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ORIGINAL RESEARCH

- Cross-cultural adaptation and measurement properties
- of the Brazilian Version of the Michigan Neuropathy
- Screening Instrument
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KEYWORDS

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Diabetes mellitus; Diabetic polyneuropathies; Questionnaires; Reliability; Measurement properties

Abstract

Background: The Michigan Neuropathy Screening Instrument (MNSI) is an easy-to-use questionnaire aimed at screening and detecting diabetic polyneuropathy (DPN).

Objective: To translate and cross-culturally adapt the MNSI to Brazilian Portuguese and evaluate its measurement properties.

Methods: Two bilingual translators translated the MNSI from English into Brazilian Portuguese and made a synthetic version. The synthetic version was back translated into English. A committee of specialists and the translator checked the cultural adaptations and developed a pre-final questionnaire in Brazilian Portuguese (prefinal version). In pretesting, the prefinal version was applied to a sample of 34 subjects in which each subject was interviewed to determine whether they understood each item. For the later assessment of measurement properties, 84 subjects were assessed.

Results: A final Brazilian Portuguese version of the MNSI was produced after obtaining 80% agreement (SEM < 0.01%) among diabetic patients and specialists. We obtained excellent intrarater reliability (ICC_{3,1} = 0.90), inter-rater reliability (ICC_{2,1} = 0.90) and within-subject reliability ICC_{3,1} = 0.80, excellent internal consistency (Cronbach's alpha > 0.92), reasonable construct validity for the association between the MNSI and Neuropathy Symptom Score (r = 0.46, p < 0.05) and excellent association between the MNSI and Neuropathy Disability Score (r = 0.79, p < 0.05). We did not detect floor and ceiling effects (<9.5% of patients with maximum scores).

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33 34 35 36 37 Conclusions: The Brazilian Portuguese version of the MNSI is suitable for application in the Brazilian diabetic population and is a reliable tool for the screening and detection of DPN. The MNSI can be used both in clinical practice and also for research purposes.

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Introduction

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Diabetic polyneuropathy (DPN) is a common complication of diabetes mellitus. The progressive and irreversible course of the disease ultimately leads to an increase in ulceration and limb amputation rates. 1,2 Different clinical scoring systems have been developed as quantitative instruments to diagnose the presence of DSN and classify its severity, including the Michigan Neuropathy Screening Instrument (MNSI)³⁻⁶; the Neuropathy Disability Score^{7,8} and Neuropathy Symptom Score^{6,7,9}; the Diabetic Neuropathy Symptom Score; the Neuropathy Impairment Score¹⁰; and the Toronto Clinical Scoring System. 11 These screening instruments, typically developed in English, assess the impact of these diseases on the quality of life of patients and are widely used in the literature. Specifically, the MNSI is an easy-to-use questionnaire effective at screening and identifying DPN because it addresses the major signs and symptoms that comprehensively map the disease, such as sensibility, reflexes, and orthopedic complications.3 In order to map DPN, the MNSI includes two assessments of signs and symptoms: a 15-item self-administered questionnaire and a set of physical assessments of the lower limbs. Impairment is determined by the number of positive responses or abnormal clinical findings. Compared to other instruments, MNSI is much more detailed about the reported symptoms of DPN and provides more information during the clinical assessment, which is crucial for the proper guidance of therapeutic actions.

Although the MNSI is one of the most widely used instruments in diabetes research worldwide, 3-5,12-18 it is only available in English and in European Portuguese, 4 and therefore, cannot be applied in Brazil. The existing studies using a translated MNSI^{4,5,15,16,18,19} worked with a simple translation, not a validated and adapted version, that was probably chosen based on its advantages over other instruments and its detailed characterization of the neuropathy. The translation, cross-cultural adaptation, and validation of instruments developed for use in a certain language and culture are important because this enables their effective application in other languages and cultural contexts, while maintaining the same measurement properties as the original version. 20,21 The entire process is essential to ensure that the instrument is culturally accepted in the desired country and equivalent to the original.

There are currently two Portuguese versions of the MNSI: one was carried out by Barbosa et al.,⁴ who translated and validated the questionnaire for European Portuguese, and the other by Oliveira et al.,⁵ who translated and cross-culturally adapted it to Brazilian Portuguese without

testing the instrument for its measurement properties. However, since the translation in the former study was carried out in Portugal, it exhibits semantic, idiomatic, cultural, and conceptual differences from Brazilian Portuguese and, therefore, cannot be used in Brazil. The second study failed to test the Brazilian Portuguese version of the questionnaire, making it impossible to determine whether the translation displays the same measurement properties as the original. Therefore, we proceeded with the cross-cultural adaptation and measurements properties of the MNSI in Brazilian Portuguese, applying the COSMIN²⁰ recommendations, to ensure that all of the methodological procedures were carried out.

Therefore, the aim of the present study was to translate and cross-culturally adapt the MNSI to Brazilian Portuguese and to evaluate its measurement properties for use in research and clinical practice.

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Methods 103

Participants and design

The study was conducted at the Physical Therapy, Speech and Occupational Therapy department, School of Medicine, Universidade de Sao Paulo (USP), São Paulo, SP, Brazil. The study sample consisted of individuals diagnosed with type 1 or 2 diabetes, according to the criteria of the American Diabetes Association (ADA), treated at Associação Nacional de Assistência ao Diabético (ANAD) between May and December 2016. The number of participants evaluated were as follows: pretest phase - 19 patients and 15 professional healthcare specialists in diabetes care; and investigation of the measurement properties was assessed in 84 patients. Exclusion criteria were: people who did not fluently speak Brazilian-Portuguese, those suffering from blindness, cognitive disorders, liver disease, hypothyroidism, collagen diseases, vasculitis, and other causes of DPN (alcohol consumption, kidney failure). The study was approved by the Research Ethics Committee of the School of Medicine, USP.

The study was carried out in two stages: (1) translation and cross-cultural adaptation, and (2) testing of the measurement properties. The first stage followed the methods recommended by Beaton et al.'s²¹ guidelines and the second stage was in line with the recommendations of Terwee et al.²² All participants were advised of the procedures that would be performed and gave written, informed consent. Before the study began, we contacted the author of the original version⁶ of the MNSI (Dr. Eva Feldman) from the

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