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#### Translation and cultural adaptation of a Danish version of the Foot Health Status Questionnaire for individuals with plantar heel pain

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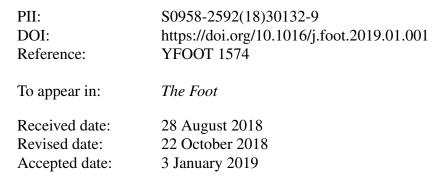
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### Accepted Manuscript

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Translation and cultural adaptation of a Danish version of the Foot Health Status Questionnaire for individuals with plantar heel pain

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### Highlights

- The FHSQ was translated using the dual-panel approach
- The FHSQ-DK had high face validity among patients with plantar heel pain
- Panels and patients found it difficult to differentiate between two of the items

### Abstract

**Background.** The Foot Health Status Questionnaire (FHSQ) is recommended as a valid and reliable patient-reported outcome for individuals with plantar heel pain (PHP). The aim of this study was to translate and culturally adapt the FHSQ into Danish and investigate face and construct validity among patients with PHP.

**Methods.** The translation was made using the dual-panel approach. The first panel of bilingual translators translated the questionnaire and the translation was then presented to a lay panel who reviewed and revised the translated version. This version was presented to patients with PHP (n=6) who were interviewed about the comprehensibility, if they found it easy to fill out, and if they found the questionnaire to be relevant to them. Correlation between mean weekly heel pain and FHSQ scores were used to assess construct validity in another patient sample (n=30).

**Results.** The first panel of five translators reached consensus on all 13 items. The layman panel of five participants rephrased two items. Both the layman panel and patients had difficulties with differentiating between items 12 and 13 but concluded that making better phrasings that would work in Danish was not possible. The questionnaire was evaluated as relevant and comprehensible. No revisions were made after the interviews. Pain and function domains correlated with heel pain but not footwear or general foot health.

**Conclusion.** The FHSQ was translated into a Danish version (FHSQ-DK) which demonstrated both face and construct validity. More psychometric properties of the FHSQ-DK should be established in future studies.

### Introduction

One in every four adults will experience foot pain during their lifetime and up to four in ten runners will suffer from foot-related pain complaints.(1,2) Some of the most commonly reported causes of foot pain are plantar heel pain,(3) osteoarthritis,(4) deformities such as hallux valgus, and nail and skin complaints.(5)

To understand how pain and other complaints impact an individual, we need to use patientreported outcomes. During the past 30 years, there has been a shift from a focus on objective clinical and laboratory measures to include patient-reported outcomes. An increasing interest in the patients' perspectives and growing burden of chronic conditions are considered reasons for this development.(6)

A systematic review of patient-reported outcomes for foot pain identified seven different questionnaires.(7) The Foot Health Status Questionnaire (FHSQ) was highlighted as a questionnaire with a high validity and reliability (ICC=0.74-0.92) that could be used in both research and in clinical settings.(8) This is the recommended questionnaire when evaluating patients with plantar heel pain.(9) The FHSQ has been translated into Brazilian Portuguese and Spanish but has yet to be translated into Danish.(10,11) Therefore, the aim of this study was to translate and culturally adapt the FHSQ into Danish and investigate face and construct validity in a plantar heel pain population.

### **Material & Methods**

#### **Ethics**

The study was conducted according to the Declaration of Helsinki.(12) Because the study did not include any intervention, no approval by the Ethics Committee of the North Denmark

Region was required according to Danish law. In connection with enrolment in concurrent studies, all participants provided written informed consent. Before the translation process started permission was obtained by Bennett, P., first author of the questionnaire development paper.(8)

#### The Foot Health Status Questionnaire

The FHSQ was developed in Australia to assess foot health among patients suffering from various foot complaints. It consists of 13 items divided into four domains: foot pain, foot function, footwear, and general foot health. It takes the respondent less than 10 minutes to complete. The FHSQ software in which answers are entered provides a score for each domain ranging from 0 (lowest score) to 100 (highest score).(8) Landorf et al. investigated the minimal important difference of three of the four domains and found differences of 14.1 points in the pain domain, 7.4 points in the foot function domain, and 9.2 points in the general foot health domain to be clinically important among patients with plantar heel pain.(13)

#### **Translation process**

The translation was made using the dual-panel approach.(14) This method has been found to be superior to forward-backward translation with regards to target population and lay people preferences.(15) The first panel consisted of bilingual translators. This panel was informed about the original questionnaire and its intended use. The panel translated the questionnaire during a group discussion. Any disagreements that could not be solved during this meeting were noted and decided by the second panel which was the lay panel. This panel consisted of lay people with no health professional degree or history of being in the target population (i.e. a history of plantar heel pain or other foot disorders). This panel reviewed and revised the translated version and had no knowledge of the original questionnaire to make sure that they

were not affected by what they thought the translated items should mean based on the original wording but rather what they did mean according to the translated version. A single coordinator was present at both panel discussions. His role was to make sure that the conceptual equivalence of the items was maintained throughout the translation process, to present the second panel with alternative wordings on which the first panel could not reach consensus, and to document the process. After the lay panel had revised the translated version, it was presented to patients of the target population. They tested the questionnaire and were asked during single-person interviews about the ease of filling out the questionnaire, if they had encountered any items that were incomprehensible, and if they thought that the questionnaire was relevant to them to assess face validity.

#### Recruitment

According to recommendations on using the dual-panel approach five to seven people were needed in each panel for a fruitful discussion.(14) Participants for the two panels were recruited among a convenience sample of university staff, and family and acquaintances of the study coordinator. A representative sample of six patients with plantar heel pain were recruited among participants in a concurrent study at the Research Unit for General Practice in Aalborg, Department of Clinical Medicine, Aalborg University (NCT03264729). Sample size of patients was based on the information power of individual participants to reach data saturation and was not defined before recruitment.(16)

#### **Construct validity**

We evaluated the construct validity of the FHSQ-DK by assessing the correlation between each of the domain scores and mean heel pain (0 to 100 mmVAS) during the past week prior to assessment using Pearson's correlation coefficient. We used baseline scores of a random

sample of 30 individuals with plantar heel pain who were enrolled in a concurrent study at the Research Unit for General Practice in Aalborg, Department of Clinical Medicine, Aalborg University (NCT03304353). The analysis of construct validity was performed after all analyses of the concurrent study had been performed. Sample size was determined using large sample case.(17)

### Results

The first panel consisted of five participants (three females) with ages ranging from 27 to 48 years. All participants held either a health professional degree or an academic Master's degree. The translation lasted 1 hour and 35 minutes. The panel reached consensus on all 13 items but wanted the second panel to pay special attention to the comprehension of items 4, 6, 11, and 12, and to the response options to item 1. They also wanted the second panel to assess if *Moderat* was the best possible word to describe response option C in items 5, 6, 7, and 8.

The second panel consisted of five participants (four females) with ages ranging from 26 to 69 years. Three participants were skilled workers, one was an unskilled worker, and one held a Master's degree. The panel discussion lasted 25 minutes. The panel agreed that items 5 and 9 had to be rephrased and made new wordings. The panel had difficulties with differentiating between items 12 and 13. The coordinator presented them with the original English version of these two items which did not help. The panel concluded that Danish is a simpler language than English and it would not be possible to make a better phrasing than that of the first panel as *condition* and *health* has the same meaning when translated into Danish.

The characteristics of the six female patients who tested the Danish translation and were interviewed are presented in Table 1. They all evaluated the questionnaire as being relevant to

them and comprehensible and completion in all cases took less than 10 minutes. Three patients had difficulties with differentiating between items 12 and 13 and all three said that they would just choose the same response option in both items. No revisions to the questionnaire were made based on the interviews. The original and translated items are displayed in Table 2.

#### **TABLE 1:** PATIENT CHARACTERISTICS

Γ

AGE years	37 (28 to 51)
HEIGHT cm	167 (165 to 168)
WEIGHT kg	89 (85 to 95)
<b>BMI</b> kg/m <sup>2</sup>	34 (29 to 35)
SYMPTOM DURATION months	11 (3 to 24)
PAIN DURING PAST WEEK /100 mm	57 (47 to 62)
DATA ARE PRESENTED AS MEDIAN (INTER-QUARTILE RANGE).	

#### **TABLE 2:** FOOT HEALTH STATUS QUESTIONNAIRE COMPARISONS

ORIGINAL	DANISH	
FOOT PAIN DOMAIN		
What level of foot pain have you had during the past week?	I hvilken grad har du oplevet smerte i fødderne i løbet af den seneste uge?	
How often have you had foot pain?	Hvor ofte har du oplevet smerte i fødderne?	
How often did your feet ache?	Hvor ofte har du oplevet ømhed i fødderne?	
How often did you get sharp pains in your feet?	Hvor ofte har du oplevet pludselige stærke smerter i dine fødder?	
FOOT FUNCTION DOMAIN		
Have your feet caused you to have difficulties in your work or activities?	Har du oplevet problemer med at udføre dit arbejde eller andre aktiviteter på grund af dine fødder?	
Were you limited in the kind of work you could do because of your feet?	Har du været begrænset i at udføre dine arbejdsopgaver på grund af dine fødder?	

How much does your foot health limit you walking? How much does your foot health limit you climbing stairs?	Hvor begrænset er du i at gå på grund af dine fødder? Hvor begrænset er du i at gå på trapper på grund af dine fødder?	
FOOTWEAR DOMAIN		
It is hard to find shoes that do not hurt my feet.	Det er svært at finde fodtøj, der ikke gør ondt på mine fødder.	
I have difficulty in finding shoes that fit my feet.	Jeg har svært ved at finde fodtøj, der passer mine fødder.	
I am limited in the number of shoes I can wear.	Jeg er begrænset i hvilket fodtøj, jeg kan bruge.	
GENERAL FOOT HEALTH DOMAIN		
How would you rate your overall foot health?	Hvordan vil du overordnet vurdere dine fødders sundhed?	
In general, what condition would you say your feet are in?	Hvordan vil du generelt vurdere dine fødders tilstand?	

There was a significant correlation between mean heel pain and the pain and function

domains (r=-0.523, P=0.003 and r=-0.449, P=0.013, respectively) but no correlation between

mean heel pain and footwear and general foot health domains (r=-0.045, P=0.815 and r=-

0.085, P=0.657, respectively). The characteristics of the patients whose questionnaire data

were used for these analyses are presented in Table 3.

#### TABLE 3: PATIENT CHARACTERISTICS FOR CONSTRUCT VALIDITY

AGE years	46.9 (11.7)
HEIGHT cm	170.7 (10.1)
WEIGHT kg	85.5 (19.7)
<b>BMI</b> kg/m <sup>2</sup>	29.4 (6.3)
SYMPTOM DURATION* months	10 (6 to 30)
PAIN DURING PAST WEEK /100 mm	57.6 (20.0)
DATA ARE PRESENTED AS MEAN (SD)	
*MEDIAN (INTER-QUARTILE RANGE)	

### Discussion

This study used the dual-panel approach to translate FHSQ into Danish and was conducted among a group of patients with plantar heel pain who represent one of the most common types of foot complaints. The FHSQ-DK pain and function domains correlated with mean weekly heel pain and demonstrated a high face validity among patients with plantar heel pain. Patients were able to complete the questionnaire within 10 minutes.

#### Dual-panel versus forward and back translation

A forward-backward translation is a more common choice of methodology when translating questionnaires, but concerns using this method have been raised as each of the steps rely heavily on each other. If both the forward and backward translations are good the backward translation will most likely look nothing like the original questionnaire which can lead to misleading impressions of the quality of the translations. Therefore, the dual-panel approach focusses on producing a single translation of high quality.(14) Even though the participants of both panels had very different educational backgrounds only two out of 13 items were rephrased after the lay panel meeting. This emphasizes the quality of the translation. Furthermore, all patients considered the questionnaire to be of relevance to them and easy to understand and use. This indicates that the face validity of the original FHSQ was kept throughout the translation process. The one issue that both panels and patients encountered was to differentiate between items 12 and 13. None of the previous translations into Spanish or Brazilian Portuguese reported problems with these two items.(10,11) This might be an issue related to simplicity of the Danish language compared with English as *condition* and health has the same meaning when translated into Danish. This is what both panels and patients concluded. We could have decided to merge these two items into one, however, this would compromise the comparability with the original questionnaire and the use of the FHSQ software to provide a score for the general foot health domain. Issues concerning this specific

domain have been raised before as the number of items may lead to clustering of answers and very little discrimination between responders and further limiting the number of items could potentially lead to even more clustering of answers.(9) Adding to the challenges of the domain, we found no correlation between general foot health and mean weekly heel pain (P=0.657) which further questions the use of the domain in this patient group. Both the pain and function domains correlated with patients' symptoms, thus, these domains had a higher construct validity and may be more informative.

#### **Patient population**

The sample of patients who evaluated face validity only consisted of women whereas the two panels consisted of both sexes. Even if foot pain affects both sexes, women account for the majority of cases and 90% of participants in the study from which the sample was recruited were women.(18) This emphasizes that the sample was representative of the specific patient population. However, the FHSQ was not developed with the sole purpose of being used among patients with plantar heel pain.(8) The questionnaire should be validated and minimal important differences should be calculated in all populations among which it is intended to be used. So far, this has only been done among patients with plantar heel pain.(7) Additionally, more psychometric properties of the translated version should also be established in the future among different target populations as a final step of the translational process.(14)

### Conclusions

We used the dual-panel approach to translate the FHSQ into a Danish version (FHSQ-DK) which patients with plantar heel pain found to be comprehensible, easy to use and relevant. Both pain and function domains correlated with patients' self-reported pain, but additional psychometric properties of the FHSQ-DK should be established in future studies in various

populations suffering from foot complaints.

## **Conflict of interest**

We wish to declare that none of the authors have any conflicts of interest associated with this work.

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