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Study Protocol

Translation, Cross-Cultural Adaptation of the Lower Extremity Functional Scale into Filipino, and Analysis of its Psychometric Properties: A Study Protocol

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Abstract

Background: Impairment and functional limitations from musculoskeletal conditions are evaluated using outcome measure tools. The Lower Extremity Functional Scale (LEFS) is one of the outcome measure tools (OMT) that assess the functional capacity of patients who have lower extremity conditions. It was originally developed in English and translated later into other languages; however, no Filipino version is available. **Objective:** This study aims to translate, cross-culturally adapt the LEFS into Filipino, and evaluate its psychometric properties. **Methods**: Using a psychometric study design, the LEFS will be translated and cross-culturally adapted into Filipino following the guidelines set by Beaton et al. and Sousa and Rojjanasrirat. These include six stages: (1) forward translation into Filipino, (2) synthesis, (3) backward translation, (4) expert committee review, (5) pilot testing/cognitive interview, and (6) psychometric testing. Filipinos with lower extremity conditions will be recruited for the pilot (n= 10) and psychometric testing (n= 200). Validity will be evaluated using face validity index, content validity index, independent t-test (known-group validity), and Spearman rho (concurrent validity). Reliability will be assessed using Cronbach alpha for the internal consistency and intraclass correlation coefficient for the stability. Floor and ceiling effects will also be computed. **Expected results:** The LEFS will be successfully translated and cross-culturally adapted into Filipino. It will be a valid and reliable outcome measure tool that physical therapists and other healthcare professionals can use for the functional assessment of patients. This study can also serve as a reference for future translation studies.

Keywords: *Filipino Translation, lower extremity, validity, questionnaire*

INTRODUCTION

A musculoskeletal condition is defined as an affectation to one or more functional components of the body, such as muscles, bones, and other soft tissues.[1] In the Philippines, these conditions tend to affect the younger population ages 15 to 30, with males being more affected than females.[2] The lower extremity (LE) is the second most commonly reported body part involved in occupational injuries and diseases with an 18.7% prevalence.[3] Impairment and functional limitations caused by these conditions can be assessed using outcome measure tools (OMTs), which provide baseline data during physical examinations and are necessary for planning interventions and reevaluating the functional rehabilitation goals.[4]

LE OMTs typically concentrate on a single joint area, such as the Foot and Ankle Ability Measure, the Knee Injury and Osteoarthritis Outcome Score, and the Hip Impairment and Osteoarthritis Outcome Survey; however, only the Lower Extremity Functional Scale (LEFS) could assess the LE as a whole.[1] The LEFS was originally developed in English and has been translated and cross-culturally adapted by several Asian countries.[5-6] Translation and cross-cultural adaptation are needed if the

questionnaire will be used in another country and another language.[7]

The LEFS is a patient-reported 20-item questionnaire that assesses lower extremity function. It is scored on a five-point Likert scale ranging from 0 to a maximum of 4 (0 = unable to perform the activity; 1 = quite a bit of difficulty; 2 = moderate difficulty; 3 = a little bit of difficulty; 4 = no difficulty) The maximum score is 80.[8] The reported score represents the current level of difficulty that the patient experiences when performing the activities itemized in the questionnaire. The lower the score, the more severe the patient's LE condition limits activity. Meanwhile, a higher score would indicate that activity limitation caused by the condition is less severe.

A systematic review of the measurement properties revealed that the LEFS has an excellent test-retest reliability with intraclass correlation coefficients (ICC) ranging between 0.85 – 0.99 and Pearson correlation coefficient values of greater than 0.07.[9] Responsiveness was also excellent with consistent high effect sizes (>0.80) in patients with various LE conditions. The pooled estimate of the minimal detectable change at 90% confidence interval is six points to indicate a true change. Minimal clinical important difference (MCID) is nine points to indicate a clinically meaningful change. The internal consistency for the LEFS scores was excellent with Cronbach α>0.92.[9]

The LEFS psychometric properties have already been established. However, cultural adaptation and language barriers may significantly affect its validity if the English version is administered to a population that is as ethnically diverse as the Philippines. Patients' concerns about OMTs include issues concerning ethnic and cultural sensitivity, and language barriers, especially for those not fluent in English. The diversity of the population indicates the need for a translated, cross-culturally adapted, and validated OMT to provide better quality patient care.[7] There is currently no Filipino translation of LEFS. Thus, to promote a culturally sensitive, patient-centered rehabilitation in the country focusing on LE function, there is a need for LEFS translation into Filipino.

This study aims to translate and cross-culturally adapt the LEFS into Filipino and to determine the psychometric properties of the translated questionnaire, specifically content, construct, known-group validity, internal consistency, and test-retest reliability. To this end, Fil-LEFS can be used as an OMT by Filipino Physical Therapists (PTs) and healthcare professionals when evaluating patients with LE conditions. Moreover, using OMTs in a language that patients can comprehend and with culturally relevant questions reduces the risk of misinterpretation. This, in turn, will help PTs create a more appropriate goal and healthcare plan. This will also serve as a future reference for studies with the same research objectives of translating and culturally adapting other OMTs into Filipino.

METHODS

Ethical Consideration. The Ethics Review Committee of the University of Santo Tomas-College of Rehabilitation Sciences (UST-CRS) reviewed and approved this study. This study will adhere to the Declaration of Helsinki, National and International Ethical guidelines, and the Data Privacy Act of 2012.

Study Design. This study will utilize a quantitative, psychometric research design[5-6] to determine the validity and reliability of the translated Fil-LEFS.

Participants. The researchers will recruit participants from all over the Philippines through infographics dissemination on online social media platforms. Eligible participants for pilot and psychometric testing will be 18-year-old or above Filipino adults who are literate enough in the Filipino language. There will be two groups of participants that will be recruited. The symptomatic group will be those who have any lower extremity musculoskeletal conditions, while the asymptomatic group will be those who do not have any musculoskeletal conditions.[5-6, 8, 10, 11]

This study will not consider chronicity or severity of conditions due to previous LEFS studies' recommendations to explore wide-range diagnosis and severity.[5-6, 11] Moreover, it will exclude participants with any cognitive

impairments affecting their ability to answer the questionnaire, including dementia, traumatic brain injury, or mental retardation.[6] The 6-item Cognitive Impairment test (6-CIT) will be used to assess cognitive problems. Only those who will score 0 to 7 will be provided with control numbers to be eligible to answer the Fil-LEFS through Google Forms.[12] The researchers will not store all information during screening. Participants with limited to no access to technology and internet connectivity or are unfamiliar with navigating online platforms are ineligible to participate unless with researchers' direct supervision.

The study will use purposive sampling due to the limitations of the online setup.[5, 13] The sample size for the pilot testing is n= 10. Sousa and Rojjnasrirat recommend 10-40 participants on pilot testing of health care instrument validation.[14] For the psychometric testing, there will be a total of 200 participants based on the computed respondent-to-item ratio of 10:1. This follows the rule of thumb ratio and satisfies a fair sample size for validation studies.[15]

Setting. This study will take place all over the Philippines through online platforms. All meetings will be conducted through Zoom, while asynchronous communication will be via Google mail or Yahoo mail. The recruitment process will be done through Facebook and Messenger. Securing informed consent and administration of the Fil-LEFS will be conducted through Google Forms.

Data Gathering Procedures. The whole process of translation, cross-cultural adaptation, and validation of the LEFS is presented in Figure 1. This procedure was based on the guidelines set by Beaton et al.[7] and Sousa and Rojjansrirat.[14]

The research will have two phases: translation and validation. A permission letter for the use of the LEFS was sent to the original developer. Upon the receipt of the approval, the translation began.

Phase 1: Translation phase.

Forward translation. Two bilingual translators with Filipino native language will forward translate the original questionnaire from English into Filipino. The translators will include a

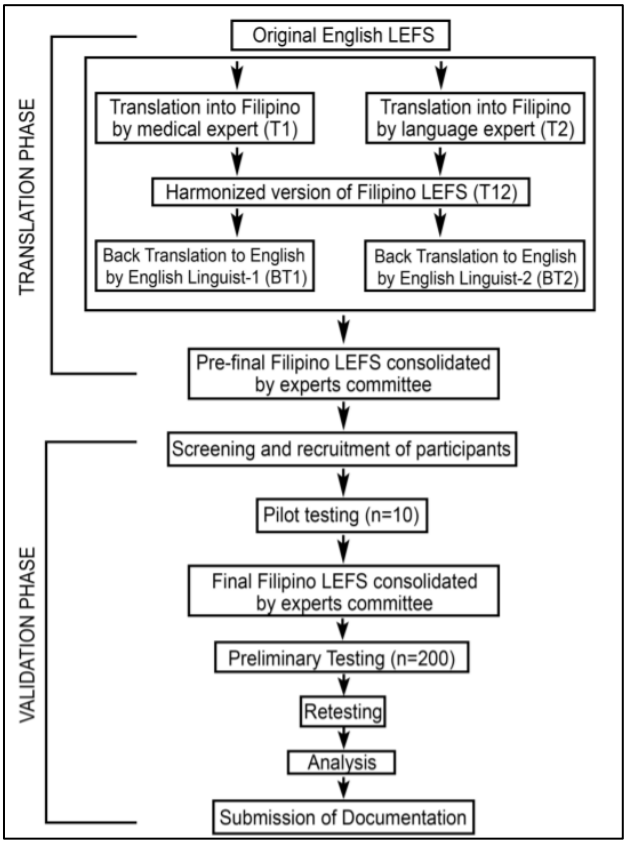

Figure 1. Overview of the whole process of the translation, cross-cultural adaptation, and validation of LEFS.

Filipino PT who uses LEFS (T1) and a Filipino Linguist (T2).

Synthesis. In an online meeting set by the researchers, the two bilingual translators (T1, T2) and a recording observer will synthesize the two forward translations to settle differences in translations. Discrepancies and poor word choices in the translation will be resolved through a discussion to create a common translation (T12).

Backward Translation. From T12, backward translations will be done by two bilingual English linguists with no medical background. Both will be blinded from the original LEFS English version, and each of them will translate the T12 version back to English (BT1, BT2) for validity check.

Expert Review Committee. An expert committee will consist of (a) two PTs with specialization in musculoskeletal conditions and experience using

LEFS, (b) one rehabilitation doctor with specialization in musculoskeletal conditions, (c) one statistician with experience in psychometric research, (d) one Filipino and two English linguists with no familiarity with the medical concepts included on the questionnaire, (e) one layperson, and (f) one socio-cultural expert with a background in Filipino cultural adaptation. All of them will consolidate the versions of LEFS questionnaires (T1, T2, T12, BT1, BT2) to create a pre-final version. Their decision will be made based on semantic, idiomatic, experiential, and conceptual equivalence. Semantic equivalence pertains to the presence of multiple meanings or grammatical difficulties in an item. Idiomatic equivalence checks for the equivalent expression in Filipino of colloquial terms from the original version. Experiential equivalence ensures that the items capture the experiences of the daily life of Filipinos. Meanwhile, conceptual equivalence refers to the applicability of the concept of each item in the Philippines.[7] They will also evaluate the overall content of the pre-final version using the COSMIN Criteria.

Phase 2: Validation phase

Screening. A scheduled synchronous (Google Meet, Zoom, or Facebook Messenger) screening session with a research team member will ensure that inclusion criteria are met. The researcher will require the participants to show a valid I.D. with birth date information for age verification. Any medical document or proof that the participant has a condition that affects the lower extremities' function will also be requested. For exclusion, the 6-item Cognitive Impairment test (6-CIT) will be administered to assess the presence of cognitive impairment, especially to the older population. Once they pass the inclusion criteria, they will be given the informed consent form and participant information sheet. Those who will voluntarily join the study will be provided with the link to the questionnaires.

Pilot testing/Cognitive Interview. The pre-final version will undergo pilot testing based on the guidelines set by Sousa and Rojjanasrirat[14] to examine its face and content validity by the target population. Ten subjects will answer the questionnaire and undergo a cognitive interview with a researcher to assess their understanding of the questions. For content validity testing, subjects will rate the clarity and comprehensibility of each item question using a four-point Likert scale (1= the item is not clear and understandable; 4 = the item is very clear and understandable). At least 80% inter-rater agreement is required; meanwhile, less than 80% would subject the item question for re-evaluation.[14] The subjects' feedback and comments will be discussed by the experts. These will all be incorporated in the final Filipino-LEFS version.

Psychometric Testing. The final version of Fil-LEFS will be administered twice to the participants to assess its test-retest reliability and internal consistency. A Google Form link containing the Fil-LEFS will be sent to them via email or Facebook Messenger. They are given one week to answer the questionnaire. The English version will be provided two hours after answering the Filipino version for comparison to measure the construct validity. Meanwhile, the Fil-LEFS will be re-administered two days later to minimize short-term clinical changes, similar to the original and previous LEFS translations.[1, 8] This time interval will ensure no clinical changes in the participants' conditions and initial responses are not recalled.[8] Patients will also be reminded to avoid activities that will cause dramatic changes to their conditions within the two-day interval.[8] The researchers will send a follow-up email to them if there is no response two days after the initial administration of the questionnaires. There will only be a maximum of three follow-up attempts to the participants. Those who will not be able to send within the allotted time will be considered non-response.

Data analysis. Data analysis will be performed using IBM SPSS Statistics 22. Descriptive statistics, such as mean and standard deviations, will be used to summarize participant characteristics. The face validity will be assessed using the Face Validity Index (FVI) during the experts' committee meeting. The FVI score will be the average of all scores on each item number of the questionnaire with at least 0.80 as the acceptable cut-off score.[16]

Content validity will be determined using the Content Validity Index (CVI) on the individual items (I-CVI) and the whole scale (S-CVI/Ave).

For I-CVI, each expert will be asked to rate each item's relevance through a four-point scale from 1 (not relevant) to 4 (very relevant) and divided by the total number of experts. An I-CVI of more than 79% is deemed relevant, while revision is needed if it falls between 70% to 79%. Moreover, if it is less than 70%, it will be removed from the scale.[17] For the S-CVI/Ave, the average I-CVI score across all items will be utilized. A score of at least 0.80 is required for the scale to be acceptable.[17]

The COSMIN criteria and rating system will also be utilized to evaluate the content validity of the Fil-LEFS as a whole. It assesses the relevance, comprehensiveness, and comprehensibility through the experts' rating to each criterion if sufficient, insufficient, or indeterminate.[18]

An Independent t-test will be used to assess the questionnaire's known-group validity. The Fil-LEFS scores of both the symptomatic and asymptomatic participants will be compared. Spearman rho coefficient will be used to determine the correlation between the Fil-LEFS and the English LEFS.

Construct validation will be accomplished through concurrent validation using Spearman rho correlation to assess the relationship of the participant's scores on both the Filipino and English LEFS. The obtained correlation value will be classified as follows: 0.90-1.00 is very strong, 0.70-0.89 is strong, 0.40-0.69 is moderate, 0.10-0.39 is weak, and 0.00-0.10 is negligible.[19]

Internal consistency will be tested using Cronbach's alpha coefficient. This will be based on the number of items in the questionnaire and item homogeneity during the preliminary testing period.[11] A Cronbach alpha value greater or equal to 0.95 reflects an excellent internal consistency.[10] The test-retest reliability will be determined by calculating the intraclass correlation coefficient (ICC).[11, 13] With a 95% CI, a cut-off ICC score of 0.90 is considered acceptable for a clinical measure.[20] The floor and ceiling effects will also be assessed during the preliminary testing and retesting.[10] Both effects are significant if 15% or more of the sample achieves the highest or the lowest possible scores.[13]

EXPECTED RESULTS

The expected results of the study will include the outputs from each of the stages of translation and cross-cultural adaptation. This will include a tabulated summary of the modifications from the experts during the expert review committee to ensure idiomatic, conceptual, semantic, and experiential equivalence of the questionnaire. There will also be tables that summarize the findings from the face, content, construct, known-group validity, and test-retest reliability. After an iterative process of modifications, the I-CVI and S-CVI of the questionnaire are expected to be within the minimum acceptable indices. The known-group validity will show a significant difference in the score of the asymptomatic and symptomatic patients since the asymptomatic patients do not have the specific characteristics that the tool measures. This will mean that the constructs of the translated questionnaire can appropriately be used to distinguish patients with symptoms. A significantly high correlation is expected between the Filipino and English questionnaire versions for the concurrent validity as both assess the same construct. Furthermore, excellent test-retest reliability is expected since previous LEFS translations have proven that repeated tests after initial questionnaire administration showed a high degree of unchanged test scores.[10, 11] This will mean that the questionnaire is stable and will not show variability over time. Internal consistency is expected to be excellent, comparable to the original LEFS. This will measure the homogeneity of the items in the questionnaire. No floor or ceiling effects are expected to ensure that the questionnaire can evaluate the wide ranges of lower extremity musculoskeletal conditions regardless of the severity and chronicity. The whole process will produce a translated, cross-culturally adapted, valid, and reliable Filipino version of the LEFS. This tool can further help healthcare professionals collect valid and reliable assessment data, contributing to the appropriateness of the goal setting and plan of care of patients.

Individual author's contributions

K.S.; F.C; Conceptualized the study design. K.S.; F.C.; L.B.; M.D.; L.D.; W.M.; A.N.; J.R.; P.S. S.V.; Wrote the methodology, reviewed related literature, and drafted and revised the study protocol.

Disclosure statement

The authors declare that this study did not receive funding from organizations, institutions, or agencies.

Conflicts of interest

The authors of this paper declare no conflicting interest.

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