# Translation, cross-cultural adaptation, validity and reliability of the German Diabetes Foot Self-Care Behavior Scale (DFSBS-D)

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## List of abbreviations

| | |
|---|---|
| ANOVA | Analysis of variance |
| BMI | Body mass index |
| BP | Bodily pain |
| BT | Back-translator |
| C-DSCS | Chinese version of the diabetes self-care scale |
| CI | Confidence interval |
| CKQ | Christliches Krankenhaus Quakenbrück |
| COSMIN | Consensus based Standards for the selection of health measurement Instruments |
| DDG | Deutsche Diabetes Gesellschaft *(German Diabetes Association)* |
| DFS | Diabetic foot syndrome |
| DFSBS | Diabetes Foot Self-Care Behavior Scale |
| DFSBS-D | Diabetes Foot Self-Care Behavior Scale, German version |
| DKRS | Deutsches Register Klinischer Studien |
| DM | Diabetes mellitus |
| FAS-PräDiFuß | Frankfurter Aktivitätenkatalog der Selbstpflege - Prävention Diabetisches Fußsyndrom *(FCFSP)* |
| FCFSP | Frankfurter Catalogue of Foot Self-Care - Prevention of the Diabetic Foot Syndrome |
| GH | General health |
| GPE | Global perceived effect |
| HbA1c | Glycated hemoglobin |
| HRQL | Health-related quality of life |
| i.e. | Id est *(lat.)* |
| IBM | International Business Machines Corporation |
| ICC | Intraclass correlation coefficient |
| IDF | International Diabetes Federation |
| kg | Kilogram |
| KMO | Kaiser-Meyer-Olkin |
| LOA | Limit of agreement |
| $m^2$ | square meter |
| MDC | Minimal detectable change |
| $MDC_{group}$ | Minimal detectable change on group level |
| $MDC_{ind}$ | Minimal detectable change on individual level |
| MH | Mental health |
| PAOD | Peripheral arterial occlusive disease |

| | |
|---|---|
| PF | Physical functioning |
| PNP | Polyneuropathy |
| PRO | Patient-reported outcome |
| RE | Role emotional |
| RP | Role physical |
| $r_s$ | Spearman's correlation coefficient |
| SD | Standard deviation |
| SDSCA | Summary of Diabetes Self-Care Activities Measures |
| SDSCA-G | Summary of Diabetes Self-Care Activities Measures, German version |
| SE | Standard error |
| SEM | Standard error of measurement |
| SF | Social functioning |
| SF-36 | Short Form Health Survey 36 |
| SPSS | Statistical Package for the Social Sciences, IBM Corporation, Armonk, New York, Version 25 |
| T1 | Translator 1 |
| T12 | Merged translations of T1 and T2 |
| T2 | Translator 2 |
| VT | Vitality |

# 1. Research motivation

The prevalence of diabetes mellitus (DM) has reached epidemic proportions and continues to rise (Bundesärztekammer et al. 2010, Klonoff et al. 2009). Now, DM also affects younger people, resulting in new (long-term) preventive challenges as a result of the prolonged course of the disease and the complications experienced more frequently as a result (Bundesärztekammer et al. 2010). Consequently, DM poses considerable clinical and socio-medical problems. Above all, DM can have a serious impact on the lives of individuals (Lechleitner 2019, Müller-Wieland et al. 2019, Bundesärztekammer et al. 2010, Rose et al. 2005).

Diabetes mellitus is characterized by long-lasting, high blood sugar levels and the resulting consequential damage to various organ systems, including the vascular and nervous system (Bundesärztekammer et al. 2010). Diabetic foot syndrome (DFS) is one of the most common sequelae of DM (Arastéh et al. 2009). The term DFS encompasses various clinical pictures and is characterized by lesions in the foot region of the DM patient, which can lead to complications (Bundesärztekammer et al. 2010). If management is delayed or ineffective, DFS can result in amputation of the entire limb.

According to Lobmann et al. (2013), statistically speaking, a DM-related amputation is performed every 15 minutes in Germany. Following a DFS-related amputation, up to 70% of the patients die within five years (Mavrogenis et al. 2018). Mortality even increases with the level of amputation (Mavrogenis et al. 2018).

The main objectives related to foot problems in DM patients are the identification of persons at increased risk for foot complications and the avoidance of DM-associated foot lesions (Bundesärztekammer et al. 2010). The *German Diabetes Association (Deutsche Diabetes Gesellschaft, DDG)* recommends regular examinations of the feet, stockings and shoes of DM patients. The DM patients themselves must carry out regular self-examinations of their feet and shoes (Lauterbach et al. 2010, Vileikyte et al. 2006, Bell et al. 2005, Ronnemaa et al. 1997, Pieber et al. 1995, Litzelman et al. 1993, Malone et al. 1989).

In Germany there are few instruments available for assessing diabetic self-care (Kamradt et al. 2014, Schmitt et al. 2013, Schmidt et al. 2005). However, those instruments are neither easy to administer during brief, time-limited consultations nor focus on diabetic foot self-care primarily. Chin and Huang (2013) developed the Chinese 7-item *Diabetes Foot Self-Care Behavior Scale* (DFSBS) specifically for patients with DFS and tested its psychometric properties (Chin and Huang 2013). The DFSBS showed evidence of validity and reliability.

A valid and reliable version of the DFSBS translated into English is available, but no German version of the DFSBS exists. In order to use the DFSBS within a German-speaking DM

population, a valid and reliable German version is needed. Hence, the aim of this study was to translate and cross-culturally adapt the DFSBS into German (DFSBS-D) according to the *Consensus based Standards for the selection of health measurement Instruments* (COSMIN) guidelines and test its psychometric properties in a cohort of DM type 1 and 2 patients. In conclusion, this research project aims to answer the following research questions: (1) Does the final DFSBS-D show construct validity, i.e. does it relate well to other measurement instruments in accordance with previous defined hypotheses? (2) Does the DFSBS-D show reliability, i.e. does it have a high internal consistency, high test-retest-reliability and a low measurement error?

We hypothesize that the DFSBS is a valid and reliable scale once translated and culturally adapted into German. The DFSBS-D will be a convenient scale, focusing primarily on foot self-care, for the use for both, research in foot self-care in German speaking type 1 and 2 DM patients, and clinical screening of DM patients´ foot-self-care behavior as soon as it has been proven to be valid and reliable.

# 2. Background

## 2.1 Diabetes mellitus

Diabetes mellitus is a heterogenic group of metabolic diseases characterized by an increase in blood glucose, called hyperglycemia, in response to an insulin production disturbance (Harreiter & Roden 2019, Müller-Wieland 2019, De Vet et al. 2018, p. 10). The two main representatives of the group are type 1 and 2 DM (Arastéh et al. 2009). Diabetes mellitus is one of the major common diseases: according to the *International Diabetes Federation* (IDF), worldwide one out of eleven adults has DM. In Germany, 6.7 million people are currently diagnosed with DM (Mohrmann et al. 2018, Müller-Wieland & Kröger 2018). In addition, two million unreported cases of DM are assumed (Mohrmann et al. 2018, Müller-Wieland & Kröger 2018, Bahrmann et al. 2018). More than 90% of the diagnosed DM patients suffer from type 2 DM (Müller-Wieland 2019, Mohrmann et al. 2018, Müller-Wieland & Kröger 2018). In the last quarter of a century, the number of people affected increased by more than a third (Müller-Wieland & Kröger 2018). The increase in DM prevalence in recent years has mainly been attributable to population groups aged 65 and over, people with low educational status, high body mass index (BMI ≥ 30 kg/m²), and low physical exercise (Heidemann 2016). In addition, the socioeconomic status is not only an essential risk factor for development of DM type 2, but also for complications and sequelae (Mohrmann et al. 2018). The most common morbidity and mortality causes in DM patients are cardiovascular diseases (Baloglu 2019, Jansson et al. 2010). Compared to general population, the all-cause mortality rate of elderly DM patients is significantly higher (Bertoni et al. 2002). Said all this, DM has a special relevance. Therefore,

a modern, evidence-based, patient-centered care and management, as well as the prevention of the disease and its consequences are a key concern of the German health care system.

Chronic hyperglycemia is associated with long-term damage and dysfunction in body tissues and organs (Harreiter & Roden 2019). Regarding DM type 2, dysfunctions with an increased risk of macrovascular consequences are present long before clinical manifestation (Harreiter & Roden 2019). The aim of DM therapy is to prevent or delay metabolic and vascular complications to improve quality of life and life expectancy, such as the following long-term secondary diseases: macroangiopathy (coronary heart disease, stroke, arterial occlusive disease), microangiopathy (eyes and kidney), neuropathy (disease of the nerve pathways) and DFS (neuropathy and blood vessels) (Müller-Wieland & Kröger 2018, Arastéh et al. 2009). Diabetes training and self-management must be accessible for all DM patients (Weitgasser et al. 2019). Adequate personnel, spatial, organizational, and financial conditions must be structured to be able to offer a validated training program (Weitgasser et al. 2019). Diabetes training is used to motivate patients to confront their illness and improve their knowledge, skills and capability (Weitgasser et al. 2019). In addition, detection and treatment of acute complications (hypoglycemia, hyperglycemia, infections), diabetic follow-up screening for retinopathy, nephropathy, neuropathy and DFS, as well as of additional cardiovascular risk factors (blood pressure, blood lipids, smoking, obesity) and complications (heart attack, stroke, peripheral circulatory disorder) is taught and trained (Weitgasser et al. 2019). Besides the increase in knowledge about the disease itself, it has been shown that structured DM training can positively affect parameters such as blood glucose, glycated hemoglobin (HbA1c), blood pressure and body weight (Weitgasser et al. 2019).

## 2.2 Diabetic foot syndrome

The term diabetic neuropathy includes mono- and polyneuropathy (PNP), diabetic plexopathy, radiculopathy and autonomic neuropathy (Lechleitner 2019). Chronic sensorimotor distal PNP (Figure 1) is the most common presentation of neuropathy in DM (Boulton 2005, Cameron 2001). Up to 50% of diabetic PNP is asymptomatic (Riddle et al. 2019, Juster-Switlyk & Smith 2016, Boulton 2005). Therefore, these patients are at special risk for injuries to their insensate feet (Riddle et al. 2019). The term DFS refers to foot lesions in DM patients, which can become infected and lead to an ulcer or gangrene with corresponding complications such as an increased risk for amputation (Arastéh et al. 2009). Diabetic neuropathy and DFS are late diabetic complications that significantly affect the patient's quality of life (Lechleitner 2019, Rose et al. 2005). A special form of DFS is the Charcot foot syndrome (Figure 2), which begins with a relatively painless, load-dependent edema and leads to strongly deforming foot changes and trauma with limited load-bearing capacity in advanced stages (Poll & Chantelau 2010).

***Figure 1: Neuropathic foot*** *with dry and cracked skin on the soles of the feet and pronounced callus formation on predisposed pressure points as expression of PNP*

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***Figure 2: Charcot foot syndrome*** *with several ulcers and amputations within the level of the lower limbs*

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### 2.2.1 Epidemiology

Every fourth DM patient suffers DFS during his/her lifetime (Mavrogenis 2018, Lawall 2018, Dörr et al. 2018, Peter-Riesch 2016). The current prevalence of DFS varies between four and 15% (Dörr et al. 2018). The most significant consequences of DFS are ulcers and amputations (Schönbach & Spraul 2018). The prevalence of foot ulcer in DM population is 1.5-10% (Schönbach & Spraul 2018). Per 100 DM patients, a corresponding incidence of 2.2-5.9 cases is reported (Schönbach & Spraul 2018). Patients with healed plantar neuropathic ulcer are at extremely high risk of developing recurrence (Schönbach & Spraul 2018). Several studies have shown a recurrence rate of 30-40% within a year of healing, despite a good supply of footwear and chiropody (Schönbach & Spraul 2018).

Approximately 40-70% of all non-traumatic lower limb amputations worldwide are performed in DM patients (Schönbach & Spraul 2018). In Germany, there has been a demonstrable reduction in major-amputations since 2004 (Schönbach & Spraul 2018, Morbach et al. 2018). But still today, about 65% of all amputations in Germany are carried out in DM patients (Schönbach & Spraul 2018, Morbach et al. 2018). According to the *German Diabetes Association's* Health Report in 2019, about 40.000 annual amputations are caused by poorly managed DFS (Müller-Wieland et al. 2019).

The prevalence of peripheral arterial occlusive disease (PAOD), skin lesions and amputations in DM patients with PNP is significantly higher than in DM patients without PNP, because the warning symptoms are often missing (Lawall 2018, Prompers et al. 2008). Arterial circulatory disorders of the lower limbs are of outstanding importance, since in the presence of a hemodynamically relevant POAD delays wound healing significantly and thus increases amputation risks (Lawall 2018). Regarding the management, only about 60% of all patients with ischemia-related DFS can be revascularized surgically or interventionally (Amann et al.

2005). The amputation rate in ischemic DFS is about ten times higher than in neuropathic DFS (Amann et al. 2005).

### 2.2.2 Risk factors

Foot lesions in DM patients develop as a result of multifactorial events that often involve several risk factors (Müller-Wieland et al. 2019, Morbach et al. 2013, Bundesärztekammer et al. 2010). Peripheral neuropathy, ischemia and infections are the three essential pathological factors for the formation of a diabetic foot lesion (Lawall 2018). A bacterial infection is often the result of an initial lesion. Diabetes-specific risk factors of ulcers and possibly following amputations are peripheral PNP, DM duration, course, and poor glycemic control (Riddle et al. 2019, Lawall 2018). Moreover, non-specific risk factors involve (in alphabetical order): (1) alcohol/tobacco abuse, (2) bacterial infections, (3) barefoot walking, (4) biopsychosocial factors such as depression, neglect, disease convictions, or lack of social support, (5) calluses, (6) dry skin with pre-ulcerative calluses or corns, (7) foot deformities, (8) higher age, (9) history of foot ulcer, (10) immunosuppression including intake of glucocorticoids, (11) limited joint mobility (arthropathy (hip/knee/talocrural joint) or joint implant with functional impairment/contracture), (12) motor function restriction/paresis of one or both legs, (13) obesity (BMI ≥ 35 kg/m²), (14) peripheral arterial or venous circulatory disorders, (15) previous amputations, (16) secondary diseases such as renal insufficiency and stroke, (17) unsuitable footwear, (18) visual impairment, and (19) wrong or insufficient pedicure (Riddle et al. 2019, Lawall 2018, Morbach et al. 2017, Bundesärztekammer et al. 2010).

### 2.2.3 Clinic and Classification

A distinction is made between the neuropathic diabetic foot and the ischemic foot (Arastéh et al. 2009). Ulcers are called neuroischemic, if there is both PNP and peripheral arterial disease (Schönbach & Spraul 2018). In approximately one third of patients with DFS, the disorders occur in combination (Mavrogenis et al. 2018, Arastéh et al. 2009). Neuropathic diabetic feet (Figure 1) typically present warm with dry skin and well palpable foot pulses (Arastéh et al. 2009). Around severe cornification, sharply punched, mostly painless ulcers can be found. The absence of pain often lends patients to not seek medical attention until advanced stages of the disease (Arastéh et al. 2009). Ischemic feet usually present as painful gangrene with lesions on the toes and the heel (Arastéh et al. 2009). The foot is pale and cold, with impalpable pulses. Compared to non-DM patients, the symptoms are more discrete because of the often-involved neuropathy (Arastéh et al. 2009). Typically, foot ulcers are located on predisposed locations, such as the first and fifth metatarsal heads or the tip of the toes (Dörr et al. 2018). They present circular and are surrounded by a hyperkeratotic rim (Dörr et al. 2018). A significant depth extension with bone contact or subclinical infection may occur during exploration, even in case

of apparently bland findings (Dörr et al. 2018). Therefore, the lesion´s extent must be determined and debrided (Dörr et al. 2018).

If a lesion in a patient is diagnosed as DFS, it should be classified according to the extent of tissue destruction and the presence of infection and/or ischemia (Morbach et al. 2017). Various diabetic foot ulcer classification systems are currently available, although none of these have become widespread in use (Schaper 2004). In Germany, the most commonly used scale is the combined *Wagner-Armstrong wound classification* (Table 1; Teichmann & Sabo 2009).

***Table 1: Wagner-Armstrong wound classification for describing diabetic foot syndrome***

| | | **Wagner grade** | | | | | |
|---|---|---|---|---|---|---|---|
| | | **0** | **1** | **2** | **3** | **4** | **5** |
| **Armstrong stage** | **A** | pre- or post-ulcerative foot | superficial wound | wound up to the level of tendons or capsule | wound up to the level of bones and joints | necrosis of parts of foot | necrosis of the entire foot |
| | **B** | with infection | | | | | |
| | **C** | with ischemia | | | | | |
| | **D** | with infection and ischemia | | | | | |

Adapted from Morbach S et al., Diabetic Foot Syndrome, Exp Clin Endocrinol Diabetes 2014; 122: 416–424

***Figure 3: Wagner grade 0;*** *epithelialized pre- or postulcerative lesion*

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***Figure 4: Wagner grade 5;*** *gangrenous foot with infected and necrotized lesions*

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### 2.2.4 Management

The therapy of DFS is also based on the *Wagner-Armstrong wound classification* (Table 1, Morbach et al. 2017). In case of no lesion but possibly foot deformation or cellulite (Wagner 0, Figure 3), regular control of the feet is necessary (Morbach et al. 2017). With a superficial

ulceration or deep ulcer up to the joint capsule or tendons (Wagner 1 and 2), emphasis is laid on pressure relief and local wound management (Morbach et al. 2017). For deep ulcer with abscessing, osteomyelitis and/or infection of the joint capsule (Wagner 3) the therapy is based on infection control. While smaller osteomyelitic lesions usually heal under systemic antibiosis and consistent pressure relief (Morbach et al. 2017), larger lesions must be resected surgically (Morbach et al. 2017). In any case, a regular X-ray check should be carried out (Morbach et al. 2017). Normally, even minor processes require an antibiotic management of six weeks or more (Morbach et al. 2017). In case of limited necrosis in the forefoot or heel area (Wagner 4) or necrosis of the entire foot (Wagner 5, Figure 4), the main aim is to keep the amputation limit as distal as possible and to prevent an ascending infection (Morbach et al. 2017). If PAOD is suspected or present, angiography should be performed before each amputation (Morbach et al. 2017).

The management of DFS is an interprofessional medical challenge as patients are often multimorbid (Dörr et al. 2018). A profound knowledge of the indication and use of wound therapeutics, as well as general internistic, diabetological, angiological, orthopedic, and surgical knowledge is required (Dörr et al. 2018). About four-fifths of the amputations performed in DM patients can be avoided by a multi-professional management approach in specialized facilities (Dörr et al. 2018).

The main elements of DFS management are: (1) Metabolic control and therapy of comorbidities, (2) infection management, (3) wound debridement and stage-adapted local wound management, (4) effective pressure relief, (5) therapy of peripheral vascular diseases, (6) patient training, (7) medical foot-care as follow-up and (8) foot surgery for correction of toe deformities (Lawall 2018, Morbach et al. 2014).

Ischemia decisively influences the prognosis of wound healing (Lawall & Lobmann 2019, Yang Zhao 2010, Prompers 2008). Therefore, the basis of all conservative and surgical therapy is the assurance of a well-vascularized wound bed (Dörr et al. 2018, Lobmann 2013). Rapid arterial revascularization of ischemic or neuroischemic diabetic foot lesions is of relevant importance (Peter-Riesch 2016). Appropriate management options are chosen depending on the respective patient´s morbidity, the vascular lesions morphology and the center´s expertise (Lawall 2018).

The superiority of surgical over non-surgical management is still being discussed. Rescue of the lower leg in diabetic foot infections often requires multiple surgical interventions (Schönbach & Spraul 2018). Selected authors do not consider non-surgical management to be a viable option, as patients ultimately need lower leg amputation when all rescue attempts have failed (Schönbach & Spraul 2018, Mauler et al. 2017). However, according to Hong et al.

(2017), most patients prefer multiple rescue attempts for diabetic foot infection, even if they end up resulting in lower leg amputation (Schönbach & Spraul 2018, Hong et al. 2017).

### 2.2.5 Prophylaxis of foot ulcer

Prevention and early therapeutic intervention are of crucial importance to avoid ulcers and amputations (Schaper et al. 2019, Morbach et al. 2017, Pscherer et al. 2012). Foot ulceration is usually caused by local trauma, which has an extrinsic cause in four out of five ulcers (Peter-Riesch 2016). The most important trigger for lesions is unsuitable footwear (Morbach et al. 2017). Most foot ulcers are caused by avoidable factors, including: (1) inadequate shoes or soles, (2) foreign bodies in shoes, (3) neglected calluses, (4) inadequate nail and foot-care, and (5) thermal trauma (Peter-Riesch 2016).

The *International Working Group on the Diabetic Foot* (2019) recommends the following key points of foot ulcer prevention: (1) regularly inspecting and examining the at-risk foot, (2) identifying the at-risk foot, (3) educating the patient, family and healthcare professionals, (4) ensuring routine wearing of appropriate footwear, and (5) treating risk factors for ulceration (Schaper et al. 2019).

The most important preventive measure is regular wearing of pressure-relieving beddings in suitable footwear (Morbach et al. 2017). In addition, the detection and timely management of pre-ulcerative foot lesions such as newly occurring calluses and redness is crucial (Morbach et al. 2017). This also includes foot surgery measures such as Achilles tendon lengthening in the case of a hollow foot or tendon lengthening in the case of claw toes (Morbach et al. 2017). With the examination intervals the individual risk profile of the patient must be considered (Morbach et al. 2017). Diabetes-related major-amputations can be avoided by adequate foot management, including standardized foot screening examinations (Schönbach & Spraul 2018, Paisey et al. 2018). An adequate infrastructure for DFS care is crucial for a reduction in the major-amputation rate. According to Schönbach & Spraul (2018), a missing management structure for patients with DFS is no longer tolerable. Mavrogenis et al. (2018) recommend education for patients regarding foot hygiene, nail care and proper footwear to reduce the risk of DFS and its complications. They further state, that education alone may effectively reduce the incidence of DFS and consequently the rate of amputation (Mavrogenis et al. 2018).

In conclusion, one approach to improve health outcomes in patients with DM is self-management (Chao et al. 2019, Sharoni 2017). One of the most important self-management procedures to prevent diabetic foot ulcers and thus avoid subsequent complications such as amputations is adequate foot self-care (Chin and Huang 2013, Vileikyte et al. 2006). The following foot self-care behavior measures serve to prevent possible diabetic foot complications: (1) daily cleaning with lukewarm water, (2) applying moisturizing cream, (3)

appropriate blunt nail care, (4) removal of calluses, and (5) supply of suitable footwear (Bundesärztekammer et al. 2010). However, research shows that adequate foot self-care is only practiced by the fewest of those affected (Chin and Huang 2013, Bell et al. 2005, Pollock, Unwin and Connolly 2004). A German questionnaire, which covers all aspects of regular foot self-care while being reliable and valid does not currently exist. The availability of such a questionnaire could help to locate foot ulcers at an early stage and to assess therapy results and progress.

## 2.3 Psychometric properties

Evaluation of psychometric properties after the translation and cross-cultural adaptation of the DFSBS are important for the determination of the quality of this survey (De Vet et al. 2018, p. 2). The COSMIN panel defines validity as “the degree to which an instrument truly measures the construct(s) it purports to measure” (De Vet et al. 2018, p. 150, Mokkink et al. 2010). Construct validity is “the degree to which the scores of a measurement instrument are consistent with hypotheses, e.g. with regard to internal relationships, relationships with scores of other instruments or differences between relevant groups” (De Vet et al. 2018, p. 169, Mokkink et al. 2010). Two types of construct validity must be distinguished for this study: structural validity and hypotheses testing. Structural validity is “the degree to which the scores of a measurement instrument are an adequate reflection of the dimensionality of the construct to be measured” and is assessed by factor analysis (De Vet et al. 2018, p. 169, Mokkink et al. 2010). For the acquirement of substantial evidence that the instrument is measuring what it purports to measure (i.e. the amount of foot self-care in DM patients in the current study), hypotheses testing, as a basic principle of construct validation is used (De Vet et al. 2018, p. 172). There are two aspects of formulated hypotheses: discriminant validity and known-group validity (De Vet et al. 2018, p. 172). The principle of discriminant validity is about the magnitude of relationships of scores on the instrument with scores on other instruments measuring similar or dissimilar constructs (De Vet et al. 2018, p. 172). Known-group validity distinguishes the differences in the instrument scores between subgroups of patients (De Vet et al. 2018, p. 172). Reliability analysis measures the consistency of a measure (Field 2018, p. 829) and is defined as “the extent to which scores for patients who have not changed are the same for repeated measurement under several conditions” by Mokkink et al. (2010) (De Vet et al. 2018, p. 97). For this study, reliability was assessed in terms of internal consistency, measurement error and test-retest reliability (Mokkink et al. 2010). Internal consistency is defined as the “degree of interrelatedness among the items” by the COSMIN committee and is best assessed using Cronbach’s alpha (De Vet et al. 2018, p. 80ff., Field 2018, p. 822, Mokkink et al. 2010). According to Cortina et al. (1993), an acceptable Cronbach’s alpha reflects high correlation of the items within one scale (De Vet et al. 2018, p. 84). Values between 0.70 and 0.90 are most established and generally accepted (De Vet et al. 2018, p. 83, Nunnally and Bernstein 1994).

Redundancy of items is indicated by Cronbach's alpha >0.90 (De Vet et al. 2018, p. 83). Internal consistency should be assessed following factor analysis (De Vet et al. 2018, p. 81). Concerning internal consistency, standard error (SE) is calculated to reflect the ability of the item to identify the discrepancy between patients (De Vet et al. 2018, p. 139). The standard error of measurement (SEM), as a reliability measure, is calculated, to assess response stability on individual level (De Vet et al. 2018, p. 111). The SEM is the standard deviation (SD) of the error around any single score (De Vet et al. 2018, p. 111). The minimal detectable change (MDC) is the required difference on the score to detect a change between two groups over time. Minimal detectable change is estimated by means of the SEM in patients who self-assess as unchanged. Bland and Altman (1986) proposed another parameter of measurement error called Bland and Altman method and developed a plot to represent the systematic error (De Vet et al. 2018, p. 113). The intraclass correlation coefficient (ICC) as a parameter of reliability is used for test-retest reliability. The test-retest method compares the stability of the measurement with abandoning the timing of the measurement (Rammstedt 2010). It aims to reduce memory effects on the items and their responses and thus to represent independent measurements as far as possible (Rammstedt 2010). The scale is submitted to the respondents a second time after a certain time interval (Rammstedt 2010). The correlation of the respondent's scores at both measurement times is seen as an index of reliability (Rammstedt 2010).

# 3. Material and Methods

## 3.1 Study design

This prospective cross-sectional study consisted of two stages. First, the English DFSBS was translated and culturally adapted into German according to the international recognized COSMIN guidelines (De Vet et al. 2018, p. 182). Second, the translated version (DFSBS-D) was tested for validity and reliability (Prinsen et al. 2018). The study was conducted in agreement with the *World Medical Association Declaration of Helsinki* (2013). The institutional review board, *Medical Ethical Committee of the School of Medicine, Carl von Ossietzky University Oldenburg* was informed about the study and asked for a written approval, which was given under the registration-number: 2018-063. In addition, the study was registered in the *German Clinical Trials Register* (*Deutsches Register Klinischer Studien*, DKRS-ID: DRKS00014962).

## 3.2 Establishment of the German version of the DFSBS

The DFSBS was translated from English into German by a forward-backward procedure following the established COSMIN guidelines (De Vet et al. 2018, p.182). The original questionnaire (Appendix A) was translated into German by two independent translators (T1 and T2) who are fluently in both languages, English and German. One of the translators (T1) was a bilingual assistant doctor of internal medicine. The other translator (T2) was a German state-approved translator with no medical background. Both translated versions were synthesized into a preliminary German version (T1 and T2 into T12; Appendix G-I). This was done in a consensus meeting with the two translators and this study´s research team from the University Hospital for Orthopedics and Trauma Surgery Pius-Hospital, Medical Campus University of Oldenburg. The resultant preliminary German version was tested for wording, phrasing and understanding on a convenience sample of 12 patients with DM type 1 or 2. After evaluation of responses of the test-patients, consensus was reached on cultural adaptation and re-phrasing within the research team. The back translation of the DFSBS-D into English was done by a non-medical bilingual person, who was unknowing of the original English DFSBS version (BT; Appendix J). The retranslated version was compared to the original English questionnaire. Comments on the retranslated version were discussed in a point-wise fashion with all the involved bilingual translators to find a consensus and incorporate final adjustments to the German version of the DFSBS (DFSBS-D). All steps during the process were documented in detail. The detailed report of the translation process can be provided by the authors on demand. For the final version of the DFSBS-D, see Appendix D.

## 3.3 Validation of the DFSBS-D

Recruiting of eligible patients took place in a consecutive, face-to-face manner before or during

patients' appointments or hospitalization on the diabetes ward. In each respective study site, one person was responsible for patient recruiting. Patients willing to participate got a questionnaire consisting of (1) the newly established DFSBS-D, (2) the German version of the Summary of Diabetes Self-Care Activities Measures (SDSCA-G), (3) Frankfurter Catalogue of Foot Self-Care-Prevention of the Diabetic Foot Syndrome (FCFSP), and (4) the Short Form Health Survey 36 (SF-36) (Appendix D). After a brief introduction, the participant was asked to completely fill in the questionnaire and then return it to the responsible person prior to leaving the institution. Two weeks after returning the first questionnaire, participants were asked to complete the DFSBS-D again, to assess test-retest reliability (Appendix E). A two-week interval was chosen to avoid any recall bias. This period is considered adequate to assure that clinical change had not occurred (Terwee et al. 2007, Saris & Gallhofer 2007). For this purpose, a letter was sent to the participants containing (1) a letter of information, (2) the DFSBS-D, and (3) an addressed and stamped envelope to minimize the effort and costs required for the patient to participate in the study. Participants were additionally requested to evaluate their current state of health in relation to their diabetic feet using a simple question that had to be rated on a Global Perceived Effect (GPE) Score (Appendix F). Patients were asked to send back the second questionnaire within 2 weeks. After this time, a follow-up phone call was made to remind the patients.

### 3.3.1 Recruitment sites

The recruitment took place at the following two medical institutions: Diabetes Center Quakenbrück, department of diabetology, metabolic diseases and endocrinology at the Christliches Krankenhaus Quakenbrück (CKQ), Medical Campus University Oldenburg and a clinic for chiropody, called "Praxis am Hafen", in Oldenburg. This outpatient practice is specialized in management of a DM population. At the Diabetes Center Quakenbrück both, inpatients of the three diabetes wards and outpatients of the podiatric outpatient department were asked to participate.

### 3.3.2 Subjects

Subjects were considered eligible if they (1) were 18 years or older, (2) suffering from type 1 or 2 DM, and (3) signed a written informed consent form (Appendix C). Patients were excluded from this study, if they (1) were not able to read or understand the German questionnaires utilized for gaining self-reported information, or (2) had either bilateral leg or foot amputation. Study participants were free at any time to withdraw their consent of study participation. Patients were made aware of this both verbally in the context of recruitment and in writing through an information letter (Appendix B) and the consent form (Appendix C).

### 3.3.3 Sample

The study sample comprises a consecutive sample of 150 DM type 1 or 2 patients, visiting the aforementioned study centers during November 2018 to February 2019. The sample size was chosen to account for a 40% drop out rate and to follow the COSMIN checklist that proposes (1) a minimum number of 100 subjects to assess internal consistency of health-related patient-reported outcome (PRO) and (2) at least 50 subjects of the same sample to evaluate test-retest-reliability (De Vet et al. 2018, p. 191, Terwee et al. 2012, Terwee et al. 2007).

### 3.3.4 Subject characteristics

As part of the questionnaire, patients were first asked to answer sociodemographic questions including age, sex, height, weight, personal life situation, and educational background (Appendix D). Subsequently, patients were required to report DM related information: number of years diagnosed with DM, type of DM, use of insulin therapy, foot complaints and if so, which type of foot complaints (for example calluses, fissures or ulcers). In addition, patients had to provide information about their pre-existing comorbidities in the last six months such as vascular disease or PNP.

## 3.4 Measurement instruments

Vulnerability to foot ulcers and resultant amputation in the DM patient creates a need for an instrument which measures aspects of daily foot self-care in DM patients, with good reliability and validity (Chin and Huang 2013). In Germany, there are few instruments available for assessing diabetic self-care. Yet, no instrument, which focuses primarily on diabetic foot self-care has been established in Germany until now. In order to test the DFSBS-D´s validity and reliability, it was compared to other German DM specific and generic questionnaires, which psychometric properties have already been established. All participants received the following questionnaires in German: (1) DFSBS-D, (2) SDSCA-G, (3) FCFSP, and (4) SF-36 (Appendix D). A short description at the beginning of each questionnaire explained how to fill in the instruments accurately. The used instruments will be shortly explained in the following sections.

### 3.4.1 Diabetes Foot Self-Care Behavior Scale (DFSBS)

The DFSBS is a patient self-reported assessment measuring basic foot self-care routines in DM patients (Chin and Huang 2013; Appendix A). The scale is provided in Chinese and English (Chin and Huang 2013). The original DFSBS was developed by Chin and Huang in 2013 (Chin and Huang 2013). The final scale consists of seven items which are divided into two parts: (1) the first four items (*checking the bottom of the feet and between the toes, washing between the toes and drying between the toes after washing*) relate to certain DM self-care activities

over the last seven days. Patients must state the number of days on which the activity has been carried out in the past week, (2) for the last three items (*applying lotion, inspecting the inside of the shoes and breaking in new shoes*) the patients are asked to mark the frequency that best suits to their behavior. If the participant has been ill for the last seven days, s/he is encouraged to respond regarding to the last seven days s/he has not been ill. All responses are rated on a 5-point Likert scale. In part 1, each answer ranges from 0 days per week [1], 1-2 days per week [2], 3-4 days per week [3], 5-6 days per week [4] to 7 days per week [5]. In part 2, answers vary from never [1] to always [5]. The total score of the DFSBS ranges from 7-35. Higher scores represent more frequent basic foot self-care behaviors in patients with DM (Chin and Huang 2013). Chin and Huang (2013) determined evidence of validity and reliability of the DFSBS and recommended the screening of patients' foot self-care behavior to clinicians and researchers by this questionnaire (Chin and Huang 2013).

### 3.4.2 Diabetes Self-Care Activities Measure (SDSCA-G)

The SDSCA is a brief multidimensional self-report questionnaire of DM self-management. It was first developed in English by Toobert and colleagues in 1994. Over the years, number and item content have been changed several times. The latest version was released by Toobert & Glasgow in 2000 and showed satisfactory psychometric properties (Kamradt et al. 2014, Schmitt et al. 2013, Toobert et al. 2000). In 2013, a German translation (SDSCA-G) was published using forward-backward-translation technology by Kamradt et al. (2014). The SDSCA-G is structured as follows: the total scale is divided into five subscores, namely (1) *general diet*, (2) *specific diet*, (3) *exercise*, (4) *blood-glucose testing*, and (5) *foot-care*, which consist of two items each. In addition, the eleventh item detects possible smoking behavior. This last item is excluded from the overall evaluation (Kamradt et al. 2014). Participants are asked to tick the number of days a certain self-care behavior was performed within the past week on a 7-point Likert scale. The mean number of days is calculated for each subscale and is used to predict and explore the level of self-care (Freitas et al. 2014). The score of item four must be reversed as the question is reverse-phrased. According to Kamradt et al. (2014), the SDSCA-G is a reliable and valid instrument which assesses general self-management in adults with type 2 DM in Germany.

### 3.4.3 Frankfurter Catalogue of Foot Self-Care (FCFSP)

The FCFSP was designed by Schmidt et al. in 2005 and intends to measure disease-related self-care of DM patients. It describes everyday self-care activities that a DM patient should carry out to prevent DFS (Panfil et al. 2005, Schmidt et al. 2005). The FCFSP helps to identify and protocol deficiencies in the disease-related self-care of the feet in DM patients (Schmidt et al. 2005). The 19 items of the FCFSP are divided into three domains: *self-control of the feet*

(items 1-9), *professional assistance in foot-care* (items 10-14) and self-*control of shoes and socks* (items 15-19) (Schmidt et al. 2008). Each question can be answered on a 5-point Likert scale ranging from never [0], seldom [1], sometimes [2], frequently [3], to always [4]. The analysis is made for the score in total and for each subscale (Panfil 2013, Schmidt et al. 2006). All items, except item 14, are positive descriptions of activities. Accordingly, values must be reversed for item 14. A high total value illustrates an undergoing adequate disease-related self-care of the patient (Panfil 2013, Schmidt et al. 2006, Panfil et al. 2005). According to Panfil et al. (2005), the patient needs support and guidance of healthcare professionals in the daily self-care of the feet, if the score of the total scale or of one of the subscales is close to zero. Values regarding the FCFSP's validity are not available, although the authors mention that it was a valid tool (Panfil 2013, Schmidt et al. 2006, Panfil et al. 2005). The test-retest reliability of the 19 item FCFSP can be considered acceptable (Panfil 2013, Schmidt et al. 2006).

### 3.4.4 Short-Form-36-Health Survey (SF-36)

The SF-36 is a standard instrument developed by the Medical Outcome Study for cross-health assessment of health-related quality of life (HRQL) (Bullinger 1995). It is the most frequently used international instrument for measuring the subjective generic quality of life (Scoggings et al. 2009, Radoschewski 2000, Ellert et al. 1999) and is considered the current gold standard of this construct (Lüthi 2007, Velanovich 1998). The SF-36 comprises 35 items into eight dimensions: *physical functioning* (PF, 10 items), *role physical* (RP, 4 items), *bodily pain* (BP, 2 items), *general health* (GH, 5 items), *vitality* (VT, 4 items), *social functioning* (SF, 2 items), *role emotional* (RE, 3 items) and *mental health* (MH, 5 items) (Kurth & Ellert 2002, Ware et al. 2000, 1998, 1994). One additional item, namely *retrospective assessment of health-change over one year*, cannot be assigned to a specific item subgroup (Kurth & Ellert 2002, Ware et al. 2000, 1998, 1994). Response options are either dichotomous (i.e. yes/no) or multiple scaled (i.e. 6-dimension Likert scales). Quality of life is reflected by a sum score that can be calculated from the subscales. Each scale ranges from 0-100, assuming each question has the same weighting in the questionnaire (Bullinger et al. 2000). There is no total score. For the SF-36, 100 represents the highest and 0 the lowest quality of life to be achieved (Bullinger et al. 2000). The German SF-36 was proven to be psychometrically robust for data completeness, validity and reliability within other European samples (Ware et al. 1995, Bullinger 1995, Bullinger et al. 1997, Ware et al. 1998, Bullinger & Kirchberger 1998, Bullinger et al. 2000, Lüthi 2007).

## 3.5 Statistical analysis

Statistical analysis was performed utilizing IBM®´s *Statistical Package for the Social Scientists* (SPSS, Version 25; IBM® Corporation, Armonk, NY, USA). Since most of the data was ordinal, nonparametric statistics were utilized. Normal distribution of metric data was checked by

skewness, kurtosis and Shapiro-Wilk test. In case of normal distribution of metric data, parametric tests were used to test for significant differences between established groups. Mann-Whitney-U test was used as the non-parametric equivalent to the parametric t-test where test data violated the assumption of normality. Single-factor analysis of variance (ANOVA) was used to test whether mean values of several independent groups defined by a categorical independent variable differ from each other. Statistical significance was accepted at $p \leq 0.05$. Research execution tried to minimize missing values by checking the returned questionnaires for completeness directly. A percentage of less than 3% of missing scores was considered acceptable (De Vet et al. 2018, p. 68).

### 3.5.1 Validity

Exploratory factor analysis was used to identify clusters of items (Field 2018, p. 779). We expected that the DFSBS-D is also uni-dimensional, as the original DFSBS consists of one factor according to Chin and Huang (2013). Kaiser-Meyer-Olkin (KMO) measure of Sampling Adequacy and Bartlett's test of sphericity were first assessed to verify that the data set is suitable for factor analysis (Kaiser 1974). The total number of factors was extracted by principal component analysis with varimax rotation and based on the initial eigenvalues and the scree plot. The scree plot is a graph plotting each factor (X-axis) against its eigenvalue (Y-axis) (Field 2018, p. 1034). An eigenvalue ≥1.0 was defined as extraction criterion, and factor loadings ≥0.40 were considered to represent high correlation with the respective factor (Yong et al. 2013). To establish construct validity, 21 apriori hypotheses regarding the relationship between the DFSBS-D and the SDSCA-G, the FCFSP and SF-36 were defined, following the COSMIN guidelines (De Vet et al. 2018, p. 172). Construct validity was considered good if at least 75% of the predefined hypotheses were confirmed (Prinsen et al. 2018, Terwee et al. 2007). Spearman´s correlation coefficients ($r_s$) were calculated for the evaluation of the predefined hypotheses. Spearman´s correlation coefficients were interpreted according to the cut-off points formulated by Domholdt (2000): 0.00 to 0.25 very weak, 0.26 to 0.49 weak, 0.50 to 0.69 moderate, 0.70 to 0.89 strong, and 0.90 to 1.00 very strong. The highest correlation was expected between the DFSBS, the SDSCA-G subscale foot-care and the FCFSP, since all these questions cover the same construct. Spearmen correlation coefficients of 0.5 or higher were expected. Examples of items with expected high correlation are given in Table 2. The widely used SF-36 is a generic health status questionnaire. Correlations of less than 0.26 were expected to exist between the DFSBS and the SF-36 subscales, as they assess two different constructs. For an overview of the predefined hypotheses and Spearman correlation coefficients, please refer to Table 10 in chapter 4.3.2. According to Chin and Huang (2013), DM patients with a history of foot ulcers had significant higher average scores on the DFSBS than DM patients without such history. Based on known group validity, we hypothesized, that

DM patients with a history of wounds and/or amputations score significantly higher on the DFSBS-D than DM patients without a history of foot ulcers and/or amputations.

*Table 2: Examples of items (in German and English) with expected high correlation (Spearmen correlation coefficients of 0.5 or higher)*

| Language | DFSBS-D: item 1 | SDSCA-G: item 9 | FCFSP: item 1 |
|---|---|---|---|
| **German** | Ich untersuche (mein/e Pfleger/in untersucht) meine Fußsohlen. | An wie vielen der letzten SIEBEN TAGE haben Sie Ihre Füße untersucht? | Ich schaue meine Füße täglich genau an. |
| **English** | I (my caregiver) examine the bottoms of my feet..... | On how many of the last SEVEN DAYS did you check your feet? | I take a close look at my feet every day. ▸ |
| **Language** | **DFSBS-D: item 6** | **SDSCA-G: item 10** | **FCFSP: item 15** |
| **German** | Bevor ich meine Schuhe anziehe, überprüfe ich (überprüft mein/e Pfleger/in) die Innen-seite der Schuhe. | An wie vielen der letzten SIEBEN TAGE haben Sie die Innenseite Ihrer Schuhe kontrolliert? | Ich taste vor dem Anziehen der Schuhe die Schuhinnenseiten ab. |
| **English** | Before I put on my shoes, I (my caregiver) check the inside of the shoes. | On how many of the last SEVEN DAYS did you inspect the inside of your shoes? | Before putting on my shoes, I feel the inside of the shoe. ▸▸ |

*▸unofficial translation of the German FCFSP for comprehension purposes; ▸▸translated by Schmidt et al. (2008)*
*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale; FCFSP, Frankfurter Catalogue of Foot Self-Care-Prevention of the Diabetic Foot Syndrome; SDSCA-G, German version of the Summary of Diabetes Self-Care Activities Measures*

### 3.5.2 Reliability

For the analysis of measurement error, SEM was calculated with the following formula, using the pooled SD of the total scores of the DFSBS-D: $SEM = SD\sqrt{1-ICC}$ (De Vet et al. 2018, p. 112). Minimal detectable change was calculated on individual level ($MDC_{ind}$): $MDC_{ind} = 1.96 * \sqrt{2} * SEM$. Calculation of MDC on group level ($MDC_{group}$) was done by dividing the $MDC_{ind}$ with $\sqrt{n}$ (Beaton et al. 2000). Bland and Altman analysis was used to analyze absolute agreement between the first and second administration of the DFSBS-D. The mean differences with 95% confidence interval (CI) of both administrations were calculated. Zero lying between 95% CI of the mean difference was considered to represent absolute agreement, indicating no systemic bias (Bland & Altman 1986). Limits of agreements (LOA) were defined as the mean difference $\pm 1.96 * SD_{mean\ difference}$ (Bland & Altman 1986). The LOA indicate how much scores can vary in stable patients, because not every change on an instrument is real or true but can

also be based on measurement errors (De Vet et al. 2018, p. 242). Stable patients were identified by answering the additional question of the re-test questionnaire after two weeks. Test-retest reliability was assessed by calculating two-way random-effects, absolute agreement ICCs with a 95% CI. An ICC of ≥0.7 is regarded as good test-retest reliability (Prinsen et al. 2018, De Vet et al. 2018, p. 120, Mokkink et al. 2010, Nunally and Bernstein 1994). The resulting ICCs were expected to be ≥0.7 for both subscales (Mokkink et al. 2010). In conclusion, Table 3 summarizes the predefined research hypotheses in terms of the psychometric properties.

*Table 3: Summary of predefined psychometric research hypotheses*

| | |
|---|---|
| **Research hypothesis 1:** | The DFSBS-D will show sufficient construct validity. To evaluate this, Spearman´s correlation coefficients will be calculated between the DFSBS-D, the SDSCA-G, the FCFSP, and the SF-36 subscales and/or items and compared to predefined hypotheses. |
| **Research hypothesis 2:** | The DFSBS(-D) will show high internal consistency (Cronbach's alpha is expected to be between 0.70 and 0.90) once translated and culturally adapted into German. |
| **Research hypothesis 3:** | The DFSBS-D will show good test-retest-reliability. To measure this, stable patients will be identified via a GPE and fill in the DFSBS-D again two weeks after its first completion. The resulting ICCs are expected to be ≥0.7. |

*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale; FCFSP, Frankfurter Catalogue of Foot Self-Care – Prevention of the Diabetic Foot Syndrome; GPE, Global perceived effect; SDSCA-G, German version of the Summary of Diabetes Self-Care Activities Measures; SF-36, Short Form Health Survey 36*

# 4. Results

## 4.1 Translation

While comparing the translations of T1 and T2, attention was paid to whether it could be expected that a responding patient would answer each question identically in English and German. This means whether the statements are understood in the same way and whether the two language versions are made comparably strong/weak. A direct comparison of the original and translated texts made it possible to identify any remaining problem areas in the German DFSBS version in order to obtain certainty about the validity of the translation (Appendix G-J). Table 4 shows examples of the translation of T1 and T2, aspects considered problematic and proposed solutions.

*Table 4: Examples (item 3-5) of the translation of the original English DFSBS into DFSBS-D by T1 and T2*

| DFSBS | T1 | T2 | Problem | Consensus: DFSBS-D |
|---|---|---|---|---|
| **I (my caregiver) wash between my toes...** | Ich oder mein/e Pfleger/in waschen meine Zehen-zwischen-räume. | Ich wasche (mein/e Pfleger/in wäscht) meine Füße zwischen den Zehen. | Determination of the grammatical gender and conjugation of verbs in German.<br><br>The translation of the term "interdigital space" in German.<br><br>The translation of T2 is more literal and direct than T1. Determination of appropriate verbs and nouns of the linguistic usage of the cohort. | Ich wasche (mein/e Pfleger/in wäscht) meine Zehenzwi-schenräume. |
| **I (my caregiver) dry between my toes after washing...** | Ich oder mein/e Pfleger/in trocknen nach dem Waschen meine Zehen-zwischen-räume. | Nach dem Waschen trockne ich (trocknet mein/e Pfleger/in) meine Füße zwischen den Zehen. | | Ich trockne (mein/e Pfleger/in trocknet) nach dem Waschen meine Zehen-zwischen-räume. |
| **If my skin is dry, I (my caregiver) apply moisturizing lotion to my feet.** | Wenn meine Haut trocken ist, versorgen ich oder mein/e Pfleger/in meine Füße mit Feuchtig-keitscreme. | Wenn meine Haut trocken ist, creme ich (cremt mein/e Pfleger/in) meine Füße mit einer Feuchtigkeits-lotion ein. | | Wenn meine Haut trocken ist, versorge ich (versorgt mein/e Pfleger/in) meine Füße mit einer Feuchtigkeits-creme. |

*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale; T1, bilingual assistant doctor of internal medicine; T2, German state-approved translator with no medical background*

The first draft of the DFSBS-D was tested in a convenience sample of 12 DM patients at the University Hospital for Orthopedics and Trauma Surgery Pius-Hospital for comprehensibility,

relevance, acceptability, and feasibility of the instrument. During such qualitative pilot testing, patients were invited to state what they are thinking while filling out the DFSBS-D, according to the “think aloud” method (De Vet et al. 2018, p. 58). All patients found the translated DFSBS-D to be well comprehensible and had no problems with the response categories. Thus, no changes had to be made to the initial version of the DFDBS-D.

## 4.2 Descriptive statistics

### 4.2.1 Demographic characteristics

Of the 150 invited patients, 141 (94%) returned the completed questionnaire (Figure 5; Appendix D). Five questionnaires had to be excluded from final analysis, as one patient reported suffering from prediabetes, another patient stated DM type 3, one patient requested his completed questionnaire back, and two patients reported having both feet amputated. Of the remaining 136 (91%) questionnaires, used for data analyses, 71 (52%) were collected in the inpatient department, 27 (20%) in the outpatient department of the CKQ and 38 (28%) were collected in the clinic of chiropody “Praxis am Hafen”. The mean age of all patients was 60 years (range 20-86), 61% participants were male. In total, 72% of the cohort were diagnosed with type 2 DM of which 72% depended on insulin therapy. Table 5 shows a detailed overview of patient demographics.

In total 116 patients were approached to answer the DFSBS-D a second time (Appendix E-F). The number of 116 patients resulted from consecutive recruitment to obtain the minimum number of 50 questionnaires for test-retest reliability analysis. A total of 75 (65%) patients completed the second questionnaire and returned it. Of these, 58 (77%) patients did not report any change of symptoms due to their feet in the last 2 weeks. According to the GPE, these were classified as “stable” and thus included in the test-retest reliability analysis. The participants composed as followed: 37 (64%) patients of the inpatient department, 4 (7%) of the outpatient department of the CKQ and 17 (29%) of the clinic of chiropody. The mean age of these 58 patients was 59 years (range 24-86), 66% participants were men. Thirty-two (55%) patients stated general foot problems regarding DM.

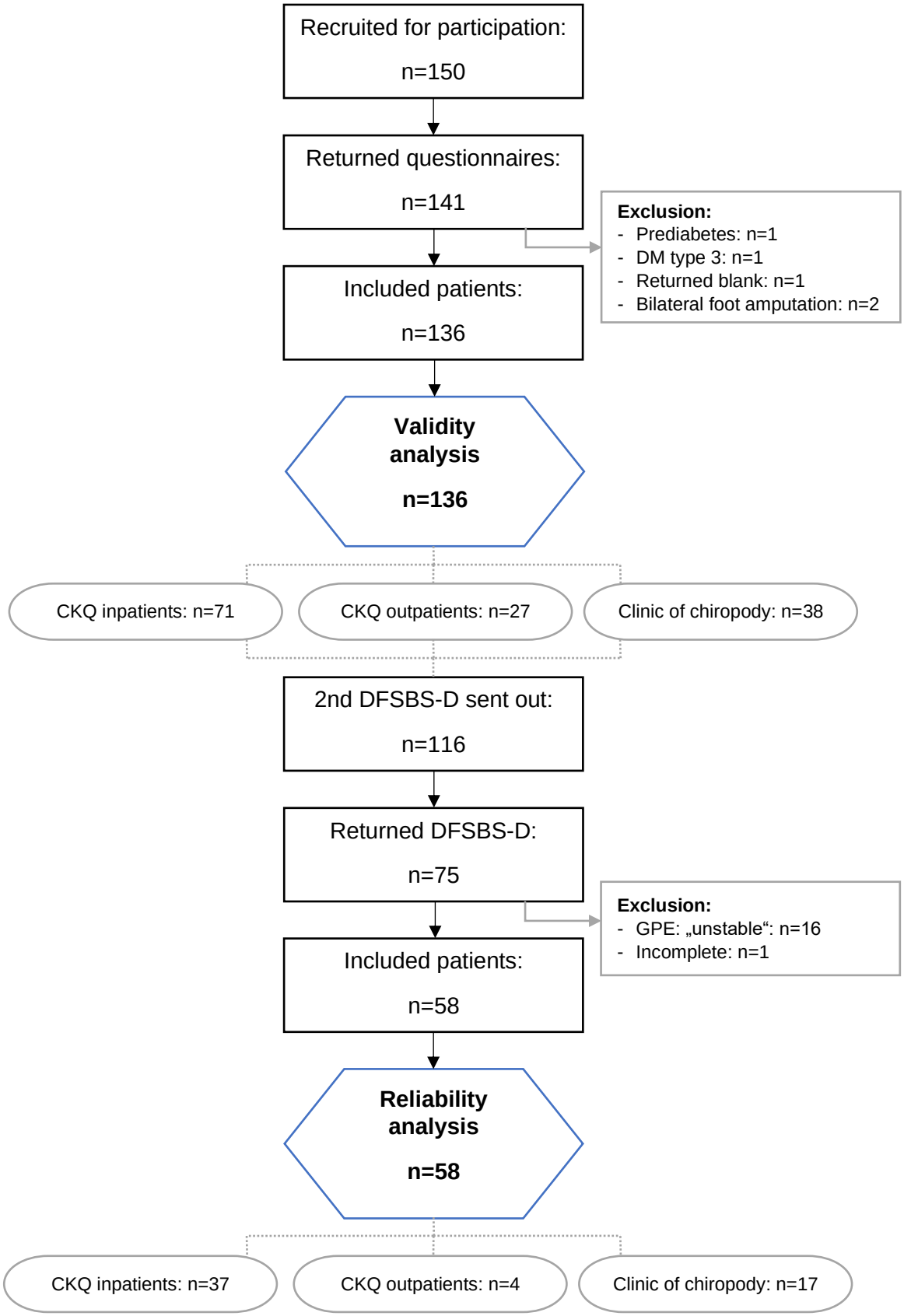


***Figure 5: Flow chart of inclusion of participants***
*Abbreviations: CKQ, Christliches Krankenhaus Quakenbrück; DM, Diabetes mellitus; DFSBS-D, German version of the Diabetes Foot Self-Care Behavior Scale; GPE, Global perceived effect; n, number of patients*

*Table 5: Demographic characteristics*

| Characteristic | Value[▸] |
|---|---|
| Mean age [years] (n=136) [▸▸] | 60 ±14 (20-86) |
| Sex (n=136) | |
| Male | 83 (61%) |
| Female | 53 (39%) |
| Mean BMI [kg/m$^2$] (n=136) [▸▸] | 30.8 ±6.6 (15.8-56.8) |
| Living arrangements (n=136) | |
| Alone | 38 (28%) |
| With partner, and/or children | 93 (68%) |
| Other | 5 (4%) |
| Educational level (n=136) | |
| Elementary school | 60 (44%) |
| Secondary school | 55 (40%) |
| Higher education | 21 (15%) |
| Type of DM (n=135) | |
| Type 1 | 38 (28%) |
| Type 2 | 97 (72%) |
| Mean number of years diagnosed with DM (n=134) [▸▸] | 17.2 ±11.3 (0-44) |
| <10 years | 40 (30%) |
| >10 years | 94 (70%) |
| Insulin depended DM (n=136) | |
| Yes | 108 (79%) |
| No | 28 (21%) |
| Foot problems regarding DM (n=136) | |
| Yes | 83 (61%) |
| No | 53 (39%) |
| Diabetic foot problems (n=103) [▸▸▸] | |
| Callus | 73 (71%) |
| Ulcers | 5 (5%) |
| Wounds | 52 (51%) |
| Pain | 43 (42%) |
| Amputations | 15 (15%) |
| Other | 38 (37%) |

*[▸]Values are n (%) unless otherwise specified. [▸▸]Mean ± SD (range), [▸▸] multiple answers possible*
*Abbreviations: BMI, body mass index; DM, Diabetes mellitus; n, number of patients; SD, standard deviation*

Of 136 patients, 83 (61%) answered the following question in the affirmative: "Do you now have, or have you had foot problems in the past due to diabetes?". Regarding known-group validity (Chapter 4.3.3), Table 6 describes a detailed differentiation of patients with or without DM related foot problems. Statistically significant differences of these two groups were found regarding age, type of DM and specific DM foot complaints: patients stating foot problems were significantly older, suffered more often of type 2 DM and foot complications like wounds and amputations (Table 6).

*Table 6: Demographic differences within patients with or without foot problems*

| Characteristic | Value* | | *p*-value |
|---|---|---|---|
| | **Foot problems** (n=83) | **No foot problems** (n=53) | |
| Mean age [years] ** | 62 ±13 (30-85) | 55 ±16 (20-86) | .01 |
| Sex | | | |
| Male | 51 (61%) | 32 (60%) | .90 |
| Female | 32 (39%) | 21 (40%) | |
| Mean BMI [kg/m$^2$] ** | 31.6 ±7 (16.8-56.8) | 29.7 ±6 (15.8-49.1) | .18 |
| Living arrangements | | | |
| Alone | 23 (28%) | 15 (28%) | .10 |
| With partner, and/or children | 57 (69%) | 36 (68%) | |
| Other | 3 (4%) | 2 (4%) | |
| Educational level | | | |
| Elementary school | 38 (46%) | 22 (42%) | .67 |
| Secondary school | 34 (41%) | 21 (40%) | |
| Higher education | 11 (13%) | 10 (19%) | |
| Type of DM *** | | | |
| Type 1 | 14 (17%) | 24 (46%) | <.01 |
| Type 2 | 69 (83%) | 28 (54%) | |
| Mean number of years diagnosed with DM **, **** | 18.1 ±11.2 (0-44) | 15.8 ±11.4 (0-40) | .17 |
| <10 years | 21 (25%) | 19 (37%) | .14 |
| >10 years | 62 (75%) | 32 (63%) | |
| Insulin depended DM | | | |
| Yes | 66 (80%) | 42 (79%) | .97 |
| No | 17 (20%) | 11 (21%) | |
| Diabetic foot problems ***** | | | |
| Callus | 56 (29%) | 17 (55%) | .12 |
| Ulcers | 5 (3%) | 0 (0%) | .26 |
| Wounds | 47 (24%) | 5 (16%) | .01 |
| Pain | 37 (19%) | 6 (19%) | .28 |
| Amputations | 15 (8%) | 0 (0%) | .04 |
| Other | 35 (18%) | 3 (10%) | .05 |

**Values are n(%) unless otherwise specified; **Mean ±SD (range); ***n(no foot problems)=52; ****n(no foot problems)=51, *****n(no foot problems)=20, multiple answers possible;*
*Abbreviations: BMI, body mass index; DM, Diabetes mellitus; n, number of patients; SD, standard deviation*

### 4.2.2 Instrument characteristics

The total DFSBS-D score was 23.0 (±7.2) out of 35. The best mean value was scored by the item asking about *washing between the toes* with 3.7 (±1.4). Based on the mean values, it can be stated that most patients do not *check the inside of the shoes before putting them on* (2.7 (±1.5). An overview of the scores of the relevant scales and subscales is shown in Table 7.

*Table 7: Instrument characteristics*

| Scale | Subscale | Value* | SD | Min. | Max. | n |
|---|---|---|---|---|---|---|
| **DFSBS-D** | | 23.0 | 7.2 | 7 | 35 | 136 |
| **SDSCA-G** | exercise | 2.8 | 2.0 | 0 | 7 | 136 |
| | blood sugar | 5.3 | 2.5 | 0 | 7 | 136 |
| | foot-care | 3.2 | 2.4 | 0 | 7 | 136 |
| **FCFSP** | self-control of the feet | 22.3 | 9.1 | 0 | 36 | 133 |
| | professional assistance in foot-care | 15.1 | 6.8 | 0 | 20 | 134 |
| | self-control of shoes and socks | 12.1 | 5.1 | 0 | 20 | 135 |
| **SF-36** | PF | 55.8 | 32.3 | 0 | 100 | 136 |
| | RP | 45.6 | 43.8 | 0 | 100 | 136 |
| | BP | 58.1 | 31.3 | 0 | 100 | 136 |
| | GH | 48.5 | 20.2 | 0 | 95 | 136 |
| | VT | 49.7 | 21.5 | 0 | 100 | 136 |
| | SF | 69.9 | 28.1 | 0 | 100 | 136 |
| | RE | 67.4 | 41.5 | 0 | 100 | 136 |
| | MH | 66.9 | 19.4 | 8 | 100 | 136 |

**values are mean or sum scores*
*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale; FCFSP, Frankfurter Catalogue of Foot Self-Care-Prevention of the Diabetic Foot Syndrome; Max., maximal score; Min., minimal score; n=number of patients; SD, standard deviation; SDSCA-G, German version of the Summary of Diabetes Self-Care Activities Measures; SF-36, Short Form Health Survey 36 (PF, physical functioning; RP, role physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role emotional; MH, mental health)*

The Mann-Whitney-U test was used to investigate differences in the scores of the total DFSBS-D and the subscales of the SDSCA, FCFSP and SF-36, considering subgrouping of the cohort. In case of more than 2 categorical variables, ANOVA was used to test whether mean values of the subgroups differ. The subgroups were based on the following characterizations: sex, living arrangements, level of education, type of DM, insulin dependency, number of years diagnosed with DM and recruitment site.

A significant difference in the total scores of the DFSBS-D was found within the recruitment sites and is shown in Figure 6: inpatients of the CKQ scored significantly lower (mean=21.2 ±7.1 (7-35), $p$=.004) than outpatients (mean=26.3 ±5.9 (16-35)) and patients of the clinic of chiropody (mean=24.1 ±7.5 (7-35)). Further significant differences within the three recruitment sites are shown in Table 8. Population and DM related characteristics had no significant influence on the total score of the DFSBS-D.

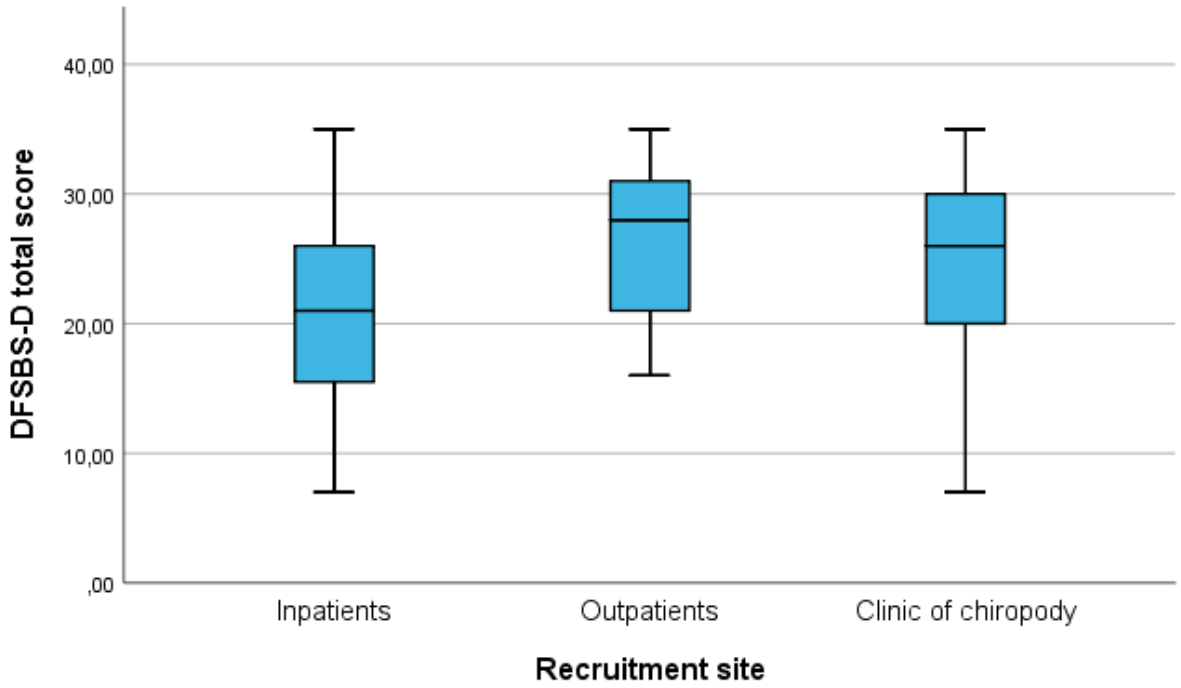


***Figure 6: Boxplot of the DFSBS-D total score within patients of different recruitment sites;*** *representation of the median (midline), the 25% quartile (lower bound of the box) and 75% quartile (upper limit of the box). The largest or smallest value is indicated by the T-line. Abbreviation: DFSBS-D, German version of the Diabetes Foot Self-Care Behavior Scale*

With a *p*-value of .027, the difference of scores of the FCFSP subscale *self-control of the feet* is significant within the educational level of the patients: patients with the highest educational level scored less (mean=18.1 ±7.8 (0-36)) than patients with lower levels of education, like secondary school (mean=22.0 ±8.6 (7-36)) and primary school (mean=24.2 ±9.5 (0-30)). Patients with type 1 DM scored significantly higher on the subscale *blood sugar* of the SDSCA-G (mean=6.2 ±1.9 (0-7), *p*=.004), than patients suffering of type 2 DM (mean=5.0 ±2.6 (0-7)). They also scored significantly higher on the subscale *PF* (mean=69.5 ±31.7 (0-100) versus 50.3 ±31.3, *p*=.001) and subscale *RP* (mean=57.9 ±41.1 (0-100) versus mean=40.2 ±43.8, *p*=.031) of the SF-36. Type 1 DM patients scored significantly lower on the FCFSP subscale *professional assistance in foot-care* (mean=12.5 ±7.9 (0-20) versus mean=16.0 ±6.1, *p*=.013). Patients who are dependent on insulin for their therapy also achieved higher values in the SDSCA-G subscale *blood sugar* (mean=5.9 ±2.0 versus 3.0 ±2.7 (0-7), *p*≤.001). This is also reflected within the subgroup of type 2 DM patients: insulin dependent patients scored significantly higher (mean=5.8 ±2.1 versus 3.0 ±2.7 (0-7), *p*≤.001) within the SDSCA-G subscale *blood sugar*. No further significant differences between the above-mentioned subgroups were found.

*Table 8: Significant differences in instrument characteristics within the different recruitment sites*

| Scale | Subscale | Values* of recruitment site | | | *p*-value |
|---|---|---|---|---|---|
| | | **Inpatients** n=71 | **Outpatients** n=27 | **Clinic of chiropody** n=38 | |
| **DFSBS-D** | | 21.2 ±7.1 | 26.3 ±7.1 | 24.1 ±7.5 | ≤.01 |
| **SDSCA-G** | foot-care | 2.9 ±2.3 | 4.9 ±2.2 | 2.7 ±2.0 | ≤.01 |
| **FCFSP** | self-control of the feet** | 19.7 ±9.4 | 26.3 ±6.8 | 24.4 ±8.4 | ≤.01 |
| | professional assistance in foot-care*** | 12.2 ±7.9 | 17.4 ±4.7 | 18.8 ±1.9 | ≤.01 |
| | self-control of shoes and socks**** | 10.8 ±5.2 | 13.9 ±5.1 | 13.3 ±3.9 | ≤.01 |
| **SF-36** | PF | 62.9 ±34.9 | 33.0 ±26.5 | 58.7 ±23.2 | ≤.01 |
| | RP | 52.8 ±44.2 | 26.9 ±38.6 | 45.4 ±43.4 | .03 |

**values are mean or sum scores ± SD; **n(inpatients)=69, n(clinic of chiropody)=37;*
**** n(inpatients)=70, n(clinic of chiropody)=37; ****n(clinic of chiropody)=37;*
*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale; FCFSP, Frankfurter Catalogue of Foot Self-Care – Prevention of the Diabetic Foot Syndrome; n, number of patients; SD, standard deviation; SDSCA-G, German version of the Summary of Diabetes Self-Care Activities Measures; Short Form Health Survey 36 (PF, physical functioning; RP, role physical)*

## 4.3 Validity

### 4.3.1 Structural validity

A factor analysis was conducted on the seven items. Kaiser-Meyer-Olkin measure (KMO = 0.76) verified sample adequacy. The total number of factors was based on the initial eigenvalues. Principal component analysis showed two factors with initial eigenvalues greater than 1.0, explaining a cumulative percentage of 69.9% of total variance (Table 9). The scree plot (Figure 7) showed two factors above the bending point. Varimax rotation confirmed the division of the DFSBS-D into two factors. According to the factor loadings, the first factor represents the first part of the DFSBS-D (first four items, alpha=0.88) and factor two represents part two of the scale (last three items, alpha=0.66). Item factor loadings ranged from -0.08 to 0.86. Factor loadings after varimax rotation are shown in Table 9.

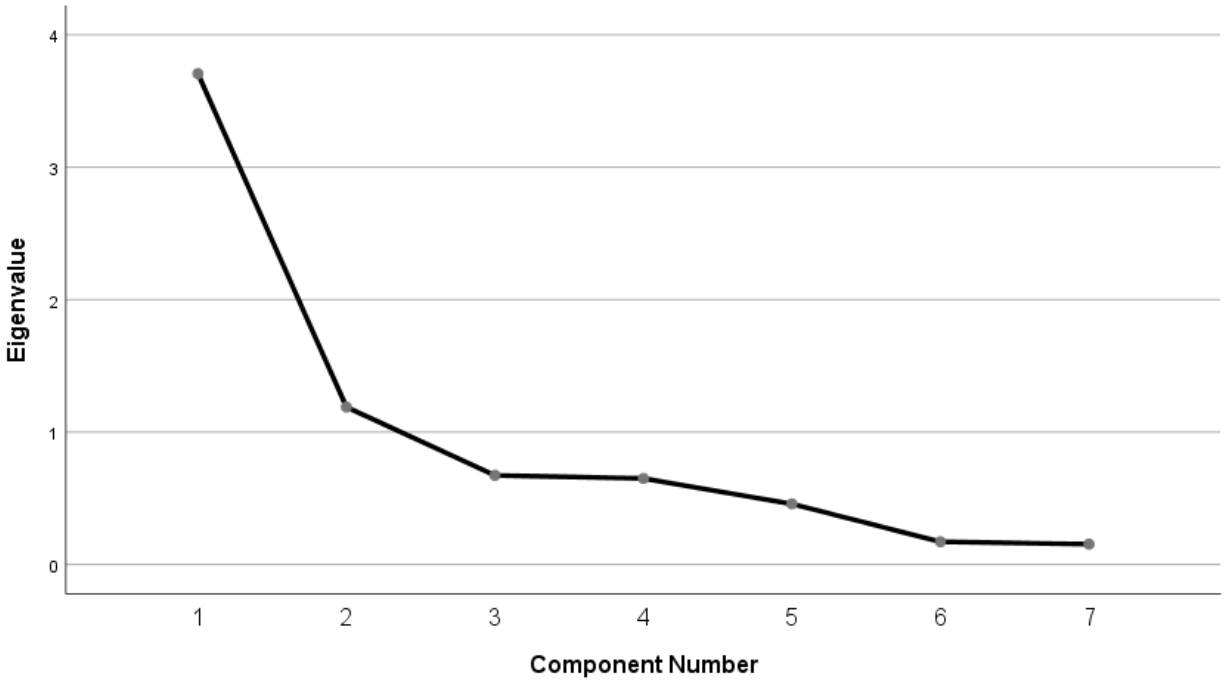


*Figure 7: Scree plot of the German version of the Diabetes Foot Self-Care Behavior Scale*

*Table 9: Factor loadings of the DFSBS-D (n=136) and explained variances of factors and items; total variance explained: 69.94%; extraction method: main component analysis, values after Varimax with imperial normalization;*

| Item | | Rotated factor loadings | | Communalities |
|---|---|---|---|---|
| | | I | II | |
| **1.** | I (my caregiver) examine the bottoms of my feet. | **0.81** | 0.24 | 0.71 |
| **2.** | I (my caregiver) examine between the toes of my feet. | **0.84** | 0.20 | 0.75 |
| **3.** | I (my caregiver) wash between my toes. | **0.86** | 0.10 | 0.75 |
| **4.** | I (my caregiver) dry between my toes after washing. | **0.84** | 0.16 | 0.74 |
| **5.** | If my skin is dry, I (my caregiver) apply moisturizing lotion to my feet. | 0.40 | **0.65** | 0.58 |
| **6.** | Before I put on my shoes, I (my caregiver) check the inside of the shoes. | 0.39 | **0.71** | 0.66 |
| **7.** | I break in new shoes slowly. | -0.08 | **0.83** | 0.70 |
| Eigenvalues (>1.0)<br>(% of variance explained) | | 3.14<br>(44.8) | 1.76<br>(25.1) | 4.89 |

*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale*

### 4.3.2 Hypotheses testing

Thirteen (62%) out of 21 predefined hypotheses were confirmed. Spearman correlation coefficients showed correlations ranging from 0.50-0.76 between (items of) the DFSBS-D and items/subscale about *foot-care* of the SDSCA-G. Correlations between items of the DFSBS-D and (items of) FCFSP subscales were lower than hypothesized. The DFSBS-D and the SF-36 subscales showed low correlations, as expected. The correlation between the DFSBS-D and the FCFSP subscale *self-control of the feet* was $r_s$= 0.65 which was higher than the correlation between the DFSBS-D and FCFSP subscale *self-control of shoes and socks*, confirming hypothesis 21. All calculated correlations between the DFSBS-D and other scales are shown in Table 10.

*Table 10: Predefined hypotheses with expected correlation and true correlation (Spearman correlation coefficients)*

| Scales, subscales and items compared | | Correlation | | Confirmation of hypothesis | p-value |
|---|---|---|---|---|---|
| | | Expected | True | | |
| **1** | DFSBS-D and SDSCA-G subscale foot-care‣ | >0.70 | **0.71** | Yes | ≤.01 |
| **2** | DFSBS-D item 1 and SDSCA-G item 9 | >0.70 | **0.62** | No | ≤.01 |
| **3** | DFSBS-D item 2 and SDSCA-G item 9 | >0.70 | **0.50** | No | ≤.01 |
| **4** | DFSBS-D item 6 and SDSCA-G item 10 | >0.70 | **0.76** | Yes | ≤.01 |
| **5** | DFSBS-D and FCFSP subscale self-control of the feet‣‣ | >0.50 | **0.65** | Yes | ≤.01 |
| **6** | DFSBS-D and FCFSP subscale self-control of shoes and socks‣‣‣ | >0.50 | **0.57** | Yes | ≤.01 |
| **7** | DFSBS-D item 1 and FCFSP subscale self-control of the feet‣‣ | >0.70 | **0.46** | No | ≤.01 |
| **8** | DFSBS-D item 2 and FCFSP subscale self-control of the feet‣‣ | >0.70 | **0.43** | No | ≤.01 |
| **9** | DFSBS-D item 6 and FCFSP subscale self-control of shoes and socks‣‣‣ | >0.70 | **0.59** | No | ≤.01 |
| **10** | DFSBS-D item 1 and FCFSP item 1 | >0.90 | **0.47** | No | ≤.01 |
| **11** | DFSBS-D item 2 and FCFSP item 7 | >0.90 | **0.43** | No | ≤.01 |
| **12** | DFSBS-D item 6 and FCFSP item 15 | >0.90 | **0.77** | No | ≤.01 |
| **13** | DFSBS-D and SF-36 subscale PF | <0.26 | **-0.25** | Yes | ≤.01 |
| **14** | DFSBS-D and SF-36 subscale RP | <0.26 | **-0.14** | Yes | .10 |
| **15** | DFSBS-D and SF-36 subscale BP | <0.26 | **-0.09** | Yes | .28 |
| **16** | DFSBS-D and SF-36 subscale GH | <0.26 | **-0.13** | Yes | .13 |
| **17** | DFSBS-D and SF-36 subscale VT | <0.26 | **-0.09** | Yes | .28 |
| **18** | DFSBS-D and SF-36 subscale SF | <0.26 | **-0.06** | Yes | .49 |
| **19** | DFSBS-D and SF-36 subscale RE | <0.26 | **-0.12** | Yes | .16 |
| **20** | DFSBS-D and SF-36 subscale MH | <0.26 | **0.00** | Yes | .97 |
| **21** | The DFSBS-D is expected to correlate higher with FCFSP subscale self-control than FCFSP subscale shoes | | | Yes | |

*‣ SDSCA-G subscale foot-care = SDSCA-G item 9+10;*
*‣‣ FCFSP subscale self-control of the feet = FCFSP item 1-9;*
*‣‣‣ FCFSP subscale self-control of shoes and socks = FCFSP item 15-19;*
*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale; FCFSP, Frankfurter Catalogue of Foot Self-Care – Prevention of the Diabetic Foot Syndrome; SD, standard deviation; SDSCA-G, German version of the Summary of Diabetes Self-Care Activities Measures; SF-36, Short Form Health Survey 36 (PF, physical functioning; RP, role physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role emotional; MH, mental health)*

### 4.3.3 Known-group validity

To assess known-group validity, the Mann-Whitney-U test was used to investigate if there is a significant difference in the DFSBS-D total score between patients who reported general foot problems regarding DM and those who did not. The mean difference of both groups was 4.9 ($p$<.001). Patients stating to have foot problems due to DM had significant higher DFSBS-D mean scores (24.9 ±6.7, n=83) than patients without such complaints (20.0 ±7.1, n=53) (Figure 8). Further significant differences within these two groups are shown in Table 11.

Further analysis was done to determine if patients with ulcers, wounds and/or amputations had higher average scores of the DFSBS-D than patients without ulcers, wounds and/or amputations. The mean difference of both groups was 0.8 (p>0.05). Patients with a history of ulcers, wounds and/or amputations (mean=24.6 ±6.5, n=53) had no significant higher average scores than patients without such a history (mean=23.7 ±7.7, n=50) (Figure 9).

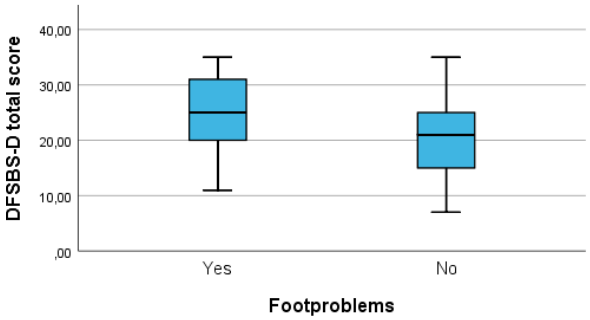


***Figure 8: Boxplot of DFSBS-D total score by patients stating foot problems regarding DM;*** *representation of the median (midline), the 25% quartile (lower bound of the box) and 75% quartile (upper limit of the box). The largest or smallest value is indicated by the T-line.*

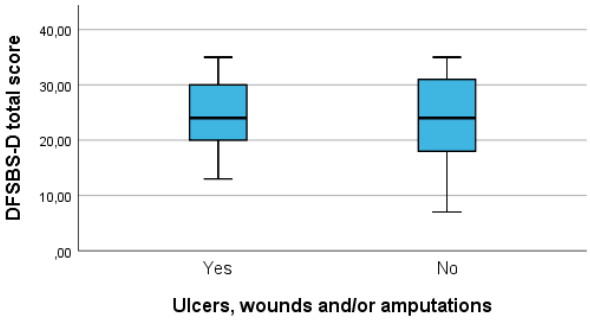


***Figure 9: Boxplot of DFSBS-D total score by patients stating ulcers, wounds and/or amputations;*** *representation of the median (midline), the 25% quartile (lower bound of the box) and 75% quartile (upper limit of the box). The largest or smallest value is indicated by the T-line.*

*Table 11: Significant differences in instrument characteristics within patients with or without foot problems*

| Scale | Subscale | Values* | | *p*-value |
|---|---|---|---|---|
| | | Foot problems n = 83 | No foot problems n = 53 | |
| **DFSBS-D** | | 24.9 ±6.7 | 20.0 ±7.1 | ≤.001 |
| **SDSCA-G** | foot-care | 3.7 ±2.4 | 2.5 ±2.2 | .003 |
| **FCFSP** | professional assistance in foot-care** | 16.8 ±5.4 | 12.5 ±7.9 | .007 |
| | self-control of shoes and socks*** | 13.4 ±4.7 | 10.1 ±4.9 | ≤.001 |
| **SF-36** | PF | 44.9 ±28.9 | 72.7 ±30.3 | ≤.001 |
| | RP | 31.9 ±40.6 | 67.0 ±40.1 | ≤.001 |
| | GH | 43.8 ±19.3 | 55.8 ±19.6 | ≤.001 |
| | VT | 44.7 ±21.1 | 57.6 ±19.9 | .001 |
| | SF | 63.7 ±28.9 | 79.5 ±23.9 | .001 |

**values are mean or sum scores ± SD; **n(foot problems)=81; ***n(no foot problems)=52;*
*Abbreviations: DFSBS-D, German version of the Diabetic Foot Self-care Behavior Scale; FCFSP, Frankfurter Catalogue of Foot Self-Care – Prevention of the Diabetic Foot Syndrome; SD, standard deviation; SDSCA-G, German version of the Summary of Diabetes Self-Care Activities Measures; Short Form Health Survey 36 (PF, physical functioning; RP, role physical; GH, general health; VT, vitality; SF, social functioning;)*

## 4.4 Reliability

Cronbach's alpha of the DFSBS-D was 0.84 (95% CI: 0.80-0.88, n=135) indicating good internal consistency. Cronbach's alpha's of part one and two of the scale were 0.89 and 0.67, respectively. Test-retest measures are shown in Table 12. The ICC of the DFSBS-D over a two-week time interval was 0.73 (95% CI: 0.57-0.84), indicating acceptable reliability. Bland and Altman analysis showed that zero was lying outside the 95% CI of the mean difference of both administrations (Figure 10), indicating systematic bias.

***Table 12: Reliability measures of the DFSBS-D (n=58)***

| Measure | Value |
|---|---|
| First administration mean (±SD) | 22.07 (±7.21) |
| Second administration mean (±SD) | 23.84 (±6.75) |
| Mean difference (95% CI) | 1.78 (0.48, 3.07) |
| ICC (95% CI) | 0.73 (0.57, 0.84) |
| SEM | 2.54 |
| $MDC_{ind}$ | 7.04 |
| $MDC_{group}$ | 0.92 |

*Abbreviations: CI, confidence interval; ICC, intraclass correlation coefficient; MDC, minimal detectable change; SD, standard deviation; SEM, standard error of measurement*

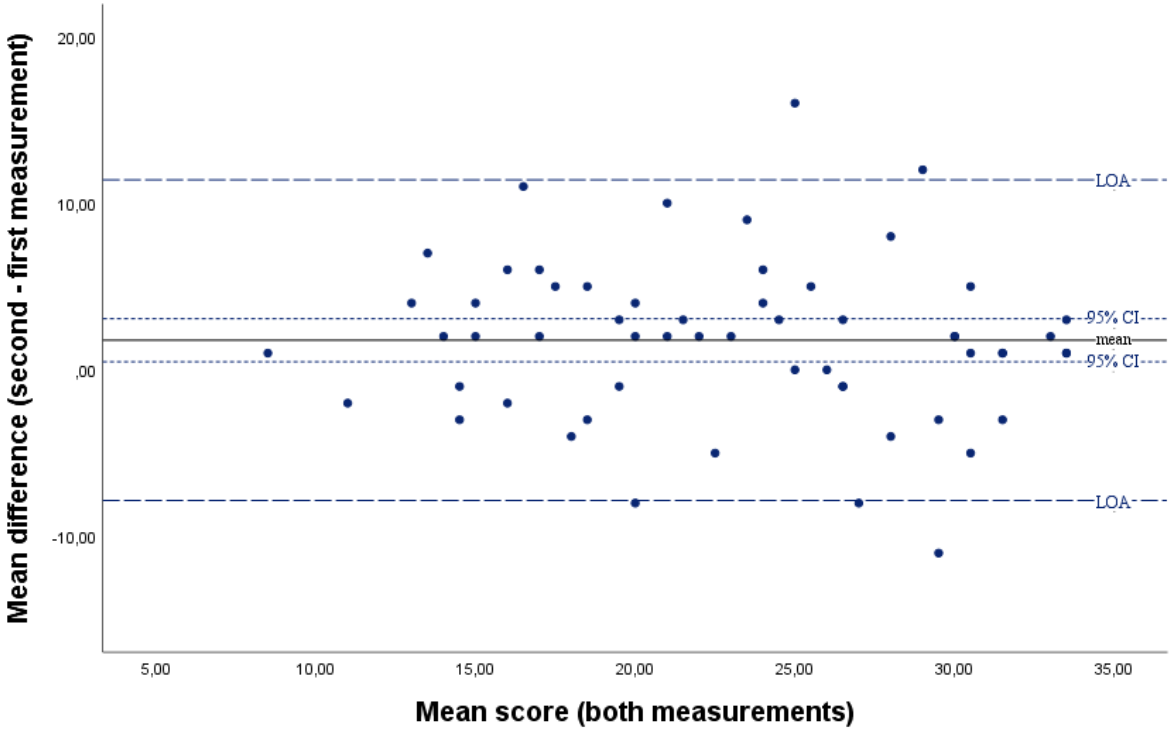


***Figure 10: Bland and Altman plot visualizing absolute agreement;*** *Abbreviations: CI, confidence interval; LOA, limits of agreement*

# 5. Discussion

The aim of this study was to translate and culturally adapt the DFSBS into German (DFSBS-D). Psychometric properties of the DFSBS-D were assessed in terms of validity and reliability to consistently investigate foot self-care behavior in German-speaking patients with DM type 1 and 2 in the future. The results indicate moderate validity and good reliability: the DFSBS-D can be considered as an instrument with good structural validity, internal consistency and test-retest reliability. However, construct validity appears to be questionable. The DFSBS is available in Chinese and English by Chin and Huang (2013). The scale has only been used in validation study of the developers and therefore, all results found in the present study regarding the DFSBS-D are compared with the results of the original DFSBS.

In the following, the results are discussed first, since the subject of this study was the testing of validity and reliability of the DFSBS-D. In the second part, the methods of this study are discussed.

## 5.1 Discussion of results

In general, one strength of this study was the small amount of missing data. Once the patients submitted the completed questionnaire, it was checked for completeness. If there were items unanswered, the patient was asked to take his/her time and answer them.

### 5.1.1 Descriptive analysis

In the present study, a significant difference in age and type of DM was found regarding DM related foot problems. Patients stating foot problems were significantly older and suffered more often of type 2 DM. This is consistent with the results of Bohn et al. (2018) and Lauterbach et al. (2010): DM patients with DFS are older, more often male and have a longer DM duration compared to DM patients without DFS (Bohn et al. 2018). In addition, the prevalence of DFS within type 2 DM patients is higher compared to type 1 DM patients (Bohn et al. 2018, Lauterbach et al. 2010). However, in this study, if patients with ulcers, wounds and/or amputations were grouped together, a significant difference in gender and not in age was seen. These results, regarding age and gender, are consistent with Nongmaithem et al. (2016) and Al Kafrawy (2014). The latter compared 50 DM patients with foot ulcers to 200 patients without foot ulcers and found a significant difference in gender: male DM patients suffered more frequently from foot ulcers (Nongmaithem et al. 2016, Frykberg et al. 1998). However, they found no significant difference in age. In the present study, as mentioned before, no detailed analysis of the feet of the DM patients was aimed, as the study focuses primarily on the psychometric testing of the DFSBS-D. Therefore, and because of the limited sample size, it is not useful to further differentiate within the group of DM patients with foot problems whether patients have risk factors for ulcer development or whether patients have an already existing

DFS (see known-group validity, Chapter 4.3.3). Nevertheless, the risk factors should be identified: Lauterbach et al. (2010) made aware, that the prevalence of risk factors, which often lead to the development of DFS, is considerably higher than the prevalence of DFS itself. If relevant risk factors are diagnosed at an early stage, preventive measures such as podological treatment and adequate shoe care must be adapted, implemented and monitored (Lauterbach et al. 2010). This once again underlines the importance of an instrument on foot self-care behaviors in DM patients.

Diabetes mellitus patients stating foot problems regarding DM had significant lower average scores on the subscales *PF*, *RP*, *GH*, *VT* and *SF* than patients without such complaints (Table 11). These results of the present study confirm the previous assumptions. In general, the quality of life of DM patients, particularly regarding physical and psychological functions, is lower compared to general population (Almeida et al. 2013, Matthaei et al. 2013, Garcia-Morales et al. 2011, Naess et al. 2004,). Several studies compared the quality of life of DM patients with foot ulcers to that of DM patients without foot ulcers (Almeida et al. 2013, Garcia-Morales et al. 2011, Nabuurs-Franssen 2005, Valensi 2005, Meijer 2001). Diabetes mellitus patients with foot ulcers scored significantly lower across all SF-36 domains (Acker 2014, Almeida et al. 2013, Garcia-Morales et al. 2011). Peter-Riesch (2016) explained the decline in quality of life due to loss of working time and social activities, which leads to social isolation, loneliness and depression (Peter-Riesch 2016, Acker 2014). Nevertheless, small amputations are reported to improve the quality of life (Peter-Riesch 2016, Ragnarson Tennvall & Apelqvist 2000). The extent to which amputations influenced the quality of life of DM patients in the present study cannot be reported due to the small sample of patients with amputations.

In conclusion, the demographic data for the DM patient cohort presented here coincide with studies already published and can therefore be regarded as representative. However, it needs to be discussed why a significant difference in the total scores of the DFSBS-D was found within the recruitment sites (Figure 6, Table 8). Outpatients and patients of the clinic of chiropody scored approximately equal on the DFSBS-D. Compared to inpatients, those subgroups scored significantly better. It can therefore be assumed that these patients perform more frequent foot self-care, or have it performed by their caregivers. In addition, DM patients who regularly go to chiropody may have already had DFS complications in the past and have their feet examined and managed regularly as prevention of recurrence. Outpatients, on the other hand, are currently suffering of foot complications and must therefore be regularly examined, managed and cared for their existing ulcer(s) and/or wound(s). Furthermore, DM patients in the clinic of chiropody and outpatient department are advised during each consultation to do adequate foot self-care and look at their feet regularly, so no (further) ulcers and/or wounds occur. In conclusion, the direct and subjective concern with DM related foot problems and the active and passive knowledge transfer during consultations in the outpatient

department and in the clinic of chiropody could be the reason why these two groups were roughly equal and significantly better than inpatients in the DFSBS-D. In addition, most type 1 DM patients (65%) were recruited as inpatients. As already mentioned, the prevalence of DFS is lower in type 1 DM patients. Moreover, type 1 DM patients were on average younger than type 2 DM patients. Younger type 1 DM patients may be less confronted with late complications of DM, such as PNP and angiopathy, and therefore are less attentive about foot self-care in everyday life. This may have led to a distortion of the representativeness of the DFSBS-D data.

In general, the analysis must consider which patient types are regularly treated at the clinic of chiropody. For a more detailed description of this point of discussion, please see chapter 5.2. In Germany, the indication for the recommendation of a podological complex management for DM patients consists in the case of persisting pressure points and/or foot deformities and/or ulcer anamnesis in connection with a sensory neuropathy and/or a POAD as well as in the case of pronounced visual impairment or blindness and/or physical disability, which makes self-treatment impossible and/or other criteria leading to an increase risk (Bundesärztekammer et al. 2010). Therefore, a certain selection bias must be assumed, since both, the feet of the outpatients and those of the patients of the clinic of chiropody are regularly inspected and managed by qualified medical personnel. In this study, this bias was attempted to counteract by the fact that the combined proportion of these outpatients is approximately the same as the proportion of inpatients (see Figure 5, Chapter 4.2.1). Furthermore, the DM patients were recruited in an unselected order and thus further counteracted this bias: patient recruitment took place in a consecutive manner and was not influenced by the interviewers, as all patients were informed about this study during the recruitment period.

### 5.1.2 Translation and cultural adaptation

Following the previous pilot study of this study, no major challenges were identified in translating and adapting the English DFSBS into German and content validity was assured. This maintenance of equivalency of content between original and translated instrument was tried by the process of cross-cultural adaptation (Beaton et al. 2000). Researchers should, however, be particularly aware of item-level translations according to Herdmann et al. (1998) (Beaton et al. 2000). It is often assumed, that the translated item is a conclusive reflection of health in another culture (Beaton et al. 2000). Regarding questions about footwear of the DFSBS, which are discussed in detail in the lower section, there are also cultural differences, which must be considered: according to Neil (2002), DM patients living in (sub-) tropical regions seldom wear socks and shoes during summer months. Chin and Huang (2013) recruited the patients from two hospitals in northern Taiwan. Taiwan's climate is subtropical in the north and tropical in the south (Wetter-Altas 2019). In contrast, Germany is a temperate climate zone (Wetter-Altas 2019). These external factors are examples which must be considered regarding

the applicability of the DFSBS(-D). As an additional example, Chin and Huang (2013) also discussed patients wearing sandals or slippers outside and are barefoot at home as fungus infection prevention strategy. Fungal infections are more common in temperate climates (Gupta et al. 2018). In addition, DM patients are more susceptible to fungal infections and to following secondary infection complications than non-DM patients (Gupta et al. 2018, Oz et al. 2017). However, preventing fungal infection by wearing sandals and walking barefoot is counterproductive as these are risk factors for foot ulcers (see Chapter 2.2.2; Riddle et al. 2019, Lawall 2018, Morbach et al. 2017, Bundesärztekammer et al. 2010). Furthermore, unsuitable footwear increases the risk of trauma to the nail plate and thus also the risk of a fungal infection (Gupta et al. 2018). This point again shows the importance of early selection of high-risk DM patients with a valid and reliable instrument and the education and training of DM patients.

Retention of validity and reliability of an instrument is also not ensured after translation: if the new culture approaches a DM self-care activity differently, changes in validity, particularly at item and scale level are certain (Beaton et al. 2000). For example, regarding the fourth item *(drying between the toes after washing)* of the DFSBS, it is difficult to assess whether it is culturally influenced to dry the feet after washing with a hairdryer, as one patient indicated in this survey, as currently no studies are available on this topic. This item of the DFSBS is discussed in detail in chapter 5.2.4.

In general, a point of criticism could be the lack of consideration of the culturally different significance of health, functionality and quality of life in DM patients (Bullinger & Schmidt 2008). For example, the risk of DFS is generally increased within certain ethnicities: Europeans are at higher risk than Indians, Asians and Africans (Peter-Riesch 2016). According to Peter-Riesch (2016), this might be explained by better foot care in the religious traditions of these ethnicities. Furthermore, amputation rates correlate with health beliefs and cultural habits (Peter-Riesch 2016). Geographical disparities in resources must also be considered (Peter-Riesch 2016).

### 5.1.3 Validity

Kaiser-Meyer-Olkin measure showed that the patterns of correlations for the DFSBS-D were relatively compact in terms of sampling adequacy. This means that factor analysis yields distinct and reliable factors (Field 2018, p.1021). A value of 0.73 is considered being good (Field 2018, p.1021, Kaiser & Rice 1974). The number of relevant factors within factor analysis can be decided based on several criteria, meaning (1) by retaining factors with eigenvalue larger than 1, (2) by the eigenvalues plotted against the factors in a scree plot, and (3) checking cumulative percentage of explained variance after each factor (De Vet et al. 2018, p. 75). The original DFSBS consists of seven items and was considered unidimensional by Chin and

Huang (2013). They set the number of factors to one, based on the scree plot. Based on eigenvalues, they determined two factors with eigenvalues greater than 1.0, but only one factor was above the elbow of the scree plot (Chin and Huang 2013). Finally, one factor was chosen for the DFSBS, explaining 39% of total sample variance (Chin and Huang 2013). The principal component analysis of the factor analysis of the DFSBS-D did not support the one-factor structure. Varimax rotation was additionally used and indicated the DFSBS-D can be divided in two factors. The scree plot also showed two factors above the bending point. Nevertheless, Stevens et al. (2002) recommend a sample of more than 200 subjects for the scree plot to provide a reliable criterion for extraction (Field 2018, p. 1034). Regarding the DFSBS-D, one factor explained 45%, which is higher than the DFSBS. Two factors explained a cumulative percentage of 70% of total variance. Nevertheless, the two factors of the DFSBS-D consist of only four and three items. Factors with less than 5 items are considered weak and unstable (Costello and Osborne 2005). De Vet at al. (2018, p. 77) note that the interpretation of factors in exploratory factor analysis is requiring the researchers to make subjective choices at some point. Subjectively, the division into two factors is conclusive, as part one of the DFSBS focuses specifically on the number of days foot examination, washing and drying of the feet was executed by the patient or his/her caregiver in the past week (varying from 0-7 days). Part two consists of three items asking about the frequency the patient or his/her caregiver is moisturizing the feet and how often s/he is paying attention to suitable footwear (varying from never (1) to always (5)).

Based on the COSMIN guidelines, at least 75% of the hypotheses must be confirmed for the indication of sufficient construct validity (Prinsen et al. 2018, Terwee et al. 2007). Therefore, construct validity of the DFSBS-D has to be considered questionable, since only 62% of the 21 predefined hypotheses were confirmed (see Chapter 4.3.2). Hypotheses testing was assessed by correlating the results of the DFSBS-D with other scales measuring self-care behavior in DM patients (SDSCA-G), foot self-care behavior in DM patients (FCFSP) and health status and health related quality of life (SF-36). Except the SDSCA, these questionnaires have not been used for hypotheses testing of the DFSBS before. Therefore, the predefined hypotheses of the FCFSP and the SF-36 were theoretically derived and not based on available research findings.

We found high correlation ($r_S$=0.71) between the DFSBS-D and SDSCA-G subscale *foot-care*. This met our expectations, as both measure a comparable construct. Chin and Huang (2013) also indicated high positive correlation ($r_S$=0.87) between the original DFSBS and the SDSCA subscale *foot-care*. Consequently, we conclude that, based on correlations between the DFSBS-D and SDSCA subscale *foot-care* and the consistency with previous findings in the Chinese validation study, the construct of the DFSBS-D is valid.

Based on item level, only one of three hypotheses regarding the DFSBS-D and SDSCA-G subscale *foot-care* could be confirmed: item one and two of the DFSBS-D showed only moderate correlations with the item nine of the SDSCA-G, whereas item six of the DFSBS-D correlated highly with item 10 of the SDSCA-G (Domholdt 2000). As shown in the examples in Table 2 (see Chapter 3.5.1), the items are subjectively very similar. The following aspects might be responsible for the lack of confirmation of the hypotheses on item level: item 1 of the DFSBS-D asks specifically about the examination of the soles of the feet. Item 2 explicitly asks about the examination between the toes of the patient's feet. In item 9 of the SDSCA-G, however, it is generally asked how often the patient checks his/her feet. All questions of the DFSBS are directed not only to the patient him-/herself, but also to his/her caregiver. The SDSCA-G asks only directly the patient. Regarding item 6 of DFSBS-D and item 10 of SDSCA-G, however, the hypothesis was confirmed despite the fact of asking patient and caregiver.

Correlations between the DFSBS-D and the two FCFSP subscales *self-control of the feet* and *self-control of shoes and socks* were confirmed. We expected moderate correlations between the DFSBS-D and FCFSP, since the instruments are both about foot self-care activities of DM patients. However, the correlations we found on item level between the DFSBS-D and FCFSP were weak. According to Prinsen et al. (2018), correlations between 0.30-0.50 are expected between instruments measuring related, but dissimilar constructs. The correlations we found met this criterion, except for item 6 of the DFSBS-D and subscale *self-control of shoes and socks* of the FCFSP ($r_s$=0.59) and FCFSP item 15 ($r_s$=0.77). Regarding the correlation between item 1 of DFSBS-D and item 1 of FCFSP, we expected $r_s$ >0.90. A true correlation of $r_s$=0.47 was found. One reason for this difference could be the reduced mobility of elderly patients: the DFSBS-D question focuses more on the examination of the bottom of the feet, which are difficult to see when mobility is limited. The FCFSP question is more about looking at feet in general, which some patients may only do from above. De Gabriele (2008) therefore recommend the usage of mirrors for self-examination in case of limited mobility. Furthermore, the argument, stated above, that the DFSBS-D asks not only about the examination of the patient him/herself but also of his/her caregiver applies to all items. Regarding the lack of correlation between DFSBS-D item 2 and FCFSP item 7 ($r_s$=0.43), which both ask about the examination between the toes of the feet, this could be the decisive factor.

Regarding correlation between item 6 of the DFSBS-D and item 15 of the FCFSP, we also expected $r_s$ >0.90. We had to reject this hypothesis, since the correlation was $r_s$=0.77. The reason could be in the interpretation of the different verbs in the two items: the DFSBS-D asks about *checking* the inside of the shoes. The FCFSP asks about *feeling* the inside of the shoe. The verb *checking* could mean more to the patient than just to feel, as for example also to see. Another point of discussion is that some patients stated that, instead of feeling with their hands

before putting the shoes on, they feel with their feet already in their shoes. As already indicated, this would not be in the sense of preventive foot self-care for DM patients with PNP.

In general, evaluation of measurement properties based on total scores or subscales of an instrument is preferred compared to item basis (Prinsen et al. 2018). However, as stated above, the DFSBS-D has only seven items and, according to Chin and Huang (2013), no subscales, but at least ten hypotheses must be formulated to test validity (Terwee et al. 2007). In conclusion, these item-based hypotheses might have been too detailed. On the other hand, they almost scored the expected correlation. Furthermore, they provide a relevant information about the measured construct.

The lack of information about validity and reliability of the German-language FCFSP must be considered. The process of translating the valid and reliable original DFSBS following the COSMIN guidelines, without concrete results of psychometric properties of the FCFSP is less reliable. Deufert et al. (2007) note, that, regarding the psychometric testing of the FCFSP, the sample of 53 participants is certainly too small to obtain valid and reliable data and does not claim to be representative. In addition, according to Deufert et al. (2007), the final item selection was based on the findings of factor analysis, discriminatory power and internal consistency. No concrete measurement values are available for the validity of the 19-item FCFSP.

Regarding the SF-36 it could be hypothesized that less health issues in DM patients are a result of more (foot) self-care, leading to greater health-related quality of life in the respective patient cohort. According to Bonner et al. (2016) and Grady et al. (2011), the quality of life of type 2 DM patients would increase with the implementation of self-management education. Nonetheless, since the interdependence of foot self-care and quality of life is yet unknown, only weak correlations could be expected to exist between the DFSBS-D and the SF-36, respectively. This was also confirmed in the results: the correlations between the DFSBS-D and all SF-36 subscales were very weak ($r_s$ <0.26).

In conclusion, less than 75% of the predefined hypotheses were confirmed and therefore construct validity is considered insufficient (Mokkink et al. 2010). One challenge of this study was to follow the COSMIN guidelines to assess the validity of the construct, as little is known about the relationships between DFSBS and other instruments. As mentioned above, the DFSBS was only used in the original validation study. Chin and Huang (2013) compared the DFSBS with the *foot care* subscales of the SDSCA and the C-DSCS. However, the C-DSCS is not available in German. Overall, it is assumed that the interpretation of the results of this study with a special focus on the association of the DFSBS-D and the subscale *foot-care* of the SDSCA-G suggests that the construct validity of the DFSBS-D is sufficient. To verify this, the DFSBS should be translated into other languages and psychometrically tested.

According to Chin and Huang 2013, previous research found that DM patients with a history of foot ulcers had better foot self-care behaviors than did those without (Schmidt et al. 2008, Johnston et al. 2006). This was also confirmed by known-group validity in their study about the original DFSBS (Chin and Huang 2013). In the present study, the subgroups must be discussed in terms of known-group validity: to have a sufficient number of patients for analysis, we included patients who indicated foot problems in the present and/or past. These patients did score significantly higher in the total score of the DFSBS-D, compared to patients not suffering of foot problems (Table 11, see Chapter 4.3.3). Regarding the subgroups of DM patients with and without ulcers, wounds and/or amputations, no significant difference in the DFSBS-D score was found. Due to the non-significance of this data, a post hoc power analysis was established and revealed a power of just 0.09 and an effect size of 0.12. Hence, no valid conclusion can be drawn on the here presented data regarding patient's foot self-care behavior and presence or history of ulcers, wounds and/or amputations. However, regarding the subgrouping of patients with foot problems, a power of 0.97 and an effect size of 0.7 was calculated. This result leads us to the assumption, that there is a connection between foot problems and foot self-care behavior. Future research should include a tailored multicenter study including a larger sample of patients with specific DM related foot complaints, to be sufficiently powered.

### 5.1.4 Reliability

The results of the present study suggest that the DFSBS-D is a reliable patient self-reported instrument. The internal consistency of the DFSBS-D was alpha=0.84, which was higher than found in the DFSBS (Cronbach's alpha=0.73) (Chin and Huang 2013). In general, when using Cronbach's alpha in the reliability analysis, various aspects need to be considered. First, Cronbach's alpha increases with the number of items in the questionnaire and in the present study, the number of items is low (Field 2018, p. 823, De Vet et al. 2018, p. 84, Cortina 1993). Second, according to Cronbach (1951), the calculation of Cronbach's alpha must be performed separately for each individual subscale (Field 2018, p. 823). Regarding further discussion of the subdivision into subscales, please refer to Chapter 5.1.3. Since in the present study a subdivision into two factors was made by factor analysis, Cronbach's alpha was calculated for the two dimensions of the DFSBS-D: Cronbach's alpha of part one and two of the scale were 0.89 and 0.67. These results indicate also acceptable internal consistency (Nunnally and Bernstein 1994).

Based on Mokkink et al. (2010), test-retest reliability of the DFSBS-D is interpreted as acceptable, with ICC=0.73 (De Vet et al. 2018, p. 120, Nunally and Bernstein 1994). For the original DFSBS, the ICC for test-retest reliability over a 2-week period was 0.92, which is considered better (De Vet et al. 2018, p. 120, Chin and Huang 2013, Nunally and Bernstein

1994). It must be considered, that the ICC is sample-dependent (De Vet et al. 2018, p. 120). The difference in the two ICCs could be, for example, because the inclusion criteria, recruitment site and/or culture of the present study differ to Chin and Huang's (2013) (see Chapter 5.1.2., De Vet et al. 2018, p. 120).

Self-report measures produce larger measurement error, according to Field (2018). Nevertheless, the relatively high measurement error (SEM 2.54 and $MDC_{ind}$ 7.04) indicates that the DFSBS-D is not an appropriate instrument to distinguish changes between two or more different measurement time points (De Vet et al. 2018 p. 101, Field 2018, p. 1036). A difference of at least the $MDC_{ind}$ is required to indicate that a true change has occurred between two assessments of an individual (De Vet et al. 2018 p. 101, Field 2018, p. 1036). This is quite high considering that the total scores of the DFSBS-D vary between 7-35. A difference of the mean score on the DFSBS between the two groups could be detected. However, differences in scores smaller than the SEM cannot rule out measurement error. Therefore, a difference of at least 2.54 is required to detect a statistically significant difference between two scores of the DFSBS-D. Since no minimal important change (MIC) values were assessed in this study, it is unclear if this also indicates a clinically relevant difference. To determine the MIC of the DFSBS-D further research is required (De Vet et al. 2018, p. 246).

A systemic bias of data cannot be excluded, because Bland and Altman plot (Figure 10) showed zero lying outside of the 95% CI. This might be due to better foot self-care behavior initiated by the first administration of the DFSBS-D itself, or by the increase in knowledge at the individual recruitment sites, as discussed earlier. People scored on average 1.78 points higher on the DFSBS-D at the second administration.

## 5.2 Discussion of methods

### 5.2.1 Recruitment sites

The limited representativeness of the care situation of DM patients in Germany must be regarded as methodological limitation of this study. Outpatient care for most DM patients in Germany is provided by general practitioners and internists, in case of need in practices of diabetology and exceptionally in specialized diabetology outpatient and inpatient clinics (Petrak et al. 2011). No local general practice or practice of diabetology could be found for this study, as doctors feared that recruitment interfered considerably with everyday clinical routine. However, an attempt was made to ensure the broadest possible representation of German DM patients by recruiting both outpatients and inpatients in a multicenter study. The practical relevance and meaningfulness of these studies are generally higher (Röhrig et al. 2009). Multicenter studies allow more in-depth conclusions than monocentric studies, reveal more informative and generalizable results, and they contribute to quality assurance in the

cooperating centers (Röhrig et al. 2009). To date, no results have been obtained on the question of whether doctors at different levels of care treat differently burdened DM patient groups and whether the patients' therapeutic adherence differs (Petrak et al. 2011). According to Müller-Wieland & Marx (2017), interdisciplinary diabetology, both outpatient and inpatient, must contribute to the efficient identification of individuals at risk, the effective treatment of the disease and improved care structures for those affected. Therefore, this cohort, which consists of outpatients and inpatients, is a representation of German DM patients, who are all at risk of developing a DFS and its complications.

Country-specific differences in preventive foot care and the inclusion of the clinic of chiropody as a recruitment site in this study must be considered in the results. In Taiwan, there are no certified chiropodists (Chin and Huang 2013). According to Chin and Huang (2013), the government does not issue a professional certification and beauticians often handle the foot management. In Germany, in the last ten years, a significantly better care structure for people with DFS has been established (Lobmann & Kersken 2018). This is accompanied by a decrease in amputations (Lobmann & Kersken 2018). In addition to physicians of different specializations, especially of the field of diabetology, orthopedic shoemakers and qualified medical assistants, chiropodists are an essential element of medical care in Germany (Lobmann & Kersken 2018). With the creation of the profession of chiropody in 2001 and the inclusion of chiropody management of the DFS, the basic prerequisites for qualified pedicure care of foot at risk patients have been created in Germany (Bundesärztekammer et al. 2010). The DDG has established specific guidelines for chiropody management of DFS (Lobmann & Kersken 2018). Chiropody management is indicated, if a foot with DM-associated sequelae, such as PNP and/or POAD, has a wound and a pathological nail-change or hyperkeratosis on intact skin at the same time. With this indication, DM patients can receive regular chiropody on medication prescription (Lobmann & Kersken 2018). As mentioned in chapter 5.1.1, since these patients are seen by specialized chiropodists regularly, the assumption is made, that they also tend to pay attention to their feet in the sense of foot self-care behavior and therefore scored higher on the DFSBS-D.

All inpatients are offered specific DM training during their stay in the diabetology ward of the CKQ. The DM training schedule also includes a session about foot self-care. Therefore, it cannot be ruled out that new information or new knowledge was imparted to the respondents within the interview interval. However, DM patients should also be made aware of appropriate foot self-care behavior at each consultation, both in the clinic of chiropody and in outpatient foot clinic. Consequently, it can be assumed that a learning effect took place during the consultation at all three recruitment sites. The gaining of new information and knowledge about foot self-care could also affect the answer on the retest. In addition, the patient's response might have been influenced by social desirability, as the patient may want to appear more

compliant, especially after DM training, to the researcher and team. To what extent this was the case, and whether and to what extent the habits of the respondents have changed, cannot be answered.

Recall bias cannot be excluded, as the DFSBS-D asks patients to report their DM self-care activities over the last seven days. This applies in particular to inpatients of the CKQ who may have spent the last seven days in hospital. An inpatient admission may be necessary for various reasons: in addition to treatment problems that cannot be solved within the framework of outpatient therapy (e.g. in a specialist practice), serious secondary or concomitant illnesses often constitute a reason for inpatient admission (Diabetes-Zentrum Quakenbrück 2019). Nevertheless, if possible, DM patients should also continue their foot self-care behavior in the hospital. Regarding this aspect, patients were informed at the beginning of the DFSBS-D that, if they were sick during the last seven days, they should complete the questions thinking back to the last 7 days that they were not sick (Appendix D).

### 5.2.2 Sample

A strength of this study is the sample size (De Vet et al. 2018, p. 191). As stated previously, a sample size of 100 or more is considered excellent to assess validity for PRO instruments (De Vet et al. 2018, p. 191, Terwee et al. 2012, Terwee et al. 2007). This number was achieved with a total of 136 patients in the present study. According to the COSMIN guidelines, for factor analysis, there are two aspects to determine sample size: four to ten subjects per item with an absolute minimum of 100 subjects (De Vet et al. 2018, p. 191). In the present study, the DFSBS-D consists of seven items and in total 136 DM patients were included. Therefore, the subject-to-item ratio was greater than ten to one. The number of people included for reliability analyses was 58, which is considered a good sample size to assess test-retest reliability (De Vet et al. 2018, p. 126).

### 5.2.3 Subject characteristics

Chin and Huang (2013) exclusively included type 2 DM patients with diabetic neuropathy in their study. They excluded patients who could not walk and/or had unhealed foot lesions (Chin and Huang 2013). The present study included all DM patients who were in one of the three study sites at the time of recruitment according to the inclusion and exclusion criteria mentioned above. Further studies are needed to investigate a possible impact of this study methodology on the results. In the present study, nevertheless, the focus was primarily on the validation and reliability analysis of the DFSBS-D and not on the evaluation of the cohort and the DFS risk factors itself.

### 5.2.4 Measurement instrument: DFSBS

The final DFSBS includes the important aspects of daily foot care according to McInnes et al. (2011) (Chin and Huang 2013). Item 4 of the DFSBS, which asks about drying between toes after washing must be discussed, as the activity of "drying" was interpreted differently by patients. Some patients commented next to this question, that they dry their feet with a hairdryer after washing. Diabetes mellitus patients with PNP have lower skin sensation than non-diabetic patients (Momeni et al. 2018). Thus, because of this reduced sensation, they are at a high risk of suffering burn injuries accidentally (Momeni et al. 2018, Barsun et al. 2013, De Gabriele 2008). These injuries can happen while warming the feet, for example with hot water, or usage of hot air for drying of the skin, for example with a hairdryer (Barsun et al. 2013, De Gabriele 2008). This possible inaccuracy in the question and a lack of information for the patients could destroy the actual intention of the DFSBS-D and of this study, namely the prevention of foot ulcers and its complications.

An important factor of ulcer prevention, with clear evidence especially for the prevention of ulcer recurrence for high-risk patients, are the measures detecting potential trauma and therapeutic footwear (Lechner 2017, Peter-Riesch 2016, Bus et al. 2012, Uccioli et al. 1995). In general, prescriptions for therapeutic footwear are mostly underused for logistical reasons (Peter-Riesch 2016). Furthermore, most patients consider therapeutic footwear unattractive and therefore refuse to wear them (Peter-Riesch 2016). In addition, DM patients need to wear therapeutic shoes not only outside, but also at home (Peter-Riesch 2016). In the last two items of the DFSBS, patients are asked about their footwear. After completing the DFSBS-D, some patients criticized that they are wearing special and individual adapted shoes and therefore would not have to break in new shoes slowly. They also relied on the fact that the inside of the shoes would not cause any trauma, because the shoes were made by a specialized shoemaker. This revealed some deficits in the patients' knowledge of their foot self-care behavior. Diabetes mellitus patients with tailor-made shoes must also check the inside of their shoes before putting them on. This is because, as mentioned above, the PNP that may be present means that patients do not feel any pressure points, as foreign bodies or seams, in their shoes. In addition, even though the shoes are individually fitted, it is necessary to check regularly whether the foot itself is developing new deformities or the shape and seams of the shoe cause pressure points.

The pilot study revealed no problems in understanding of the DFSBS-D for DM patients. Nevertheless, focus groups should be conducted for inclusion of patient's views and experiences to prevent misunderstandings of some subgroups, for example high-risk patients wearing therapeutic shoes. Patients might become frustrated when items are asked, which appear irrelevant to them (Terwee et al. 2018). Furthermore, if, according to the patient, some

important questions are not asked in the instrument, results could become biased, or the study must accept low response rate (Terwee et al. 2018).

Chin and Huang (2013) note, that the original DFSBS is not addressing all foot self-care behaviors listed in care guidelines. Thus, they do not recommend the DFSBS as education instrument for DM patients (Chin and Huang 2013). On the other hand, the DFSBS is a convenient questionnaire for time-limited clinical consultations, as the seven-item scale can be completed by the patients in less than or around five minutes (Chin and Huang 2013).

## 6. Conclusion

The original DFSBS was successfully translated and culturally adapted into German. Results showed that psychometric properties of the DFSBS-D are good in terms of structural validity, internal consistency and test-retest reliability. Construct validity appeared to be questionable, however, a more in-depth interpretation of the results leads to the assumption that the construct validity of the DFSBS-D is sufficient. Overall, we conclude that the DFSBS-D is a valid and reliable instrument to assess foot self-care behaviors in DM patients in Germany. The available results should be considered in the sense of a large pilot study and need to be replicated in a representative and larger study before general conclusions are drawn.

In the future, further studies are needed to test the applicability of the DFSBS-D regarding patients with and without PNP and/or POAD, as these are the two main underlying pathologies of the DFS (Peter-Riesch 2016). Data on the diagnoses of the patients are available and can be analyzed within further studies.

Responsiveness of the DFSBS and the DFSBS-D has not been examined in the present nor in previous studies. Further research is needed to obtain information about the ability of detection of clinically important changes over time by the DFSBS and DFSBS-D.

# 7. Abstract

**Background:** Adequate foot self-care is one of the most important self-management behaviors to prevent the development of foot ulcers and amputations in diabetic patients. Scientific studies show that adequate foot self-care is only practiced by very few of those affected. In order to improve the quality of the prevention of diabetic foot syndrome and its complications, a valid and reliable instrument for measuring daily foot care in diabetes patients is necessary. There is currently no such instrument available in the German language.

**Objective:** The aim of this study was the translation, intercultural adaptation and validation of the original English "Diabetic Foot Self-Care Behavior Scale" (DFSBS) according to the internationally recognized "Consensus-based Standards for the Selection of Health Status Measurement Instruments" (COSMIN) guidelines.

**Methods:** The translation of the original DFSBS questionnaire into German was carried out in a forward/backward procedure as recommended by the COSMIN guidelines. A total of 136 questionnaires, consisting of (1) the translated German version of the "Diabetes Foot Self-Care Behavior Scale" (DFSBS-D), (2) the German version of the "Diabetes Self-Care Activities Measure" (SDSCA-G), (3) of the " Frankfurter Catalogue of Foot Self-Care " (FCFSP), and (4) of the "Short Form 36" (SF-36), were collected to assess the validity of the DFSBS-D, based on 21 predefined hypotheses. Seventy-four patients responded to the DFSBS-D a second time after two weeks to assess the reliability of the DFSBS-D.

**Results:** The DFSBS-D consists of seven items, with one factor explaining 45% of the total variance. Thus, the DFSBS-D showed a good structural validity. To assess construct validity, 21 hypotheses were formulated a priori, of which 13 (62%) were confirmed. Strong correlations were found between the DFSBS-D and the foot care subscale of the SDSCA-G ($r_s \approx 0.7$). The internal consistency of the DFSBS-D was good (Cronbach's alpha = 0.84). The intra-class correlation coefficient between test and re-test was 0.73, indicating good reliability.

**Conclusion:** The DFSBS-D was successfully translated into German. The statistical analyses showed good structural validity and reliability. The construct validity can be regarded as worthy of discussion.

# 8. Zusammenfassung

**Hintergrund:** Eine angemessene Fußselbstpflege ist eine der wichtigsten Selbstmanagementverhaltensweisen zur Prävention der Entstehung von Fußgeschwüren und Amputationen bei DiabetespatientInnen. Wissenschaftliche Untersuchungen zeigen, dass eine angemessene Fußselbstpflege allerdings nur von den wenigsten Betroffenen praktiziert wird. Um eine Qualitätsverbesserung in der Prävention des Diabetischen Fußsyndroms und seiner Komplikationen zu ermöglichen, ist ein valides und zuverlässiges Instrument zur Messung der täglichen Fußpflege bei DiabetespatientInnen notwendig. In deutscher Sprache existiert aktuell kein solches Instrument.

**Ziel:** Das Ziel dieser Studie war die Übersetzung, interkulturelle Anpassung und Validierung der im Original englischen „Diabetic Foot Self-Care Behavior Scale“ (DFSBS) gemäß den international anerkannten „Consensus-based Standards for the Selection of Health Status Measurement Instruments“ (COSMIN)-Richtlinien.

**Methoden:** Die Übersetzung des originalen DFSBS-Fragebogens ins Deutsche erfolgte gemäß COSMIN-Leitfaden in einem Vorwärts-Rückwärts-Verfahren. Insgesamt 136 Fragebögen zur Selbstpflege von diabetischen Füßen, bestehend aus (1) der übersetzten Deutschen Version des „Diabetes Foot Self-Care Behavior Scale“ (DFSBS-D), (2) der Deutschen Version der „Diabetes Self-Care Activities Measure“ (SDSCA-G), (3) des „Frankfurter Aktivitätenkatalog der Selbstpflege – Prävention Diabetisches Fußsyndrom“ (FAS-PräDiFuß) und (4) des „Short Form 36“ (SF-36), wurden erhoben, um die Validität der DFSBS-D, basierend auf 21 vordefinierten Hypothesen, zu beurteilen. Vierundsiebzig PatientInnen beantworteten die DFSBS-D nach zwei Wochen ein zweites Mal, um die Reliabilität der DFSBS-D zu beurteilen.

**Ergebnisse:** Die DFSBS-D besteht aus sieben Items, wobei ein Faktor 45% der gesamten Varianz erklärte. Somit zeigte die DFSBS-D eine gute strukturelle Validität. Zur Beurteilung der Konstruktvalidität wurden a priori 21 Hypothesen formuliert, von denen 13 (62%) bestätigt wurden. Es zeigten sich starke Korrelationen zwischen der DFSBS-D und der Subskala „Fußpflege“ des SDSCA-G ($r_S \approx 0.7$). Die interne Konsistenz der DFSBS-D war gut (Cronbach’s alpha = 0.84). Der Intraklassen-Korrelationskoeffizient zwischen Test und Wiederholungstest betrug 0.73 was auf eine gute Reliabilität hinweist.

**Schlussfolgerung:** Die DFSBS-D wurde erfolgreich ins Deutsche übersetzt. Die statistischen Analysen zeigten eine gute strukturelle Validität und Reliabilität. Die Konstruktvalidität kann als diskussionswürdig angesehen werden.

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# 11. Appendices

## Appendix A: DFSBS (English)

The Diabetes Foot Self-Care Behavior Scale (DFSBS)

Part 1 – The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

| | The number of days performed during the past 7 days | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. I (my caregiver) examine the bottoms of my feet..... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. I (my caregiver) examine between the toes of my feet. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. I (my caregiver) wash between my toes..... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. I (my caregiver) dry between my toes after washing... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Part 2 – Please circle the category which best reflects what you actually do.

| | Never | Seldom | Sometimes | Frequently | Always |
|---|---|---|---|---|---|
| 1. If my skin is dry, I (my caregiver) apply moisturizing lotion to my feet. | 1 | 2 | 3 | 4 | 5 |
| 2. Before I put on my shoes, I (my caregiver) check the inside of the shoes. | 1 | 2 | 3 | 4 | 5 |
| 3. I break in new shoes slowly. | 1 | 2 | 3 | 4 | 5 |

# Appendix B: Information letter for the initial questionnaire (German)

CARL VON OSSIETZKY universität OLDENBURG
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CHRISTLICHES KRANKENHAUS QUAKENBRÜCK

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Sehr geehrte/r Frau/Herr

in Zusammenarbeit mit der Fußambulanz des Christlichen Krankenhauses Quakenbrück, akademisches Lehrkrankenhaus der Universität Oldenburg/European Medical School Oldenburg-Groningen und der Praxis Schoppa am Hafen betreibt die Universitätsklinik für Orthopädie und Unfallchirurgie am Pius-Hospital wissenschaftliche Forschung zum Diabetischen Fußsyndrom, um die Qualität in der Versorgung betroffener Patienten und Patientinnen zu gewährleisten und zu verbessern.

In einer Studie wollen wir einen Fragebogen zum Diabetischen Fuß auf seine Gebräuchlichkeit untersuchen. Dieser Fragebogen gibt Aufschluss über die Selbstversorgung von Patienten mit Diabetes. Dazu haben wir einen im Original englischsprachigen Fragebogen, der im Ausland bereits verwendet wird, ins Deutsche übersetzt. Dieser Fragebogen gibt Aufschluss über die Fußpflege bei Diabetespatienten und -patientinnen.

Sie sind auf Grund Ihres Diabetes Patient/Patientin der Fußambulanz des Christlichen Krankenhauses Quakenbrück oder der Praxis Schoppa am Hafen. Um festzustellen, ob die übersetzte Version des Fragebogens für den Gebrauch in Deutschland geeignet ist, benötigen wir Ihre Mitarbeit und laden Sie daher herzlich zur freiwilligen Teilnahme an unserer Studie mit dem Titel

**Übersetzung und Validierung einer deutschen Version der englischen *Diabetes Foot Self-Care Behavior Scale (DFSBS)***

ein. Wir würden uns freuen, wenn Sie den Ihnen ausgehändigten Fragebogen ausfüllen. Dies dauert ungefähr 20 Minuten. Gegebenenfalls erscheint es Ihnen beim Ausfüllen so, als wiederholten sich einige Fragen bzw. als ähnelten sie sich z.T. sehr. Dennoch ist es wichtig, dass Sie bitte alle Fragen beantworten. Nur so können wir die Daten später für unsere Auswertung nutzen.

Um zu untersuchen, ob der übersetzte Fragebogen zuverlässig ist, bitten wir Sie zudem, eine kürzere Version des Fragebogens auszufüllen, die Sie 14 Tage nach dem heutigen Ausfüllen durch uns per Post zugesendet bekommen. Dies wird ca. 5-10 Minuten Ihrer Zeit in Anspruch nehmen. Die Rücksendung des vollständig ausgefüllten Fragebogens ist für Sie durch einen beiliegenden frankierten und an uns adressierten Rückumschlag selbstverständlich kostenlos.

Die Fragebögen sowie die Ergebnisse der Studie werden von uns vertraulich behandelt. Für die Auswertung der erhobenen Daten sind der Studienleiter (Prof. Dr. med. habil. Lazovic) und seine wissenschaftlichen Mitarbeiterinnen (Gesine Seeber (MSc) und Linda Lecker) verantwortlich. Die Aufzeichnung und Auswertung Ihrer Daten erfolgt pseudonymisiert unter Verwendung einer Nummer und ohne Angaben Ihres Namens. Es existiert pro Studieneinrichtung eine Kodierliste, die Ihren Namen mit der Ihnen zugewiesenen Nummer verbindet. Diese Kodierlisten werden getrennt von den anderen Daten aufbewahrt und sind nur den Projektmitarbeitern der jeweiligen Studieneinrichtung zugänglich, d.h. nur sie können die erhobenen Daten falls nötig mit Ihrem Namen in Verbindung bringen. Nach Abschluss der Datenaufnahme und -auswertung werden die Kodierlisten gelöscht. Ab diesem Zeitpunkt sind die Daten anonymisiert, d.h. es ist niemandem mehr möglich, die erhobenen Daten mit Ihrem Namen in Verbindung zu bringen. Die innerhalb dieser Studie erhobenen Daten werden ausschließlich für Forschungszwecke verwendet und in anonymisierter Form gespeichert.

Die Teilnahme an der Studie birgt für Sie keine Risiken. Entscheiden Sie sich heute für eine Teilnahme, haben Sie das Recht, Auskunft (einschließlich unentgeltlicher Überlassung einer Kopie) über Ihre von uns im Rahmen dieser Studie erhobenen personenbezogenen Daten zu erhalten bzw. gegebenenfalls deren Berichtigung und/oder Löschung zu verlangen. Zudem haben Sie jederzeit das Recht, Ihre Teilnahmezustimmung schriftlich und/oder mündlich zu widerrufen, ohne dass Ihnen dadurch Nachteile für Ihre weitere medizinische Versorgung entstehen. Bei Rücktritt von der Studie kann auf Wunsch bereits gewonnenes Datenmaterial vernichtet werden. Wenn allerdings die Kodierlisten bereits gelöscht wurden, kann Ihr Datensatz nicht mehr identifiziert und somit auch nicht mehr gelöscht werden. Ihre Daten sind dann anonymisiert.

Die Durchführung dieser Studie wurde von der Medizinischen Ethikkommission der Carl-von-Ossietzky Universität genehmigt. Die Datenschutzbeauftragte des Christlichen Krankenhauses Quakenbrück, Frau Malek, hat das Vorhaben ebenfalls geprüft und keine Einwände gegen die Durchführung erhoben. Bei einem Verstoß gegen die Datenschutzauflagen haben Sie jederzeit das Recht, gemäß Art. 13 II EU-DSGVO, bei dem Datenschutzbeauftragen der datenschutz nord GmbH (Dr. Uwe Schläger, kirche@datenschutz-nord.de) offiziell Beschwerde einzulegen.

Sollten Sie Fragen zu unserer Untersuchung haben oder Unklarheiten bestehen, zögern Sie bitte nicht, mit Frau Seeber über E-Mail (gesine.seeber@pius-hospital.de) oder telefonisch mit dem zuständigen Studiensekretariat (0441-229-1588) Kontakt aufzunehmen.

Vielen herzlichen Dank für Ihre Mitarbeit an dieser Studie.

Mit freundlichen Grüßen,

Prof. Dr. med. D. Lazović
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Christliches Krankenhaus Quakenbrück,
akademisches Lehrkrankenhaus der Carl von
Ossietzky Universität Oldenburg / European Medical
School Oldenburg-Groningen

# Appendix C: Declaration of consent for patients (German)

CARL VON OSSIETZKY universität OLDENBURG
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**<u>EINVERSTÄNDNISERKLÄRUNG</u>**

zur Mitwirkung an der Studie

**Validierung einer deutschen Version der englischen *Diabetes Foot Self-Care Behavior Scale (DFSBS)***

Ich wurde vollständig über Wesen, Bedeutung und Tragweite der o.g. Studie aufgeklärt. Ich habe das Informationsschreiben genau gelesen und verstanden. Ich hatte die Möglichkeit, Fragen zu stellen. Diese wurden zufriedenstellend beantwortet. Ich habe die Antworten verstanden und akzeptiere sie. Ich bin über die mit der Teilnahme an der Studie verbundenen Risiken und auch über den möglichen Nutzen informiert.
Ich hatte ausreichend Zeit, mich zur Teilnahme an der Studie zu entscheiden und weiß, dass die Teilnahme freiwillig ist. Ich wurde darüber informiert, dass ich jederzeit und ohne Angabe von Gründen meine Zustimmung zur Studienteilnahme mündlich oder schriftlich widerrufen kann, ohne dass dadurch Nachteile für mich entstehen.

Mir ist bekannt, dass ich mein Einverständnis zur Aufbewahrung bzw. Speicherung meiner Daten schriftlich oder mündlich widerrufen kann ohne dass mir daraus Nachteile entstehen. Ich bin darüber informiert worden, dass ich jederzeit das Recht auf Auskunft (einschließlich unentgeltlicher Überlassung einer Kopie) über die im Rahmen dieser Studie erhobenen personenbezogenen Daten habe und ggf. deren Berichtigung und/oder Löschung verlangen darf. Zudem kann ich die Löschung aller meiner weiteren, im Zusammenhang mit dieser Studie stehenden Daten verlangen. Wenn allerdings die Codierliste bereits gelöscht ist, kann mein Datensatz nicht mehr identifiziert und somit auch nicht mehr gelöscht werden. Meine Daten sind dann anonymisiert. Ich wurde darüber informiert, dass ich bei einem Verstoß gegen die Datenschutzauflagen jederzeit, gemäß Art. 13 II EU-DSGVO, das Recht habe, bei dem Datenschutzbeauftragen der datenschutz nord GmbH (Dr. Uwe Schläger, kirche@datenschutz-nord.de) offiziell Beschwerde einzulegen. Ich bin einverstanden, dass meine Daten zu Forschungszwecken verwendet werden.

**Ich wurde darüber aufgeklärt und stimme zu, dass meine in der Studie erhobenen Daten in pseudonymisierter Form aufgezeichnet, ausgewertet, ggf. auch in anonymisierter Form weitergegeben werden können und 10 Jahre im Christlichen Krankenhaus Quakenbrück, Fachabteilung für Diabetologie, Stoffwechselkrankheiten und Endokrinologie, gespeichert werden. Dritte erhalten jedoch keinen Einblick in personenbezogene Unterlagen. Bei der Veröffentlichung von Ergebnissen der Studie wird mein Name ebenfalls nicht genannt.**

Ich habe eine Kopie des Informationsschreibens und dieser Einverständniserklärung erhalten. Ich erkläre hiermit meine freiwillige Teilnahme an der o.g. Studie

| | |
|---|---|
| _____ | _____ |
| Ort, Datum | Unterschrift Teilnehmer |
| _____ | _____ |
| Ort, Datum | Unterschrift Aufklärender |

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Appendix D: Initial questionnaire (German)

# Fragebogen

**Übersetzung und Validierung einer deutschen Version der englischen Diabetes Foot Self-Care Behavior Scale (DFSBS)**

Fragebogennummer:_____

# Allgemeine Daten

Die folgenden Fragen beziehen sich auf Ihre Lebenssituation, Ausbildung und Diabetes-Erkrankung. Bitte füllen Sie die zutreffende Antwort aus oder markieren Sie die Antwort, die am besten auf Sie zutrifft.

1. Wie alt sind Sie? ..... Jahre

2. Geschlecht ○ männlich ○ weiblich

3. Wie groß sind Sie? .....cm

4. Wie viel wiegen Sie? ..... kg

5. Wie ist Ihre Lebenssituation?
   ○ alleine
   ○ mit Partner/in
   ○ mit Partner/in und Kindern
   ○ mit Kindern
   ○ Ansonsten, nämlich .....

6. Was ist der höchste von Ihnen erworbene Abschluss?
   ○ Hauptschulabschluss (Volksschule)
   ○ Realschulabschluss (mittlere Reife)
   ○ Gymnasium (allg. oder fachgebundene Hochschulreife/Abitur)
   ○ Fachhochschulabschluss
   ○ Universitätsabschluss (Diplom, Magister, Staatsexamen, Bachelor/Master)
   ○ Promotion/Habilitation
   ○ Ansonsten, nämlich .....

7. In welchem Jahr wurde bei Ihnen die Diagnose „Diabetes mellitus“ gestellt? .....

8. An welchem Diabetes-Typ sind Sie erkrankt? .....

9. Verwenden Sie Insulin für Ihren Diabetes? ○ ja ○ nein

10. Haben Sie jetzt oder hatten Sie in der Vergangenheit Fußbeschwerden aufgrund von Diabetes? ○ ja ○ nein

11. Wenn ja, welche der folgenden Antworten treffen auf Sie zu? (Mehrfachnennungen möglich)

- ○ Hornhaut
- ○ Geschwüre
- ○ Wunden
- ○ emotionale Beschwerden
- ○ Schmerzen
- ○ Amputationen
- ○ andere Beschwerden, nämlich: .....

# Allgemeine Gesundheit

Auf den folgenden Seiten finden Sie eine Reihe von Krankheiten und Störungen. Bitte geben Sie an, ob die jeweilige Krankheit/der jeweilige Zustand derzeit und/oder in den vergangenen 6 Monaten bei Ihnen vorlag oder nicht, indem Sie entsprechend ***Ja*** oder ***Nein*** ankreuzen.

| | **Ja** | **Nein** |
|---|---|---|
| 1. Chronische Atemwegserkrankungen (z.B. Asthma, Bronchitis) | ○ | ○ |
| 2. Entzündungen der Nasennebenhöhlen/Stirnhöhle/Kieferhöhle | ○ | ○ |
| 3. Schmerzen in der Brust oder Herzgegend | ○ | ○ |
| 4. Herzinfarkt | ○ | ○ |
| 5. Herzrhythmusstörungen | ○ | ○ |
| 6. Bluthochdruck (stabil; unter Kontrolle) | ○ | ○ |
| 7. Schlaganfall oder Hirnblutung | ○ | ○ |
| 8. Gefäßverkalkung/ Gefäßverengung | ○ | ○ |
| 9. Chronische Darmerkrankungen | ○ | ○ |
| 10. Chronische Lebererkrankungen | ○ | ○ |
| 11. Chronische Nierenerkrankungen | ○ | ○ |
| 12. Gebärmuttersenkung (Frauen) | ○ | ○ |
| 13. Schilddrüsenerkrankungen (stabil; unter Kontrolle) | ○ | ○ |
| 14. Chronische Rückenbeschwerden (inkl. Bandscheibenvorfälle) | ○ | ○ |
| 15. Gelenkverschleiß | ○ | ○ |
| 16. Rheumatoide Arthritis | ○ | ○ |
| 17. Andere Erkrankungen des rheumatischen Formenkreises | ○ | ○ |
| 18. Epilepsie | ○ | ○ |
| 19. Schwindel/ Gleichgewichtsstörungen | ○ | ○ |
| 20. Migräne | ○ | ○ |
| 21. (Ernste) Hauterkrankungen | ○ | ○ |

| | | |
|---|---|---|
| 22. Chronische Erkrankungen des Nervensystems (z.B. chronische Nervenentzündung, Morbus Parkinson, neurologische Muskelerkrankungen, Polyneuropathie, Multiple Sklerose) | ○ | ○ |
| 23. Psychische Erkrankungen (z.B. Depressionen oder Demenz) | ○ | ○ |
| 24. Osteoporose (Knochenschwund) | ○ | ○ |
| 25. Krebs (bösartige Erkrankung) | ○ | ○ |

# The Diabetes Foot Self-Care Behavior Scale (DFSBS)

Teil 1 - Die untenstehenden Fragen beziehen sich auf die Pflege Ihrer Füße **in den letzten 7 Tagen**. Wenn Sie in den letzten 7 Tagen krank waren, antworten Sie bitte in Bezug auf die letzten 7 Tage, an denen Sie nicht krank waren.

| | Anzahl der Tage, an denen die Tätigkeit in den letzten 7 Tagen ausgeführt wurde. | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. Ich untersuche (mein/e Pfleger/in untersucht) meine Fußsohlen. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. Ich untersuche (mein/e Pfleger/in untersucht) meine Zehenzwischen-räume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. Ich wasche (mein/e Pfleger/in wäscht) meine Zehenzwischenräume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. Ich trockne (mein/e Pfleger/in trocknet) nach dem Waschen meine Zehenzwischenräume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Teil 2 - Bitte markieren Sie die Antwortmöglichkeit, die am ehesten Ihrem Verhalten entspricht.

| | Nie | Selten | Manchmal | Häufig | Immer |
|---|---|---|---|---|---|
| 1. Wenn meine Haut trocken ist, versorge ich (versorgt mein/e Pfleger/in) meine Füße mit einer Feuchtigkeitscreme. | 1 | 2 | 3 | 4 | 5 |
| 2. Bevor ich meine Schuhe anziehe, überprüfe ich (überprüft mein/e Pfleger/in) die Innenseite der Schuhe. | 1 | 2 | 3 | 4 | 5 |
| 3. Ich laufe neue Schuhe langsam ein. | 1 | 2 | 3 | 4 | 5 |

# Diabetes Self-Care Activities Measure (SDSCA-G)

Die untenstehenden Fragen beziehen sich auf die Pflege Ihrer Füße in den **letzten 7 Tagen**. Wenn Sie in den letzten 7 Tagen krank waren, kreuzen Sie bitte die Anzahl der Wochentage in Bezug auf die letzten 7 Tage an, an denen Sie nicht krank waren.

| **Ernährung** | **Anzahl der Wochentage** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. An wie vielen von den letzten SIEBEN TAGEN haben Sie sich gesund ernährt? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. An wie vielen TAGEN PRO WOCHE im letzten Monat haben Sie sich im Durchschnitt gesund ernährt? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. An wie vielen der letzten SIEBEN TAGE haben Sie fünf oder mehr Portionen Obst oder Gemüse gegessen? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. An wie vielen der letzten SIEBEN TAGE haben Sie fetthaltige Produkte wie rotes Fleisch oder nicht fettreduzierte Milchprodukte gegessen? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| **Körperliche Aktivität** | | | | | | | | |
| 5. An wie vielen der letzten SIEBEN TAGE haben Sie sich mindestens 30 Minuten lang am Stück körperlich betätigt (auch Spazierengehen, Garten- oder Hausarbeit)? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 6. An wie vielen der letzten SIEBEN TAGE haben Sie Sport getrieben (z.B. Schwimmen, Nordic Walking, Radfahren)? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| **Blutzuckertest** | | | | | | | | |
| 7. An wie vielen der letzten SIEBEN TAGE haben Sie Ihren Blutzucker gemessen? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 8. An wie vielen der letzten SIEBEN TAGE haben Sie Ihren Blutzucker so oft gemessen, wie man es Ihnen von medizinischer Seite empfohlen hat? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Fußpflege**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9. An wie vielen der letzten SIEBEN TAGE haben Sie Ihre Füße untersucht? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 10. An wie vielen der letzten SIEBEN TAGE haben Sie die Innenseite Ihrer Schuhe kontrolliert? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Rauchen**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 11. Haben Sie in den letzten SIEBEN TAGEN eine Zigarette – auch nur einen Zug – geraucht? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

# Selbstpflege bei Diabetischem Fußsyndrom FAS – PräDiFuß

Überlegen Sie nicht zu lange; kreuzen Sie die Antwort an, die am ehesten zutrifft:

| | Nie | Selten | Ab und zu | Oft | Immer |
|---|---|---|---|---|---|
| 1. Ich schaue meine Füße täglich genau an. | o | o | o | o | o |
| 2. Ich kontrolliere meine Füße speziell auf Hornhaut. | o | o | o | o | o |
| 3. Ich überprüfe meine Füße speziell auf Fußpilz. | o | o | o | o | o |
| 4. Ich schaue meine Füße auf Verletzungen, Wunden, Rötungen, Schwellungen und infizierte Nägel an. | o | o | o | o | o |
| 5. Ich kontrolliere meine Nägel darauf, dass sie nicht einwachsen. | o | o | o | o | o |
| 6. Ich überprüfe meine Fußnägel speziell auf Nagelpilz. | o | o | o | o | o |
| 7. Ich schaue speziell zwischen den Zehen. | o | o | o | o | o |
| 8. Ich kontrolliere meine Füße bei gutem Licht. | o | o | o | o | o |
| 9. Ich schaue bei der Fußkontrolle, ob ich Hühneraugen habe. | o | o | o | o | o |
| 10. Ich gehe zur medizinischen Fußpflegerin zum Nagelschneiden. | o | o | o | o | o |
| 11. Ich informiere die Fußpflegerin, dass ich zuckerkrank bin. | o | o | o | o | o |
| 12. Ich achte darauf, dass meine medizinische Fußpflegerin meine Füße genau anschaut. | o | o | o | o | o |
| 13. Ich lasse Hornhaut und Schwielen von Fachpersonal entfernen. | o | o | o | o | o |
| 14. Ich behandele Fußnagelprobleme selbst, z.B. eingewachsene Nägel, Nagelpilz oder Nagelbettentzündungen. | o | o | o | o | o |
| 15. Ich taste vor dem Anziehen der Schuhe die Schuhinnenseiten ab. | o | o | o | o | o |
| 16. Ich trage Schuhe mit ausreichend Platz für die Zehen. | o | o | o | o | o |
| 17. Ich kontrolliere beim Kauf von Schuhen die Schuhe von innen mit der Hand. | o | o | o | o | o |
| 18. Ich trage Strümpfe ohne Nähte. | o | o | o | o | o |
| 19. Ich kontrolliere bei Strumpfschäden, ob diese von den Füßen her stammen. | o | o | o | o | o |

# SF-36

In diesem Fragebogen geht es um die Beurteilung Ihres Gesundheitszustandes. Der Bogen ermöglicht es, im Zeitverlauf nachzuvollziehen, wie Sie sich fühlen und wie Sie in Ihrem Alltag zurechtkommen.

*Bitte beantworten Sie **jede Frage**, indem Sie bei den Antwortmöglichkeiten die Zahl ankreuzen, die am besten auf Sie zutrifft!*

1. Wie würden Sie Ihren Gesundheitszustand im Allgemeinen beschreiben?

   (1) Ausgezeichnet
   (2) Sehr gut
   (3) Gut
   (4) Weniger gut
   (5) Schlecht

2. Im Vergleich zum **vergangenen Jahr**, wie würden Sie Ihren derzeitigen Gesundheitszustand beschreiben?

   (1) Derzeit viel besser
   (2) Derzeit etwas besser
   (3) Etwa wie vor einem Jahr
   (4) Derzeit etwas schlechter
   (5) Derzeit viel schlechter

3. Im Folgenden sind einige Tätigkeiten beschrieben, die Sie vielleicht an einem normalen Tag ausüben. Sind Sie durch Ihren **jetzigen** Gesundheitszustand bei diesen Tätigkeiten eingeschränkt? Wenn ja, wie stark?

| | **Ja, stark eingeschränkt** | **Ja, etwas eingeschränkt** | **Nein, überhaupt nicht eingeschränkt** |
|---|---|---|---|
| 3a. **anstrengende Tätigkeiten**, z. B. schnell laufen, schwere Gegenstände heben, anstrengenden Sport treiben | 1 | 2 | 3 |
| 3b. **mittelschwere Tätigkeiten**, z. B. einen Tisch verschieben, Staubsaugen, Kegeln, Golf spielen | 1 | 2 | 3 |
| 3c. Einkaufstaschen heben oder tragen | 1 | 2 | 3 |
| 3d. **mehrere** Treppenabsätze steigen | 1 | 2 | 3 |
| 3e. **einen** Treppenabsatz steigen | 1 | 2 | 3 |
| 3f. sich beugen, knien, bücken | 1 | 2 | 3 |
| 3g. **mehr als 1 Kilometer** zu Fuß gehen | 1 | 2 | 3 |
| 3h. **mehrere** Straßenkreuzungen weit zu Fuß gehen | 1 | 2 | 3 |
| 3i. eine Straßenkreuzung weit zu Fuß gehen | 1 | 2 | 3 |
| 3j. sich baden oder anziehen | 1 | 2 | 3 |

4. Hatten Sie **in den vergangenen 4 Wochen** aufgrund Ihrer **körperlichen Gesundheit** irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause?

| | **Ja** | **Nein** |
|---|---|---|
| 4a. Ich konnte **nicht so lange** wie üblich tätig sein | 1 | 2 |
| 4b. Ich habe **weniger geschafft** als ich wollte | 1 | 2 |
| 4c. Ich konnte **nur bestimmte Dinge** tun | 1 | 2 |
| 4d. Ich hatte **Schwierigkeiten** bei der Ausführung | 1 | 2 |

5. Hatten Sie **in den vergangenen 4 Wochen** aufgrund **seelischer Probleme** irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause (z. B. weil Sie sich niedergeschlagen oder ängstlich fühlten)?

| | **Ja** | **Nein** |
|---|---|---|
| 5a. Ich konnte **nicht so lange** wie üblich tätig sein | 1 | 2 |
| 5b. Ich habe **weniger geschafft** als ich wollte | 1 | 2 |
| 5c. Ich konnte **nicht so sorgfältig** wie üblich arbeiten | 1 | 2 |

6. Wie sehr haben Ihre körperliche Gesundheit oder seelische Probleme **in den vergangenen 4 Wochen** Ihre normalen Kontakte zu Familienangehörigen, Freunden, Nachbarn oder zum Bekanntenkreis beeinträchtigt?

(1) Überhaupt nicht
(2) Etwas
(3) Mäßig
(4) Ziemlich
(5) Sehr

7. Wie stark waren Ihre Schmerzen **in den vergangenen 4 Wochen**?

(1) Keine Schmerzen
(2) Sehr leicht
(3) Leicht
(4) Mäßig
(5) Stark
(6) Sehr stark

8. Inwieweit haben die Schmerzen Sie **in den vergangenen 4 Wochen** bei der Ausübung von Alltagsaktivitäten zu Hause oder im Beruf behindert?

(1) Überhaupt nicht
(2) Ein bisschen
(3) Mäßig
(4) Ziemlich
(5) Sehr

9. In diesen Fragen geht es darum, wie Sie sich fühlen und wie es Ihnen in den **vergangenen 4 Wochen** gegangen ist. (Bitte kreuzen Sie in jeder Zeile die Zahl an, die Ihrem Befinden am ehesten entspricht).

| **Wie oft waren Sie in den vergangenen 4 Wochen…** | **Immer** | **Meistens** | **Ziemlich oft** | **Manch-mal** | **Selten** | **Nie** |
|---|---|---|---|---|---|---|
| 9a. … voller Schwung? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9b. … sehr nervös? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9c. ... so niedergeschlagen, dass Sie nichts aufheitern konnte? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9d. … ruhig und gelassen? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9e. … voller Energie? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9f. …entmutigt und traurig? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9g. ... erschöpft? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9h. … glücklich? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9i. … müde? | 1 | 2 | 3 | 4 | 5 | 6 |

10. Wie häufig haben Ihre körperliche Gesundheit oder seelischen Probleme **in den vergangenen 4 Wochen** Ihre Kontakte zu anderen Menschen (Besuche bei Freunden, Verwandten, usw.) beeinträchtigt?

(1) Immer
(2) Meistens
(3) Manchmal
(4) Selten
(5) Nie

11. Inwieweit trifft **jede** der folgenden Aussagen auf Sie zu?

| | **Trifft ganz zu** | **Trifft weitgehend zu** | **Weiß nicht** | **Trifft weitgehend nicht zu** | **Trifft überhaupt nicht zu** |
|---|---|---|---|---|---|
| 11a. Ich scheine etwas leichter als andere krank zu werden. | 1 | 2 | 3 | 4 | 5 |
| 11b. Ich bin genauso gesund wie alle anderen, die ich kenne. | 1 | 2 | 3 | 4 | 5 |
| 11c. Ich erwarte, dass meine Gesundheit nachlässt. | 1 | 2 | 3 | 4 | 5 |
| 11d. Ich erfreue mich ausgezeichneter Gesundheit. | 1 | 2 | 3 | 4 | 5 |

**Bitte überprüfen Sie, ob Sie alle Fragen vollständig beantwortet haben.**

# Nochmals vielen Dank für Ihre Mitarbeit!

# Appendix E: Information letter for second questionnaire (test-retest) (German)

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CHRISTLICHES KRANKENHAUS QUAKENBRÜCK

Sehr geehrte/r Studienteilnehmer/in,

vor zwei Wochen haben Sie sich freundlicherweise bereit erklärt, an unserer Studie zur Überprüfung der Zuverlässigkeit der deutschen Version der *Diabetes Foot Self-Care Behavior Scale (DFSBS)* teilzunehmen. Dafür bedanken wir uns sehr herzlich!

Wie bereits in unserem ersten Schreiben angekündigt, möchten wir Sie heute bitten, eine kürzere Version des Fragebogens (anliegend) noch ein zweites Mal auszufüllen und uns zusätzlich eine Frage zu Ihrem derzeitigen Gesundheitszustand zu beantworten. Dies wird etwa 5-10 Minuten Ihrer Zeit in Anspruch nehmen. Den komplett ausgefüllten Fragebogen schicken Sie bitte anschließend mittels des beiliegenden, adressierten und frankierten Rückumschlags gebührenfrei an uns zurück.

Wenn Sie an unserer Studie nicht mehr teilnehmen wollen, schicken Sie den Fragebogen bitte unausgefüllt an uns zurück.

Wir möchten erneut darauf hinweisen, dass alle Ihre Daten vertraulich behandelt werden. Alle Ihre bei dieser Untersuchung erhobenen Daten werden unter einer persönlichen Nummer gesammelt, nach Abschluss der Studie anonymisiert und nur im Rahmen dieser Studie weiterverarbeitet.

Bei Fragen oder Unklarheiten die Studie betreffend, zögern Sie bitte nicht, per E- Mail (gesine.seeber@pius-hospital.de) oder telefonisch mit dem zuständigen Studiensekretariat (0441-2291588; Frau G. Seeber) Kontakt aufzunehmen.

Wir bedanken uns erneut ganz herzlich für Ihre Mitarbeit an dieser Studie.

Mit freundlichen Grüßen,

Prof. Dr. med. D. Lazović
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pius Hospital Oldenburg
Medizinischer Campus Universität Oldenburg

## Appendix F: Second questionnaire (test-retest) (German)

# Übersetzung und Validierung einer deutschen Version der englischen Diabetes Foot Self-Care Behavior Scale (DFSBS)

Teil 1 - Die untenstehenden Fragen beziehen sich auf die Pflege Ihrer Füße **in den letzten 7 Tagen**. Wenn Sie in den letzten 7 Tagen krank waren, antworten Sie bitte in Bezug auf die letzten 7 Tage, an denen Sie nicht krank waren.

| | Anzahl der Tage, an denen die Tätigkeit in den letzten 7 Tagen ausgeführt wurde. | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. Ich untersuche (mein/e Pfleger/in untersucht) meine Fußsohlen. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. Ich untersuche (mein/e Pfleger/in untersucht) meine Zehenzwischen-räume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. Ich wasche (mein/e Pfleger/in wäscht) meine Zehenzwischenräume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. Ich trockne (mein/e Pfleger/in trocknet) nach dem Waschen meine Zehenzwischenräume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Teil 2 - Bitte markieren Sie die Antwortmöglichkeit, die am ehesten Ihrem Verhalten entspricht.

| | Nie | Selten | Manchmal | Häufig | Immer |
|---|---|---|---|---|---|
| 1. Wenn meine Haut trocken ist, versorge ich (versorgt mein/e Pfleger/in) meine Füße mit einer Feuchtigkeitscreme. | 1 | 2 | 3 | 4 | 5 |
| 2. Bevor ich meine Schuhe anziehe, überprüfe ich (überprüft mein/e Pfleger/in) die Innenseite der Schuhe. | 1 | 2 | 3 | 4 | 5 |
| 3. Ich laufe neue Schuhe langsam ein. | 1 | 2 | 3 | 4 | 5 |

---

Die folgende Frage bezieht sich auf die Entwicklung Ihres Gesundheitszustandes in Bezug auf Ihre diabetischen Füße **in den vergangenen zwei Wochen**. Bitte markieren Sie die zutreffende Antwort.

| | Ja | Nein |
|---|---|---|
| Haben sich Ihre Symptome aufgrund Ihrer diabetischen Füße im Vergleich zu **vor 2 Wochen** verändert? | ○ | ○ |

ems european medical school oldenburg-groningen

**Vielen Dank für Ihre Mitarbeit!**

Christliches Krankenhaus Quakenbrück

pius Hospital Oldenburg Medizinischer Campus Universität Oldenburg

# Appendix G: Forward translation 1 of the DFSBS (T1)

**The Diabetes Foot Self-Care Behavior Scale (DFSBS)**

**Teil 1 - Die untenstehenden Fragen beziehen sich auf die letzten 7 Tage. Wenn Sie in den letzten 7 Tagen krank waren, antworten Sie bitte in Bezug auf die letzten 7 Tage, an denen Sie nicht krank waren.**

| | | Anzahl der Tage, an denen die Tätigkeit in den letzten 7 Tagen ausgeführt wurde | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1. | Ich oder mein/e Pfleger/in untersuche meine Fußsohlen… | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. | Ich oder mein/e Pfleger/in untersuche meine Zehenzwischenräume… | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. | Ich oder mein/e Pfleger/in wasche meine Zehenzwischenräume… | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. | Ich oder mein/e Pfleger/in trockne nach dem Waschen meine Zehenzwischenräume… | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Teil 2 - Bitte markieren Sie die Antwortmöglichkeit, die am ehesten Ihrem Verhalten entspricht.**

| | | Nie | Selten | Manch -mal | Häufig | Immer |
|---|---|---|---|---|---|---|
| 1. | Wenn meine Haut trocken ist versorge ich oder mein/e Pfleger/in meine Füße mit Feuchtigkeitscreme. | 1 | 2 | 3 | 4 | 5 |
| 2. | Bevor ich meine Schuhe anziehe überprüfe ich oder mein/e Pfleger/in die Innenseite der Schuhe. | 1 | 2 | 3 | 4 | 5 |
| 3. | Ich laufe neue Schuhe langsam ein. | 1 | 2 | 3 | 4 | 5 |

# Appendix H: Forward Translation 2 of the DFSBS (T2)

**The Diabetes Foot Self-Care Behavior Scale (DFSBS)**

**Teil 1 – Im Folgenden werden Sie nach den Aktivitäten befragt, die Sie zur Diabetes-Selbstbehandlung in den vergangenen 7 Tagen durchgeführt haben. Falls Sie während der vergangenen 7 Tage krank waren, denken Sie bitte an die letzten 7 Tage zurück, an denen Sie nicht krank waren.**

| | | Anzahl der Tage, an denen dies in den vergangenen 7 Tagen durchgeführt wurde. | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1. | Ich untersuche (mein/e Pfleger/in untersucht) meine Fußsohlen. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. | Ich untersuche (mein/e Pfleger/in untersucht) meine Füße zwischen den Zehen. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. | Ich wasche (mein/e Pfleger/in wäscht) meine Füße zwischen den Zehen. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. | Nach dem Waschen trockne ich (trocknet mein/e Pfleger/in) meine Füße zwischen den Zehen. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Teil 2 – Bitte umkreisen Sie die Kategorie, die am besten widerspiegelt, was Sie tun:**

| | | Nie | Selten | Manchmal | Häufig | Immer |
|---|---|---|---|---|---|---|
| 1. | Wenn meine Haut trocken ist, creme ich (cremt mein/e Pfleger/in) meine Füße mit einer Feuchtigkeitslotion ein. | 1 | 2 | 3 | 4 | 5 |
| 2. | Bevor ich meine Schuhe anziehe, überprüfe ich (überprüft mein/e Pfleger/in) das Innere der Schuhe. | 1 | 2 | 3 | 4 | 5 |
| 3. | Ich laufe meine Schuhe langsam ein. | 1 | 2 | 3 | 4 | 5 |

## Appendix I: Forward Translation of the DFSBS, combined (definitive) version (T12)

# The Diabetes Foot Self-Care Behavior Scale (DFSBS)

**Teil 1 - Die untenstehenden Fragen beziehen sich auf die Pflege Ihrer Füße in den letzten 7 Tagen. Wenn Sie in den letzten 7 Tagen krank waren, antworten Sie bitte in Bezug auf die letzten 7 Tage, an denen Sie nicht krank waren.**

| | Anzahl der Tage, an denen die Tätigkeit in den letzten 7 Tagen ausgeführt wurde. | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. Ich untersuche (mein/e Pfleger/in untersucht) meine Fußsohlen. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. Ich untersuche (mein/e Pfleger/in untersucht) meine Zehenzwischenräume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. Ich wasche (mein/e Pfleger/in wäscht) meine Zehenzwischenräume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. Ich trockne (mein/e Pfleger/in trocknet) nach dem Waschen meine Zehenzwischenräume. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Teil 2 - Bitte markieren Sie die Antwortmöglichkeit, die am ehesten Ihrem Verhalten entspricht.**

| | Nie | Selten | Manchmal | Häufig | Immer |
|---|---|---|---|---|---|
| 1. Wenn meine Haut trocken ist, versorge ich (versorgt mein/e Pfleger/in) meine Füße mit einer Feuchtigkeitscreme. | 1 | 2 | 3 | 4 | 5 |
| 2. Bevor ich meine Schuhe anziehe, überprüfe ich (überprüft mein/e Pfleger/in) die Innenseite der Schuhe. | 1 | 2 | 3 | 4 | 5 |
| 3. Ich laufe neue Schuhe langsam ein. | 1 | 2 | 3 | 4 | 5 |

# Appendix J: Backward Translation of the DFSBS-D (BT)

## The Diabetes Foot Self-Care Behavior Scale (DFSBS)

Part 1 – The following questions relate to the previous 7 days. If you were ill in the last 7 days, then please answer the questions for the last 7 days you were not ill.

| | Amount of days for which the activity was carried out in the last 7 days. | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. I examine (my carer examines) the soles of my feet..... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. I examine (my carer examines) in between my toes..... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. I wash (my carer washes) in between my toes..... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. I dry (my carer dries) in between my toes after being washed..... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Part 2 – Please select the options that most fit your behaviours.

| | never | rarely | sometimes | often | always |
|---|---|---|---|---|---|
| 1. When my skin is dry, I apply (my carer applies) cream to my feet. | 1 | 2 | 3 | 4 | 5 |
| 2. Before putting on my shoes, I inspect (my carer inspects) the inside of my shoes. | 1 | 2 | 3 | 4 | 5 |
| 3. I break in new shoes slowly. | 1 | 2 | 3 | 4 | 5 |

# I. Declaration of oath

## Erklärung nach § 3 Abs. 2 Nr. 7-10

Ich erkläre, dass ich die der Fakultät für Medizin und Gesundheitswissenschaften zur Promotion eingereichte Dissertation mit dem Titel „Translation, cross-cultural adaptation, validity and reliability of the German Diabetes Foot Self-Care Behavior Scale (DFSBS-D)“ in der Universitätsklinik für Orthopädie und Unfallchirurgie Oldenburg unter Betreuung von Herrn Prof. Dr. med. D. Lazovic mit der Unterstützung durch Frau G. Seeber (MSc PT, Universitätsklinik für Orthopädie und Unfallchirurgie Oldenburg), Dr. I. van den Akker-Scheek (Faculty of Medical Sciences, Center for Sports Medicine & Orthopedics, UMCG) in Zusammenarbeit mit der Abteilung für Diabetes und Stoffwechselerkrankungen des Christlichen Krankenhauses Quakenbrück unter Betreuung von Dr. med. F. Thienel sowie in Zusammenarbeit mit der Praxis am Hafen Oldenburg (Fr. Schoppa) ohne sonstige Hilfe durchgeführt und bei der Abfassung der Dissertation keine anderen als die dort aufgeführten Hilfsmittel benutzt habe.

Die Gelegenheit zum vorliegenden Promotionsverfahren ist mir nicht kommerziell vermittelt worden. Insbesondere habe ich keine Organisation eingeschaltet, die gegen Entgelt Betreuerinnen und Betreuer für die Anfertigung von Dissertationen sucht oder die mir obliegenden Pflichten hinsichtlich der Prüfungsleistungen für mich ganz oder teilweise erledigt.

Ich habe diese Dissertation bisher an keiner in- oder ausländischen Hochschule zur Promotion eingereicht. Weiterhin versichere ich, dass ich den beantragten Titel bisher noch nicht erworben habe.

Ich erkläre, dass die Leitlinien guter wissenschaftlicher Praxis der Carl von Ossietzky Universität Oldenburg von mir befolgt wurden.

Aachen, 25.03.2020

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CHRISTIAN-ALBRECHTS-UNIVERSITÄT ZU KIEL, KIEL

ÜBERSETZUNG, INTERKULTURELLE ANPASSUNG, VALIDITÄT UND RELIABILITÄT DER DEUTSCHEN DIABETES FOOT SELF-CARE BEHAVIOR SCALE (DFSBS-D)

**2018 – HEUTE**

**PROMOTION ZUM ERWERB DES DOKTORGRADES DER HUMANMEDIZIN**

„TRANSLATION AND VALIDATION OF THE DIABETES FOOT SELF-CARE BEHAVIOR SCALE (DFSBS) INTO GERMAN“

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„ENTWICKLUNG UND AUSWERTUNG EINES FRAGEBOGENS ZUR EVALUATION VON THERAPIEERFOLG BEI INTELLIGENZGEMINDERTEN RECHTSBRECHERN IN DER KLINIK FÜR FORENSISCHE PSYCHIATRIE UND PSYCHOTHERAPIE DER KARL-JASPERS-KLINIK IN WEHEN“

Aachen, 25.03.2020

## List of presentations related to this thesis:

Lecker L, Seeber GH, Thienel F, Lazovic D. Übersetzung, interkulturelle Anpassung, Validität und Reliabilität der deutschen Diabetes Foot Self-Care Behavior Scale (DFSBS-D). 4. Konferenz für studentische Forschung, 26.-27. September 2019, Kiel