

# Development and Validation of a Diabetes Foot Self-Care Behavior Scale

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## ABSTRACT

**Background:** Foot self-care practice is one of the most important self-management behaviors to prevent the occurrence of diabetic foot ulcers. A tool that measures all aspects of daily foot care routines and demonstrates good reliability and validity is essential to pinpointing specific foot ulcer problems and evaluating intervention outcomes. There is currently no such tool available.

**Purpose:** This study developed a diabetes foot self-care behavior scale (DFSBS) and tested its psychometric properties.

**Methods:** The researchers reviewed the literature to generate the initial item pool. After expert confirmation of final draft scale content validity, we used convenience sampling to recruit 295 patients with diabetes and peripheral neuropathy who completed the scale. We analyzed results to determine the scale's psychometric properties, including construct validity, internal consistency, and test-retest reliability.

**Results:** The final scale consisted of a one-factor structure with seven items. The analysis of the scale indicated the DFSBS score as significantly correlated with the foot care subscale score of the Chinese version of the summary of diabetes self-care activity questionnaire ( $\rho = .87, p < .001$ ) and the Chinese version of the diabetes self-care scale ( $\gamma = .45, p < .001$ ). Importantly, the DFSBS was found to differentiate between participants with and without a history of foot ulcers (Mann-Whitney  $Z = -3.09, p < .01$ ). Internal consistency was acceptable (Cronbach's  $\alpha = .73$ ), and intraclass correlation coefficient for test-retest reliability over a 2-week period was .92.

**Conclusion/Implications for Practice:** This study provides evidence of the DFSBS validity and reliability. Clinicians may use the DFSBS to screen patients' foot self-care behavior, and researchers can use it to elucidate foot self-care issues.

## KEY WORDS:

diabetic foot, self-care, scale development.

2007). Diabetes-related hyperglycemia affects the immune system, neurology, and circulation, causing a higher rate of fungal foot infections and peripheral neuropathy in diabetic compared with nondiabetic patients (Lipsky & Berendt, 2006). The prevalence of peripheral neuropathy in patients with diabetes is approximately 30% (Tesfaye, 2006). Peripheral neuropathy may result in foot abnormalities such as calluses, fissures, deformities, and loss of the protective sensation of pain. Thus, patients with diabetes and peripheral neuropathy are at high risk for developing foot ulcers. The annual incidence rate of foot ulcers among such patients is 8% (Boyko, Ahroni, Cohen, Nelson, & Heagerty, 2006), and the incidence over an 18-month interval is as high as 19% (Gonzalez et al., 2010).

Patients with diabetes have twice the risk of peripheral artery insufficiency disease than do those without diabetes (Norman, Davis, Bruce, & Davis, 2006). The prevalence of peripheral artery insufficiency disease in patients with diabetes ranges from 6.5% to 29.3% (Norman et al., 2006). Peripheral artery insufficiency may cause ischemic foot ulcers and poor wound healing. Diabetes is a major cause of non-traumatic lower limb amputations: more than 25% (Boulton, Vileikyte, Ragnarson-Tennvall, & Apelqvist, 2005).

Appropriate foot self-care can prevent foot ulcer occurrence and subsequent amputation (Vileikyte et al., 2006). Research, however, has shown that foot self-care behaviors in patients with diabetes are underpracticed. Approximately 20% of diabetic patients never examine their feet over the course of a week (Bell et al., 2005; Pollock, Unwin, & Connolly, 2004), and around 15% report never drying between their toes after washing their feet (Bell et al., 2005). Patients at high risk of foot ulcers such as those with diabetes and peripheral neuropathy should implement aggressive foot self-care regimens, including daily foot self-examinations (Pinzur,

## Introduction

Diabetes is a common chronic disease. The overall prevalence of diabetes is 7.8%–8.6% in the United States (Guthrie & Guthrie, 2009) and 6.8%–8.2% in Taiwan (Bureau of Health Promotion, Department of Health, Taiwan, ROC,

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Slovenkai, Trepman, & Shields, 2005). However, approximately 50% of diabetic patients with peripheral neuropathy symptoms fail to do so (Wang, Balamurugan, Biddle, & Rollins, 2011).

While a number of foot care behavior scales have been developed (Chiou, 2002; Johnston et al., 2006; Lincoln, Jeffcoate, Ince, Smith, & Radford, 2007; Schmidt, Mayer, & Panfil, 2008; Wang, 1997). Only two foot care subscales of the diabetic behavior scale have been utilized in more than two studies in Chinese population (Wang & Shiu, 2004; Wu et al., 2007, 2008), namely the foot care subscale of the Chinese version of the diabetes self-care scale (C-DSCS) and the foot care subscale of the summary of diabetes self-care activity questionnaire (SDSCA). The C-DSCS has been widely used in Taiwan. The foot care subscale of the C-DSCS has five items, with responses rated on a 5-point scale from *never* (1) to *always* (5). Item factor loading ranged from .31 to .84 (Wang, 1997), and the Cronbach's alpha for the C-DSCS was assessed at .63 (Wang, 1997). The foot care subscale of the C-DSCS measures several foot self-care behaviors, including wearing appropriate footwear, foot self-examination, applying moisturizing lotion, and management of abnormalities of the toenails and foot. However, the behavior of washing and drying between toes, which has been identified as an important part of a daily foot care routine (McInnes et al., 2011), is not included. In addition, three items of the C-DSCS assess level of compliance with recommendations from healthcare personnel, which makes the scale inappropriate for patients who had not previously received foot care education or recommendations from healthcare personnel.

The SDSCA has been used in various diabetes self-care behavior studies (Eigenmann, Colagiuri, Skinner, & Trevena, 2009). Item responses on the SDSCA foot care subscale rated the number of days a respondent performed foot self-care behavior over a 7-day period (Toobert, Hampson, & Glasgow, 2000). The foot care subscale of the Chinese version of the SDSCA has three items. The content validity of the Chinese version of the SDSCA is good (Chiou, 2002), with a 2-week test-retest reliability of .86 (Chiou, 2002).

The SDSCA, in comparison, measures the number of days foot self-care behavior was performed over a 7-day period. Thus, it can be used to measure the foot self-care behaviors of those who have not yet received formal foot self-care education. Nevertheless, the C-SDSCA measures only three foot self-care behaviors, namely drying between toes after washing, inspecting the feet, and inspecting the insides of shoes (Chiou, 2002). The C-SDSCA does not measure the behavior of lotion application, which has been identified as an important aspect of daily foot care routines (McInnes et al., 2011).

There is currently no instrument that measures all aspects of daily foot care routines and shows good reliability and validity in the world. Such a foot self-care behavior scale would help specify patient problems and may be used in research to explore factors of influence and evaluate intervention outcomes.

Diabetic patient vulnerability to foot ulcers and resultant amputation create a need for a scale to assess foot care behavior. The purpose of this study was to develop a diabetes foot self-care behavior scale (DFSBS) and then to test its validity and reliability in patients with diabetes and peripheral neuropathy.

## Methods

After developing initial DFSBS items, the authors conducted a cross-sectional survey to gather data to test the scale's psychometric properties.

### Developing Initial Items

Foot self-care behavior refers to patient behaviors followed to promote foot health. We developed our initial 18-item scale after a comprehensive review of the literature to identify diabetic patient foot care guidelines and existing foot self-care behavior scales. The scale was developed with two parts. The first assessed the number of days a respondent performed a certain behavior during a 1-week period. We categorized the number of days for each foot care measure in the first part across five groups (0 days, 1–2 days, 3–4 days, 5–6 days, and 7 days) The second rated how often a respondent performed a certain behavior (e.g., 1 = *never* to 5 = *always*).

Six experts in the foot care field, including one senior diabetes physician, one diabetes nurse practitioner, two senior diabetes educators, and two nurse researchers, evaluated the initial version of the scale. Experts rated the adequacy and clarity of each item using a 4-point Likert scale, ranging from *not relevant* (1) to *highly relevant and succinct* (4). We divided the total number of 3 and 4 scores for an item by the total number of experts to obtain a content validity index score for that item. Content validity index scores ranged from .83 to 1. A pilot study with a convenience sample of 11 patients with diabetic neuropathy was then conducted, with results indicating that participants could easily understand and respond to all items.

### Establishing Psychometric Properties

After the pilot study, we conducted a cross-sectional survey for item analysis and establishing psychometric properties. First, item analysis was utilized to exclude items with a low item discrimination index (critical ratio  $\alpha > .05$ ) and low factor loading (factor loading  $< .40$ ; Chiou, 2006). Psychometric properties of the final scale, including construct validity, and internal consistency were then tested. Exploratory factor analysis, convergent validity analysis, and known-groups validity analysis assessed DFSBS construct validity. Convergent validity testing was based on the hypothesis that the DFSBS score should correlate positively with the foot care subscale scores of both the SDSCA and C-DSCS. The testing of known-groups scale validity was based on

the hypothesis that patients with a history of foot ulcers would more likely engage in foot self-care practice than those without. The first 30 participants in the cross-sectional survey were invited to participate in a second DFSBS interview, conducted 2 weeks later, with collected data used to assess test-retest reliability.

## Sample/Setting

A group of 295 subjects were recruited from two hospitals in northern Taiwan. Type 2 diabetes patients were invited for receiving the monofilament assessment. Those who had at least one point insensitive among four site tests by the 10-g Semmes Weinstein monofilament (Singh, Armstrong, & Lipsky, 2005) and were over 20 years old were included. Data were collected from March 2010 to May 2011. Patients were excluded if they could not walk, had unhealed foot lesions on their feet, or had apparent cognitive or communication impairments.

## Data Collection

As participants were generally elderly persons and not well educated, the first author and three well-trained assistants collected data using face-to-face interviews. Before beginning data collection, data collectors assessed and interviewed 10 patients with diabetes and used the interview data to examine interrater reliability, which was found to be satisfactory (Kappa coefficient = .87).

Approval from the hospital's institutional review board was obtained before contacting participants and collecting data (IRB No. 98-3420B). All participants provided signed informed consent. Participants were interviewed to obtain data on demographics and foot ulcer history as well as to determine DFSBS, C-DSCS subscale, and SDSCA foot care subscale scores. The first 30 participants were invited to participate in a second DFSBS interview, conducted 2 weeks later, with collected data used to assess test-retest reliability.

## Statistical Analysis

Item analysis excluded items with a low item discrimination index (critical ratio  $\alpha > .05$ ) and low factor loading (factor loading  $< .40$ ; Chiou, 2006). To calculate the discrimination index of each DFSBS item, we ranked participants by DFSBS score and then used an independent  $t$  test to calculate the difference between the top 27% group and bottom 27% group (Chiou, 2006). An item with a low discrimination index was defined as nonsignificant ( $p > .05$ ) in the independent  $t$  test (Chiou, 2006). Principal component factor analysis, which used a single factor model, was conducted to calculate the factor loading of each item. Items with a factor loading of less than .40 were excluded from the scale (Stevens, 2009).

Exploratory factor analysis using principal component factor analysis with a varimax rotation explored the final

scale construct. To determine convergent validity, Spearman's rho and Pearson's correlation coefficients calculated the relationship between the foot care subscale of the SDSCA and the DFSBS and between the foot care subscale of the C-DSCS and the DFSBS. For known-groups validity, an independent  $t$  test used DFSBS scores to determine whether a difference existed between patients with and without a history of foot ulcers. Cronbach's alpha was used to assess internal consistency. Test-retest reliability was assessed by calculating the intraclass correlation coefficient between scores from two assessments with a 2-week interval. SPSS for Windows 15.0 (SPSS, Inc., Chicago, IL, USA) performed all statistical analyses.

## Results

Participant mean age was 66.93 years ( $SD = 11.05$  years). Just over half ( $n = 151, 51.2\%$ ) were male, 213 (72.2%) had 6 or fewer years of education, and 106 (35.9%) reported a history of foot ulcers. Participants all completed the initial 18-item interview in less than 10 minutes.

## Item Analysis

Discrimination analysis found the two items that assessed the toenail trimming and foot heat application behavior to be nonsignificant. A total of 285 (96.6%) participants indicated that they cut their toenails straight across, and 267 (90.5%) participants stated that they never put heating pads or hot water bags on their feet.

Principal component factor analysis, using a one-factor model, revealed that 11 items, including the above two lowly discriminating items, had factor loadings below .40. These items were subsequently dropped from the final DFSBS, after which its psychometric properties were tested.

## Validity

### Exploratory factor analysis

Principal component factor analysis obtained a Kaiser-Meyer-Olkin value of .72, indicating the sample size was of medium adequacy for factor analysis (Kaiser, 1974). Bartlett's test of sphericity was 475.86 ( $p < .001$ ), indicating high correlation among items. These results indicated the data set was suitable for factor analysis. The number of factors was determined based on eigenvalues and the scree plot. There were two factors with eigenvalues greater than 1.0, but only one factor was above the elbow of the scree plot. Thus, one factor was chosen. Results revealed that one factor explained 39.00% of total sample variance (Table 1). Item factor loadings ranged from .45 to .80.

## Convergent Validity

A total of 233 participants completed the interviews necessary to determine DFSBS and C-DSCS and SDSCA

**TABLE 1.**  
**DFSBS Factor Analysis Results (N = 295)**

Item		Factor Loading	Eigenvalue	Percentile of Variance
A1	I (my caregiver) examine the bottoms of my feet.	.77	2.73	39.00
A2	I (my caregiver) examine between the toes of my feet.	.80		
A3	I (my caregiver) wash between my toes.	.57		
A4	I (my caregiver) dry between my toes after washing.	.68		
B2	If my skin is dry, I (my caregiver) apply moisturizing lotion to my feet.	.54		
B7	Before I put on my shoes, I (my caregiver) check the inside of the shoes.	.48		
B9	I break in new shoes slowly.	.45		

Note. DFSBS = diabetes foot self-care behavior scale.

subscale scores. A Pearson's correlation coefficient between scores on the DFSBS and the foot care subscale of the C-DSCS indicated a moderate positive correlation ( $\gamma = .45$ ,  $p < .001$ ). A statistical normality test and graphic plot indicated that scores on the foot care subscale of the SDSCA had non-normal distribution, so the Spearman's rho was used to assess the relationship between the foot care subscale of the SDSCA and the DFSBS. The Spearman's rho between scores on the DFSBS and the foot care subscale of the SDSCA also indicated high positive correlation ( $\rho = .87$ ,  $p < .001$ ).

### **Known-groups validity**

There was a statistically significant difference between the DFSBS scores of patients with and without a history of foot ulcers (Mann-Whitney  $Z = -3.09$ ,  $p < .01$ ). Those with such a history ( $n = 106$ , mean = 22.73,  $SD = 7.87$ ) earned a higher average DFSBS score than those without ( $n = 189$ , mean = 19.77,  $SD = 7.50$ ).

### **Reliability**

The Cronbach's alpha coefficient for the seven-item scale was .73. Data from the first 30 participants interviewed for the DFSBS twice were used to determine test-retest reliability. The intraclass correlation coefficient for test-retest reliability over a 2-week period was .92 ( $p < .001$ ).

## **Discussion**

The final DFSBS contained seven items: checking the bottom of the feet and between toes, washing between toes, drying between toes after washing, applying lotion, inspecting the insides of shoes, and breaking in new shoes. The DFSBS includes the important aspect of daily foot care routines, which were identified by McInnes and colleges (2011).

The DFSBS measures frequency of foot self-care behavior and can be used with patients who have not yet received foot care education. The DFSBS assesses a broader range of foot

self-care behavior than the SDSCA. However, because of low item discrimination index and low factor loading, several items related to footwear, toenails, and foot abnormality management measured in the C-DSCS were excluded. In previous studies, items related to footwear and toenail management also had low item total correlations (Johnston et al., 2006; Vileikyte et al., 2006). No scale includes items related to foot abnormality management except for the C-DSCS.

Environmental factors may explain why items related to footwear behavior do not reflect overall foot self-care behavior. Neil (2002) noted that, although diabetic patients are concerned about foot health, those living in tropical/subtropical regions seldom wear socks and shoes during summer months. Taiwan experiences hot and humid conditions during the summer. To prevent fungus infections on the foot, some patients wear sandals or slippers outside and keep their home clean to allow going barefoot at home. Although some health-care personnel disagree with the efficacy of doing so, some patients use going barefoot at home as a fungus infection prevention strategy.

The population characteristics combined with environmental factors may cause items related to toenail management fail to reflect overall foot self-care behavior. As most participants (96.6%) stated they cut their toenails straight across, the item relating to this did not reflect overall foot self-care behaviors. With regard to the use of tools for trimming toenails, certain physical factors may explain why items related to toenail-trimming behaviors do not reflect overall foot self-care behaviors. Nail mycosis is a common disease in patients with diabetes (Lipsky & Berendt, 2006). In Taiwan, beauticians often handle toenail management. However, as the government does not issue a professional certification for podiatrists, there are no certified podiatrists available for toenail management. Patients with heavy toenails resulting from nail mycosis may need to cut nails with a scissors or box cutter. In regard to foot abnormality management, patients without such abnormalities were unable to provide an experience-based response to abnormality management-related questions and thus gave answers that

did not reflect actual performance or overall foot self-care behaviors.

In terms of reliability, the Cronbach's alpha coefficient was higher for the DFSBS than that for C-DSCS foot care subscales. The Cronbach's alpha coefficient of .73 indicates acceptable internal consistency (Nunnally & Bernstein, 1994). Furthermore, test-retest reliability (.92) was satisfactory (Burns & Grove, 2005). The results of the exploratory factor analysis showed good construct validity for the DFSBS. The DFSBS was also positively correlated with the foot care subscale of the C-DSCS and SDSCA. Previous research found that patients with a history of foot ulcers had better foot care behaviors than did those without (Johnston et al., 2006; Schmidt et al., 2008). This is consistent with our findings and supports good known-groups validity for the scale.

In summary, the DFSBS provides good validity and reliability. It includes daily foot care items that have been proposed as key foot self-care behaviors (McInnes et al., 2011). Thus, it is appropriate for assessing basic foot self-care behaviors in patients with diabetes. There are, however, several limitations that need to be mentioned. First, the initial item development of the DFSBS was based on the literature on foot self-care behaviors and guidelines for diabetic foot care. Although a pilot study revealed that the wording of items was easy to understand for patients, focus groups should be conducted to include patient views and experiences. Second, participants in this study all had diabetic neuropathy, and most had 6 or fewer years of education (72.2%). Further study is needed to test the applicability of the DFSBS in non-neuropathic and well-educated populations. Third, the DFSBS did not address all foot self-care behaviors listed in diabetic foot care guidelines. Thus, this scale should not be used as a patient education instrument.

## Conclusions

In conclusion, the DFSBS demonstrates adequate validity and reliability and may be used by researchers to assess foot self-care behaviors and by healthcare personnel as a screening instrument. The DFSBS contains a relatively small number of items (7) and requires no more than 5 minutes to complete. It is thus convenient and easy to administer during brief, time-limited clinic visits.

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# 糖尿病足部照護行為量表之發展及測試

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- 背景** 合宜的足部自我照護行為能預防糖尿病足部潰瘍。為評估病患足部照護行為以及評值足部照護行為促進措施之成效，應使用合宜之足部照護行為量表，但目前並無涵蓋每日足部照護行為且具信效度之量表可供使用。
- 目的** 本研究目的為發展糖尿病足部自我照護行為量表並測試其信、效度。
- 方法** 文獻查證建立題庫，經專家進行內容效度檢測之後，採方便取樣，於 295 位糖尿病併發周邊神經病變患者進行量表信效度之測試：測試量表之建構效度、內在一致性、以及再測信度。
- 結果** 糖尿病足部照護行為量表共七題，為單因素結構。量表得分與中文版糖尿病自我照顧量表之足部照護分量表 ( $\rho = .87, p < .001$ ) 及糖尿病自我照護行為量表之足部照護分量表得分 ( $\gamma = .45, p < .001$ ) 具相關性，達統計上顯著水準；有無足部潰瘍病史之研究對象的量表得分有顯著差異 (Mann-Whitney  $Z = -3.09, p < .01$ )。量表內在一致性為可接受 (Cronbach's  $\alpha$  值 .73)，兩週後再測信度的組內相關係數為 .92。
- 結論／實務應用** 本研究結果顯示，糖尿病足部照護行為量表具信、效度，臨床人員可使用此量表於患者足部照護行為之篩檢，研究人員亦可使用此量表於足部自我照護相關議題之探討。

**關鍵詞：**糖尿病足、自我照顧、量表發展。

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