Validity of the Mexican version of the combined Foot Care Confidence / Foot-Care Behavior scale for diabetes

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ABSTRACT

Objective. *To 1) translate / transculturally adapt the original (English-language) combined Foot Care Confidence Scale / Foot-Care Behavior instrument (FCCS-FCB) to produce a Mexican-Spanish version and 2) determine its validity and reliability in a population with diabetes in Tijuana, Mexico.*

Methods. *The original FCCS-FCB was translated (and back-translated), the content validated (by a group of health professional experts), and the instrument applied to 304 patients 23–78 years old in diabetes support groups in Tijuana, Mexico. Internal consistency for the study constructs ("self-efficacy," and risk / preventive foot self-care behaviors) was measured using Cronbach's alpha. The constructs were validated using principal component factor analysis.*

Results. *The Cronbach's alpha values for internal consistency were 0.782 for self-efficacy and 0.505 for behaviors. Based on the analysis, two factors explained 49.1% of the total variance for self-efficacy, and six factors explained 57.7% of the total variance for behaviors. The results were consistent with those for the original (English) version of the FCCS-FCB.*

Conclusions. *The Mexican version of the FCCS-FCB is a reliable and valid instrument recommended for use with Mexican-Spanish–speaking patients with diabetes.*

Key words Validation studies; reproducibility of results; diabetic foot; self care; self efficacy; Mexico.

Diabetes is a chronic disease affecting approximately 9% of the adult population and is responsible for 1.5 million deaths worldwide. It is estimated that 80% of diabetes deaths occur in low- and middle-income countries like Mexico (1). The prevalence of diabetes among people 20–79 years old is reported to be 11.0% in North America and the Caribbean and 8.0% in South and Central America (2). In Mexico, diabetes affects more than 9 million people (3), causes 87 245 deaths annually, and is the leading cause of death among people 45–64 years old (4). People with diabetes require lifelong treatment to address the complications their chronic condition can trigger. These complications include cardiovascular problems, neuropathy, renal failure, vision problems, and loss of limbs by amputation (5), all of which often overwhelm health services. Diabetic foot (DF) (foot ulcer) is one of the most common complications that cause a significant amount of disability. DF is defined as an "ulceration, infection, and/or deep tissue destruction associated with neuropathy or peripheral vascular disease in the lower extremities of people with diabetes" (6, 7). Prevalence of DF ranges from 1.5% to 10% and its cumulate incidence is between 2.2% and 5.9%. This

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means that each year about 4 million people with diabetes will develop foot ulcers (8).

While interventions are needed to improve medical treatment of DF, foot protection through patient self-care is recognized as the first line of prevention to avoid the amputation of lower limbs (9, 10). One of the most useful approaches in preventive and health promotion programs involves the cognitive process that occurs in measuring one's level of "self-efficacy"—a concept referring to a sense of adequacy, efficiency, and ability to cope with life. Bandura introduced the concept of self-efficacy in his social cognitive theory (SCT) (11), which defines it as the belief that an individual has about the result he/she would get if he/she performs a certain behavior (10, 12, 13). Given this cognitive process, effective diabetes care programs should consider 1) diabetes patients' level of confidence in their treatment, and 2) their self-care behaviors.

In this report, diabetes self-care behaviors are divided into risk (potentially damaging), and protective. Protective behaviors include any activity that is perceived as "healthy" and undertaken by an individual for the purpose of preventing or detecting illness (14). This type of self-care is critical for people with diabetes to prevent the development of foot ulcers. In recent years, several scales have been developed to assess the severity of foot ulcers (15, 16), screen for high risk (17, 18), and/or assess the impact of foot ulcer treatment on quality of life (19, 20). These include the Confidence in Diabetes Self-care scale (CIDS), which was designed to assess diabetes-specific self-efficacy among Dutch and U.S. patients (but includes only three items related to foot care), and a seven-item scale developed more recently that evaluates foot self-care behaviors (21). However, very few scales evaluate both 1) diabetes self-care risk / preventive behaviors and 2) patients' perceptions of their self-efficacy in carrying them out, and to the best of the authors' knowledge no such scales have been validated for use among Spanish-speaking populations.

The Foot Care Confidence Scale (FCCS) (10) is a questionnaire designed to measure foot-care self-efficacy. The Foot-Care Behavior (FCB) scale (22) measures self-care behaviors (preventive and risk) in performing important foot care. The FCCS and FCB were originally developed and validated separately, in English, by Sloan (10) and Vileikyte et al. (22) respectively; in 2009, Perrin et al. (9) presented them together as one integrated instrument (the FCCS-FCB).

The desire for valid and reliable scales that assess health in its broadest sense and the use of health services in particular has led to the production of questionnaires that collect data on variables previously ignored by health professionals, such as functional, psychological, and social aspects. Although most of these scales have been developed in English-speaking countries (mainly the United States), at present they are being used more broadly in other languages (23, 24). The FCCS-FCB is an accepted, valid, and reliable combination scale that allows for collection of important information about preventive and risk behaviors related to diabetes plus simultaneous analysis of foot care and the construct of self-efficacy. The goal of this research was to 1) translate / transculturally adapt the original (English-language) FCCS-FCB to produce a Mexican-Spanish version and 2) determine its validity and reliability among a population with diabetes in Tijuana, Mexico.

MATERIALS AND METHODS

Between November and December 2012, two separate Spanish translations of the original (English) version of the FCCS-FCB were combined into one consensus version (Version 1), which was validated by a group of experts (generating Version 2), tested in a focus group feasibility study, and back-translated for comparison with the original English text (generating Version 3). Version 3 was then applied in a cross-sectional survey to gather data for testing the scale's psychometric properties. Internal consistency for the study constructs ("self-efficacy," and risk / preventive foot self-care behaviors) was measured using Cronbach's alpha; the constructs were validated using principal component factor analysis. Based on the analyses, Version 3 was revised to produce the final version of the Mexican-Spanish FCCS-FCB) (Figure 1).

Translation

Two professional Spanish–English translators translated the English questionnaires independently, generating two Spanish versions of the same material. Two researchers then systematically reviewed and integrated the two Spanish versions, including the response categories, and the instructions, to generate the first consensus version of the Mexican-Spanish FCCS-FCB (Version 1).
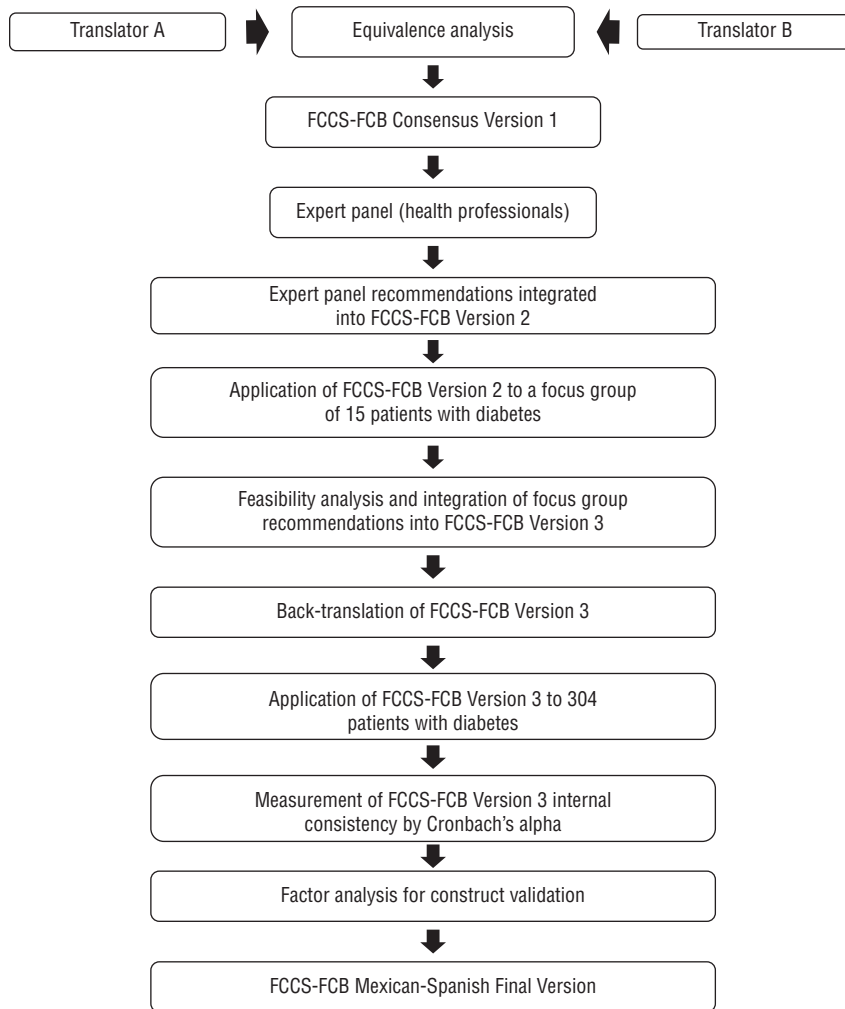
Content validation

To validate Version 1, recorded interviews were conducted with a group of health professional experts (a neurologist, an angiologist, a psychologist, and a podiatrist) to assess its content, clarity, and readability. To evaluate the content, the experts used a checklist to score each questionnaire item (with "1" meaning the item was clear and understandable, "2" if it was difficult to understand, and "3" if it was completely unintelligible). The experts also provided opinions and suggestions about the questionnaire's language, based on cultural, technical, and local semantic considerations. The experts rated 75% of the questions as clear and understandable and 25% as difficult to understand. None of the questions were rated incomprehensible. One recommendation from the experts was to make the wording of the questionnaire more consistent/uniform. After reviewing the recorded interviews with the experts and their completed checklists, the researchers incorporated the experts' recommendations and designed a second version of the Mexican-Spanish FCCS-FCB (Version 2). The participation of the health professional experts was essential in this process.

Items pretesting with intended target population

A feasibility analysis was conducted by administering Version 2 to a focus group of 15 diabetes patients with characteristics similar to the selection criteria for the study sample. The goal of this phase of the research was to assess the level of clarity and readability of the adapted FCCS-FCB content according to users similar to the instrument's ultimate target group (diabetes patients focused on foot self-care). The principal investigator (JAG) moderated the focus group session with the help of two social workers. The session was recorded and transcribed and all focus group participant comments and questions analyzed. The participants required 10–15 minutes to answer the questionnaire. All questions

FIGURE 1. Validation of the Spanish translation and transcultural adaptation of the combined Foot Care Confidence Scale / Foot-Care Behavior instrument (FCCS-FCB) in people with diabetes, Tijuana, Mexico, 2013

of its diabetes program, DiabetIMSS (*Programa de atención al paciente diabético*), which provides comprehensive care to patients diagnosed with diabetes. DiabetIMSS is run by a multidisciplinary team consisting of a family doctor, nurse, dentist, social worker, nutritionist, and psychologist.

The research team surveyed 304 patients with diabetes who were more than 20 years old and attending DiabetIMSS support groups during the five-day workweek (two in the morning shift and one in the afternoon shift). Patients who had suffered ulceration, infection, and/or deep-tissue destruction associated with neuropathy and/or peripheral vascular disease in the lower extremities were excluded from the survey. The age of the participants ranged from 23 to 78 years with a mean age of 54 (± 10.4). A total of 101 were men (33.2%) and 203 (66.8%) were women.

Scale description

The survey collected information on socio-demographic, self-efficacy, and foot-care behavior variables. The FCCS-FCB includes 29 items—12 for self-efficacy, nine for preventive behaviors, and eight for risk behaviors. The FCCS section of the questionnaire evaluates self-efficacy in foot care based on survey participant responses to various statements (e.g., "I can protect my feet"), using a five-point Likert scale (with 5 meaning "very sure" and 1 meaning "not sure at all"). The FCB section evaluates two different domains of diabetes foot self-care: preventive behaviors and risk behaviors. For the preventive behavior domain, there are six possible responses ("twice daily," "daily," "every three days," "twice a week," "once a week," or "never") to nine questions about self-care (e.g., "During the past week how often did you examine your feet?"). For the risk behavior domain, there are four possible responses ("always," "most of the time," "occasionally," or "never") to questions about risk behaviors (e.g., "In general, how often do you use chemical agents or plasters to remove corns and calluses?"). The total score for the FCCS (self-efficacy) scale ranges from 12 to 60 points, with higher scores representing greater self-efficacy (as perceived by the patient). The total score for the FCB (preventive and risk behaviors) scale ranges from 17 to 86 points, with higher scores

and wording were understood except the Spanish term for "podiatrist," which was changed to the Spanish term for "foot care specialist." The replacement of this one term was the only change to the content of Mexican-Spanish FCCS-FCB Version 3. Once the revision was completed, the entire text of Version 3 was back-translated into English by a professional translator who was not familiar with the original FCCS-FCB. Forward–backward translation was carried out to ensure the integrity of the instrument at the conceptual level (23) by testing equivalence between the original English text and the translated/adapted version (24).

Establishment of psychometric properties

After confirming the equivalence of Mexican-Spanish FCCS-FCB Version 3

with the original instrument, a self-administered survey was carried out in a sample of 304 participants to measure the translated instrument's internal consistency and factor structure. The estimated sample size was based on criteria recommending the inclusion of 10 subjects per item to validate an instrument (25). Once the purpose of the study was explained to the participants and they provided signed informed consent, a questionnaire including the FCCS-FCB scales was administered by the researchers.

Survey setting and population

The survey was conducted at a Family Medicine Unit of the Mexican Social Security Institute (*Instituto Mexicano del Seguro Social*, IMSS) in Tijuana, Baja California, Mexico. The clinical unit was selected because

representing higher risk of potential foot-damaging behaviors.

Data analysis

Cronbach's alpha coefficient was used to measure the reliability of Version 3 according to the internal consistency method. A principal components factor analysis with orthogonal Varimax rotation was then performed to evaluate the construct validity. To determine if the items correlation matrix was factorable, the researchers performed a Bartlett test of sphericity and the Kaiser-Meyer-Olkin test (KMO), which assesses the strength of partial correlations among scale items and measures sample adequacy. A KMO coefficient > 0.6 indicates a good sample size (26, 27). The factors that showed eigenvalues greater than 1 were retained (26), and included items with a factorial loading > 0.40 (27). SPSS statistical package version 16 (SPSS Inc., Chicago, Illinois, United States) was used for all statistical analysis.

Ethical considerations

The research protocol was approved by the Bioethics Committee of the School of Medicine and Psychology of the Universidad Autónoma of Baja California. Participants signed an informed consent that explained the study objective in detail and were informed that they would not receive any incentives for participating and their information would be kept confidential. Any participants that required clinical assistance for their feet also received information about available health services.

RESULTS

The sample included 304 participants with a mean age of 54 years old (± 10.4), of which 101 (33.2%) were men and 203 (66.8%) were women. A total of 181 (65.6%) had completed six years of schooling or less, and of those 17 (5.6%) were illiterate, 55 (18.1%) had completed middle school, 17 (5.6%) had completed high school, and 23 (7.6%) had completed higher education (technical/university). With regard to marital status, 183 (60.0%) were married, 35 (11.5%) were single, 35 (11.5%) were widowed, 24 (7.9%) were cohabiting with a partner, and 14 (4.6%) were divorced. A total of 143 (47.0%) listed their occupation as "housework,"

55 (18.1%) were employed, 27 (8.9%) were retired, 23 (7.6%) were merchants, 11 (3.6%) were laborers, and 29 (9.5%) had occupations classified as "Other."

Principal component factor analysis generated a KMO value of 0.758 ($P <$ 0.001, Bartlett test of sphericity), indicating the sample size was acceptable for factor analysis. As shown in Table 1, two factors or structures for the self-efficacy construct explained 49.1% of the total variance, with 39.4% attributable to the first factor (items 1, 2, 3, 5, 7, 8, 9, and 11), which assessed foot self-care, and the remainder attributable to the second factor (items 4, 6, 10, and 12), which assessed clinical aspects of foot care. For the behaviors construct, six factors explained 57.7% of the total variance. The greatest percentage (14.1%) was attributable to the first factor (items 19, 20, 22, 23, and 29), which assessed risk (potentially damaging) behaviors for foot care, with the rest attributable to the remaining five factors. The second factor (items 13, 15, and 16) assessed footwear, the third factor (items 14, 17, and 18) assessed foot-care hygiene, the fourth factor (items 21 and 26) assessed use of proper footwear, the fifth factor (items 25 and 27) assessed the purchase of proper footwear, and the sixth factor (items 24 and 28) assessed foot care (Table 1).

Figure 2 shows how the constructs of self-efficacy and behaviors are distributed in the FCCS-FCB and their respective Cronbach's alpha values for internal consistency. The reliability results indicated an estimated internal consistency of 0.782 for the self-efficacy construct and 0.505 for the behaviors construct, with 10 and 12 items respectively with a factorial loading > 0.50, grouped by constructs and dimensions. For self-efficacy, two factors or dimensions emerged from the factor analysis: foot self-care and foot-care clinical aspects. For behaviors, the items were grouped as "preventive" or "potentially damaging" (i.e., risk) according to the criteria described by Perrin et al. (9).

DISCUSSION

This research produced a transculturally adapted version of the FCCS-FCB in Spanish (see Supplementary material) with psychometric properties consistent with the original (English) version (9, 10, 22).

The methodology that was used was recommended by experts in the field of scale validation for obtaining an instrument that is culturally adapted for the local population yet semantically equivalent to the original version. This type of adaptation allows those modifying the scale to capitalize the intellectual and technical work of the researchers who developed the original version, thus avoiding the complex and expensive process of creating a new instrument. This methodology also allows for the use of reference values from the construction and validation of the original instrument (28).

This survey sample included men and women with low levels of education, a characteristic consistent with other populations of people with diabetes and peripheral neuropathies found to be at high risk of having diabetes-related foot problems (5, 29, 30). Although some researchers have shown an acceptable correlation between self-efficacy and preventive behavior, suggesting that a high level of self-efficacy implies favorable preventive behavior (31–33), self-efficacy did not act as a predictor of self-care behaviors in this study, perhaps due to cultural aspects. Without disqualifying the valuable role played by the belief system as a means of modifying behavior (as per the SCT), some studies explain that, along with self-efficacy, people require skills, knowledge, and incentives to stimulate and reinforce self-care behavior (34). More detailed analysis of related environmental and psychological variables is needed to establish the conditions driving higher prevention levels in behaviors.

The results of this study must be interpreted within the context of some limitations. First, the cross-sectional nature of the research design limited study of the sample to a given point in time, precluding exploration of any patterns of change (trends) over time in patients' perception of their self-efficacy, their actual conduct, and/or development of a foot pathology. Qualitative studies would have allowed for 1) assessment of diabetes patients' actual behavior, providing a better understanding of the relationships between background, behaviors, and consequences (35), and 2) measurement of certain behaviors that must be identified within their natural context. Second, the FCCS-FCB was adapted and validated in Spanish spoken in Mexico and therefore the results reported here might not be

TABLE 1. Factor analysis for the combined Foot Care Confidence Scale / Foot-Care Behavior instrument (FCCS-FCB) (Spanish version) in people with diabetes, Tijuana, Mexico, 2013

Item	Factor						% Explained variance
	1	2	3	4	5	6	
Self-efficacy							49.1
1 "I can protect my feet."	0.734						
2 "Even without pain/discomfort, I can look at my feet daily to check for cuts, scratches, blisters, redness, or dryness."	0.575						
3 "After washing my feet, I can dry between my toes."	0.600						
4 "I can judge when my toenails need to be trimmed by a podiatrist."		0.736					
5 "I can trim my toenails straight across."	0.505						
6 "I can figure out when to use a pumice stone to smooth corns and/or calluses on my feet."		0.796					
7 "I can test the temperature of the water before putting my feet into it."	0.436						
8 "If told to do so, I can wear shoes and socks every time I walk (including walking indoors)."	0.466						
9 "When I go shopping for new shoes, I can choose shoes that are good for my feet."	0.622						
10 "I can call my doctor about problems with my feet."		0.529					
11 "Before putting them on, I can check the insides of my shoes for problems that could harm my feet."	0.705						
12 "If directed to do so, I can routinely apply lotion to my feet."		0.695					
Behaviors							57.7
13 During the past week how often did you examine your feet?		0.691					
14 During the past week how often did you wash your feet?			0.566				
15 During the past week how often did you use moisturizing oils or creams for your feet?		0.745					
16 During the past week how often did you change your socks?		0.480					
17 During the past week how often did you test the water temperature with your hand/elbow before taking a bath or shower?			0.771				
18 During the past week how often did you walk barefoot indoors?			0.636				
19 During the past week how often did you walk barefoot outdoors?	0.623						
20 During the past week how often did you wear shoes without the socks?	0.835						
21 During the past week how often did you check the inside of your shoes?				0.480			
22 In general, how often do you use chemical agents or plasters to remove corns and calluses?	0.493						
23 In general, how often do you yourself treat corns or calluses with a blade?	0.654						
24 In general, how often do you cut your toenails straight across?					0.533		
25 In general, how often do you have your feet measured when buying a new pair of shoes?					0.458		
26 In general, how often do you wear trainers/sneakers or lace-up shoes?				0.652			
27 In general, how often do you rely on feeling the fit of new shoes (versus being measured) when buying a new pair?					0.701		
28 In general, how often do you wear sandals or slip-ons?						0.777	
29 In general, when your feet feel cold at night, how often do you use hot water bottles/heating pads to warm them?	0.490						

generalizable to other Spanish-speaking populations.

Strengths of the study included the extensive translation and adaptation process, and the equivalency that was obtained between the original English text and the resulting Spanish version. During the transcultural adaptation process, the FCCS-FCB content was modified based on comments and suggestions from both diabetes patients and the group of health professional experts. While only moderate internal consistency coefficients were obtained for the adapted scale, the values were similar to those for the original (English) version. Aside from the language revisions, no technical or conceptual changes had to

be made to the adapted version to obtain a semantically and culturally equivalent version of the FCCS-FCB in Spanish.

Conclusions

The final version of the Mexican-Spanish FCCS-FCB was a short instrument with simple questions that may be suitable for use with any Spanish-speaking diabetes-suffering population. This combination scale can be used in different community settings, including outpatient care and educational programs for patients with diabetes. Additional research should be carried out to explore the instrument's strength in predicting outcomes related to the

self-efficacy scale (the FCCS) in terms of self-care behaviors, and its sensitivity to changes in patient behavior.

FIGURE 2. Self-efficacy and behaviors factor model for the combined Foot Care Confidence Scale / Foot-Care Behavior instrument (FCCS-FCB) scale (Spanish version), by internal consistency coefficient (α), dimension (D), item factor loading coefficient > 0.5 (fl), and item number, in people with diabetes, Tijuana, Mexico, 2013
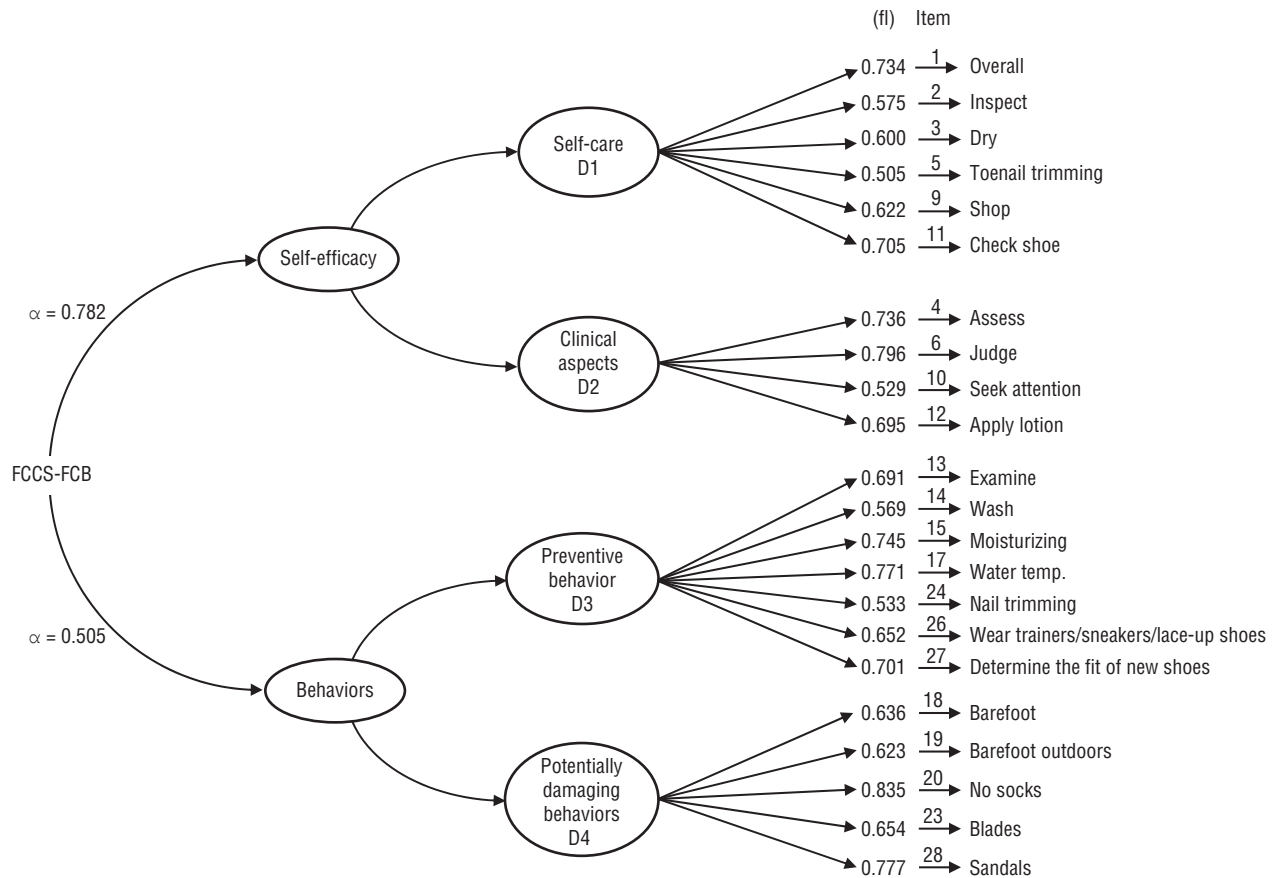
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RESUMEN

Validez de la versión mexicana del instrumento combinado de las escalas Foot Care Confidence Scale y Foot Care Behavior para la diabetes

Objetivo. 1) traducir o adaptar transculturalmente el instrumento original combinado (en inglés) de las escalas Foot Care Confidence Scale (Escala de Competencia en el Cuidado del Pie) y Foot Care Behavior (Comportamientos del Cuidado del Pie) (FCCS-FCB) para crear una versión en español de México, y 2) determinar su validez y fiabilidad en una población de personas con diabetes de Tijuana, México.

Métodos. Se tradujo al español la escala original FCCS-FCB (y se volvió a traducir al inglés), su contenido fue validado (por un grupo de expertos), posteriormente se aplicó el instrumento a 304 pacientes de 23 a 78 años de edad, pertenecientes a grupos de apoyo al control de la diabetes de Tijuana, México. Mediante el alfa de Cronbach, se midió la coherencia interna de los constructos ("competencia personal" y "comportamientos de riesgo o preventivos de autocuidado del pie"). Los constructos fueron validados mediante análisis factorial de componentes principales.

Resultados. El valor de alfa de Cronbach correspondiente a competencia personal fue de 0,782 y de 0,505 para los comportamientos. En el análisis factorial, dos factores explicaron el 49,1% de la variancia total para la competencia personal, y seis factores explicaron el 57,7% de la variancia total para los comportamientos. Los resultados concordaron con los de la versión original (en inglés) del FCCS-FCB.

Conclusiones. La versión mexicana del FCCS-FCB es un instrumento fiable y válido recomendado para su empleo en pacientes mexicanos de habla hispana con diabetes.

Palabras clave Estudios de validación; reproducibilidad de resultados; pie diabético; autocuidado; autoeficacia; México.