RESEARCH ARTICLE

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Received: 10.06.2024 Acceptance: 10.10.2024 DOI: 10.18521/ktd.1498688

Konuralp Medical Journal e-ISSN1309–3878

e-ISSN1309–3878 konuralptipdergi@duzce.edu.tr konuralptipdergisi@gmail.com www.konuralptipdergi.duzce.edu.tr

Turkish Version of the Norwich Patellar Instability Score: Minimal Detectable Change among Patients with Traumatic Patellar Dislocation

ABSTRACT

Objective: This study aimed to calculate the minimal detectable change (MDC) in the Norwich Patellar Instability score (NPI) and validate the score for Turkish-speaking individuals with patellar instability.

Method: Sixty-four patients (mean age 21.87 ± 9.44 years) who had experienced at least one patellar dislocation during athletic activities participated in the study. The Turkish version of the NPI (NPI-T) was evaluated for reliability and internal consistency. The Minimal Detectable Change was calculated as an overall value for the participants. MDC was calculated based on the standard error of measurement (SEM) and the selected confidence level (ICC) for the study population. Pearson's correlations were examined to assess construct validity between the Kujala Patellofemoral Disorder score and the Lysholm Knee Score.

Results: The MDC for the NPI-T was 17.29, with a SEM of 6.24. The score demonstrated high internal consistency, with a Cronbach's alpha value of 0.85, indicating substantial reliability. The consistency of measurements was excellent, with an ICC2,1 of 0.95. Additionally, the NPI-T score exhibited a strong negative correlation with both the Kujala (r = -0.85, p < 0.001) and Lysholm (r = -0.89, p < 0.001) scores. A floor effect was observed, but no ceiling effect was present.

Conclusion: The study confirms that the NPI-T demonstrates strong psychometric properties, with high internal consistency and excellent reliability, as evidenced by its low MDC and SEM. The utility of the NPI-T as a reliable and valid tool for evaluating patellar instability in patients with patellar dislocation, providing valuable insights for clinicians.

Keywords: Patellofemoral Instability, Minimal Detectable Change, Reliability, Validity.

Norwich Patellar İnstabilite Skorunun Türkçe Versiyonu: Travmatik Patellar Dislokasyonu Olan Hastalarda Minimal Tespit Edilebilen Değişiklik ÖZET

Amaç: Bu çalışmanın amacı, Norwich Patellar İnstabilite Skoru'nun (NPI) minimum tespit edilebilir değişikliğini (MDC) hesaplamak ve patellar instabilitesi olan Türkçe konuşan bireyler için skoru doğrulamaktır.

Yöntem: Çalışmaya, spor aktiviteleri sırasında en az bir patella çıkığı yaşayan 64 hasta (ortalama yaş $21,87 \pm 9,44$ yıl) katılmıştır. NPI'nin Türkçe versiyonu (NPI-T) güvenilirlik ve iç tutarlılık açısından değerlendirilmiştir. MDC, katılımcılar için genel bir değer olarak, çalışma popülasyonu için standart ölçüm hatasına (SEM) ve seçilen güven düzeyine (sınıf içi korelasyon katsayısı, ICC) dayalı olarak hesaplanmıştır. Kujala Patellofemoral Bozukluk Skoru ile Lysholm Diz Skoru arasındaki yapı geçerliliğini değerlendirmek için Pearson korelasyonları incelenmiştir.

Bulgular: NPI-T'nin MDC'si 17,29 ve SEM'i 6,24 olarak bulunmuştur. Skor, 0,85'lik Cronbach alfa değeriyle yüksek bir iç tutarlılık sergilemiş; bu da önemli bir güvenirliğe işaret etmektedir. Ölçümlerin tutarlılığı 0,95'lik ICC2,1 ile mükemmel seviyede bulunmuştur. Ek olarak, NPI-T puanı hem Kujala (r = -0,85, p < 0,001) hem de Lysholm (r = -0,89, p < 0,001) puanlarıyla güçlü bir negatif korelasyon göstermiştir. Zemin etkisi gözlenmiş ancak tavan etkisi mevcut olmamıştır.

Sonuç: Çalışma, NPI-T'nin düşük MDC ve SEM ile yüksek iç tutarlılık ve mükemmel güvenilirliğe sahip olduğunu doğrulamaktadır. NPI-T'nin patellar dislokasyonu olan hastalarda patellar instabiliteyi değerlendirmede güvenilir ve geçerli bir araç olarak kullanılması, klinisyenlere değerli bilgiler sunmaktadır.

Anahtar Kelimeler: Patellofemoral İnstabilite, Minimal Tespit Edilebilir Değişiklik, Güvenilirlik, Geçerlilik.

INTRODUCTION

Patellar instability presents significant challenges for individuals, impacting their performance and overall well-being. Accurately assessing the severity of patellar instability and comprehending its effects on the patients are crucial for effective management and rehabilitation. It is known that even after biomechanically successful treatment of patellar instability, patients experience fear during movements, which affects their function (1). Therefore, a comprehensive evaluation of patellar instability is very important. Patellar instability is a multifactorial issue that may develop depending on joint geometry, limb alignment, and contractile and non-contractile soft tissue quality (2). The incidence is higher among adolescent patients and the female gender, with a high-risk group aged 10-17 years (3, 4). Various factors contribute to the etiology of patellar instability, including acute traumatic events, anatomical pathologies such as trochlear dysplasia, muscle imbalances, hyperlaxity, and limb misalignments such as increased femoral anteversion, genu valgum, external tibial torsion, and an increased Q angle (2). Patients with patellar instability often experience complaints such as swelling, stiffness, and pain, in addition to a sense of instability in the knee (2).

Several knee-specific tools are available to assess pain intensity, function, and activity levels(5, 6). While the Kujala Patellofemoral Disorder Score, Lysholm Score, and Tegner Activity Score are commonly employed to evaluate patellofemoral instability, there has been no specific scale for assessing patellar instability (2, 7). These existing scales did not evaluate the particular sense of instability related to various activities. Until 2013, no disease-specific tools were designed to assess symptoms in patients with patellar instability. In response to this need, the Norwich Patellar Instability (NPI) score was developed in 2013, addressing the deficiency in the literature (8). The questions in the NPI score cover a wide range of activities, from daily tasks to athletic pursuits, and are designed to assess a broad spectrum of movement, including high energy efforts and both unidirectional and multidirectional movement patterns. Standardized patient-reported outcome measures are crucial for comprehensively assessing treatment efficacy and clinical responsiveness. The NPI Score exhibited good responsiveness to change, demonstrating a substantial effect size during the transitions from baseline to 12 months (E.S.: 0.43; 95% CI: 0.42 to 0.10) and from 12 to 36 months (E.S.: 0.67; 95% CI: 0.60 to 0.15) in individuals with recurrent patellar dislocation (9).

The absence of a disease-specific assessment tool for Turkish-speaking individuals with patellar instability presents challenges in evaluating patellofemoral instability and demonstrating the evidence-based effectiveness of treatments. In objective measurements based on quantitative data, calculating the Minimal Detectable Change (MDC) is important as it provides valuable information about the reliability and interpretability of measurements. MDC aids in distinguishing true changes from measurement error, and informs clinical decision-making and research design. MDC provides a threshold for determining whether changes in a measurement are clinically significant. If changes exceed the MDC, they are more likely to be meaningful and not simply due to chance or measurement error.

This current study aimed to calculate the MDC in the Norwich Patellar Instability score and validate the score for Turkish-speaking patients who had experienced at least one patellar dislocation during athletic activities We employed hypothesis testing to evaluate construct validity, adhering to the C.O.S.M.I.N. criteria regarding comparison with other outcome measurement instruments (18). We hypothesize that the adapted Turkish version of the Norwich Patellar Instability Score (NPI-T) will exhibit strong psychometric properties among Turkish-speaking patients who have experienced traumatic patellar dislocation. Specifically, we predict that the NPI-T will demonstrate high internal consistency and reliability, as evidenced by a low Minimal Detectable Change and Standard Error of Measurement.

MATERIALS AND METHODS

All procedures performed in studies involving human participants were by the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethics committee approval for the study was obtained from the Institutional Review Board affiliated with the authors, and written informed consent was obtained from all participants. This study was designed by C.O.S.M.I.N. standards, which define the methodological quality of studies assessing health-related research and scales' measurement properties (10). For the Turkish version of the Norwich Patellar Instability Score, permission was acquired from the original survey owner via email on 2017 (8). The translation and cultural adaptation of the questionnaire were conducted following the guidelines established by Beaton (11). The study was conducted in the Department of Orthopedics and Traumatology, Faculty of Medicine, Gazi University, with patients admitted to the hospital between April 2022 and December 2022. Questionnaires were administered to 64 patients who met the inclusion criteria and agreed to participate in the study during their initial visit, irrespective of their treatment history. To ensure the questionnaire's reliability, a test-retest was performed seven days after the initial assessment, involving a random selection of 38 out of the 64 patients. The Minimal Detectable Change was calculated as an overall value for the participants. MDC was calculated based on the standard error of measurement and the selected confidence level. The convergent validity of the NPI-T questionnaire was assessed using the Kujala Patellofemoral Disorder Score and the Lysholm Knee Score.

Translation and Cultural Adaptation: The original NPI score underwent translation from English into Turkish following the translation and back-translation process outlined in the international guidelines by Beaton (11). Two independent bilingual translators translated the original NPI score into Turkish in the initial step. One of them was familiar with the questionnaire, while the other was unaware of the research. In the second step, the two translators assessed and discussed translation discrepancies after producing each "forward" translation version. A synthesis of the versions both translators agreed on was then developed (T12).

The third step involved two native English translators back-translating the T12 Turkish version into English, creating the RT1 and RT2 versions. In the fourth step, a multidisciplinary Coordinating Committee, including an orthopedic surgeon problems, specializing knee in two physiotherapists, a linguist, and translators, reviewed all versions (original, T1, T2, T12, RT1, and RT2) to generate the pre-final version of the NPI-Turkish. In the final stage, twenty patients were invited to complete the pre-final version of the NPI-Turkish. They were subsequently interviewed to identify any possible difficulties in understanding the questionnaire. Patients evaluated this pre-final version for relevance, comprehensiveness, clarity, brevity, cultural appropriateness, and usability. Subsequently, the pre-final version of the Turkish NPI score was designated as NPI-T and subjected to evaluation in terms of its reliability and validity.

Subjects: Sixty-four patients (42 females / 22 males, mean age 21.87 ± 9.44 years) had experienced at least one patellar dislocation included in the study. The inclusion criteria were: 1) at least 18 years old, 2) literate in Turkish, 3) patients who had experienced at least one lateral patellar dislocation during sports or athletic activities 4) exhibited patellar instability during physical examination or had patellar instability findings on M.R.I after the injury. Patients with other orthopedic problems that could lead to dysfunction in the patellofemoral and knee joints (such as ligament and meniscus injuries, osteochondral lesions, and osteoarthritis) and those who experienced patellar instability due to hypermobility were excluded from the study. The number of subjects participating in the study met the acceptable criteria outlined by C.O.S.M.I.N. (10).

Self-Report Measures: The Norwich Patellar Instability Score, developed by Smith et al., is a valid and reliable scale designed to understand the extent of patellar instability better and customize treatment plans accordingly (8). The NPI score consists of a 19-item self-report scale. These items cover both uniplanar (14 items) and multidirectional (5 items) daily living and sports activities, with 12 items related to low-energy activities and seven items for high-energy activities. A five-point Likert scale response ranging from "always" to "never" was used in the score to assess the feeling of instability during these activities. Each option has a point value between 0 and 25; the highest raw score obtained from the scale is 250. To get the final NPI score, the total score from each completed item is divided by the sum of the highest possible scores from the completed items and then multiplied by 100, thereby representing the score as a percentage. The total score is between 0 and 100, and a higher score indicates a more severe feeling of patellar instability (8).

The Kujala Patellofemoral Disorder Score was developed by Kujala et al. in 1993 (12). The score is a 13-item scale developed to evaluate the quality and level of patellofemoral complaints. The questions consist of 3, 4, or 5 items determining the severity of difficulty in activities and symptoms such as atrophy and pain. Each option in the scale carries a score ranging from 0 to 25, and the overall scale is rated between 0 and 100. Higher scores indicate more favorable outcomes. Higher scores indicate better results (12). The validity and reliability study of the Turkish version of the Kujala Patellofemoral Score was performed by Kuru et al., and the Turkish version of the questionnaire was found to be valid and reliable (13).

The Lysholm Knee Score was developed by Lysholm et al. in 1982 to facilitate the follow-up of surgical results in knee ligament injuries (14). The score includes eight items that evaluate symptoms of limping, using support, locking, instability, pain, swelling, climbing stairs, and squatting. It is scored from 0 to 100; a high score represents high functionality (14). The validity and reliability study of the Turkish version of the Lysholm Knee Score was performed by Çelik et al., and the Turkish version of the questionnaire was found valid and reliable (15).

Statistical Analysis: Windows-based S.P.S.S. (IBM SPSS Statistics, Version 23.0, Armonk, NY, U.S.A.) package program was used for statistical analysis. The conformity of the variables to the normal distribution was examined with the Kolmogorov-Smirnov test. Data were expressed as mean, standard deviation, frequency, and percentage. Test-retest and internal consistency analyses were applied to determine the reliability of the Norwich Patellar Instability Score. To assess the reproducibility, 38 patients were randomly chosen

to complete the NPI-T again seven days after their first visit without receiving any treatment. Internal consistency was evaluated using the intraclass correlation coefficient average measures and a oneway random effects model (ICC_{2,1}) analysis. Interpretation of ICC_{2,1} was as follows: 1- 0.75 indicates excellent, 0.60–0.75 shows good, and 0.40–0.59 indicates fair reliability (16). Internal consistency reliability of the NPI-T score was determined by calculating Cronbach's alpha. The acceptable range for Cronbach's alpha values is 0.70 to 0.95 (17).

To determine the measurement error, we used the standard error of the measurement and minimal detectable change at 95% confidence interval levels as follows: SEM= SD* $\sqrt{(1-ICC)}$, MDC₉₅=1.96*SEM* $\sqrt{2}$, respectively (18). The MDC was calculated as an overall value for the patient group. The MDC represents the slightest change in the group's measurements that can be considered accurate and not due to measurement error. The group-level MDC was based on the S.E.M. and the confidence level chosen for the study population.

The new questionnaire was compared to previously validated questionnaires with a similar context to assess construct validity. The NPI-T was tested against the Kujala Patellofemoral Disorder and Lysholm Knee scores. The correlation was calculated using the Pearson correlation coefficient. Correlation coefficients within the 1.0–0.81, 0.8– 0.61, 0.6–0.41, 0.4–0.21, and 0.20-0.00 indicated excellent, very good, good, fair, and poor validity, respectively (19).

It was determined if floor or ceiling effects existed by calculating the percentage of NPI-T total scores concentrated at the bottom and top of the questionnaire range. More than 15% of floor or ceiling effects were significant (20).

RESULTS

The demographic and clinical characteristics of the patients are presented in Table 1. The translation and cultural adaptation process were completed following the abovementioned procedure, and no problems were reported.

Table 1. Description of the subjects

Variable	Value		
Age (X±SD) (years)	21.87 ± 9.44		
Body Mass Index (X±SD) (kg/m ²)	23.01 ± 2.31		
Gender n (%)			
Female	42 (65.6)		
Male	22 (34.4)		
Operative procedure			
MPFL reconstruction	34 (53)		
Conservative treatment	30 (47)		
Number of episodes of dislocation (X±SD)	4.20 ± 6.51		
Questionnaire scores (X±SD)			
NPI-T	-T 33.14 ± 28.40		
Kujala Score	69.34 ± 21.25		
Lysholm Score	71.06 ± 22.27		

NPI-T: Norwich Patellar Instability - Turkish version

The Turkish version of the NPI score and scoring sheet are in the appendix. The MDC and SEM of the NPI-T were 6.24 and 17.29, respectively. The test-retest analysis involved 38 participants who were assessed seven days apart. These participants did not undergo any interventions that might have induced changes in their symptoms or clinical status during this period. In the assessment of testretest reliability, the initial NPI score for the patients had an average of 14.96 ± 11.68 , while the subsequent score showed an average of 16.25 \pm 18.26. Cronbach's α for the NPI-T was 0.85, indicating acceptable internal consistency. The ICC value was 0.95, indicating excellent reliability. Test-retest results, ICC scores, and Confidence Intervals (CI) are summarized in Table 2. A strong negative correlation was observed between the NPI-T and the Kujala Patellofemoral Disorder Score (r = -0.85; p < 0.001) and the Lysholm Knee Score (r =-0.89; p < 0.001) (Table 3). A floor effect was detected in the NPI-T, and there was no ceiling effect.

Table 2. Internal consistenc	y, test-retest reliability	, and minimal	detectable change	of the NPI-7
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	Internal consistency Test-retest reliability (n=64) (n=38)		Measurement error		
	Cronbach's α	ICC (95% CI)	SEM	MDC95	
NPI-T	0.85	0.95(0.90-0.74)	6.24	17.29	

NPI-T: Norwich Patellar Instability -Turkish version, ICC: Intraclass Correlation Coefficient, SEM: Standard Error of Measurement, MDC₉₅: Minimal Detectable Change.

	NPI-T (n=64)		
	Score (X±SD)	r	р
Kujala Patellofemoral Disorder Score	69.34 ± 21.25	-0.85	< 0.001*
Lysholm Knee Score	71.06 ± 22.27	-0.89	< 0.001*

*Statistical significant, NPI-T: Norwich Patellar Instability -Turkish version

DISCUSSION

This study support the use of the NPI-T as a reliable and valid tool for evaluating patellar instability in patients with traumatic patellar dislocation. The low MDC and SEM values indicate that the NPI-T has good sensitivity to detect true changes in patellar instability scores. The MDC for the NPI-T was found to be 17.29, with a SEM of 6.24. Any change in the NPI-T score greater than 17.29 can be considered a true change and not just due to measurement variability. This information is crucial for making informed decisions about treatment effectiveness and monitoring patient progress in patellar instability related sports injuries.

In a study evaluating knee-specific outcome measures in patient assessment after an acute patellar dislocation, reporting that only the Fulkerson and Lysholm scales could be used to distinguish between patients with and without patellar instability (5). In 2008, Smith et al. systematically reviewed knee outcome measures and emphasized their suitability for patellofemoral dysfunction and ligament injuries, highlighting the need for outcome measures specific to patellofemoral instability (21). The absence of a patellar instability-specific scoring system hindered demonstrating the evidence-based efficacy of patellofemoral instability treatment. The NPI score assesses the instability during sports and daily living activities, incorporating questions related to physically challenging and less demanding activities. It provides an objective scoring of perceived patellar instability (22). Disease-specific tools are crucial for demonstrating evidence-based results of evaluations and treatment efficacy rather than relying on general tools. The MDC helps clinicians interpret changes in scores. By comparing the magnitude of change to the MDC, it can determined whether the observed change is meaningful and not just a result of measurement error. Therefore, verifying the Turkish version of NPI's MDC and reliability was necessary. The Turkish version of the NPI score is the sole diseasespecific tool for evaluating patellar instability for Turkish patients.

Examining the psychometric properties of the NPI score. Smith et al. reported that the minimally important clinical change and minimally clinically important difference should be determined for the NPI score, which is crucial for its interpretation, guiding future clinical trial sample size calculations, and strengthening the validity of the NPI score(9). MDC allows researchers and clinicians to quantify the amount of measurement error associated with a particular assessment tool. This understanding helps in interpreting changes observed in subsequent measurements. MDC provides a threshold for determining whether changes in a measurement are clinically significant. If changes exceed the MDC,

they are more likely to be meaningful and not simply due to chance or measurement error. The MDC of 17.29 points and SEM of 6.24 points for the NPI-T indicate the level of change that can be considered beyond measurement error and the average amount of variability in the measurements, respectively. These values provide important information for clinicians and researchers when interpreting and evaluating the NPI-T scores in the context of patellar instability in sports injury.

Internal consistency refers to the interrelatedness of the items within a sample of the test. When Cronbach's alpha demonstrates high internal consistency, it suggests that the items in the scale are measuring the same underlying construct. The original English version of the NPI score has high internal consistency with a Cronbach's alpha of 0.93 (8). Similarly, Van Sambeek et al. reported a high level of internal consistency for the Dutch version of the NPI score (Cronbach's alpha=0.97) (23). Likewise, the Turkish version of the NPI score displayed significant internal consistency, with a Cronbach's alpha of 0.85, confirming the scale's reliability for assessing patellar instability. This high level of consistency among the items suggests that they reliably measure the same construct, thus strengthening the overall reliability of the scale in assessing patellar instability.

Reliability, a critical parameter in outcome measurements, pertains to the consistency of which measurement. Test-retest reliability, measures the consistency of results over time, is essential to medical field scales due to the diverse nature of the parameters being assessed (e.g., symptoms, disability) (16). This study, 38 patients were included in the test-retest reliability analysis, with a one-week interval between the two tests. While the original NPI score's test-retest reliability has not been established, the Turkish version of the NPI score demonstrated excellent test-retest reliability, as indicated by an ICC value of 0.95. It is worth noting that previous studies on the Dutch and Brazilian versions of the NPI score did not investigate the test-retest reliability of the scale (23, 24). Therefore, the current research contributes valuable insights by providing evidence of the testretest reliability of the NPI score.

The Kujala Patellofemoral Disorder Score and Lysholm Knee Score are commonly used to assess knee joint symptoms and functional outcomes. These scales primarily focus on patellofemoral evaluating dysfunction, each featuring only one item dedicated to assessing patellofemoral instability (12, 14). The convergent validity of the original English NPI score was evaluated using the Kujala and Lysholm scores. The original English NPI score was moderately correlated with the Kujala Patellofemoral Disorder Score (rho = -0.66; p < 0.01) and Lysholm Knee Score (rho = -0.54; p = 0.03) (8). In this study, we used the same questionnaires for convergent validity. The Turkish version of the NPI score exhibited a strong negative correlation with the Kujala and Lysholm scores (r = -0.85 and r = -0.89, respectively). This strong correlation confirms the convergent validity of the Turkish version of the NPI score. The Turkish version of the NPI score had a higher correlation coefficient with both questionnaires than the original version of the NPI score. There are some possible explanations for this difference. In our study, 53% of the participants (34 of 64 patients) underwent operative treatment, whereas 38% (39 of 102 patients) received operative treatment in the original study. However, for the assessment of convergent validity, the Kujala score was applied to 60 subjects, while the Lysholm score was administered to only 17 subjects in the original NPI score study. The authors did not specify how many patients who completed the Kujala and Lysholm scores had undergone surgical treatment. Additionally, the current study excluded patients with orthopedic disorders that could potentially result in patellofemoral and knee joint dysfunction, such as ligament and meniscus injuries. As a result, the participants in our study exhibited less patellofemoral dysfunction, leading to higher Kujala and Lysholm scores. In the original version of the NPI score study, the median Kujala score of the patients was 55.0, and the Lysholm score was 56.0, while, in our study, the median Kujala score was 71.50, and the Lysholm score was 75.0.

Factor analysis was not performed in other versions of the NPI score studies. The original NPI score study did not include an analysis of floor or ceiling effects (8). However, in a study involving the NPI score applied to individuals conservatively managed following their first-time patellar dislocation, T. Smith et al. reported that 13 out of 19 items exhibited a floor effect. In contrast, no ceiling effect was observed (25). The Dutch version of the NPI score found a floor effect but no ceiling effect (23). Similarly, a floor effect was detected in the present study, and no ceiling effect was evident. The presence of a floor effect in these studies, including the current study, indicates that the NPI score may have limited sensitivity in detecting lower levels of patellar instability. Clinically, the scale might not effectively differentiate between individuals with very mild symptoms and those with no symptoms at all. As a result, the NPI score may be more suitable for assessing moderate to severe patellar instability rather than mild cases. This information may be beneficial when interpreting the NPI score in cases of patellar instability with mild symptoms. Smith et al. performed a responsiveness analysis of the NPI, revealing that the score demonstrated sensitivity to changes from baseline to 12 months post-injury (8). However, in this study, responsiveness analysis, accuracy analysis, sensitivity, and specificity analysis for the Turkish NPI score were not performed.

The current study has several limitations. Firstly, we did not calculate a Minimum Important Clinical Change (MICC) for the NPI-T score. The determination of MICC is crucial for comprehending the clinical significance of changes in NPI scores and would have offered valuable insights into interpreting our findings. Additionally, the study did not include an analysis of the NPI-T score's responsiveness to changes in patients' conditions over time. Understanding how the score detects clinically meaningful changes and its sensitivity to interventions is essential for evaluating its utility in clinical practice. Moreover, the study did not explore the NPI-T score's responsiveness to various treatments for patellar instability, such as surgical and conservative These limitations approaches. prevent a comprehensive understanding of the magnitude of clinically meaningful changes observed in NPI-T scores.

CONCLUSION

The present study showed that the Turkish version of the NPI score is reliable and valid with a MDC of 17.29 points for assessing patientperceived patellar instability during activities in patients who have experienced at least one patellar dislocation during sport.

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