

Full length article

Test-retest reliability and construct validity of the King's Parkinson's Disease Pain Scale – Brazilian version

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ABSTRACT

The 14-item King's Parkinson's disease Pain Scale (KPPS) measures the frequency and intensity of various painful symptoms reported by people with Parkinson's disease (PD). For the Brazilian population, KPPS has undergone cross-cultural adaptation, but some measuring properties still need to be investigated. By evaluating the reliability and construct validity of the KPPS-Brazil, this study aims to fill this gap. The KPPS-Brazil was completed by participants with PD in two sessions. On the initial administration, participants also completed the McGill Pain Questionnaire (MPQ), Beck Depression Inventory (BDI), Parkinson's Disease Sleep Scale (PDSS), and Parkinson's Disease Quality of Life Questionnaire (PDQ-39). Test-retest reliability was calculated for each domain and total scores. The Bland-Altman plot was used to confirm the limits of the agreement. Calculations were made for the standard error of measurement (SEM) and minimum detectable change (MDC). The KPPS-Brazil and other measures were successfully completed by fifty people (30 men, 68.9 years old). Intraclass correlation coefficient (ICC) was 0.992 (95 % confidence interval [95 %CI] 0.983 – 0.996; $p < 0.001$), and all domains showed good to excellent levels of reliability. The SEM and MDC values were 1.09 and 3.02, respectively. These values are within the recommended range and 75 % of the hypotheses we have established are supported by our findings. KPPS-Brazil is a reliable instrument that can be used in clinical and research settings to evaluate pain in Brazilians with PD.

1. Introduction

Parkinson's disease (PD) is a progressive and chronic neurodegenerative disorder [1] characterized by prominent motor symptoms [2]. However, it also leads to a range of non-motor symptoms, including sensory disturbances such as pain [3]. Although pain was mentioned in early descriptions of PD, it has only gained extensive attention and investigation in recent decades [4,5].

Pain in PD is attributed to multiple mechanisms, including including degeneration of the mesolimbic pathway, impairment of descending monoaminergic projections, and motor fluctuations [6]. A longer disease duration, younger age at disease onset, and a higher levodopa equivalent daily dose have been identified as predictors of pain in PD, which is associated with motor disability and poor quality of life [4,7]. Pain prevalence rates in individuals with PD range from 40 % to 85 %

[8]. According to Ford (2010), pain in PD can be categorized into five distinct types: musculoskeletal, radicular/neuropathic, dystonic, central or primary pain, and akathisia. Among these, musculoskeletal pain is the most common, followed by dystonic, central neuropathic, radicular, and other types of pain [9].

Therefore, it is crucial to assess this non-motor symptom in PD and imperative to employ appropriate instruments. The most commonly used tools for assessing pain in PD include the Visual Analogue Scale (VAS), the McGill Pain Questionnaire (MPQ), and the Brief Pain Inventory (BPI) [10]. While these instruments are widely used, they lack specificity in evaluating the different types of pain experienced by individuals with PD [10]. The VAS is a unidimensional instrument that measures pain intensity on a scale from 0 to 10. The MPQ is a multidimensional instrument that assesses different aspects of pain, including sensory, evaluative, and affective dimensions. However, it may not

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provide a precise description of the specific types of pain experienced by individuals with PD. The BPI measures pain on a scale from 0 to 10 in relation to specific activities such as walking, work, and social interactions. Nonetheless, it does not offer a comprehensive understanding of the various aspects of pain experienced by individuals with PD.

To address this limitation, the King's Parkinson's disease Pain Scale (KPPS) was developed [11]. The KPPS consists of 14 questions divided into seven domains that assess the frequency and severity of various painful symptoms experienced by individuals with PD. According to Pérez-Lloret et al., among 11 eligible instruments, the KPPS is the only one recommended for measuring pain intensity in PD and is also suggested for pain classification [10]. The KPPS has undergone cross-cultural adaptation and assessment of its measurement properties in different populations, including Indian [12], Turkish [13], Bulgarian [14], Persian [15], Brazilian [16], Arabic [17], and Spanish [18].

The KPPS-Brazil has demonstrated adequate content validity; however, its measurement properties still need to be investigated [16]. Therefore, this study aims to assess the reliability and construct validity of the KPPS-Brazil in a sample of community-dwelling individuals with PD. Based on previous studies showing that pain and its severity are linked to difficulty falling asleep, frequent awakenings [12,19], and depression [17,20], as well as its impact on quality of life [15,17], we hypothesize that the KPPS-Brazil demonstrates satisfactory reliability and construct validity, providing valuable insights to support and advance research in Brazil.

2. Methods

2.1. Authorization and ethics approval

This cross-sectional study followed the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines [22] and the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) [21]. The use of the KPPS for scientific purposes was previously authorized by the MAPI Research Trust (N°227187, <http://mapi-trust.org/>) [16]. The local research ethics committee approved the study (CAAE: 00854318.6.0000.5149), and all participants provided written informed consent. The sample size considered sufficient for calculating reliability is 50 participants, as recommended by the COSMIN guidelines [22] and supported by previous studies [13, 14,18,23] that used this sample size for reliability and measurement error analysis.

2.2. Participants

Participants were recruited from the community between November 2021 and July 2022. The inclusion criteria were as follows: a clinical diagnosis of idiopathic PD, determined by a movement disorders specialist neurologist based on the United Kingdom Parkinson's Disease Society Brain Bank criteria [24], as used in previous studies [14–16,18], age ≥ 20 years, and a disease stage of up to 4 on the Hoehn and Yahr Scale. Individuals were excluded if they had impaired cognitive function, as determined by their Mini-Mental State Examination score [25], or if they had visual and/or auditory impairments that could hinder participation. Individuals with other adverse health conditions, such as unrelated neurological, psychiatric, or orthopedic diseases, were also excluded. Additionally, patients in stage 5 were excluded due to severe motor and functional impairments, as well as comorbidities, such as musculoskeletal conditions, which could affect KPPS scores. However, patients taking pain medication were not excluded.

2.3. Materials

The KPPS is a tool consisting of 14 items divided into 7 domains, which assess various aspects of pain. These domains include musculoskeletal pain, chronic pain, pain related to fluctuations, nocturnal pain,

orofacial pain, changes in color and edema related to pain, and radicular pain [11]. Severity is rated on a scale from 0 to 3 (0 – none, 1 – slight, 2 – moderate, and 3 – severe pain), while frequency is rated on a scale from 0 to 4 (0 – never, 1 – rarely, 2 – sometimes, 3 – frequently, and 4 – constantly experiencing pain). The severity score is multiplied by the frequency score, resulting in a value between 0 and 12 for each item. The overall score is obtained by summing the scores of all 14 items, yielding a total score ranging from 0 to 168 (12×14) points [11]. The Brazilian Portuguese version of the KPPS, developed and previously published by our research group, was utilized [16].

The MPQ assesses the sensory-discriminative, affective-motivational, and cognitive-evaluative dimensions of pain. Patients express their pain-related emotions by selecting the most appropriate descriptors. The questionnaire consists of 20 items, each containing two to six descriptors, covering sensory, affective, evaluative, and other aspects of pain [10]. The Brazilian-Portuguese versions of the MPQ (both short and long forms) were found to be reproducible, valid, and responsive for assessing pain in patients with musculoskeletal conditions, demonstrating high internal consistency (Cronbach's alpha: range = 0.70–0.79) and reliability (ICC_{2,1} range = 0.69–0.85) [26].

The BDI is a widely used self-assessment tool in clinical settings for evaluating depressive symptoms. It consists of 21 sets of statements assessing symptoms and attitudes experienced over the past week. Higher scores indicate greater severity of depressive symptoms. The Brazilian version of the BDI, which demonstrated an internal consistency of 0.88 for depressed patients, was used [27].

The PDSS is a 15-item visual scale that quantifies various aspects of nocturnal disturbances and sleep problems in PD [28]. The maximum score, obtained by summing the values of each item (with 15 items ranging from zero to ten), is 150, indicating the absence of symptoms, while a score below 100 points suggests concerning nocturnal symptoms [28]. A threshold value of less than five points for each item indicates sleep disturbance [28]. The Brazilian Portuguese translated version demonstrated satisfactory internal consistency (Cronbach's alpha: 0.82) and high test-retest reliability (0.94) and was used in this study [29].

The PDQ-39 is a well-established and reliable tool for assessing the quality of life in individuals with PD [30]. The questionnaire consists of 39 items categorized into eight dimensions: mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. The total score ranges from 0 (no problems) to 100 (maximum level of problems), with higher scores indicating a poorer perception of quality of life [30]. Carod-Artal et al. (2007) found an alpha ranging from 0.61 to 0.85, with item-total correlations between 0.46 and 0.82, which were considered satisfactory for the PDQ-39 dimensions. The ICC ranged from 0.52 (social support) to 0.80 (stigma) [31].

2.4. Procedure

Clinical and demographic information, followed by the administration of the KPPS-Brazil and other clinical measurement instruments, were collected during the first evaluation session. These data were used to investigate construct validity. To evaluate the test-retest reliability of the KPPS-Brazil, the same participants completed the KPPS-Brazil again in a second session, which was scheduled one week after the initial assessment. The same examiner (RMSR) conducted both sessions to ensure consistency. This interval was sufficient to prevent recall bias while being short enough to ensure that no significant clinical changes had occurred [23,32]. If needed, in case participants had difficulty reaching the laboratory, data were collected at their homes. The assessments were conducted through an interview to facilitate the patients' understanding of the instruments applied.

2.5. Statistical analyses

Descriptive statistics were used to characterize the sample. Data

normality was assessed using the Kolmogorov-Smirnov test. Results are presented as absolute values and percentages, means and standard deviations, or medians and interquartile ranges (IQR, represented as Q1-Q3).

Reliability was analyzed using test-retest reliability and measurement error. The test-retest reliability of individual domains and total scores was assessed using the Intraclass Correlation Coefficient (ICC2,1) with 95 % confidence intervals (CI). ICC values were interpreted as follows: < 0.40 = poor reliability; $0.40-0.75$ = moderate reliability; $0.75-0.90$ = good reliability; and > 0.90 = excellent reliability [22]. An ICC of at least 0.70 in a sample of at least 50 patients is considered to indicate acceptable reliability [22,33].

Measurement error was calculated using the standard error of measurement (SEM) based on the following formula: $SEM = SD * \sqrt{1 - ICC}$, where SD is the standard deviation from the first application of the KPPS. The minimal detectable change (MDC) was calculated using the formula: $MDC = SEM * 1.96 * \sqrt{2}$ [22,33]. SEM was also expressed as a percentage (SEM%) of the maximum possible total score, with $SEM\% \leq 5\%$ of the score range considered satisfactory. The Bland-Altman plot was used as a graphical representation of between-session agreement, displaying the mean differences along with the limits of agreement (LA). The 95 % CI for LA was calculated as follows: 95 % LA = mean difference (d) $\pm 1.96 * SD$, where SD is the standard deviation of the differences.

According to COSMIN [22], pre-defined hypotheses must be established to evaluate construct validity [33,34]. This study included the following measures: pain intensity (McGill Pain Questionnaire – MPQ), depression (Beck Depression Inventory – BDI), sleep disturbances (Parkinson’s Disease Sleep Scale – PDSS), and quality of life (Parkinson’s Disease Quality of Life Questionnaire – PDQ-39). We hypothesized that the KPPS-Brazil would show moderate to excellent correlations with these instruments, as they assess key aspects potentially related to pain in individuals with PD. The MPQ evaluates different dimensions of pain, helping to determine whether the KPPS captures similar aspects of the pain experience [15,26]. The BDI assesses depressive symptoms, with previous studies showing that patients with depression exhibit higher mean KPPS scores [17]. The PDSS assesses sleep disturbances, which are frequently associated with pain in PD [12,19]. Finally, the PDQ-39 helps determine the extent to which pain impacts patients’ quality of life [30,31]. Spearman correlation coefficients were classified as fair (<0.30), moderate ($0.30-0.70$), or excellent (>0.70) [17]. According to COSMIN criteria, an instrument’s construct validity is considered sufficient if at least 75 % of the predefined hypotheses are confirmed in a sample of at least 50 patients [22].

All the analyses were performed using SPSS statistical software v21.0 for Windows with a significance level of 5 %. JAMOVI program was used to construct the graphs.

3. Results

Ninety patients were contacted, but 28 attempts were unsuccessful. Two patients did not show up for the evaluation, and ten individuals declined to participate in the study. Fifty participants with a mean age of 68.9 ± 9.5 years completed all assessments. The participants had been experiencing PD symptoms for an average duration of 7.5 years (IQR = 4–12 years). The demographic and clinical characteristics of the sample are summarized in Table 1.

3.1. Reliability

Item-total correlation analysis revealed positive and statistically significant values (ranging from 0.865 to 0.985), as shown in Table 2. No significant differences were observed in the average scores between the two applications of the KPPS-Brazil. The ICC was calculated to be 0.992 (95 % CI = 0.983 – 0.996; $p < 0.001$). Among the seven domains evaluated, four domains (3, 4, 6, and 7) exhibited excellent test-retest reliability ($ICC > 0.90$), while three domains (1, 2, and 5)

Table 1
Demographic and clinical characteristics of study participants.

Variable	n = 50
Age (years), mean $\pm$ SD (min-max)	68 $\pm$ 9.5 (45–88)
Sex (men), n (%)	30 (60 %)
Education (years), median (IQR)	9 (5 – 12)
MMSE (0–30), median (IQR)	26 (24 – 29)
Time of symptoms (years), median (IQR)	9 (5 – 13)
Time since diagnosis (years), median (IQR)	7.5 (4 – 12)
PD onset side (left), n (%)	21 (42 %)
Use of Levodopa (yes), n (%)	48 (96 %)
Hoehn e Yahr, median (IQR)	2 (1 – 2)
MDS-UPDRS Subsection III, median (IQR)	29.5 (18 – 49)
TD phenotype, n (%)	6 (12)
PIGD phenotype, n (%)	41 (82)
Indeterminate phenotype, n (%)	3 (6)
BDI, mean $\pm$ SD (min-max)	11.4 $\pm$ 6.6 (0 – 30)
BDI ≥ 18 , n (%)	8 (16 %)
PDSS, mean $\pm$ SD (min-max)	111.6 $\pm$ 19.3 (69 – 149)

Abbreviations: BDI: Beck Depression Inventory; IQR: Interquartile Range; MDS-UPDRS: Movement Disorder Society-Unified Parkinson’s Disease Rating Scale; MMSE: Mini-Mental State Examination; PD: Parkinson’s disease; PDSS: Parkinson’s Disease Sleep Scale; SD: Standard Deviation; TD: Tremor-Dominant; PIGD: Postural Instability-Gait Disorder.

Table 2
Intraclass Correlation Coefficient (ICC) for all domains of the KPPS-Brazil.

Domain	ICC	Level of reliability
1	0.888 (CI 95 % = 0.802–0.936; $p < 0.001$)	good
2	0.867; (CI 95 % = 0.765–0.925; $p < 0.001$)	good
3	0.984; (CI 95 % = 0.971–0.991; $p < 0.001$)	excellent
4	0.974; (CI 95 % = 0.955–0.985; $p < 0.001$)	excellent
5	0.880; (CI 95 % = 0.789–0.932; $p < 0.001$)	good
6	0.979; (CI 95 % = 0.964–0.988; $p < 0.001$)	excellent
7	0.937; (CI 95 % = 0.889–0.964; $p < 0.001$)	excellent

demonstrated good test-retest reliability ($ICC 0.75 - 0.90$) (Table 2).

For the KPPS-Brazil total scores, the SEM and MDC values were 1.09 ($SEM\% = 0.65$) and 3.02, respectively. Therefore, changes greater than 3.02 points are required to demonstrate real changes in the KPPS-Brazil scores.

The Bland-Altman plot (Fig. 1) was used to compare the mean differences between the measures obtained during the test and retest. The plot showed a relatively symmetrical distribution around the midline, indicating no significant systematic errors for the total scores obtained on both occasions. The upper and lower LA were 3.06 and 4.82, respectively. These limits were not agreed upon by three individuals. Two of these differences could be explained by changes in pain, such as an increase in arm pain or a decrease in knee pain.

3.2. Construct validity

Table 3 presents the results of the correlation analysis, showing a moderate, statistically significant positive correlation between the KPPS-Brazil total score and both the MPQ total score ($r_s = 0.508$, $p < 0.001$) and the PDQ-39 total score ($r_s = 0.418$, $p = 0.003$). Conversely, a moderate, statistically significant negative correlation was found between the KPPS-Brazil total score and the PDSS total score ($r_s = -0.442$, $p = 0.001$). However, no statistically significant correlation was identified with the BDI ($r_s = 0.259$; $p = 0.070$). Notably, the obtained data support 75 % of our pre-established hypotheses, further validating the reliability of our initial assumptions.

4. Discussion

This study aimed to investigate the reliability and construct validity of the KPPS-Brazil in patients with PD. The results for both the total and

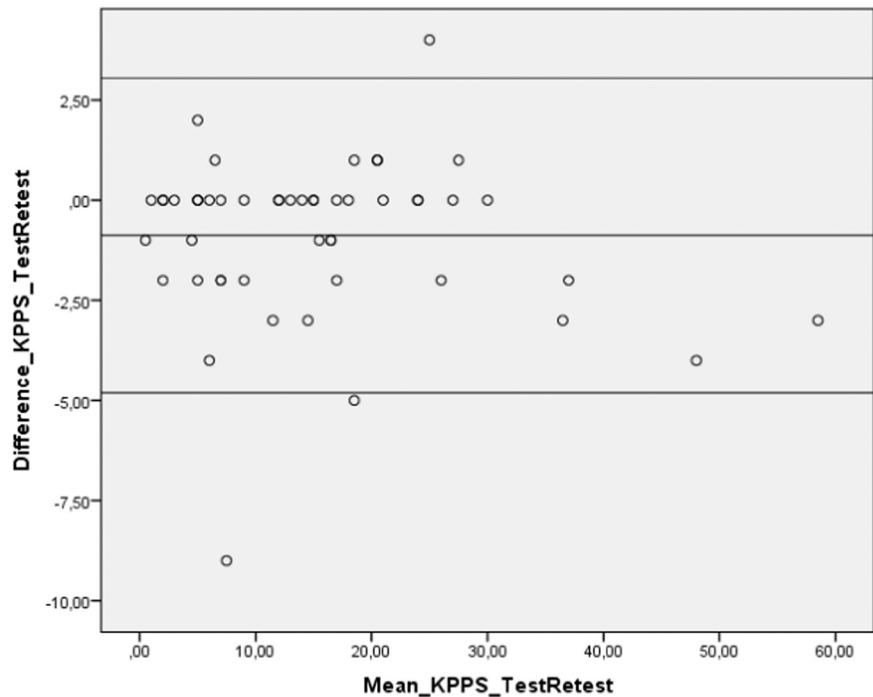


Fig. 1. Bland-Altman concordance graph of KPPS-Brazil test-retest scores (n = 50). On the X-axis (abscissa), the mean scores between the test and retest are displayed, while on the Y-axis (ordinate), the differences between the scores of the first (test) and second (retest) applications of KPPS-Brazil are shown.

Table 3
KPPS construct validity hypothesis test with expected and observed results (n = 50).

Hypotheses	Expected results	Observed results*	Confirmed
1. A moderate to strong positive correlation between KPPS and McGill is expected.	$0.30 < r_s < 1.0$	$r_s = 0.508$	Yes
2. A moderate to strong negative correlation between KPPS and PDSS is expected.	$0.30 < r_s < 1.0$	$r_s = -0.442$	Yes
3. A moderate to strong correlation between KPPS and BDI is expected.	$0.30 < r_s < 1.0$	$r_s = 0.259$	No
4. A moderate to strong positive correlation between KPPS and PDQ-39 is expected.	$0.30 < r_s < 1.0$	$r_s = 0.418$	Yes

individual domain scores demonstrated adequate test-retest reliability. Additionally, construct validity was considered sufficient when assessing quality of life, sleep dysfunctions, and pain measures.

The KPPS is the only pain assessment tool specifically developed and validated for individuals with PD [11]. It is recommended for assessing pain severity and is also suggested for classifying pain syndromes [10]. This scale evaluates various types of pain, including musculoskeletal pain, chronic pain, pain related to fluctuations, nocturnal pain, orofacial pain, pain associated with color changes and edema, and radicular pain [11]. The KPPS-Brazil demonstrated quick applicability and ease of interpretation [16].

Our results demonstrated excellent reliability (ICC = 0.992) for the KPPS-Brazil total scores, consistent with the findings of the original study (ICC = 0.96) [11] and similar versions in Bulgarian (ICC = 0.92) [14] and Persian (ICC = 0.98) [15]. Four of the domains showed excellent test-retest reliability ($r_s > 0.90$), while three exhibited good reliability ($r_s = 0.75\text{--}0.90$). These findings align with the Bulgarian study by Stoyanova-Piroth et al. (2021), which reported reliability ranging from $r_s = 0.78$ to 0.98 [14].

The Bland-Altman plot analysis revealed typical variations between the test and retest, indicating the absence of systematic errors, despite three patients falling outside the upper and lower limits of agreement. These occurrences may be explained by the fact that PD pain is often complex, variable in both location and intensity, and likely to change over time. However, the stability of the measurements obtained at different time points is supported by the other results that fall within the limits of agreement. The high reliability values observed in this study may also be attributed to the use of clear instructions and concise response options, which likely contributed to measurement stability. Additionally, the KPPS domains address common painful symptoms encountered in daily life [11,16].

The determination of SEM and MDC values for the KPPS-Brazil is essential for both clinical and scientific applications, as it will help in evaluating the intensity, severity, and frequency of different types of pain in PD. This study revealed satisfactory SEM (<5 %) and MDC (3.02) values. These values suggest that changes greater than 3.02 points can be considered as indicative of real changes in pain over time. In conclusion, our findings highlight the high reliability and consistency of the measurement, both for the total scores and individual domains, when assessed on different occasions [22,33,34].

Positive and significant correlations were observed between the total score of the KPPS-Brazil and measures of pain and quality of life. Notably, the KPPS-Brazil exhibited a moderate positive correlation with the MPQ, which is understandable, as both instruments assess pain-related dimensions. These findings further support the construct validity of the KPPS-Brazil. Despite differences in items and dimensions between the instruments used, our results align with previous studies examining the correlation between the KPPS and other pain assessment tools, such as the Short-Form McGill Pain Questionnaire-2 [35] and the VAS [13,15]. The moderate positive correlation found between the KPPS-Brazil and the PDQ-39 is justifiable, considering that pain is a key factor influencing an individual's quality of life [5,7], as demonstrated in previous studies [15,17]. Since the PDQ-39 encompasses various domains, pain is naturally integrated into these aspects, which explains the observed association between the two instruments in our study [17].

The total score of the KPPS-Brazil and the PDSS also exhibited a

moderate negative correlation in this study. The PDSS includes items that assess common sleep disorder symptoms associated with PD [11,12,19], such as decreased sleep efficiency, increased sleep latency, frequent awakenings, fragmented sleep, variations in the percentages of REM and non-REM sleep, and reduced total sleep time [28]. Additionally, one of the KPPS items specifically evaluates nocturnal pain, which is known to cause sleep disturbances and disrupted sleep patterns in individuals with PD [11,12].

Previous studies have reported significant associations between the KPPS and measures of depression [17,36–38]. However, our findings did not identify a correlation, consistent with Löhle et al., who also found no association between pain and self-reported depression [39], as well as an Indian study that reported no correlation between the KPPS and HADS-D in a cohort of PD patients [12]. These discrepancies may be attributed to differences in the assessment tools used to evaluate depressive symptoms, variations in patient characteristics such as disease duration and antidepressant use, and the use of non-specific pain assessment instruments for PD in previous studies [40,41].

Regarding the limitations of the study, it is important to note that, despite adhering to the recommended intervals between instrument applications, memory bias could not be entirely eliminated. This is particularly relevant given that participants were not informed about their prior responses. Additionally, the sample was not randomly selected, which may limit its ability to fully represent the broader population of individuals with PD. Participants who chose to participate might differ from those in the general community, as recruitment was based on voluntary participation. Another significant limitation of this study is the potential diagnostic error. Although ongoing research is investigating reliable antemortem biomarkers for PD, such as imaging techniques [42], seed amplification assays [43], and autonomic testing [44], these methods are still in the early stages and lack robust clinical validation. Moreover, these biomarkers are not yet widely available for routine clinical use. To mitigate the impact of diagnostic error, this study focused on patients followed at tertiary referral centers specializing in movement disorders. Lastly, a limitation of this study is the inability to perform sex-based stratification due to the limited sample size, which may restrict the generalizability of the findings and prevent a more detailed analysis of potential sex-related differences.

The present study has several notable strengths. First, it evaluated the key measurement properties of the KPPS-Brazil following internationally recognized guidelines. Second, the research adhered rigorously to the COSMIN criteria. Future studies should explore additional measurement properties, such as structural validity, criterion validity, and responsiveness.

5. Conclusion

The KPPS-Brazil demonstrated adequate reliability, acceptable measurement error, and appropriate construct validity. Our findings underscore its relevance and utility within the Brazilian context.

CRediT authorship contribution statement

Rocha Rafaela Moura Santos: Writing – original draft, Investigation, Formal analysis, Data curation. **Faria-Fortini Iza:** Writing – review & editing, Writing – original draft, Supervision, Conceptualization. **Scalzo Paula Luciana:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Formal analysis, Conceptualization.

Conflict of Interest

None.

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