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Original Article

Validation of the Pediatric Quality of Life Inventory 3.0 Cerebral Palsy Module (Parent Form) for use in Türkiye

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ABSTRACT

Objectives: This study was planned to test the reliability and validity of the Turkish version of the Pediatric Quality of Life Inventory (PedsQL) 3.0 cerebral palsy (CP) module (parent form) in children with CP.

Patients and methods: In the validation study conducted between June 2007 and June 2009, 511 children (299 normal children, 212 children with CP) were assessed by the seven scales of PedsQL [daily activities (DA), school activities (SA), movement and balance (MB), pain and hurt (PH), fatigue (F), eating activities (EA), and speech and communication (SC)]. Reliability was tested by internal consistency and person separation index (PSI); internal construct validity by Rasch analysis and external construct validity by correlation with the Gross Motor Function Classification System (GMFCS) and Functional Independence Measure for Children (WeeFIM).

Results: Only 13 children with CP completed the inventory by themselves and thus were excluded. Consequently, 199 children with CP (113 males, 86 females; mean age: 7.3±4.2 years; range, 2 to 18 years) and 299 normal children (169 males, 130 females; mean age: 9.4±4.0 years; range, 2 to 17 years) were included in the final analysis. Reliabilities of the seven scales of the PedsQL 3.0 CP module were adequate, with Cronbach's alphas between 0.66 and 0.96 and the PSI between 0.672 and 0.943 for the CP group. In Rasch analysis, for each scale, items showing disordered thresholds were rescored; then testlets were created to overcome local dependency. Internal construct validity of the unidimensional seven scales was good with the mean item fit of -0.107±1.149, 0.119±0.818, 0.232±1.069, -0.442±0.672, 0.221±0.554, -0.091±0.606, and -0.333±1.476 for DA, SA, MB, PH, F, EA, and SC, respectively. There was no differential item functioning. External construct validity of the instrument was confirmed by expected moderate to high correlations with WeeFIM and GMFCS (Spearman's r=0.35-0.89).

Conclusion: Turkish version of the PedsQL 3.0 CP module is reliable, valid, and available for use in clinical setting to evaluate health-related quality of life of children with CP.

Keywords: Cerebral palsy, PedsQL 3.0 CP Module, quality of life.

Cerebral palsy (CP) is one of the most common causes of developmental disorders that might have impact on a child's functioning and quality of life.[1] In Türkiye, the prevalence of CP was reported to be 4.4 per 1,000 live births.[2] This is a higher prevalence compared to 2-2.5 per 1,000 live births reported in developed countries.[3,4]

In general, there has been increasing interest in the assessment of health-related quality of life (HRQoL) of children with CP as an outcome

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measure in both clinical and research settings.[5] Thus, over the past decade, new instruments have been developed to measure HRQoL, which are both generic or disease-specific and can involve proxy reporting or self-completion.[6] One of the most common is the Pediatric Quality of Life Inventory (PedsQL).[7] The PedsQL is a generic core instrument with disease-specific modules. The 35-item PedsQL 3.0 CP module was designed to measure HRQoL dimensions specific to CP, namely daily activities, school activities, movement and balance, pain and hurt, fatigue, eating activities, and speech and communication. The PedsQL 3.0 CP module is divided into four age groups (2-4, 5-7, 8-12, and 13-18 years), comprising a self-administered and a parent-proxy form. The PedsQL 3.0 CP module was translated into several languages,[8,9] and psychometric properties of some translated versions were reported.[10] As there is an obvious need for a reliable and valid assessment tool of HRQoL for children with CP in Türkiye, this study was planned with the aim of adapting and validating the PedsQL 3.0 CP module for Türkiye.

PATIENTS AND METHODS

In the validation study, children with CP and their parents were recruited from the outpatient clinic of the physical medicine and rehabilitation departments of Ankara University and Mersin University between June 2007 and June 2009. Two hundred twelve children diagnosed with CP by a pediatric neurologist and aged 2-18 years were included in the study. The parents or caregivers of all children were capable of completing the questionnaires without any assistance. The Turkish PedsQL 3.0 CP module was completed by using the parent-proxy form since most of children were not able to complete the questionnaire due to their age or severity of impairment. In addition, the questionnaire was completed by 299 normal children. They were recruited from local kindergartens and schools and matched for age and sex with children with CP.

Adaptation

The translation and adaptation of the PedsQL 3.0 CP module was performed with the permission and supervision of the Mapi Research Institute, following their translation and adaptation guidelines.[8] Data collection for the validation study started after the approval of the Turkish version.

Measures

In addition to the Turkish PedsQL 3.0 CP module, all children were assessed by the Gross Motor Function Classification System (GMFCS) and Functional Independence Measure for Children (WeeFIM).[11-13]

The Pediatric Quality of Life Inventory 3.0 Cerebral Palsy Module

For all age groups (2-4, 5-7, 8-12, and 13-18 years), the parent-proxy questionnaire has a 5-point response scale that asks the magnitude of the problem for each item during the past one month (0=never a problem, 4=almost always a problem). Only the 5-7-year self-administered form uses a 3-point Likert scale (0=not at all a problem, 2=sometimes a problem, 3=a lot of a problem) for evaluation, while other ages have five responses. The response categories are converted to a score from 0 to 100 with a reversed linear pattern (0=100, 1=75, 2=50, 3=25, 4=0) where a higher score represents better HRQOL. However, response categories were neither reversed nor converted to 0-100 in the current study due to the requirements of the psychometric analysis. Thus, higher scores indicate poor HRQOL in this study.

Gross motor function classification system

The GMFCS is a standardized method to classify gross motor function in children with CP aged from 1 to 12 years.[11] The GMFCS is a 5-level system designed to reflect differences in gross motor function that are meaningful in the daily lives of children and their families, with an emphasis on sitting and walking. The GMFCS distinguishes between levels of motor function based on functional mobility and the need for assistive devices (walkers, crutches, and canes) and wheelchair technology. The GMFCSs I and II are defined for children with less severe motor impairments, and the GMFCSs III to V are described for children with more severe impairments. Separate descriptions are provided for children in four age groups: <2, 2-4, 4-6, and 6-12 years.[11]

Functional independence measure for children

The WeeFIM, a functional assessment scale for children, consists of two dimensions: motor and cognitive.[12] The motor scale includes self-care, sphincter control, transfer, and locomotion items; the cognitive scale includes communication, social, and cognition items. A 7-level ordinal rating system, ranging from 7 (complete independence) to 1 (total assistance), is used to score performance in

each item. The Turkish version of WeeFIM was used in this study.[12,13]

Validation studies

Internal construct validity

The internal construct validity of the scales of the PedsQL 3.0 CP module was tested by Rasch analysis. This is the formal testing of an assessment or a scale against a mathematical measurement model, which defines how fundamental measurement (interval scale) can be derived from ordinal questionnaires.[14-16] The model estimates, in this case, the child's ability independent of the items chosen and item difficulty independent of the child's ability, a requirement for producing fundamental measurement.[17] Masters'[18] partial credit model, which is an extension of the Rasch dichotomous model for polytomous (more than two response categories) items, was used in this study. The process of Rasch analysis is iterative, applied to each scale where an item set is intended to be summated to give a score. Key elements of this process are testing for the stochastic ordering of items and persons, the assumption of local independence, including unidimensionality, and invariance across key groups. Briefly, a satisfactory fit is shown by a nonsignificant chi-square statistic (Bonferroni adjusted), a breach of the local (response) independence assumption by residual correlations above 0.3, and unidimensionality by more than 5% of t-tests showing significance when person estimates are compared upon two independent sets of items. The process is widely used and described in detail elsewhere.[19] Ideal values for fit and unidimensionality are shown at the bottom of the Rasch fit table. Differential item functioning (DIF) was tested for age, sex, and GMFCS.

Reliability

The reliability of the PedsQL 3.0 CP module was initially tested by internal consistency, which is an estimate of the degree to which its constituent items are interrelated, and was assessed by Cronbach's alpha coefficient.[20] Usually, a reliability of 0.70 is required for analysis at the group level, and values of 0.85 and higher are needed for individual use.[21] Subsequently, reliability was further tested by the Person Separation Index (PSI) from Rasch analysis. Where the distribution is normal, these two reliability indicators are equivalent, but where distributions are skewed, the PSI gives a more accurate indication of internal consistency reliability. Test-retest reliability was assessed by a Spearman correlation coefficient. For test–retest reliability assessment, patients were assessed twice with a 2-weeks interval.

External validity

External validity was tested by known group validity and convergent validity. Known group validity was established by testing the gradient of the PedsQL 3.0 CP module across GMFCS. Convergent validity was assessed by correlating PedsQL 3.0 CP scores with those of the GMFCS and the Turkish version of WeeFIM.

Statistical analysis

Statistical analyses were performed with R Core Team (2015) R3.2.2 (A language and environment for Statistical Computing, Vienna, Austria), and Rasch analysis was conducted with the RUMM2030: package (RUMM Laboratory Pty Ltd, Perth, Australia).[22] For the Rasch analysis, a sample size of 100 patients will estimate item difficulty, with an alpha of 0.05, to within ±0.5 logits, given appropriate targeting.[23] Bonferroni correction was applied to both fit and DIF statistics due to the multiple testing.[24]

RESULTS

Only 13 children with CP completed the inventory by themselves and thus were excluded. The 199 children with CP (113 males, 86 females) had a mean age of 7.3±4.2 (range, 2 to 18; median age: 7) years, whereas the 299 normal children (169 males, 130 females) had a mean age of 9.4±4.0 (range, 2 to 17) years. The types of CP were diplegia (n=56, 28.3%), hemiplegia (n=23, 11.6%), total body (n=75, 37.9%), mixed (n=14, 7.1%), and others (n=30, 15.2%). The parents of 150 (75.4%) children with CP completed the PedsQL 3.0 CP module instead of their children, whereas the remaining 49 (24.6%) children completed it with their parents. The median GMFCS score was 4 (interquartile range: 3). The distribution of GMFCS levels was as follows: 9.5% level I, 17.6% level II, 19.1% level III, 24.6% level IV, and 29.1% level V. Forty-one children with CP were assessed again approximately 10 days after their first assessments for test-retest reliability analysis.

Internal construct validity

The data from the parent report of each scale were fit to the Rasch model. Four scales (movement

TABLE 1
Fit of data of the PedsQL to the Rasch Measurement Model (parent-completed for the CP group; self-reported in normal children aged >5 years)

		Targeting	Item residual	Person residual	Chi-square interaction				Unidimensionality	
Analysis	Scale	Mean person location	Mean±SD	Mean±SD	Value	DF	*p*	PSI	% t-tests	95% CI
1	Daily activities	1.91	-0.220±1.051	-0.273±0.770	28.0	18	0.06	0.77	5.17	1.2-9.1
2	School activities	1.55	0.093±0.544	-0.269±0.669	4.6	4	0.33	0.59	0.00	*
3	Movement and balance	0.45	-0.154±1.912	-0.310±0.664	31.3	15	0.00	0.74	2.61	0.0-5.8
4	Movement and balance	0.44	-0.254±1.160	-0.302±0.608	29.1	19	0.07	0.84	N/A	N/A
5	Pain and hurt	-2.21	-0.256±0.317	-0.380±0.499	25.1	17	0.09	0.62	2.05	-0.2-5.6
6	Fatigue	-0.46	0.226±1.015	-0.191±0.775	28.6	12	0.00	0.48	1.12	-2.1-4.3
7	Fatigue	-0.73	0.619±1.646ǂ	-0.446±1.130	13.9	6	0.03	0.49	N/A	N/A
8	Eating activities	0.54	-0.513±1.644	-0.289±0.511	28.3	10	0.00	0.84	2.84	-0.08-6.4
9	Eating activities	-0.34	-0.563±1.283	-0.292±0.510	27.8	14	0.02	0.82	N/A	N/A
10	Speech and communication	0.296	-0.705±1.683	-0.489±0.707	26.4	4	0.00	0.84	1.39	-3.6-6.4
11	Speech and communication	-0.862	-0.963±0.283	-0.376±0.421	8.8	3	0.03	0.48	**	**
Normal										
12	Impairment	-2.266	-0.176±0.727	-0.365±0.763	38.9	24	0.03	0.45	2.4	0.0-5.8
13	Activity limitations	-3.429	-0.630±0.875	-0.338±0.567	64.9	54	0.15	0.23	2.8	0.1-6.3
CP group										
14	Impairment	-0.421	0.175±0.307	-0.238±0.833	20.7	24	0.66	0.72	6.7	3.6-9.7
15	Activity limitations	0.896	-0.392±1.964	-0.318±0.954	197.7	81	0.00	0.88	14.0	10.8-17.2
16	Activity limitations	0.538ǂ	-0.618±0.506	-0.667±0.734	4.1	4	0.39	0.82	0.01	-3.1-4.9
Ideal		0.0	0.0±1.0	0.0±1.0			>0.05*	>0.7	<5.0	LC <5.0

PedsQL: Pediatric Quality of Life Inventory; CP: Cerebral palsy; SD: Standard deviation; * Bonferroni adjusted; ǂ Testlet solution; ** Power/Numbers too low; N/A: Not available due to item split; DF: Degrees of freedom.

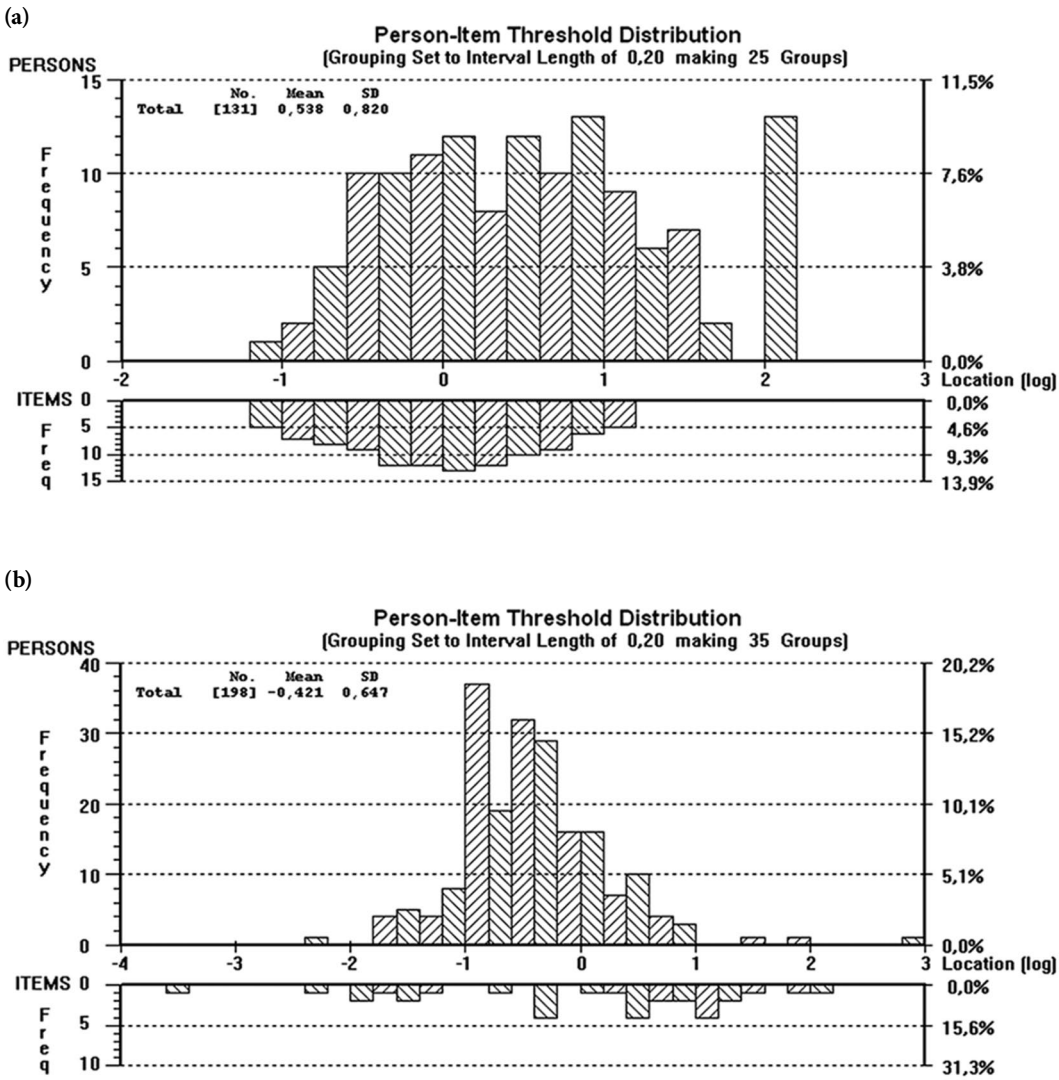

Figure 1. **(a)** Targeting activity limitation and **(b)** impairment.

and balance, fatigue, eating activities, and speech and communication) showed initial misfit to the model (analyses 3, 6, and 8 in Table 1). Other than the speech and communication scale, misfit was caused by DIF on the GMFCS assessment. After splitting items, fit to the model was achieved (analyses 4, 7, and 9 in Table 1). Otherwise, all scales were free of DIF for age and sex of the child. For the speech and communication scale, item 2 ("Is it hard for you to tell other people what you want") showed significant misfit to the model (analysis 10 in Table 1) and was deleted, resulting in fit (analysis 11 in Table 1). Several scales showed floor and ceiling effects, and the school activities scale showed both. Reliability was variable, with the Rasch-based PSI showing much lower values than alpha, reflecting the distributional effect upon the ability to discriminate across different groups of children. The current response options also showed disordering, suggesting the need to consider a simpler 3-category option whereby, in a clinical sample, a grouping of the responses of 1-2, 3-4, and 5 should be considered.

The data from the normal children could not be fitted to the Rasch model at the scale level due to extreme floor effects. However, it was possible to conceive two domains of impairment (pain and fatigue) and activity limitations (other scales) based on the International Classification of Functioning, Disability and Health (ICF) model,

TABLE 2
Raw score-to-metric transformation table of impairment and activity limitation

Impairment		Activities					
Raw score	Metric	Raw score	Metric	Raw score	Metric	Raw score	Metric
0	0.0	0	0.0	37	46.7	74	62.2
1	2.2	1	10.4	38	47.2	75	62.6
2	3.8	2	16.4	39	47.6	76	63.1
3	4.9	3	20.0	40	48.1	77	63.6
4	5.8	4	22.5	41	48.5	78	64.0
5	6.6	5	24.4	42	49.0	79	64.5
6	7.3	6	26.0	43	49.4	80	65.0
7	7.9	7	27.3	44	49.8	81	65.5
8	8.5	8	28.5	45	50.3	82	66.0
9	9.1	9	29.6	46	50.7	83	66.5
10	9.6	10	30.6	47	51.1	84	67.1
11	10.2	11	31.4	48	51.5	85	67.6
12	10.7	12	32.3	49	51.9	86	68.1
13	11.3	13	33.1	50	52.4	87	68.7
14	11.8	14	33.9	51	52.8	88	69.3
15	12.4	15	34.6	52	53.2	89	69.9
16	13.0	16	35.3	53	53.6	90	70.5
17	13.6	17	36.0	54	54.0	91	71.2
18	14.3	18	36.6	55	54.4	92	71.8
19	15.0	19	37.2	56	54.8	93	72.5
20	15.7	20	37.8	57	55.2	94	73.2
21	16.5	21	38.4	58	55.6	95	73.9
22	17.3	22	39.0	59	56.0	96	74.8
23	18.1	23	39.6	60	56.4	97	75.6
24	18.9	24	40.2	61	56.8	98	76.5
25	19.8	25	40.7	62	57.2	99	77.5
26	20.7	26	41.3	63	57.6	100	78.6
27	21.8	27	41.8	64	58.0	101	79.8
28	23.0	28	42.3	65	58.4	102	81.1
29	24.3	29	42.8	66	58.8	103	82.8
30	26.0	30	43.3	67	59.2	104	84.8
31	28.5	31	43.8	68	59.6	105	87.3
32	32.0	32	44.3	69	60.1	106	91.0
		33	44.8	70	60.5	107	97.3
		34	45.3	71	60.9	108	108.0
		35	45.8	72	61.3		
		36	46.2	73	61.8		

and these showed good fit to the model (analyses 12 and 13 in Table 1). Consequently, the parent report CP data were similarly reanalyzed on the ICF basis and again showed satisfactory fit to the Rasch model after the activity limitations domain was grouped into two testlets to accommodate local dependency (analyses 14 through 16 in Table 1). Furthermore, these ICF domain-based analyses

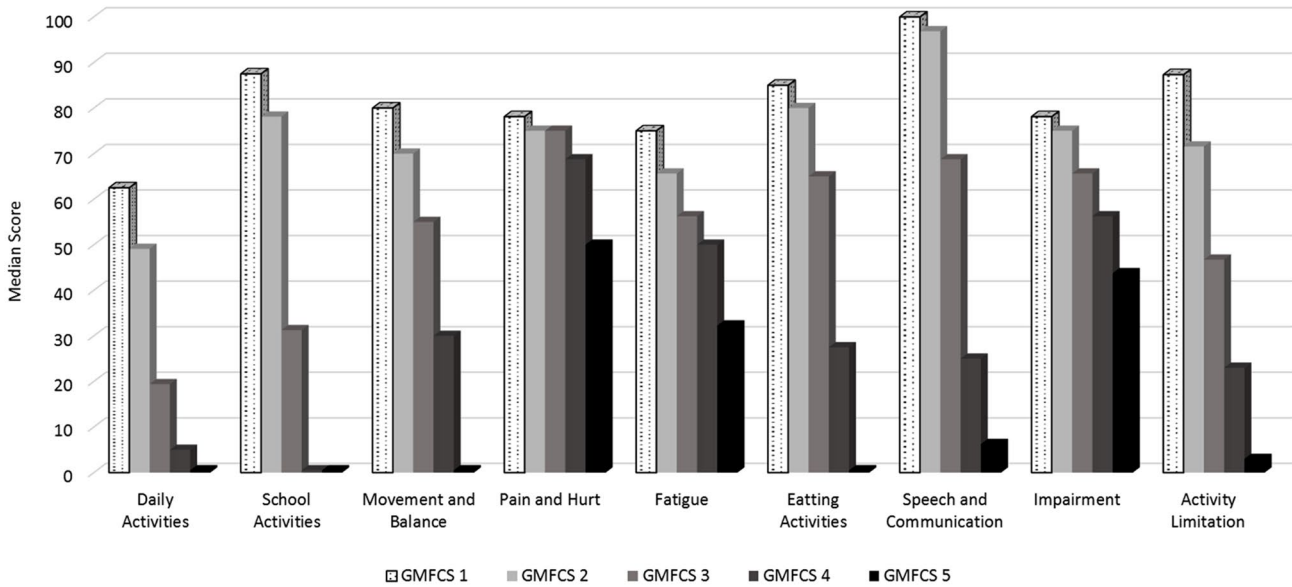

Figure 2. Known group validity for the PedsQL 3.0 CP in terms of GMFCS levels.
PedsQL: Pediatric Quality of Life Inventory; CP: Cerebral palsy; GMFCS: Gross Motor Function Classification System.

overcame the reliability limitations found in some of the individual scales. All domain scores were free of DIF for age and sex. Moreover, all the speech and communication items were included in the domain analysis. The activity limitation domain was well targeted, with the mean of the persons at 0.538 on the logit scale and few people outside of the operational range of the scale (Figure 1). The impairment domain was well targeted, with the mean of the persons at -0.421 on the logit scale (Figure 1). Given the fit to the model, it was possible to produce a transformation table for the parent-reported CP group at the level of the impairment and activity limitation domains, providing a simple raw score-to-metric conversion for when interval scale data was required (Table 2).

Reliability

Given the sufficiency of the raw score confirmed by fit to the Rasch model, internal consistencies of the seven scales were adequate at the group level, with Cronbach's alphas between 0.66 and 0.96 (total 0.97) and the PSI between 0.48 and 0.84 for the CP group. The latter range reflects the skewness of the sample in some of the scales. Test-retest reliability was confirmed by expected high correlations with Time 1 and Time 2 (r=0.83-0.99), except for the pain and hurt scale (r=0.71).

External construct validity

Known group validity

There was a strong gradient across GMFCS for all PedsQL 3.0 CP domains (Figure 2). The majority of the levels were significantly different from one another with the exception of levels I and II.

Convergent validity

Spearman correlations of the PedsQL 3.0 CP scales, except for pain and hurt and fatigue, showed expected moderate to strong correlations with comparator scales within the range of 0.63-0.86 for GMFCS and 0.59-0.88 for WeeFIM, whereas the pain and hurt and fatigue scales showed expected weak to moderate correlations between 0.26 and 0.49 with GMFCS and WeeFIM.

DISCUSSION

The present study investigated the reliability and validity of the Turkish version of the PedsQL 3.0 CP module in children with CP. The PedsQL scales were found to have internal construct validity as assessed by the Rasch model, making their raw score a sufficient statistic.[17] Reliability was found to be variable by both classical and Rasch (PSI) approaches but generally achieved a level consistent

with group use.[25] Improvement in reliability was observed when the domains were merged into higher-level domain scores. Convergent validity showed a low to moderate correlation (r=0.40 to 0.50) between the pain and hurt and fatigue scales of PedsQL and GMFCS. This is expected as the GMFCS classifies gross motor function in children, whereas pain and fatigue are impairments. While the speech and communication scale showed a high correlation with the WeeFIM cognitive scale, it did demonstrate a lack of fit to the Rasch model when assessed on its own, but all items were included in the activity limitation domain analysis. There is no total score for the PedsQL, rather each scale is used independently. The current analysis suggests there may be an opportunity to consider two domains of impairment and activity limitations, which may improve reliability and reduce floor and ceiling effects under some circumstances. Those with large established data sets of the PedsQL may wish to revisit their data and investigate this possibility from either a classical confirmatory factor analytic approach or a modern psychometric approach, such as Rasch analysis. In either case, local response dependency must be accommodated by some mechanism, such as correlating errors.

There are some limitations to the study. The sample of children with CP was a hospital population and consequently likely to be more severe in their limitations. The characteristics of the parents (e.g., educational level) of these children were not recorded, which may have affected responses. Additionally, proxy reporting by parents may not accurately reflect the levels of impairment and activity limitations of the child, particularly in more subjective domains such as pain and fatigue.[26,27] Given the skewed distributions in children with CP as well as in normal children, some of the tests used (e.g., unidimensionality) had limited power. Thus, it was not possible to analyze the scales separately in normal children, rather the domains were utilized; nevertheless, this led to interesting and possibly useful suggestions for grouping scales.

The strength of this study is that it is the first study in which the modern psychometric measurement characteristic of the PedsQL 3.0 CP module has been assessed. The Rasch model is now widely used as the standard for delivering fundamental measurements from assessments and patient-reported outcomes. Where the data fit the Rasch model, the raw score is confirmed as a sufficient statistic; that is, adding up the answers is all that is required to obtain an estimate of the child's level of functioning in a particular domain.[28] The raw score-interval scale transformation provides those in low-resourced countries with a simple way of obtaining the metric conversion when required. The focus on using ICF terminology and the potential mapping to the ICF also brings the results in line with the latest requirements for electronic health informatics and the harmonization of health information.[29]

In conclusion, the PedsQL has sufficient reliability and validity for use in Turkish children with CP. An ordinal-metric conversion is provided for this group at the domain level, should mathematical calculations be required.[30]

Ethics Committee Approval: The study protocol was approved by the Ankara University Faculty of Medicine Ethics Committee (date: 19.03.2007, no: 109-2852). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, design, writing the article: S.K., B.S.T.; Control/supervision, references and fundings: S.K.; Data collection and/or processing: M.S., B.S.T.; Analysis and/or interpretation: S.K., A.H.E., D.G., A.T.; Literature review: S.K., B.S.T., M.S.; Critical review: S.K., A.A.K., B.S.T.

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