will examine both topics longitudinal, with larger sample sizes, and uses qualitative and quantitative data collection methods. Therefore, this study can contribute to the generation of new, in-depth and more complete scientific literature, and knowledge about these topics. Furthermore, this is the first study to undertake a longitudinal analysis of the predictive value attitude towards orthopaedic shoes and quality of life may have on physical activity in diabetes patients with foot problems. Moreover, understanding the predictive value attitude towards orthopaedic shoes and quality of life may have on physical activity may ultimately be used for practical application. If it is proven that attitude towards orthopaedic shoes or quality of life affects physical activity level, podiatrists and pedorthist could discuss these topics more in depth when assigning the orthopaedic shoes. In an attempt to prevent negative attitude towards orthopaedic shoes and to identify and if possible, treat lower quality of life in order to increase quality of life and therefore physical activity.

Methods

Study design

The current study was part of the larger study called 'Socio-economic impact of motivational interviewing on adherence to orthopaedic shoes' and is funded by ZonMw (Jongebloed-Westra et al., submitted 2020). Ethical approval for the study was obtained by the METC under number NL68567.091.19. The study was approved by the ethical committee of the BMS faculty of the University of Twente under number 190141. For this study participants will be followed for a year and receive follow-up appointments every three months. Data collection started in November 2019 and is not yet finished. Part of the collected data was used in the current study; therefore, secondary data was used. The current study started in September 2020 and was finished in April 2021.

To answer the research questions of the current study, both a longitudinal design and mixed-method design was used. Longitudinal studies follow participants over prolonged period in time in which they employ repeated measures (Caruana et al., 2015). In the current study (secondary) data about physical activity, three and six months after baseline, was used. This allowed it not only to assess if there is a relationship between the independent variables' quality of life and attitude towards orthopaedic shoes, and the dependent variable physical activity. But also, if the independent variables can explain variance in physical activity. Therefore, the current study generated new and more complete scientific knowledge about the predictive value of quality of life and attitude towards orthopaedic shoes. This may be used for practical applications to prevent low physical activity levels.

Qualitative in-depth interviews were used to determine attitude towards orthopaedic shoes. As quantitative measures a questionnaire to determine quality of life was used, and a physical activity tracker to determine physical activity in steps per day. A mixed-method design combines the strengths of different research methods, leading to increased range, depth and understanding of findings. In order to lead to an expanded and strengthened study conclusion, improved knowledge and validity (Schoonenboom & Johnson, 2017). In the current research, qualitative and quantitative measures were used. Interviews were used because they give more insight, in-depth and complete data, and understanding about attitudes than quantitative measures would do (Hammarberg et al., 2016). Quantitative measures involve systematic collection of data, when factual data is required to answer the research question (Hammarberg et al., 2016). In the current research the quality of life scores and physical activity levels were needed to answer the research questions.

Participants

Participants for the study of Jongebloed-Westra et al. (submitted, 2020) were recruited when treated by a podiatrist of Voetcentrum Wender for their diabetic foot problems and received a new pair of OSA orthopaedic shoes. Inclusion criteria were:

- Age of 18 years or older
- Clinical diagnosis of diabetes mellitus type 1 or 2
- With or without previous ulcers or callus
- Risk profile 2, 3 or 4, according to the "zorgmodule preventie diabetische voetulera 2014" (Nederlandse vereniging van podotherapeuten, 2014), eligible for prescription or orthopaedic shoes (NVvP, 2014).

Exclusion criteria were:

- Not receiving new OSA orthopaedic shoes.

- Active ulcers
- Active Charcot
- Active infection
- Not being able to walk
- Not being able to read and understand the study instructions.

Addition inclusion criteria for the current study were:

- Wearing an activity tracker at T3 or T6, for at least four days.
- Filling in the RAND 36-V2 and/or participating in the in-depth interview at baseline.

A total of N=49 participants were included in the initial sample of the current study, of which 71% was male, the mean age was 67.3 year, and 71% had an history with foot ulcers. Since the research question and all sub questions examine physical activity, the initial sample was selected based on available data of physical activity at start of this thesis. All participants of the initial sample group had worn an activity tracker for at least four days at T3 or T6. All participants signed the informed consent. In Table 1 demographic characteristics of the participants are displayed.

Table 1
Demographic characteristics of the initial sample

Variable	N (%)	Mean	Standard deviation	Range
Age (years)	49 (100%)	67.3	8.9	50-88
Gender				
Female	14 (29%)			
Male	35 (71%)			
Diabetes type				
Type 1	4 (8%)			
Type 2	45 (92%)			
Diabetes duration (years)	49 (100%)	15.7	11.3	0.5-45
Risk profile				
2	3 (6%)			
3	16 (33%)			
4	28 (57%)			
Unknown	2 (4%)			
Diabetes complications				
Ulcer history	35 (71%)			
Neuropathy	47 (96%)			
Vascular disease	11 (22%)			

The current study answers six sub questions in order to answer the main research question. Different data sets were needed to answer every individual sub question. Therefore, in the current study, every individual sub question has its own participant sample group. Formation of the different participant sample groups is displayed in Figure 3.

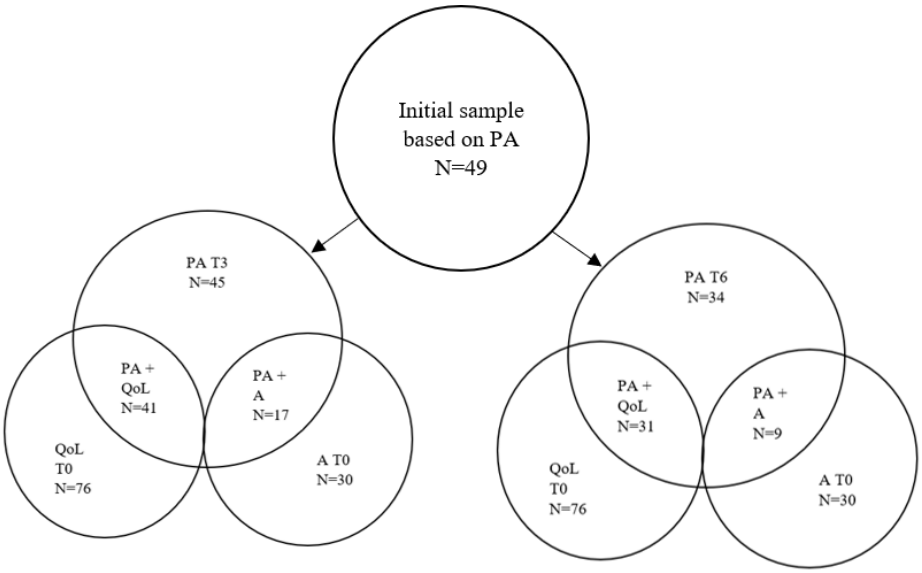

Figure 3. Formation of samples groups per sub research question. Abbreviations: PA = physical activity, QoL = quality of life, A = attitude.

To give a clear overview, all participant sample groups are displayed in Table 2. Per participant sample group it is displayed what the number of participants is, to which sub question the sample group is connected, and which data will be looked at.

Table 2
Formation of participants sample groups per sub question.

	Sample group 1	Sample group 2	Sample group 3	Sample group 4	Sample group 5	Sample group 6
N	45	34	41	31	17	9
Sub question	1	2	3	4	5	6
Physical activity T3	X		X		X	
Physical activity T6		X		X		X
Quality of life T0			X	X		
Attitude orthopaedic shoes T0					X	X

Materials

Attitude

Data on the attitude towards orthopaedic shoes of 30 participants was investigated by conducting in-depth interviews based on the MOSpost. The Monitor Orthopaedic shoes (MOS) was developed based on literature and expert interviews about the most relevant aspects of use and usability of orthopaedic shoes. Hence, the MOSpost is a valid, practical and reproducible questionnaire that measures aspects of use and usability of orthopaedic shoes from the perspective of the patient (Van Netten et al., 2009).

The interview consists of 23 questions and three components and was executed to find out what attitude diabetes patients have towards orthopaedic shoes. However, the majority of

the interview questions were excluded from the analyses in this study, because questions were leading in a certain direction or irrelevant to determine attitude. The current research question cannot be answered with these particular responses. Therefore, only responses on the first four questions of the interview were used to determine attitude. It concerns question one *"I would like to hear from you what you think about receiving custom-made orthopaedic shoes?"*, question two *"What is important to you about your orthopaedic shoes?"*, question three *"What do you think will be benefits of your orthopaedic shoes?"* and question four *"What do you think will be disadvantages of your orthopaedic shoes?"* The complete interview scheme can be found in Appendix A.

Quality of life

Data on quality of life was conducted with the RAND-36 V2. This questionnaire consists of four main dimension and eight sub dimensions. The main dimensions are functional status, well-being, general evaluation and health. The sub dimensions are; physical functioning, social functioning, emotional role impairments, physical role impairments, mental health, vitality, pain and general health evaluation. Furthermore, experienced change in health is asked (Sanderman & Van der Zee, 2012). The RAND-36 V2 is not specified on one particular disease (Sanderman & Van der Zee, 2012). The RAND-36 V2 consists of 11 main questions, of which the majority have sub questions. For example, questions are *"What do you think, generally speaking, about your health?"* answer options are *"terrific, very good, good, moderate, bad".* Another example question is "*You achieved less than you would wanted?"* with answer options *"Yes and no".* Scoring of the RAND-36 V2 takes place per subdomain. Every subdomain consists out of multiple (sub)questions with corresponding scores. Negative formulated questions are recoded so that in the end higher scores per subdomain refer to higher quality of life (Sanderman & Van der Zee, 2012). The last step is the calculation of the end scores, for every subdomain a minimum rough score, maximum rough score and score range is available. The rough score stands for the sum of the recoded scores and normal scores per domain. The formula to calculate quality of life per subdomain is ((rough scale score – minimum rough scores) / score range) x 100. Per subdomain a score between 0 and 100 will emerge (Sanderman & Van der Zee, 2012). In the diabetes population, mean population subdomain scores vary from 55.73 to 82.04, as can be seen in Table 3 (Ware et al., 1993). These scores can be used as norm values to determine how the sample groups in the current study are doing compared to the diabetes population.

Table 3
Quality of life general norm scores diabetes population (Ware et al., 1993)

	Physical functioning	Social functioning	Physical role impairments	Emotional role impairments	Mental health	Vitality	Pain	General health evaluation
Mean	67.7	82.0	56.8	75.6	76.7	55.7	68.5	56.1
SD	28.7	25.0	41.7	36.6	18.3	21.6	26.5	21.1

The RAND-36 has construct validity and has proven to have internal consistency and stability, Cronbach's alpha varies from 0.71 to 0.92 between the different sub dimensions (Sanderman & Van der Zee, 2012). In the current study Cronbach's alpha for quality of life in

sample group 3 was 0.907 and Cronbach's alpha for quality of life in sample group 4 was 0.933. The RAND-36 V2 can be found in appendix B.

Physical activity

Data on physical activity was collected with the Misfit Shine 2. The Misfit is a wearable which can be worn at the wrist. The Misfit Shine 2 collects up to 30 days of activity data. The Misfit Shine 2 is reliable and connected to the Windows version of the MisFit app in which graphs of physical activity are generated. The graphs get values appointed, these values can be transferred into Excel, in which number of steps per half-hour and number of steps per day are calculated. Other studies examining physical activity in diabetes patients often used steps per day (Manjoo et al., 2012; Weatherall et al., 2018). To ensure comparability, in the current study, number of steps per day was used to measure physical activity in diabetes patients with foot problems.

Procedure

The data collected for the current study was part of the data collection for the earlier mentioned study 'Socio-economic impact of motivational interviewing on adherence to orthopaedic shoes' of Jongebloed-Westra et al. (submitted, 2020). Therefore, the discussed procedure to collect data about physical activity, quality of life and attitude towards orthopaedic shoes was not specifically executed for the current study. In the current study, mainly secondary data was used. Between February and December 2020 primary data was collected, by conducting in-depth interviews about attitude towards orthopaedic shoes. The data collection of the study 'Socio-economic impact of motivational interviewing on adherence to orthopaedic shoes' started in November 2019 and is not yet finished. More information about the study, its procedure and process of data collection can be found in the protocol plan (Jongebloed-Westra et al., submitted 2020). All collected data was saved anonymously by participant number on a secured server of the University of Twente, the principal investigator decides who gets excess to the data.

The first appointment started with filling in the case report form. In the case report form demographic data was gathered and questions about diabetes type and duration, risk profile, ambulatory status, history regarding the use of orthopaedic shoes, educational status, socioeconomic status, and capacity for self-care are asked. Subsequently, the feet were physical examined on foot deformities and amputations, and data on the presence of peripheral artery disease, peripheral neuropathy, history of previous foot ulceration was recorded. Furthermore, the participants were asked to fill in the RAND-36 V2. At the end of the appointment the follow-up appointment, three months later, was planned.

The second appointment took place three months after inclusion, and the third appointment took place after six months. In these appointments the participant was asked how he or she was feeling and if any potential foot problems had occurred. During consultation the participant received an activity monitor and instructions form the investigator. The participants were instructed to wear the activity monitor for a whole week starting the day after the appointment. After one week the activity tracker was send back to the coordinating investigator. At the end of the appointment, the next appointment was planned.

Furthermore, at baseline an in-depth interview about attitude towards orthopaedic shoes was conducted with 30 randomly selected participants. The in-depth interviews were conducted per telephone, by two project members. First participants were called to plan the interview.

Prior to conducting the interview, a brief introduction was provided to the participants about the purpose of the interview. Before the interview started the participants were asked if they had any questions and if they gave permission for recording the interview and using their data for the study. After permission was given, the recording began, and the interview was conducted. At the end of the interview recording stopped, the participants were asked if they had any questions.

Data analysis

Physical activity

In order to answer the first two sub questions "*What is the general physical activity level of diabetes patients with foot problems 3 months after baseline"* and "*What is the general physical activity level of diabetes patients with foot problems 6 months after baseline?"* data on physical activity was collected by using an activity tracker 24 hours a day for one week at T3 and T6. Participants who wore their activity tracker for less than four days or without a weekend day were excluded, because these data was considered incomplete (Waaijman et al., 2013). All complete data sets were manually entered in excel, by a project member of the study of Jongebloed-Westra et al., (submitted, 2020). Data was further analysed and processed in IBM SPSS statistics 25. In order to answer the first two sub questions, per participant it was calculated what the mean number of steps per day over a whole week was at T3 and T6. Per participant four to seven physical activity measurements were available at T3 and/or T6. With those measurements all individual mean scores were calculated in IBM SPSS statistics 25. Next, all mean scores were summed up and the average number of steps per day and standard deviation was calculated for sample group 1 and sample group 2. Variance between participants and variance within participants was analysed by calculating the range within participants measurements at T3 and T6 in IBM SPSS statistics 25.

Physical activity guidelines for diabetes patients did not recommend a particular number of steps per day. However, there was a more general physical activity indices proposed by Tudor-Locke & Bassett (2004). Based on available evidence Tudor-Locke & Bassett (2004) suggested five activity levels. It was proposed that in healthy adults <5000 steps/day can be considered as a sedentary lifestyle index, between 5000-7499 steps/day was considered to be low active, between 7500-9999 steps/day was considered to be somewhat active, between 10000-12499 was considered to be active and >12500 was considered to be highly active (Tudor-Locke & Bassett, 2004). Based on the index of Tudor-Locke & Bassett (2004), the activity level of diabetes patients with foot problems T3 and T6 was estimated.

Quality of life

In order to answer the next two sub questions "*What is the predictive value of quality of life at baseline on physical activity level of diabetes patients with foot problems after 3 months?"* and "*What is the predictive value of quality of life at baseline on physical activity level of diabetes patients with foot problems after 6 months?"* data on quality of life was collected with the RAND-36 V2 and was manually entered in excel, by a project member of the study of Jongebloed-Westra et al., (submitted, 2020). Data was further analysed and processed in IBM SPSS statistics 25. Data of the RAND-36 V2 for quality of life was scored per participant and subdomain, using the scoring table and formula (Sanderman & Van der Zee, 2012). First quality of life at T0 was analysed by calculating average quality of life scores per subdomain for sample group 3 and sample group 4. Per subdomain all participants scores were

summed up so that a mean score per subdomain would emerge and standard deviation could be calculated per subdomain for the whole sample group. The mean subdomain scores in the current study were compared to the population subdomain scores of the diabetes population of Ware et al. (1993).

In the current study 3% of the quality of life data in sample group 3 was missing and 3.6% of the quality of life data in sample group 4. The missing data was replaced with group mean scores. According to Penny & Atkinson (2011) and Tabachnick & Fidell (2001) the choice of method for dealing with missing data is less important if the proportion of missing data is small. In sample group 3 a total 11 scores were randomly missing in seven of the eight subdomains. In the subdomains physical functioning, social functioning, physical role impairments and general health one score was missing. In subdomains mental health and pain two scores were missing and, in the subdomain, vitality three scores were missing. In sample group 4 a total of ten scores were randomly missing in seven of the eight subdomains. In the subdomains social functioning, physical role impairments, mental health and general health one score was missing. In subdomains physical functioning, vitality and pain two scores were missing. All missing data was replaced with group mean scores.

To analyse the predictive value of the subdomains of quality of life on physical activity at T3 and T6 multiple linear regression analysis and simple linear regression analysis was performed. The quality of life subdomain were predictor variables, and physical activity in mean steps per day was the dependent variable. The significance level of $p \leq 0.05$ was used in the analysis. Assumption to perform multiple linear regression were checked on forehand, and when assumptions were not met, simple linear regression was used to analyses the specific relationships.

Attitude towards orthopaedic shoes

In order to answer the last two sub questions "*What is the predictive value of attitude towards orthopaedic shoes at baseline on physical activity level of diabetes patients with foot problems after 3 months?* and *"What is the predictive value of attitude towards orthopaedic shoes at baseline on physical activity level of diabetes patients with foot problems after 6 months?"* data on attitude towards orthopaedic shoes was collected with 30 in-depth interviews at baseline. All interviews were transcribed verbatim. Analyzing and coding the transcripts was performed in Word and Excel. To determine if the general attitude of participants was positive or negative, fragments of responses were coded deductively into a negative and positive code. When participants responded on an interview question with a positive aspect of the orthopaedic shoes, the fragment was coded positive. When participants responded on an interview question with a negative aspect of the orthopaedic shoes, the fragment was coded negative. In order to perform a multiple regression analysis, per participant the total score of all negative and positive fragments was used. Qualitative data was transformed into quantitative data by assigning one positive point for every positive fragment, and every negative fragment was assigned one negative point. Per participants this resulted in a sum score for number of positive attitudes and a sum score for number of negative attitudes.

To analyse the predictive value of attitude towards orthopaedic shoes on physical activity at T3 and T6 a multiple linear regression analysis was performed. The sum scores of positive and negative attitudes were predictor variables and physical activity in mean steps per day was the dependent variable. The significance level of $p \leq 0.05$ was used in the analysis. Assumption to performed multiple linear regression were checked on forehand, when

assumptions were not met, simple linear regression was used to analyses the specific correlation. Data on attitude towards orthopaedic shoes was analysed and processed in IBM SPSS statistics 25.

In order to determine on what overlapping themes positive and negative attitudes were based, all positive and negative fragments were coded axial. All matching positive fragments received the same subcode, and all matching negative fragments received the same subcode, until al fragments had received subcode. Subcodes were based on the subject the matching positive and negative fragments had.

Results

Demographic characteristics

The demographic characteristics of all sample groups are displayed in Table 4. Table 4 shows that the first four sample groups are very similar in mean age, sample group 5 and 6 had a slightly lower mean age and age range. Furthermore, the majority of the patients in all sample groups were diagnosed with diabetes type 2 and neuropathy. What stands out, in all sample groups the majority of the participants is male, with ranges from 68% to 89% male. Finally, sample group 6 had a shorter diabetes duration range than the other sample groups.

Table 4
Demographic characteristics per sample group

Variable	Sample group 1 N=45	Sample group 2 N=33	Sample group 3 N=41	Sample group 4 N=31	Sample group 5 N=17	Sample group 6 N=9
Age (years)						
Mean	66.7	66.8	66.2	66.5	63.2	61.0
SD	8.9	10.0	9.0	10.1	6.9	7.9
Range	50-88	50-88	50-88	50-88	50-72	50-73
Gender (%)						
Female	12 (27%)	10 (30%)	10 (24%)	10 (32%)	2(12%)	1 (11%)
Male	33 (73%)	23 (70%)	31 (76%)	21 (68%)	15 (88%)	8 (89%)
Diabetes type (%)						
Type 1	3 (6%)	2 (6%)	3 (7%)	2 (6%)	2 (12%)	1 (11%)
Type 2	42 (94%)	31 (94%)	38 (93%)	29 (94%)	15 (88%)	8 (89%)
Diabetes duration (years)						
Mean	15.5	14.1	16.2	13.5	18.5	13.3
SD	11.6	10.2	11.5	9.5	12.0	7.9
Range	0,5-45	1-44	1-45	1-44	1-45	1-25
Diabetes complications (%)						
Ulcer history	31 (69%)	24 (73%)	29 (71%)	23 (74%)	13 (76%)	6 (67%)
Neuropathy	43 (96%)	31 (94%)	39 (95%)	29 (94%)	17 (100%)	9 (100%)
Peripheral Vascular disease	11 (24%)	7 (21%)	10 (24%)	7 (23%)	3 (18%)	1 (11%)

Note. Abbreviations: SD = standard deviation

Physical activity

1. What is the general physical activity level of diabetes patients with foot problems 3 months after baseline?

In order to answer the first sub question, sample group 1 (N=45) was studied. Participants who had worn an activity tracker at T3 for at least four days were selected for sample group 1. On average, the sample group walked 4485 steps per day in one week, with a standard deviation of 2924 steps per day. According the index of Tudor-Locke & Bassett (2004, see Table 4), this general activity level reflects a sedentary lifestyle. In order to get a deeper understanding of the physical activity results in sample group 1, in Table 5 the physical activity levels of Tudor-Locke & Bassett (2004) are displayed together with the associated number of participants of sample group 1. Looking at the separate activity levels, what stands out is, that the majority, 62%, of the participants had a sedentary lifestyle and nearly nobody was active or highly active according to the index of Tudor-Locke & Bassett (2004).

Table 5

Average activity levels of participants in sample group 1 (N=45)

Activity level	N (%)
Sedentary lifestyle (<5000 steps/day)	28 (62%)
Low active (5000-7499 steps/day)	11 (24%)
Somewhat active (7500-9999 steps/day)	5 (11%)
Active (10000-12499 steps/day)	1 (2%)
Highly active (>12500 steps/day)	0 (0%)

Note. Based on mean number of steps walked per day.

To understand variability in the results, variance between participants and variance within participants of sample group 1 was reported. Both are displayed in Figure 4, showing a wide range in steps per day in several individual participants. These participants showed to walk very different numbers of steps on a daily base, on some days these participants walked substantially more steps than on other days. In fact, the largest range observed in a participant was 15.816 steps; this participant ranged from 4968 to 20.784 steps in one day. While the smallest range observed in a participant was 658 steps; this participant ranged from 2010 to 2668 steps in one day. Besides, these differences in steps walked per day are not only shown within participants but also between participants. To be more precise, the lowest number of steps one participants took were 316 steps in one day, while the highest number of steps another participant took were 20.784 steps in one day.

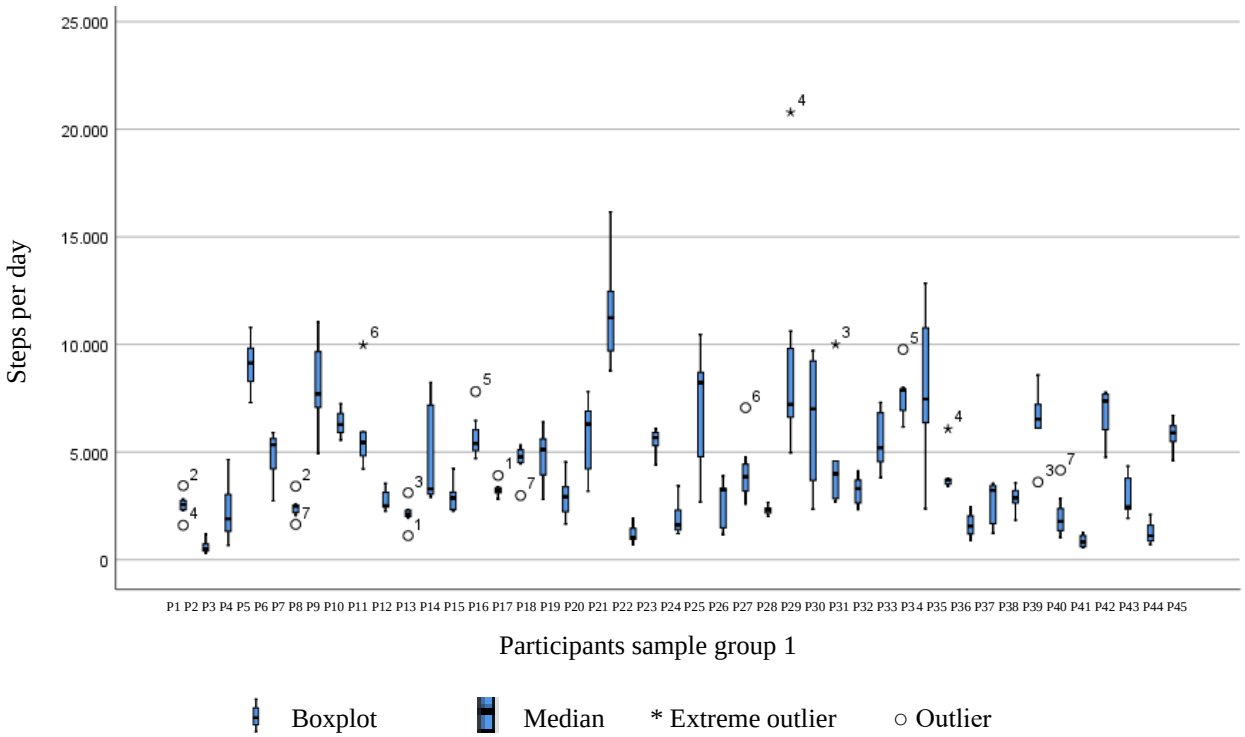

Figure 4. Range in sample group 1. Numbers near * and ○ represent which day outlier was observed.

2.What is the general physical activity level of diabetes patients with foot problems 6 months after baseline?

In order to answer the second sub question, sample group 2 (N=33) was studied. Participants who had worn an activity tracker at T6 for at least four days were selected for sample group 2. On average, sample group 2 walked 4085 steps per day in one week, with a standard deviation of 2735 steps per day. According the index of Tudor-Locke & Bassett (2004,

see Table 6), this general activity level reflects a sedentary lifestyle. In order to get a deeper understanding of the physical activity results in sample group 2, in Table 6 the physical activity levels of Tudor-Locke & Bassett (2004) are displayed, together with the associated number of participants of sample group 2. Again, what stands out is that the majority, 70%, of the participants had a sedentary lifestyle, and none of the participants was active or highly active according to the index of Tudor-Locke & Bassett (2004).

Table 6
Activity level sample group 2 (N=33)

Activity level	N (%)
Sedentary lifestyle (<5000 steps/day)	23 (70%)
Low active (5000-7499 steps/day)	6 (18%)
Somewhat active (7500-9999 steps/day)	4 (12%)
Active (10000-12499 steps/day)	0 (0%)
Highly active (>12500 steps/day)	0 (0%)

Note. Based on mean number of steps walked per day.

To understand variability in the results, variance between participants and variance within participants of sample group 2 was reported. Both are displayed in Figure 5. As can be seen, there is a wide range in steps per day in several individual participants. These participants showed to walk very different numbers of steps on a daily base, on some days these participants walked substantially more steps than on other days. In fact, the largest range observed was 10.784 steps, this participant ranged from 2336 to 13.120 steps in one day. While the smallest range observed in a participant was 440 steps, this participant ranged from 346 to 768 steps in one day. Besides, differences in steps walked per day are not only shown within participants but also between participants. To be more precise, the lowest number of steps one participants took were 346 steps in one day, while the highest number of steps another participant took were 13686 steps in one day. However, compared to sample group 1 the highest number of steps one participant took in a day is substantially lower.

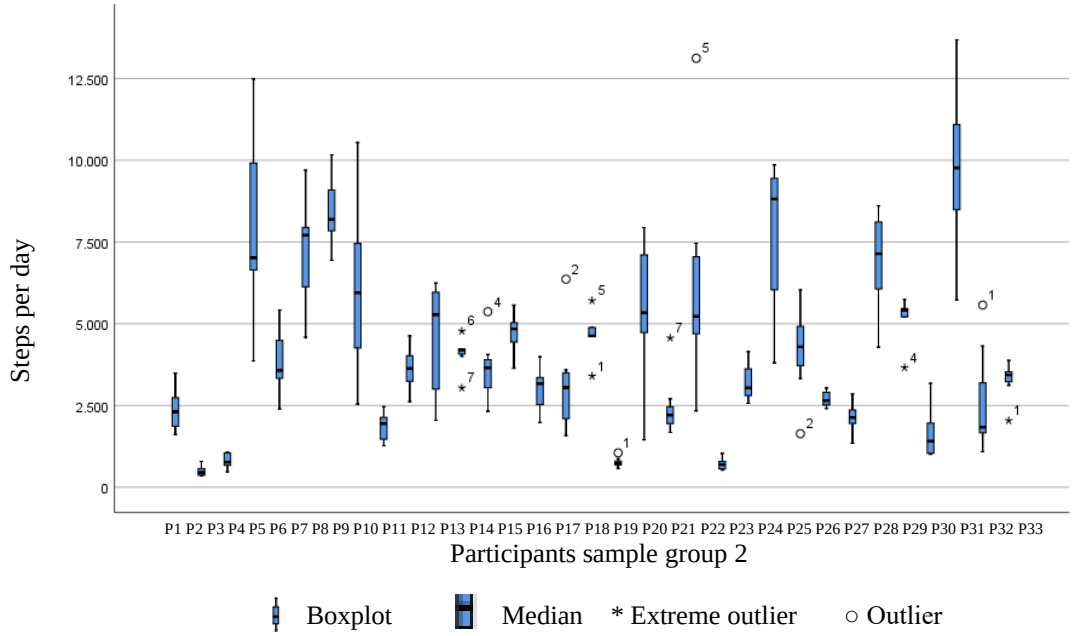

Figure 5. Range in sample group 2. Numbers near * and ○ represent which day outlier was observed.

Quality of life

3.What is the predictive value of quality of life at baseline on physical activity level of diabetes patients with foot problems after 3 months?

To answer the third sub question, sample group 3 (N=41) was studied. All participants who filled in the RAND-36 V2 at baseline and wore and activity tracker at T3 were selected for sample group 3. The quality of life sores per subdomain could range from 0 to 100, with mean population subdomain scores varying from 55.73 to 82.04 (Ware et al., 1993). As can be seen in Table 7, the average score for emotional role impairment is highest of all subdomains for sample group 3. Meaning that role impairments due to emotional problems, on average, did not substantially affect quality of life for participants in sample group 3. General health evaluation scored, on average, lowest of all subdomains. In general, the mean subscale scores ranged between 49.5 and 82.7. In the current study, the mean subdomains scores for physical functioning, social functioning and general health evaluation were lower compared to the population mean subdomain scores of Ware et al. (1993). Furthermore, not much difference could be found between the population mean subdomain scores of Ware et al. (1993) and the mean subdomains scores for physical role impairments, mental health, vitality and pain in the current study. Finally, in the current study emotional role impairments scored higher compared to the population mean subdomain score of Ware et al. (1993).

Table 7
Quality of life sample group 3 (N=41)

	Physical functioning	Social functioning	Physical role impairments	Emotional role impairments	Mental health	Vitality	Pain	General health evaluation
Mean	58.8	72.5	55.6	82.7	77.7	59.8	68.8	49.5
SD	27.2	27.0	31.7	26.0	15.2	20.0	25.8	18.7

Note. Abbreviations: SD = standard deviation.

Bivariate correlations were examined between the dependent variable physical activity, and the independent variables, the subdomains of quality of life. Bivariate correlations were examined to explore if there were significant relationships between the subdomains of quality of life and physical activity. Furthermore, the degree of correlation between the independent variables in the multiple regression analysis cannot be too high. Therefore, bivariate correlations were examined to explore if the subdomains of quality of life did not have multicollinearity. If multicollinearity between subdomains was found and no actions are undertaken, this could affect the relationship between the independent variables, the subdomains of quality of life, and the dependent variable, physical activity. Then, actual effect per subdomain is not known because precision of result is reduced and statistical power weakened.

As can be seen in Table 8, all aspects of quality of life had no or weak positive correlations with physical activity. However, only correlations with physical functioning, social functioning and physical role impairments were significant. The other remaining correlations were non-significant. To explore if the relationship between subdomains physical functioning, social functioning and physical role impairments is predictive for physical activity of diabetes patients with foot problems, expressed in mean steps per day, a multiple regression analysis was run. Doing a multiple linear regression gives understanding in the relationship between the

three independent variables and the one dependent variable. It allows us to determine the explained variance of the model and the relative contribution of each of the independent variables to the total explained variance. Doing multiple regression can give the value of a certain dependent variable at a certain value of the independent variable.

Table 8

Correlation matrix between the dependent variable physical activity and independent variables, subdomains quality of life, in sample group 3 (N=41)

	PA	PF	SF	PRI	ERI	MH	V	P	GH
PA									
PF	0.345*								
SF	0.274*	0.580*							
PRI	0.266*	0.747*	0.714*						
ERI	0.159	0.467*	0.437*	0.578*					
MH	0.012	0.530*	0.420*	0.444*	0.618*				
V	0.173	0.616*	0.628*	0.709*	0.676*	0.665*			
P	0.117	0.638*	0.663*	0.684*	0.333*	0.368*	0.596*		
GH	0.121	0.409*	0.491*	0.574*	0.425*	0.519*	0.679*	0.632*	

Note. * indicates a significant correlation at the 0.05 level (1-tailed). Abbreviations: PA = physical activity, PF = physical functioning, SF = social functioning, PRI = physical role impairments, ERI = emotional role impairments, MH = mental health, V = vitality, P = pain, GH = general health.

Assumptions to perform multiple regression were checked before performing the analysis. The assumptions for variable type and independence of observations are met, the value for Durbin-Watson was 1.6, meaning that there is minor positive autocorrelation but the errors are relatively normally distributed. Furthermore, the assumptions of linearity, independence errors and homoscedasticity were checked with scatterplots. Next, the assumption of multicollinearity was met, Pearson correlation was below 0.8 for all independent subdomains, tolerance value of all subdomains was above 0.2 and all variance inflation factor (VIF) values was below 10.0. Lastly, assumption of normally distributed errors was met based on a P-P plot.

A multiple regression analysis was run to determine the explained variance in physical activity in diabetes patients with foot problems, expressed means steps per day, and the relative contribution of the quality of life subdomains; physical functioning, social functioning and physical role impairments, to the total explained variance. As can be seen in Table 9, the multiple regression model with all three predictors (R^2=0.134; F (3,37) = 1.916; p=0.144), predicted 13.4% of the variance in physical activity and was non-significant. This means, that the model was not a significant predictor for physical activity in diabetes patients with foot problems, expressed in mean steps per day. All three quality of life subdomains did not statistically significantly predict physical activity. Later, a post-hoc analysis was performed to assess if excluding the most extreme outlier, 20784 steps, had any effect on the results. However, this did not influence any of the results of the multiple regression analysis.

Table 9
Multiple Regression analysis, coefficients

Model	Unstandardized B	Standardized Coefficients Beta	t	Sig.
(Constant)	1862.602		1.522	0.137
Physical functioning	32.142	0.335	1.450	0.155
Social functioning	13.514	0.140	0.636	0.528
Physical role impairments	-6.903	-0.084	-0.312	0.757
R^2		0.134		
F		1.916		

Note. Dependent variable: Physical activity. *p < .05. **p < .01.

4.What is the predictive value of quality of life at baseline on physical activity level of diabetes patients with foot problems after 6 months?

In order to answer the fourth sub question, participant sample group 4 (N=31) was studied. All participants who filled in the RAND-36 V2 at baseline and wore and activity tracker at T6 were selected for sample group 4. The quality of life sores per subdomain could range from 0 to 10, with mean population subdomain scores varying from 55.73 to 82.04 (Ware et al., 1993). As can be seen in Table 10, the score for emotional role impairment was again highest of all subdomains and the general health evaluation score was again lowest of all subdomains. Meaning that role impairments due to emotional problems, on average, do not substantially affect quality of life for participants in sample group 4. In general, the mean subscale scores ranged between 46.8 and 81.9, compared with quality of life scores of sample group 3 no major differences could be found. In the current study the mean subdomains scores for physical functioning, social functioning and general health evaluation were lower compared to the population mean subdomain scores of Ware et al. (1993). Furthermore, not much difference could be found between the population mean subdomain scores of Ware et al. (1993) and the mean subdomains scores for physical role impairments, mental health, vitality and pain in the current study. Finally, in the current study emotional role impairments scored higher compared to the population mean subdomain score of Ware et al. (1993).

Table 10
Quality of life sample group 4 (N=31)

	Physical functioning	Social functioning	Physical role impairments	Emotional role impairments	Mental health	Vitality	Pain	General health evaluation
Mean	58.8	71.3	53.4	81.9	74.3	56.5	62.6	46.8
SD	29.9	29.6	33.8	25.7	18.0	21.4	27.1	20.5

For the current sub question, bivariate correlations between the dependent variable physical activity, and the independent variables, the subdomains of quality of life, were examined for the same reasons as for sub question 3. As can be seen in Table 11, only physical functioning had a moderate positive correlation with physical activity. Furthermore, all correlations were significant except for emotional role impairment and mental health.

Therefore, a multiple regression analysis was performed to determine the explained variance of the model and the relative contribution of subdomains physical functioning, social functioning, physical role impairments, vitality, pain and general health evaluation to the total explained variance. Therefore, the multiple linear regression was performed for the same motives as with sub question 3.

Table 11
Correlation matrix between the dependent variable physical activity and independent variables, subdomains quality of life, in sample group 4 (N=31)

	PA	PF	SF	PRI	ERI	MH	V	P	GH
PA									
PF	0.535*								
SF	0.410*	0.606*							
PRI	0.414*	0.694*	0.834*						
ERI	0.250	0.339*	0.676*	0.607*					
MH	0.225	0.508*	0.620*	0.600*	0.662*				
V	0.324*	0.625*	0.822*	0.827*	0.660*	0.713*			
P	0.350*	0.679*	0.765*	0.773*	0.494*	0.584*	0.803*		
GH	0.437*	0.570*	0.716*	0.721*	0.416*	0.589*	0.771*	0.796*	

Note. * indicates a significant correlation at the 0.05 level (1-tailed). Abbreviations: PA = physical activity, PF = physical functioning, SF = social functioning, PRI = physical role impairments, ERI = emotional role impairments, MH = mental health, V = vitality, P = pain, GH = general health.

Assumptions to perform multiple regression were checked before performing the analysis. The assumptions for variable type and independence of observations are met, the value for Durbin-Watson was 2.3, meaning that there is minor negative autocorrelation but the errors are relatively normally distributed. Furthermore, the assumptions of linearity, independence errors and homoscedasticity were checked with scatterplots. Next, the assumption of multicollinearity was not met, Pearson correlation was above 0.8 for subdomains vitality with social functioning, physical role impairments and pain. Furthermore, social functioning and physical role impairment correlated. Therefore, vitality, social functioning, physical role impairment and pain were excluded from the multiple regression analysis and simple linear regression was performed on all four subdomains. Multicollinearity of independent variables in multiple linear regression leads to an unknown actual effect per variable, since precision of results is reduced and statistical power weakened. However, all variance inflation factor (VIF) values were below 10.0 and tolerance values of all subdomains were above 0.2. Lastly, assumption of normally distributed errors was met based on a P-P plot.

A multiple regression analysis with the dependent variable physical activity, expressed means steps per day, and independent variables; physical functioning and general health evaluation was performed. As can be seen in Table 12, the multiple regression model with both predictors produced R^2=0.312; F (2,28) = 6.343; p=0.005. This means, that the model explained 31.2% in the variance and was a significant predictor for physical activity in diabetes patients with foot problems, expressed mean steps per day. As can be seen in Table 12, only subdomain physical functioning is significantly positive correlated with physical activity (β=33.444; t (30) =2.219; p=0.035). The subdomain general health evaluation did not significantly contribute to the model.

Table 12
Multiple Regression analysis, coefficients

Model	Unstandardized B	Standardized Coefficients Beta	t	Sig.
(Constant)	1134.709		1.172	0.251
Physical functioning	33.444	0.423	2.219	0.035
General health evaluation	13.514	0.195	1.024	0.315
R^2		0.312		
F		6.343**		

Note. Dependent variable: Physical activity. *p < .05. **p < .01.

Four quality of life subdomains showed multicollinearity, individual simple linear regression was performed to investigate if the quality of life subdomains; social functioning, physical role impairment, vitality and pain could significantly predict physical activity of diabetes patients with foot problems, expressed mean steps per day. To begin with, a simple linear regression was run to test if subdomain social functioning significantly predicts physical activity of diabetes patients with foot problems, expressed mean steps per day. As can be seen in Table 13, the results of the regression with social functioning as independent variable and physical activity as dependent variable, was significant (p=0.022). Meaning, 16.8% of the variance in physical activity of diabetes patients with foot problems, expressed in mean steps per day, can be explained by social functioning. The predicted increase in physical activity is 32.704 steps per unit of social functioning (β=32.704; t (30) =2.423; p=0.022).

Table 13
Simple linear regression analysis, coefficient

Model	Unstandardized B	Standardized Coefficients Beta	t	Sig.
(Constant)	1825.461		1.757	0.089
Social functioning	32.704	0.410	2.423	0.022
R^2		0.168		
F		5.871*		

Note. Dependent variable: Physical activity. *p < .05. **p < .01.

Second, a simple linear regression was run to test if subdomain physical role impairments significantly predict physical activity of diabetes patients with foot problems, in mean steps per day. As can be seen in Table 14, the results of the regression with physical role impairments as independent variable and physical activity as dependent variable were significant (p=0.021). Meaning, 17.1% of the variance in physical activity of diabetes patients with foot problems, expressed in mean steps per day, can be explained by physical role impairments. The predicted increase in physical activity is 28.872 steps per unit of physical role impairments (β=28.872; t (30) =3.518; p=0.021).

Table 14
Simple linear regression analysis, coefficient

Model	Unstandardized B	Standardized Coefficients Beta	t	Sig.
(Constant)	2613.059		3.518	0.001
Physical role impairments	28.872	0.414	2.446	0.021
R^2		0.171		
F		5.985*		

Note. Dependent variable: Physical activity. *p < .05. **p < .01.

Third, a simple linear regression was run to test if subdomain vitality significantly predicts physical activity of diabetes patients with foot problems, in mean steps per day. As can be seen in Table 15, the results of the regression with vitality as independent variable and physical activity as dependent variable were non-significant (p=0.075).

Table 15
Simple linear regression analysis, coefficient

Model	Unstandardized B	Standardized Coefficients Beta	t	Sig.
(Constant)	2140.130		1.836	0.077
Vitality	35.694	0.324	1.846	0.075
R^2		0.105		
F		3.408		

Note. Dependent variable: Physical activity. *p < .05. **p < .01.

Finally, a simple linear regression was run to test if subdomain pain significantly predicts physical activity of diabetes patients with foot problems, in mean steps per day. As can be seen in Table 16, the results of the regression with vitality as independent variable and physical activity as dependent variable were non-significant (p=0.054).

Table 16
Simple linear regression analysis, coefficient

Model	Unstandardized B	Standardized Coefficients Beta	t	Sig.
(Constant)	2249.621		2.185	0.037
Pain	30.466	0.350	2.013	0.054
R^2		0.123		
F		4.051		

Note. Dependent variable: Physical activity. *p < .05. **p < .01.

Attitude

5. What is the predictive value of attitude towards orthopaedic shoes at baseline on physical activity level of diabetes patients with foot problems after 3 months?

In order to answer sub question 5, sample group 5 (N=17) was studied. All participants who were interviewed at baseline and wore and activity tracker at T3 were selected for sample

group 5. As can be seen in Table 17, the majority of the participants, gave relatively more positive than negative arguments regarding attitude toward orthopaedic shoes. Only two participants gave more negative than positive arguments. As can be seen in Table 18, the top three positive aspects to orthopaedic shoes were; improved walking (n=11), shoe fit (n=9), and less physical complaints (n=9). Participant number 13 (male, 61) for example mentioned *"Well the benefit is, they fit better than a confection shoe. Because they are custom-made, it does not longer pinch, so I can walk better on them"*. Participant 9 (female, 72) said *"Anyhow, the benefit is that my feet remain undamaged"*. Furthermore, other positive aspects mentioned were foot protection and quality. Participant 5 (male, 72) for example mentioned *"Well, the sole is thicker, so you are protected."* and participant 2 (male, 69) said *"I think they are of very high quality"*. On the other hand, the participants named seven negative aspects of orthopaedic shoes, of which aesthetics of the shoe was named most often (n=8). Participant 4 (male, 56) mentioned *"Well, let me put it this way, it is not the most modern and beautiful shoe".* Furthermore, waiting time, wearing time and price are also mentioned as negative aspects. On the interview question what negative aspects of the orthopaedic shoes were participant 8 (male, 50) answered *"You always have to wear them and they are quite expensive"*. Participant 15 (male, 64) mentioned delivery time of the orthopaedic shoes as a negative aspect *"The disadvantage is that you cannot immediately take them with you, it is a process"*.

Table 17

Number of arguments regarding attitudes toward orthopaedic shoes, per participant of sample group 5 (N=17)

Participant	**Positive**	**Negative**
Participant 1	3	-1
Participant 2	3	-1
Participant 3	1	0
Participant 4	3	-3
Participant 5	4	-1
Participant 6	3	0
Participant 7	2	-1
Participant 8	2	-3
Participant 9	2	-2
Participant 10	2	-2
Participant 11	4	-1
Participant 12	5	-1
Participant 13	3	-1
Participant 14	2	0
Participant 15	2	-1
Participant 16	2	-1
Participant 17	0	-2

Note. Number represents the positive or negative attitudes mentioned by the participant.

Table 18

Meaning of Positive and negative attitude towards orthopaedic shoes

	Positive	Negative
Improved walking	11	2
Supports foot position	5	0
Aesthetics of the shoes	5	8

Shoe fit	9	2
Less physical complaints	9	0
Feet protection against wounds	4	0
Quality	3	2
Price	0	2
Weight	0	1
Delivery time	0	2
Wearing time	0	2

Bivariate correlations were examined between the dependent variable physical activity and the independent variables positive attitude and negative attitude. As can be seen in Table 19, there is no to a weak negative correlation between positive attitude and physical activity and a weak to low negative correlation between negative attitude and physical activity. However, there are no significant bivariate correlations. Therefore, no multiple linear regression was performed.

Table 19
Correlation between dependent variable with independent variables in sample group 5

Independent variable	Pearson correlation with physical activity	Sig. (1-tailed)
Positive attitude	-0.011	0.483
Negative attitude	-0.327	0.100

6. What is the predictive value of attitude towards orthopaedic shoes at baseline on physical activity level of diabetes patients with foot problems after 6 months?"

To answer the last sub question, sample group 6 (N=9) was studied. All participants who were interviewed at baseline and wore and activity tracker at T6 were selected for sample group 6. As can be seen in Table 20, of the nine participants six participants gave relatively more positive than negative arguments regarding attitude toward orthopaedic shoes and one participant was equally as positive as negative about the orthopaedic shoes. Two participants gave more negative than positive arguments. As can be seen in Table 21, the four most mentioned positive aspects to orthopaedic shoes were; improved walking (n=6), shoe fit (n=4), aesthetics of shoes (n=4) and less physical complaints (n=4). Participant number 1 (female, 57) for example mentioned *"The shoes I can choose from, they just look really nice".* On the question what participants thought were benefits of the orthopaedic shoes, participant 4 (male, 56) answered *"Well, I have fewer physical complaints and I have good support, […].* However, the participants also named seven negative aspects of orthopaedic shoes of which aesthetics of the shoes again was named most often (n=5). Participant 13 (male, 61) said *"For me, the biggest disadvantage is that I can't quite choose the shoes I like".* Furthermore, a few participants mentioned warmth and weight of the shoes as negative aspects. Participant 18 (male, 73) mentioned *"I don't have disadvantages, except in the summer when it's is hot".* Participant 1 (female, 57), wears orthopaedic shoes to work and said *"Well, sometimes, I wear my work shoes, […], those are quite heavy".*

Table 20

Number of arguments regarding attitude toward orthopaedic shoes, per participant of sample group 6 (N=9)

Participant	**Positive**	**Negative**
Participant 1	3	-1
Participant 2	3	-1
Participant 4	3	-3
Participant 8	2	-3
Participant 12	5	-1
Participant 13	3	-1
Participant 16	2	-1
Participant 17	0	-2
Participant 18	3	-1

Note. Number represents the positive or negative attitudes mentioned by the participant.

Table 21

Meaning of Positive and negative attitude towards orthopaedic shoes, sample group 6

	Positive	Negative
Improved walking	6	1
Supports foot position	3	0
Aesthetics of the shoes	4	5
Shoe fit	4	1
Less physical complaints	4	0
Feet protection against wounds	1	0
Quality	2	1
Price	0	2
Weight	0	1
Warmth of the shoes	0	1
Wearing time	0	2

Bivariate correlations were examined between the dependent variable physical activity and the independent variables positive attitude and negative attitude. As can be seen in Table 22, there is no to a weak positive correlation between positive attitude and physical activity and a weak to low negative correlation between negative attitude and physical activity. However, there are no significant bivariate correlations. Therefore, no multiple linear regression was performed.

Table 22

Correlation between dependent variable with independent variables in sample group 6

Independent variable	Pearson correlation with physical activity	Sig. (1-tailed)
Positive attitude	0.171	0.330
Negative attitude	-0.352	0.177

Discussion

Summary of results

The aim of this study was to identify the predictive value of quality of life and attitude towards orthopaedic shoes at baseline for physical activity levels of diabetes patients with foot problems after three and six months. The results indicate that diabetes patients with foot problems have a sedentary lifestyle. Furthermore, quality of life in diabetes patients with foot problems at baseline did not significantly predict change in physical activity after three months. However, after six months, three of the nine quality of life subdomains, namely physical functioning, social functioning and physical role impairments, are significant predictors of change in physical activity of diabetes patients with foot problems. Based on the findings in this study, diabetes patients with foot problems generally have a more positive than negative attitude towards orthopaedic shoes. Furthermore, attitude towards orthopaedic shoes and physical activity after three and six months were not significantly correlated in diabetes patients with foot problems.

Reflecting on results

Physical activity

In line with our findings, previous studies show diabetes patients have a sedentary to respectively a low active physical activity level, according to the index of Tudor-Locke & Bassett (2004). Findings show lightly lower numbers of average steps per day than in previous studies. This may be explained by the fact that all participants suffered from foot problems (Lee et al., 2019).

Besides, the variance within participants physical activity levels is substantial. In fact, sixteen participants had a range in steps per day that was even higher than the average number of steps per day the majority of the participants took. Low physical activity levels in combination with the observed variance show that there is potential to improve physical activity levels of diabetes patients with foot problems. Based on the results of the current study, it is recommended that physical activity interventions for diabetes patients with foot problems should not set the bar too low based on average physical activity levels, but tailor aims to individual differences. The study of Peels et al. (2020), underpins the importance to tailor an physical activity intervention to baseline behaviour and to target motivational factors among participants who are below general physical activity recommendations (Peels et al., 2020). Furthermore, because of the variance within activity levels, techniques such as motivational interview can be used to explore ambivalence in individuals and activate motivation to increase physical activity (Miller & Rollnick, 2012).

Part of the variance may be clarified by the substantial number of outliers of which some are extreme. To assess if excluding the most extreme outlier, 20784 steps, had any effect on the results, a post-hoc analysis was performed. However, the result pattern was not affected. Nonetheless, the present study raises the possibility that averaging physical activity, expressed in steps per day, may not be the best possible method to assess physical activity levels, and analyse significant predictors for physical activity. The results therefore need to be interpreted with caution. Future studies at the current topic are recommended to use individual values instead of average physical activity levels, and perform multivariate linear regression analysis instead of multiple linear regression analysis.

Quality of life

Janssen et al., (2020) stated that patients with diabetes have reported lower levels of quality of life than individuals without diabetes. Compared to the general Dutch population of Sanderman & Van der Zee (2012), the diabetes patients with foot problems score substantially lower on all aspects of quality of life, with exception of emotional role impairments and mental health. While comparing the findings, a time difference of approximately 23 years, with probably an associated change on health perspective and treatment, has to be taken into account (Sanderman & Van der Zee based their study on a sample of 1998). However, differences between the general Dutch population and the studied population are that large that we assume these differences will still remain today. A possible explanation for the low quality of life scores might be that participants in the current study had diabetes related foot problems. These results confirm the association between diabetic foot problems and quality of life (Sothornwit et al., 2018). The results of the current study therefore provide evidence to underpin the importance of the research of Jongebloed-Westra et al. (2020), to investigate using motivational interviewing combined with digital shoe-fitting to improve adherence to wearing orthopaedic shoes in people with diabetes at-risk of foot ulceration. Healing of foot ulceration will increase quality of life (Hogg et al., 2012; Tzeravini et al., 2018), and based on the findings in the current study increase physical activity.

In the introduction it was hypothesized that "*lower quality of life in diabetes patients negatively affects their physical activity level".* This hypothesis was partly confirmed, results showed that both physical activity and quality of life were indeed lower than in individuals without diabetes, as reported in the literature. However, only subdomains physical functioning, social functioning and physical role impairments did significantly predict variance in physical activity, but only after 6 months. A possible explanation might be that the overlapping theme in all three subdomains is physical well-being, which seems to be more directly related to physical activity in comparison with other domains of quality of life. Furthermore, all participants in the current study have foot problems, which may have impaired their physical well-being in general. As a result, developing a physical activity intervention, such as described in the previous paragraph, is complicated. Factors influencing physical well-being in diabetes patients with foot problems, should be examined and where possible included in the intervention. For example, with personal coaching or physiotherapy increased physical well-being might be accomplished.

It is argued that pain would also influence physical well-being (Sothornwit et al., 2018) and therefore physical activity. But in the current study pain did not have any effect, this can be explained by the fact that almost all participants had neuropathy. The remaining quality of life dimensions, are focused on mental well-being and are not associated with physical activity in the current study. A possible explanation might be the way how physical well-being is operationalized in the RAND-36 V2. Questions concerning physical well-being are framed in a way they directly concern physical activity, such as questions about walking. Questions about mental well-being are more abstract and discuss the emotional and mental state of the individual, much less often in relationship to physical activity. In the current study, a generic health related quality of life scale was used. Perhaps other quality of life screening tools, focused on diabetes, its complications and burden, would have resulted different outcomes since they are tailored to the study population.

Nevertheless, after 3 months quality of life wasn't a predictor for physical activity and after 6 months only the daily functioning aspect did. A possible explanation might be that sample group 3 and 4 are not identical, sample group 3 and sample group 4 only partly consist

out of the same participants. In the discussion both sample groups are treated as equal but in fact they are not. The sample groups differ for example in sample size, mean age and diabetes complications. Therefore, caution must be applied by interpreting the results.

Attitude

In the introduction it was hypothesized that *"Negative attitude towards orthopaedic shoes will negatively affect physical activity levels in diabetes patients with foot problems and positive attitudes towards orthopaedic shoes will positively affect physical activity levels in diabetes patients with foot problems."* The results of this study did not support the hypothesis. Attitude, of diabetes patients with foot problems, towards orthopaedic shoes was not associated with physical activity. A possible explanation might be the small sample size, this may have influenced the results of the current study. There is, however, another possible explanation. In the current study, it wasn't verified whether participants took their daily steps in the orthopaedic shoes or in other confection shoes. As an example, if a participant had relatively more negative attitudes towards orthopaedic shoes than positive attitudes, he might not be wearing the orthopaedic shoes on a daily basis, instead he wears confection shoes. The results therefore need to be interpreted with caution. The study of Jongebloed-Westra et al. (submitted, 2020) monitored adherence to orthopaedic shoes with insole microsensors in combination with the activity tracker to measure physical activity. In that design it can be described what percentage of time the participants walked in orthopaedic shoes.

Strengths

This study has several strengths, first it provided new data on physical activity and quality of life in diabetes patients with foot problems. Less was known about activity levels of diabetes patients without an intervention to increase physical activity. In fact, no study reported physical activity in steps per day, of diabetes patients with foot problems, without an intervention to increase physical activity. Part of the participants in this study did receive an intervention, however the intervention was not focused on increasing physical activity. Furthermore, literature about quality of life in diabetes patients with and without foot problems was spare and outdated.

Secondly, the current study about the influence quality of life and attitude towards orthopaedic shoes have on physical activity in diabetes patients with foot problems, used a longitudinal design. This allowed not only to assess if there was a relationship between the variables, but also if the relationship is predictive. Since, it was found that how patients value their quality of life based on physical well-being is a predictor for physical activity. This can be used as a starting point for further research about predictive factors of physical activity in diabetes patients with foot problems.

Third, the findings about physical activity and physical well-being in quality of life may be used for practical applications. The newly found data can be used to better substantiate physical activity programs for diabetes patients with foot problems. Interventions should be tailored to the individual and its baseline activity level, include motivational interviewing and focus on improving physical well-being in diabetes patients with foot problems, so that they are more effective and target group oriented.

Finally, findings in the current study underpin the importance of the study of Jongebloed-Westra et al. (submitted, 2020). Findings show that diabetic foot problems are likely to have lowered physical activity and quality of life in the studied population. Increased

adherence to orthopaedic shoes, improve diabetic foot problems (Bus et al., 2013; Waaijman et al., 2013), which increases quality of life (Hogg et al., 2012; Tzeravini et al., 2018).

Limitations

This study included participants of the study of Jongebloed-Westra et al. (submitted, 2020), in which the intervention group received a digital shoe fitting procedure and a motivational interview with a podiatrist. Differences in physical activity and quality of life may be affected by the intervention. Furthermore, an activity tracker was used to measure physical activity, but this may have influenced physical activity. Since activity trackers engage patients in doing physical activity as advocates in their personalized care an healthy behaviour (Tang et al., 2020). Nevertheless, because quality of life and physical activity in the current study are both substantially lower than in individuals without diabetes, the influence of both limitations is of less impact on our results.

In the current study, the interview structure, appeared not to be the best fit. The majority of the interview questions had to be excluded and therefore less information was obtained than expected. However, attitudes could be determined based on the answers of the remaining questions. No significant correlations were found between attitude towards orthopaedic shoes and physical activity. Therefore, it was not possible to perform a sufficient mixed-method analysis, to assess which specific attitudes towards orthopaedic shoes might had influence on physical activity. Further studies about attitude towards orthopaedic shoes are recommended to develop interview structures based on their research aim. For example, general questions about attitude towards orthopaedic shoes but also about attitude towards orthopaedic shoes in relationship with physical activity. So that, the influence of attitude towards orthopaedic shoes on physical activity can be examined more sufficiently.

In the current study two directional hypotheses were examined. Because the hypotheses were directional, data was analysed with one-sided tests. However, the hypotheses were based on the little literature available and therefore not strong. Further research on this topic should consider analysing the date with two-sided tests.

The data of the current study was gathered during the COVID-19 pandemic. Previous findings showed change in activities during the lockdown (Haas et al., 2020). All age groups are less active outdoors, but especially individuals aged >65 years were much less active than before the crisis (Haas et al., 2020) Besides, Danish studies found that diabetes patients had COVID-19-specific worries related to their disease, which was associated with poorer psychosocial health (Joensen et al., 2020) and quality of life of diabetes patients decreased during the first lockdown (Madsen et al., 2021). Because the measures to contain COVID-19 had impact on, and limited daily life, quality of life and physical activity in the current research may be impaired.

In the current study six sample groups were included. The current study attempted to compose sample groups as large as possible, by selected them based on available data and not on equality between sample groups. Still, the sample groups are relatively small, and therefore caution must be applied as the findings might not be interpreted correctly. A limitation of small sample sizes is that they can produce false-positive results, they over-estimate the magnitude of an association or results are not representative for bigger sample sizes (Hackshaw, 2008). Nevertheless, the current study gathered new information about topics little or no information was available on before. Therefore, further studies at the current topics are recommended to use

bigger sample sizes, and to further asses what the predictive value of quality of life and attitude towards orthopaedic shoes is on physical activity of diabetes patients with foot problems.

Conclusion

The current study aimed to answer the following question: "*How does quality of life and attitude towards orthopaedic shoes at baseline predicts the physical activity level of diabetes patients with foot problems after 3 and 6 months?* The results show that the only aspect predicting the physical activity level of diabetes patients with foot problems, is how they value their quality of life based on physical well-being, but only after six months.

Because findings about attitude towards orthopaedic shoes and its influence of physical activity were impaired, future research is recommended to examine the same topic again with larger sample sizes and including adherence rates of orthopaedic shoes. Furthermore, further research, is needed to fully understand the role of physical well-being in quality of life and its influence on physical activity. Besides, since diabetic foot problems play a substantial role in physical activity and physical well-being, this study provides further support in emphasizing the importance of the research of Jongebloed-Westra et al., (submitted, 2020), to improve adherence to orthopaedic shoes. Finally, the findings, show that there is potential to improve physical activity in diabetes patients with foot problems, and based on the findings, several implications are recommended to achieve an effective target group-oriented intervention; Physical activity interventions in diabetes patients with foot problems should be tailored to the individual and its baseline activity level, include motivational interviewing and focus on improving physical well-being with for example coaching or physiotherapy.

References

Al-Rubeaan, K., Al Derwish, M., Ouizi, S., Youssef, A. M., Subhani, S. N., Ibrahim, H. M., & Alamri, B. N. (2015). Diabetic foot complications and their risk factors from a large retrospective cohort study. *PLoS ONE*, *10*(5), 1–17. https://doi.org/10.1371/journal.pone.0124446

American Diabetes Association. (2015). 4. Foundations of care: Education, nutrition, physical activity, smoking cessation, psychosocial care, and immunization. *Diabetes Care*, *38*(January), 20–30. https://doi.org/10.2337/dc15-S007

Boulton, A. J. M., Armstrong, D. G., Kirsner, R. S., Attinger, C. E., Lavery, L. A., Lipsky, B. A., Mills, J. L., & Steinberg, J. S. (2018). Diagnosis and management of diabetic foot complications. *Journal of Wound Care*, *6*(1), 4–8. https://doi.org/10.12968/jowc.1997.6.1.4

Bus, Si. A., Waaijman, R., Arts, M., Haart, M. De, Busch-Westbroek, T., Van Baal, J., & Nollet, F. (2013). Effect of custom-made footwear on foot ulcer recurrence in diabetes: A multicenter randomized controlled trial. *Diabetes Care*, *36*(12), 4109–4116. https://doi.org/10.2337/dc13-0996

Caruana, E. J., Roman, M., Hernández-Sánchez, J., & Solli, P. (2015). Longitudinal studies. *Journal of Thoracic Disease*, *7*(11), 537–540. https://doi.org/10.3978/j.issn.2072-1439.2015.10.63

Deshpande, A. D., Harris-Hayes, M., & Schootman, M. (2008). Epidemiology of Diabetes and Diabetes-Related Complications. *Physical Therapy*, *88*(11), 1254–1264. https://doi.org/10.2522/ptj.20080020

Forouhi, N. G., & Wareham, N. J. (2018). Epidemioogy of diabetes. *Medicine*, *47*(1), 22–27. https://doi.org/10.29085/9781783304509.002

Gu, Y., Dennis, S. M., Kiernan, M. C., & Harmer, A. R. (2019). *Aerobic exercise training may improve nerve function in type 2 diabetes and pre - diabetes : A systematic review*. *35*, 1–16. https://doi.org/10.1002/dmrr.3099

Haas, M. De, Faber, R., & Hamersma, M. (2020). Perspectives How COVID-19 and the Dutch ‘ intelligent lockdown ’ change activities , work and travel behaviour : Evidence from longitudinal data in the Netherlands. *Transportation Research Interdisciplinary Perspectives*, *6*, 1–11. https://doi.org/10.1016/j.trip.2020.100150

Hackshaw, A. (2008). Small studies: Strengths and limitations. *European Respiratory Journal*, *32*(5), 1141–1143. https://doi.org/10.1183/09031936.00136408

Hammarberg, K., Kirkman, M., & De Lacey, S. (2016). Qualitative research methods: When to use them and how to judge them. *Human Reproduction*, *31*(3), 498–501. https://doi.org/10.1093/humrep/dev334

Hogg, F. R. A., Peach, G., Price, P., Thompson, M. M., & Hinchliffe, R. J. (2012). Measures of health-related quality of life in diabetes-related foot disease : a systematic review. *Diabetologia*, *55*, 552–565. https://doi.org/10.1007/s00125-011-2372-5

Howarth, D. (2019). Preventing foot complications in people with diabetes mellitus. *Diabetes / evidence & pratice*, *34*(7), 69–74. https://doi.org/10.7748/ns.2019.e11432

Janssen, L. M. M., Hiligsmann, M., Elissen, A. M. J., Joore, M. A., Schaper, N. C., Bosma, J. H. A., Stehouwer, C. D. A., Sep, S. J. S., Koster, A., Schram, M. T., & Evers, S. M. A. A. (2020). *Research : Health Economics Burden of disease of type 2 diabetes mellitus : cost of illness and quality of life estimated using the Maastricht Study*. 1759–1765. https://doi.org/10.1111/dme.14285

Jarl, G. (2018). Methodological considerations of investigating adherence to using offloading devices among people with diabetes. *Patient Preference and Adherence*, *12*, 1767–1775. https://doi.org/10.2147/PPA.S175738

Jing, X., Chen, J., Dong, Y., Han, D., Zhao, H., Wang, X., Gao, F., Li, C., Cui, Z., Liu, Y., &

Ma, J. (2018). Related factors of quality of life of type 2 diabetes patients: a systematic review and meta-analysis. *Health and Quality of Life Outcomes*, *16*(1), 1–14. https://doi.org/10.1186/s12955-018-1021-9

Joensen, L. E., Madsen, K. P., Holm, L., Nielsen, K. A., Rod, M. H., Petersen, A. A., Rod, N. H., & Willaing, I. (2020). Diabetes and COVID-19: psychosocial consequences of the COVID-19 pandemic in people with diabetes in Denmark—what characterizes people with high levels of COVID-19-related worries? *Diabetic Medicine*, *37*(7), 1146–1154. https://doi.org/10.1111/dme.14319

Jongebloed-Westra, M. (2019). *The effect of motivational interviewing combined with digital shoe-fitting on adherence to orthopaedic shoes.* Retrieved form https://www.utwente.nl/nl/bms/therapietrouw/onderzoek/infoprof/documenten%20infoprof/onderzoeksprotocol-nl68567.091.19-versie-1-dd-22-01-19.pdf

Lee, M., van Netten, J. J., Sheahan, H., & Lazzarini, P. A. (2019). Moderate-to-Vigorous-Intensity Physical Activity Observed in People With Diabetes-Related Foot Ulcers Over a One-Week Period. *Journal of Diabetes Science and Technology*, *13*(5), 827–835. https://doi.org/10.1177/1932296819848735

Lundqvist, L., & Jarl, G. (2016). Adherence to wearing therapeutic shoes among people with diabetes : a systematic review and reflections. *Patient Preference and Adherence*, *10*, 1521–1528.

Madsen, K. P., Willaing, I., Rod, N. H., Varga, T. V., & Joensen, L. E. (2021). Psychosocial health in people with diabetes during the first three months of the COVID-19 pandemic in Denmark. *Journal of Diabetes and Its Complications*, 107858. https://doi.org/10.1016/j.jdiacomp.2021.107858

Manjoo, P., Joseph, L., & Dasgupta, K. (2012). Abdominal adiposity and daily step counts as determinants of glycemic control in a cohort of patients with type 2 diabetes mellitus. *Nutrition and Diabetes*, *2*(JANUARY), e25-6. https://doi.org/10.1038/nutd.2011.22

Matos, M., Mendes, R., Silva, A. B., & Sousa, N. (2018). Physical activity and exercise on diabetic foot related outcomes: A systematic review. *Diabetes Research and Clinical Practice*, *139*, 81–90. https://doi.org/10.1016/j.diabres.2018.02.020

Miller, W.R., & Rollnick, S. (2012). *Motivational Interviewing: Helping people change* (3th ed.). New York: The Guilford Press.

Moran, K. J., & Burson, R. (2017). Understanding Diabetes Distress. *Home Healthcare Now*, *35*(3), 171. https://doi.org/10.1097/NHH.0000000000000510

Nederlandse Vereniging voor Podotherapeuten (2014). Zorgmodule preventie diabetische voetulcera 2014. Retrieved from https://www.podotherapie.nl/files/professional/informatiemateriaal/zorgmodule-preventie-diabetische-voetulcera-2014.pdf

Paton, J., Roberts, A., Glasser, S., Collings, R., & Marsden, J. (2014). "All I wanted was a pair of shoes": A qualitative case study. *Diabetic Foot Journal*, *17*(3), 100–104.

Paton, J. S., Roberts, A., Bruce, G. K., & Marsden, J. (2013). Does footwear affect balance?: The views and experiences of people with diabetes and neuropathy who have fallen. *Journal of the American Podiatric Medical Association*, *103*(6), 508–515. https://doi.org/10.7547/1030508

Penny, K. I., & Atkinson, I. (2012). Approaches for dealing with missing data in health care studies. *Journal of Clinical Nursing*, *21*(19), 2722–2729. https://doi.org/10.1111/j.1365-2702.2011.03854.x

Polikandrioti, M., Vasilopoulos, G., Koutelekos, I., Panoutsopoulos, G., Gerogianni, G., Babatsikou, F., Zartaloudi, A., & Toulia, G. (2020). Quality of Life in Diabetic Foot Ulcer: Associated Factors and the Impact of Anxiety/Depression and Adherence to Self-Care. *International Journal of Lower Extremity Wounds*, *19*(2), 165–179.

https://doi.org/10.1177/1534734619900415
Qiu, S. H., Sun, Z. L., Cai, X., Liu, L., & Yang, B. (2012). Improving patients' adherence to physical activity in diabetes mellitus: A review. *Diabetes and Metabolism Journal*, *36*(1), 1–5. https://doi.org/10.4093/dmj.2012.36.1.1
Randriambelonoro, M., Chen, Y., Geissbuhler, A., Pu, P. (2015) Exploring Physical Activity Monitoring Devices for Diabetic and Obese Patients. 1003–1008. https://doi.org/10.1145/2800835.2800951
Rijksinstituut voor Volksgezondheid en Milieu (2020, November, 28). *Prevalentie diabetes in huisartsenpraktijk naar leeftijd en geslacht.* Retrieved, from https://www.volksgezondheidenzorg.info/onderwerp/diabetes-mellitus/cijfers-context/huidige-situatie#node-prevalentie-diabetes-huisartsenpraktijk-naar-leeftijd-en-geslacht
Robinson, D. J., Luthra, M., & Vallis, M. (2013). Diabetes and Mental Health. *Canadian Journal of Diabetes*, *37*(1), 87–92. https://doi.org/10.1016/j.jcjd.2013.01.026
Saeedi, P., Petersohn, I., Salpea, P., Malanda, B., Karuranga, S., Unwin, N., Colagiuri, S., Guariguata, L., Motala, A. A., Ogurtsova, K., Shaw, J. E., Bright, D., & Williams, R. (2019). Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. *Diabetes Research and Clinical Practice*, *157*, 107843. https://doi.org/10.1016/j.diabres.2019.107843
Sanderman, K. I. van der Z. R. (2012). *Het meten van de algemene gezondheidstoestand met de Rand-36*. Retrieved from https://tools.kenniscentrumsportenbewegen.nl/wp-content/uploads/sites/16/handleiding_rand36_2e_druk.pdf
Schoonenboom, J., & Johnson, R. B. (2017). Wie man ein Mixed Methods-Forschungs-Design konstruiert. *Kolner Zeitschrift Fur Soziologie Und Sozialpsychologie*, *69*, 107–131. https://doi.org/10.1007/s11577-017-0454-1
Shearman, C. P., & Rawashdeh, M. (2016). Foot complications in patients with diabetes. *Surgery (United Kingdom)*, *34*(4), 192–197. https://doi.org/10.1016/j.mpsur.2016.02.005
Sothornwit, J., Srisawasdi, G., Suwannakin, A., & Sriwijitkamol, A. (2018). Decreased health-related quality of life in patients with diabetic foot problems. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, *11*, 35–43. https://doi.org/10.2147/DMSO.S154304
Tabachnick, B.G. & Fidell, L.S. (2001). *Using Multivariate Statistics* (4th ed.). Boston: Pearson New International Edition
Tang, M. S. S., Moore, K., McGavigan, A., Clark, R. A., & Ganesan, A. N. (2020). Effectiveness of wearable trackers on physical activity in healthy adults: Systematic review and meta-analysis of randomized controlled trials. *JMIR MHealth and UHealth*, *8*(7), 1–13. https://doi.org/10.2196/15576
Tudor-Locke, C., & Bassett, D. R. (2004). How Many Steps/Day Are Enough? *Sports Medicine*, *34*(1), 1–8. https://doi.org/10.2165/00007256-200434010-00001
Tzeravini, E., Tentolouris, A., Tentolouris, N., & Jude, E. B. (2018). Advancements in improving health-related quality of life in patients living with diabetic foot ulcers. *Expert Review of Endocrinology and Metabolism*, *13*(6), 307–316. https://doi.org/10.1080/17446651.2018.1541403
Van Deursen, R. (2008). Physical Exercise as therapy for type II diabetes. *Diabetes/Metabolism Research and Reviews*, *24*(1), 96–100. https://doi.org/10.1002/dmrr.827
Van Netten, J. J., Dijkstra, P. U., Geertzen, J. H. B., & Postema, K. (2012). What influences a patients decision to use custom-made orthopaedic shoes? *BMC Musculoskeletal*

Disorders, *13*(92). https://doi.org/10.1186/1471-2474-13-92
Van Netten, J. J., Hijmans, J. M., Jannink, M. J. A., Geertzen, J. H. B., & Postema, K. (2009). Development and reproducibility of a short questionnaire to measure use and usability of custom-made orthopaedic shoes. *Journal of Rehabilitation Medicine*, *41*(11), 913–918. https://doi.org/10.2340/16501977-0447
Waaijman, R., Keukenkamp, R., De Haart, M., Polomski, W. P., Nollet, F., & Bus, S. A. (2013). Adherence to wearing prescription custom-made footwear in patients with diabetes at high risk for plantar foot ulceration. *Diabetes Care*, *36*(6), 1613–1618. https://doi.org/10.2337/dc12-1330
Ware, J. E., Snow, K. K., Kosinski, M., & Gandek, B. (1993). *SF-36 Health Survey Manual & Interpretation Guide* (1st ed.). Nimrod Press.
Weatherall, J., Paprocki, Y., Meyer, T. M., Kudel, I., & Witt, E. A. (2018). Sleep tracking and exercise in patients with type 2 diabetes mellitus (Step-D): Pilot study to determine correlations between fitbit data and patient-reported outcomes. *JMIR MHealth and UHealth*, *6*(6), 1–10. https://doi.org/10.2196/mhealth.8122
Zheng, Y., Ley, S. H., & Hu, F. B. (2017). Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. *Nature Publishing Group*, *14*(2), 88–98. https://doi.org/10.1038/nrendo.2017.151

Appendix

Appendix A Interview structure – Perspective of patient - Baseline

U heeft aangegeven mee te doen met het onderzoek waarbij we onderzoeken hoe we kunnen zorgen dat DM-patiënten meer therapietrouw worden aan het dragen van hun orthopedische schoenen. We willen u met het onderzoek niet alleen tot last zijn, maar juist zorgen voor een meerwaarde, omdat we met de resultaten meer inzichten krijgen in het therapietrouw zijn en weten wat de bijdrage is voor preventie van voetwonden.
Gedurende het interview zal ik u verschillende vragen stellen. Bij een deel van de vragen zal het gaan om een beoordeling te geven op een schaal van 0 tot 10. Andere vragen gaan over u ervaring en ik zal aan u vragen om voorbeelden of bijvoorbeeld voordelen en nadelen op te noemen.
Is u alles duidelijk of heeft u nog vragen? Zo ja, wat zijn u vragen? Zo nee, dan gaan we nu beginnen met het interview.

1. Graag zou ik van u horen wat u ervan vindt dat u orthopedische schoenen aangemeten mag krijgen?

2. Wat vindt u belangrijk aan uw orthopedische schoenen?

3. Wat zullen volgens u de voordelen van uw orthopedische schoenen zijn?

4. Wat zullen volgens u de nadelen van uw orthopedische schoenen zijn?

5. Verwacht u op een schaal van 0 tot 10, waarbij 0 = helemaal niet en 10 = absoluut wel, dat de voordelen van uw orthopedische schoenen opwegen tegen de nadelen?
    a. Waarom verwacht u dat?

6. Hoe gemotiveerd bent u, op een schaal van 0 tot 10, waarbij 0 = helemaal niet gemotiveerd en 10 = heel erg gemotiveerd, met betrekking tot het dragen van uw orthopedische schoenen?
    a. Waarom bent u meer of minder gemotiveerd?

7. Er zijn verschillende redenen waarom orthopedische schoenen voorgeschreven worden. Wat is voor u de belangrijkste reden dat u orthopedische schoenen voorgeschreven heeft gekregen?
    - Pijn aan voeten
    - Wondjes aan voeten
    - Voetafwijking
    - Beenlengteverschil
    - Anders, namelijk:……

8. We hadden het er net al over. Orthopedische schoenen kunnen alleen hun werk doen als ze ook gedragen worden. Hoe denkt u hierover: kunt u ervoor zorgen dat u uw orthopedische schoenen gaat dragen, op een schaal van 0 tot 10, waarbij 0 = ik heb geen invloed op het dragen en 10 = ik heb het dragen helemaal zelf in de hand?
    a. Op basis waarvan verwacht u dat?

9. Hoe vaak verwacht u uw orthopedische schoenen gemiddeld te gaan dragen?

- 6-7 dagen per week
- 4-5 dagen per week
- 2-3 dagen per week
- 1 dag per week
- nooit

10. Wat zou voor u een reden kunnen zijn om uw orthopedische schoenen niet/minder te dragen dan u zou willen?

We hebben nu gesproken over het dragen van uw orthopedische schoenen en de verwachte voor- en nadelen, maar nu wil ik het graag hebben over uw verwachtingen met betrekking tot de werkzaamheid van uw orthopedische schoenen.

11. Als u denkt aan pijn, verwacht u dat u met uw orthopedische schoenen meer of minder pijn heeft aan uw voeten, op een schaal van 0 tot 10, waarbij 0 = veel minder en 10 = veel meer pijn?

Volgende vragen niet stellen als je al weet dat de participant geen wondjes heeft.

12. Verwacht u, op een schaal van 0 tot 10, waarbij 0 = veel nieuwe wondjes en 10 = helemaal geen nieuwe wondjes, dat met uw orthopedische schoenen uw voeten dicht zullen houden of de wondjes aan uw voeten zullen genezen?

a. Waar verwacht u dat dit te maken zal hebben?
b. Niet van toepassing, participant heeft geen wondjes.

13. Hoe slecht of goed, op een schaal van 0 tot 10, waarbij 0 = heel slecht en 10 = heel goed, verwacht u dat uw orthopedische schoenen zullen passen?

a. Waarom verwacht u dat?

14. Hoe verwacht u, op een schaal van 0 tot 10, waarbij 0 = heel lelijk en 10 = heel mooi dat uw orthopedische schoenen er uit gaan zien?

a. Is het uiterlijk van uw orthopedische schoenen belangrijk voor u?
b. Wat zijn uw verdere gedachtes hierover?

15. Hoe belangrijk is het voor u wat anderen van het uiterlijk van uw schoenen zullen vinden, op een schaal van 0 tot 10, waarbij 0 = helemaal niet belangrijk en 10 = heel erg belangrijk)?

16. Wat verwacht u hoe anderen het uiterlijk van uw schoenen zullen vinden?

- Heel erg lelijk
- Lelijk
- Neutraal
- Mooi
- Heel erg mooi
- Geen idee

17. En qua gewicht, op een schaal van 0 tot 10, waarbij 0 = heel licht en 10 = heel zwaar, hoe zwaar verwacht u dat uw orthopedische schoenen zullen zijn?

a. Waarom verwacht u dat?

We hebben het tot nu toe uitvoerig over uw voetproblemen en verwachtingen van de orthopedische schoenen gesproken. Graag zou ik in het algemeen van u horen of u momenteel aan de maatschappij deel kunt nemen (participeren) zoals u zou willen en of u uw leven kunt leiden zoals u zou willen.

18. Hoe denkt u hierover? In hoeverre wordt uw leven beïnvloed door uw voetproblemen?

19. Ondervindt u participatieproblemen bij de volgende bezigheden, ja/deels/nee? (per punt uitvragen)

a. In werk/school/opleiding
b. In vrije tijd en recreatie
c. Zelfverzorging (ADL)
d. Huishouden
e. Anders, namelijk……

20. Verwacht u, met uw orthopedische schoenen, de volgende activiteiten meer of minder te gaan doen? (per punt uitvragen)

a. Binnenshuis lopen
b. Rondom het huis lopen
c. Huishoudelijke taken
d. Boodschappen doen
e. Mijn werk uitvoeren
f. Mijn hobby uitvoeren
g. In de stad winkelen
h. Een wandeling maken
i. Sporten

Proberen een inschatting te maken van wat de participant kan en op basis hiervan bepalen naar welke afstand je als eerste gaat vragen.

21. Hoever kunt u op dit moment lopen?

• Ik kan in huis lopen (0-10 meter)
• Ik kan naar de buren lopen (10-50 meter)
• Ik kan naar de hoek van de straat lopen (50-200 meter)
• Ik kan naar winkels in de buurt lopen (200-1000 meter)
• Ik kan aan één stuk een flinke wandeling maken (meer dan 1000 meter)

22. Verwacht u dat u meer of minder dan nu kunt lopen met uw orthopedische schoenen?

a. Minder dan ik nu kan lopen
b. Net zoveel als ik nu kan lopen
c. Meer dan ik nu kan lopen

Op basis van het antwoord van de vorige vraag naar afstand bepalen naar welke afstand je als eerste gaat vragen.

23. Hoeveel verwacht u met uw orthopedische schoenen te kunnen lopen? Ik verwacht dat ik…

- In huis kan lopen (0-10 meter)
- Naar de buren kan lopen (10-50 meter)
- Naar de hoek van de straat kan lopen (50-200 meter)
- Naar winkels in de buurt kan lopen (200-1000 meter)
- Aan één stuk een flinke wandeling kan maken (meer dan 1000 meter)
- Anders, namelijk…… (welke afstand)

We hebben veel besproken. Zijn er nog onduidelijkheden of heeft u nog ergens vragen over? Kan ik nog van meer informatie voorzien? Zo ja, antwoord geven op de vragen.
Ik zal ongeveer 5-7 maanden nadat u uw orthopedische schoenen heeft ontvangen opnieuw bellen voor een vervolg interview, zodat we kunnen besproken wat uw ervaring met uw orthopedische schoenen is.
Graag wil ik u bedanken voor het interview en tot de volgende keer.

Appendix B RAND-36 V2

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 meeste 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 gleden, 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. Forste 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. Een 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. Had u, ten gevolge van uw lichamelijke gezondheid, de afgelopen 4 weken één van de volgende problemen bij uw werk of andere dagelijkse bezigheden?

	Ja	Nee
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 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?

	Ja	Nee
a. U heeft minder tijd kunnen besteden aan werk of andere bezigheden	□	□
b. U heeft minder bereikt dan u zou willen	□	□
	□	□

c. U had moeite met het werk of andere bezigheden (het kostte u bijvoorbeeld extra inspanning)	□	□

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 vier 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 aankruisen dat het beste aansluit bij hoe u zich heeft gevoeld. Hoe vaak gedurende afgelopen 4 weken:

	Voortdurend	Meestal	Vaak	Soms	Zelden	Nooit
a. Voelde u zich levenslust?	□	□	□	□	□	□
b. Voelde u zich 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 of 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
- □ Meestal
- □ 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	Grotendeels juist	Weet ik niet	Grotendeels 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	□	□	□	□	□