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PSYCHOMETRIC EVALUATION OF THE PEDIATRIC QUALITY OF LIFE INVENTORY™ 3.0 DIABETES MODULE FOR TURKISH CHILDREN WITH TYPE I DIABETES MELLITUS

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ABSTRACT

Quality of life is assessed by various standardised quality of life instruments, which make data comparisons possible. In Turkey, there are no adequate substitutes for diabetes-related scales used in other countries to measure the effects of diabetes on children quality of life. Because of this shortcoming in the field, the present methodological study was conducted to investigate the validity, reliability and other psychometric properties of a Turkish version of the Pediatric Quality of Life Inventory™ 3.0 Diabetes Module-Parent Report for Children 8–12. The study sample consisted of 111 parents. Data were statistically analysed by frequency counts, percentages and content analysis index, factor analysis, and the Cronbach alpha.

The Cronbach alpha for the scale was 0.86. The Kaiser–Meyer–Olkin coefficients were found to be 0.80 and $\chi^2 = 15275$, $p < 0.001$, respectively. Item-total correlations for the scale varied between 0.32 and 0.86 ($p < 0.001$). The model fit indicators were: CFI = 0.87, IFI = 0.87, GFI = 0.78, $\chi^2 = 432.34$, df = 337, and RMSEA = 0.051, $p < 0.001$. This scale is a reliable and valid instrument that can be used by diabetes teams to measure the quality of life of Turkish children with diabetes through the perspective of their parents.

Keywords: quality of life, type 1 diabetes mellitus, reliability, validity.

AIMS AND BACKGROUND

Type 1 diabetes mellitus (T1DM) is characterised by the chronic immune-mediated destruction of pancreatic β-cells, which leads to partial or, in most cases, absolute

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insulin deficiency[1]. More than 79 000 children are diagnosed with T1DM everyday throughout the world[2]. In Turkey, it is estimated that there are about 15 000 children with diabetes, mostly of school age, and about 1500–1700 children are diagnosed with TIDM every year[3].

Quality of life in T1DM is a significant indicator of the progress of the condition, and shows the well-being of the child. Well-being and quality life of the child is as equally important as the treatment, as well as metabolic control and prevention of complications[4]. Factors, such as restricted daily life activity, weakness, disease symptoms, repeated hospitalisations or frequent check-ups, being connected to a medical device, daily insulin injections, blood sugar monitoring, deteriorate physical well-being and negatively affect quality of life of children with diabetes[5]. In the damage on beta cells, which are one of the most sensitive structures to oxidative stress, this oxidative stress causes oxidation of biomolecules like protein, carbohydrates and lipids leading to a number of physiological disorders including diabetes[6]. The oxidative stress may increase after the exposure of diabetic patients to high glucose levels in blood long time. When children with type 1 diabetes experience hyperglycemia episode, their quality of life and metabolic control adversely affected[7].

Quality of life is standardised using several quality of life scales, which renders data comparable. Measurement of quality of life in children is different from that in adults. While quality of life in adults are measured with work life, self-care, family duties and physical functions such as ability to climb stairs, it is measured in children by ability to eat, use toilet on one's own, bathe, perform simple works and play[8].

While social functionality is measured, school space and friendship are not very important in adults, however, seeing and playing with friends and level of adaptation to school have an important place in children. It is stated that areas such as emotional and cognitive functionality, body image, autonomy, family relationships, future expectations need be differently addressed in adults, adolescents and children, and that the scales used in adults should therefore not be used in adolescents, and that scales developed for adolescents should not be used in children[8,9].

Quality of life scales used in children and adolescents are grouped into two as scales developed for a specific disease and overall scales. Overall quality of life scales can be used in health adolescents and children, and adolescents and children with condition, and can be administered in public health studies to large sample groups to compare a group with condition and healthy group. The facts that overall quality of life scales have low sensitivity, are mostly long, and take up a lot of time of patients, and show small changes in children and adolescents less than condition-specific quality of life scales do, are the negative aspects of overall quality of life scales[9]. Condition-specific scales are valid for evaluation of the condition they are developed for, which increase their internal consistency, sensitivity and specificity. The facts that these scales are not developed for every condition and cannot be applicable with children and adolescents with multiple conditions are their negative aspects[12]. Identifying quality of life of children with diabetes will ensure establishing

a more realistic and holistic relationship, obtaining standard and objective feedbacks from children, thus enabling a more effective nursing care. The result of the validity and reliability study on the pediatric quality of life inventory 4.0 in Turkish children[13] has reported that it is an applicable inventory, that however, it is not adequate alone in measuring health-specific quality of life of children with a chronic condition, that additional condition-specific measurements need be made, and that age range needs be decreased to measure quality of life more significantly.

In Turkey, the Pediatric Quality of Life Inventory™ (PedsQL) Diabetes Module 3.0 Teen Report (ages 13–18) was adapted, good content and construct validity for measuring diabetes specific health related quality of life in Turkish adolescents with type 1 diabetes[14], but no diabetes-specific scale measuring effect of diabetes on quality of life of children (ages 8–12) has been found in Turkey. Due to such shortage in the field, this study was conducted to test validity and reliability of the Turkish version of the Pediatric Quality of Life in Children with Type 1 Diabetes Mellitus Module (PedsQL 3.0 Diabetes Module).

EXPERIMENTAL

Design. This study used a descriptive, cross-sectional design with psychometric analysis.

Sampling and settings. The study sample consisted of 111 children with diabetes who were diagnosed with T1DM for a minimum of six months prior to the study. In general, studies that have adapted scales have followed the rule that the sample size should be more than 100 to conduct the factor analysis, or that the sample size should be calculated by selecting 5–10 individuals per item in the scale[15]. In our study, the initial target was to reach 140 children with diabetes by selecting 5 individuals per item. However, only 111 children with diabetes meeting the inclusion criteria were reached. The age average of the children reached are 10.32 ± 1.30, 66.7% of whom are female.

To be included in the study: (a) 8–12 years of age children with diabetes; (b) the child had to be diagnosed with T1DM at least 6 months before the study; and (c) the children had to be able to read and understand the questions included in the scale in Turkish. Children with diabetes were excluded from the study: (a) if children with diabetes had diabetes-driven thyroiditis and celiac disease, which are frequently seen with diabetes; or (b) the child had neurological problems.

The researchers provided children with instructions about how to complete the scale and its intended purpose. All children with diabetes who were present in the polyclinic on the days of the data collection and met the inclusion criteria were included in the study. Randomisation was not used. All children with diabetes who were present in the polyclinic on the days of the data collection agreed to take part in the study; no children refused to take part in the study.

Ethical considerations. The study had the permission of the licensor, the approval of institution where the study conducted and the Ethics committee (25.02.2011; 2011/05–12), verbal consent from the children with diabetes and written consent was obtained from the parents before the study was conducted.

Instruments. The PedsQL™ 3.0 Diabetes Module–Children Report was developed by Varni, Burwinkle, Jacobs, Gottschalk et al.[16] The scale measures the quality of life of children 8–12 years old with T1DM. The scale consists of 28 items with five sub-scales that measure: diabetes symptoms (11 items), treatment barriers (4 items), treatment adherence (7 items), worry (3 items), and communication (3 items). A five-point Likert scale was used in which 0 = never a problem, and 4 = almost always a problem. Items were linearly transformed to a 0–100 score. The score was 100 if the items were rated 'never a problem' and 0 if the items were rated 'almost always a problem'. Thus, higher scores indicate higher health-related quality of life. Reliability coefficients of the original sub-scale were 0.81 for diabetes symptoms, 0.66 for treatment barriers, 0.66 for treatment adherence, 0.63 for worry and 0.77 for communication[16]. Children with diabetes information questionnaire were also used to collect sociodemographic information for the study, including the children age and sex.

Adaptation of the PedsQL™ 3.0-Children Report. The Turkish adaptation and use of the PedsQL™ 3.0 Diabetes Module–Children Report was undertaken with the written permission of the original authors. The scale was independently translated into Turkish by three linguists. The Turkish version was then translated back into English by a different linguist. Content validity assesses the degree to which an instrument has an appropriate sample of items for the construct being measured and whether it adequately covers the construct domain. There are various approaches for assessing content validity using an expert panel, but nurse researchers have been in the forefront of developing an approach that involves the calculation of a Content validity index (CVI). Experts in the content area analyse the items to determine whether they adequately represent the hypothetical content area in the correct direction. The CVI for the total instrument is the percentage of total items rated by the experts as being quite or very relevant based on a 4-point scale[17]. Expert opinions were sought from five nursing faculty members, two diabetes nurses, one pediatric oncologist and one faculty member from the Pediatric Diabetes Association. The experts were shown the original and translated versions of the PedsQL™ 3.0 Diabetes Module–Children Report and asked to evaluate the items for compatibility on a scale of 1–4 (1 – very compatible, 2 – compatible, 3 – requires minor modification, 4 – requires major modification). The number of expert ratings for each item in the form of 1 or 2 was determined and divided into the total number of experts to calculate the item CVI. The mean CVI was obtained by dividing the total item CVI on the scale by the number of items[18]. After the first translation, experts suggest administering the scale to 10–20 people who have similar characteristics to the study population to ask the participants to judge whether or not the items are understandable, and to correct any deficiencies and errors

prior to formatting the final instrument. This procedure is recommended with each translation[18]. Finally, the clarity, readability, and ease of application of the scale items were checked and face validity was tested again on a pilot application performed in 10 adolescents with diabetes. The pilot test results showed no detectable language problems. In other words, it was determined that the questions could be understood and no changes were made. No negative feedback was received from the child.

Data collection. The study sample consisted of an 8–12-year-old children with Type 1 Diabetes Mellitus and were registered in the Pediatric Endocrinology Polyclinic of two university hospitals and two state hospitals located in the western region of Turkey. The study was conducted between March 2011 and May 2012. Data were collected through face-to-face two interviews with children with diabetes in the training room of the diabetes nurses.

Data analysis. The data were analysed using a SPSS the version 15.0 (Chicago). Reliability was determined by the Cronbach alpha, split halves correlation and item-total correlations. Validity was evaluated with the Content Validity Index, exploratory factor analysis and confirmatory factor analysis. The reliability analysis employed the Cronbach alpha coefficient, the split-half method and item total correlation analysis. The Cronbach alpha is the most widely used method for evaluating internal consistency. A Cronbach alpha of 0.70 is acceptable for new measures, indicating that this level represents a modest degree of homogeneity[20]. The split-half correlation between the two halves of the test was the first measure of internal consistency. The scale was divided into two equal parts, and the scores of the two halves were calculated. The correlation between the scores on the two halves provided the split-half reliability[21]. In psychological measurement, experts cite reliability of 0.70 or 0.80 as being acceptable for research purposes[22]. Item-total analysis is used to explain the relationship between the item scores and the total score of the instrument. The capacity of the test items to measure the desired quality is important for the reliability of the instrument[23]. High correlation coefficients indicate a strong association of the item with the theoretical construct being measured, and that the item is able to measure the intended construct effectively.

The validity analysis employed the coherence analysis of the experts using the content validity index, and explanatory, using structural equation modelling. Content validity assesses the degree to which an instrument has an appropriate sample of items for the construct being measured and it adequately covers the construct domain. There are various approaches to assessing content validity using an expert panel, but nurse researchers have been in the forefront of developing an approach that involves the calculation of a Content Validity Index (CVI). Experts in the content area analyse the items to see if they adequately represent the hypothetical content universe in the correct direction. The CVI for the total instrument is the percentage of total items rated by the experts as being quite or very relevant based on the 4-point scale. A CVI score of above 80% represents excellent agreement, above 60% is considered substantial

levels of agreement, from 40 to 60% is moderate agreement and below 40% is considered prescriptive validity must be taken in the context of the desired outcome[17,24]. Factor analysis is a method for identifying clusters of related variables – that is, dimensions underlying a central construct[15]. The first type of factor analysis that was used is known as exploratory factor analysis (EFA), which essentially assumes no a priori hypotheses about the dimensionality of a set of items. Another analysis was also conducted: confirmatory factor analysis (CFA), which is a subset of sophisticated statistical techniques referred to as structural equation modelling[20].

RESULTS

Validity analysis. Experts in the content area analyse the items to determine whether they adequately represent the hypothetical content area in the correct direction. The CVI for the total instrument is the percentage of total items rated by the experts as being quite or very relevant based on a 4-point scale[17]. Expert opinions were sought from five nursing faculty members, two diabetes nurses, one pediatric oncologist and one faculty member from the Pediatric Diabetes Association. A CVI score of above 80% represents excellent agreement, above 60% is considered substantial levels of agreement, from 40 to 60% is moderate agreement and below 40% is considered prescriptive validity and must be taken in the context of the desired outcome[17,24].

The Keiser–Meyer–Olkin (KMO) constant of the scale was 0.60 and the result of the Bartlett test was $\chi^2 = 715.238$, $p < 0.001$. The total amount of explained variance was 68% for the explanatory factor analysis.

Factor loadings of the PedsQL™ 3.0 Diabetes Module-Children Report were 0.27–0.61 for diabetes, 0.32–0.54 for treatment barriers, 0.03–0.86 for treatment adherence, 0.52–0.74 for worry and 0.10–0.80 for the communication sub-scales. Model fit indicators were: Non-normed Fit Index (NNFI) = 0.85, Comparative Fit Index (CFI) = 0.95, Incremental Fit Index (IFI) = 0.95, Goodness of Fit Index (GFI) = 0.82, $\chi^2 = 346.48$, df = 336, and Root Mean Square Error of Approximation (RMSEA) = 0.017, $p < 0.001$ (Fig. 1).

Reliability analysis. The Cronbach α for the Turkish version of the PedsQL™ 3.0 Diabetes Module–Children Report was 0.81. Internal consistency (reliability) for the sub-scales of the Children Report was: 0.71 for diabetes symptoms, 0.32 for treatment barriers, 0.51 for treatment adherence, 0.66 for worry and 0.48 for communication. The split-half reliability was 0.71 for the first and second half of the Children Report. The correlation coefficient between the first and second halves was 0.55 ($p < 0.001$). Item-total correlations varied between –0.122 and 0.61 and were statistically significant ($p < 0.001$) (Table 1).

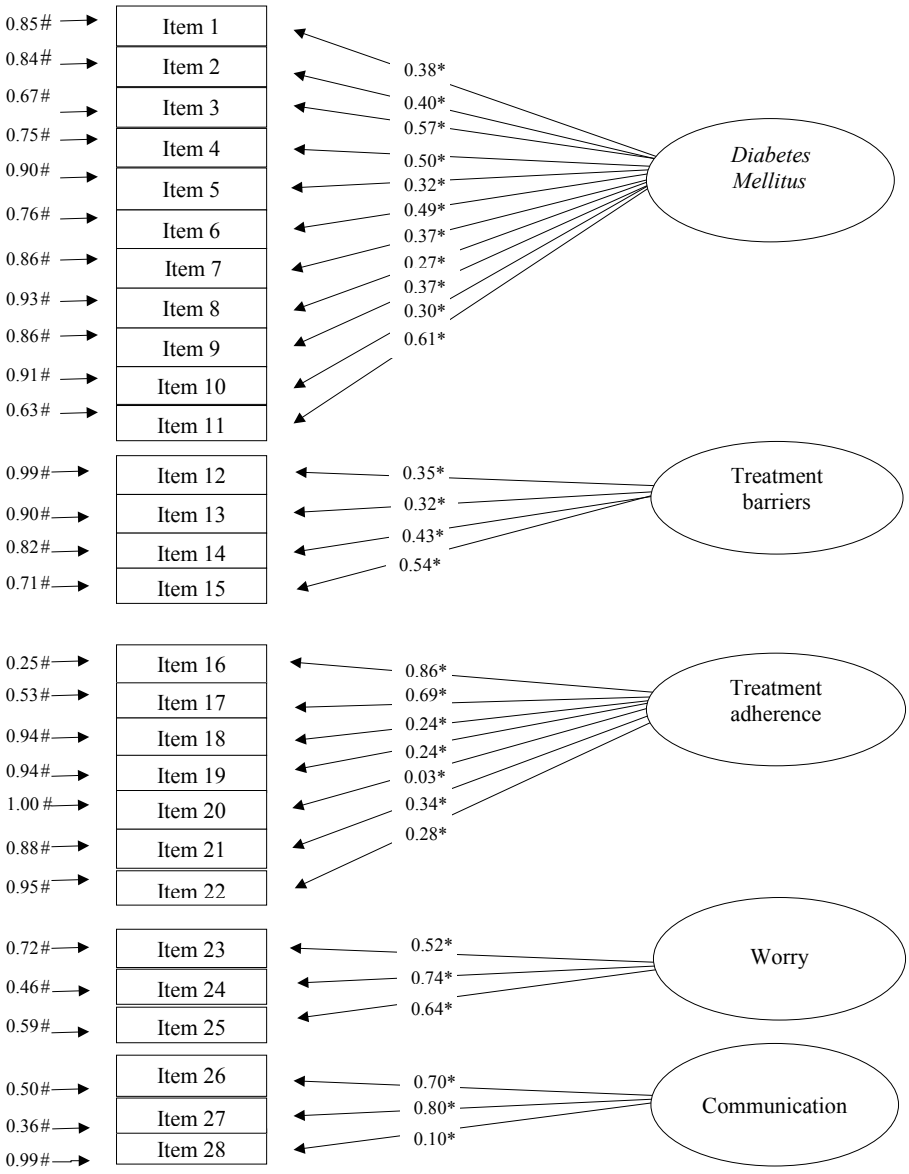

Fig. 1. Confirmatory factor analysis of the Pediatric Quality of Life Inventory™ 3.0 Diabetes Module–Children Report

*Factor loadings; # error variance; the part of the total variance caused by anything irrelevant that was not experimentally controlled.

Table 1. Item-total correlation coefficients of the Pediatric Quality of Life Inventory™ 3.0 Diabetes Module-Children Report

Item		Mean (SD)	Item total correlation
	Factor 1: Diabetes symptoms		
1	I feel hungry	2.55±0.99	0.43
2	I feel thirsty	2.32±1.09	0.38
3	I have to go to the bathroom too often	2.04±1.20	0.53
4	I have stomachaches	2.01±0.95	0.46
5	I have headaches	1.92±1.06	0.41
6	I go 'low'	2.12±1.08	0.46
7	I feel tired or fatigued	2.25±0.98	0.33
8	I get shaky	1.80±0.94	0.44
9	I get sweaty	2.69±1.09	0.31
10	I have trouble sleeping	1.58±1.05	0.32
11	I get irritable	2.60±1.27	0.61
	Factor 2: Diabetes symptoms		
12	It hurts to prick my finger or give insulin shots	1.87±1.06	0.58
13	I am embarrassed about having diabetes	1.26±0.77	0.48
14	My parents and I argue about my diabetes care	3.76±1.31	0.40
15	It is hard for me to stick to my diabetes care plan	1.61±1.07	0.47
	Factor 3: Treatment barriers		
16	It is hard for me to take blood glucose tests	1.42±0.93	0.46
17	It is hard for me to take insülin shots	1.61±1.07	0.48
18	It is hard for me to exercise	1.61±1.10	0.31
19	It is hard for me to keep track of carbonhydrates or exchanges	1.41±1.06	0.32
20	It is hard for me to wear my id bracelet	1.00±0.00	–0.122
21	It is hard for me to carry a fast-acting carbonhydrate	1.55±1.17	0.54
22	It is hard for me to eat snacks	1.40±0.87	0.32
	Factor 4: Worry		
23	I worry about 'going low'	2.18±1.15	0.53
24	I worry about whether or not my medical treatments are working	1.81±1.19	0.59
25	I worry about long -term complications from diabetes	2.51±1.24	0.50
	Factor 5: Communication		
26	It is hard for me to tell the doctors and nurses how I feel	2.01±1.48	0.45
27	It is hard for me to ask the doctors and nurses questions	1.99±1.41	0.36
28	It is hard for me to explain my illness to other people	1.81±1.35	0.31

DISCUSSION

Inter-rater agreement was tested with the Index of Content Validity, which yielded 90% agreement between the experts. A CVI score of above 80% represents excellent agreement. The results of analyses of the parent scale using the KMO coefficient and the Bartlett test indicated that the sample size and the data structure were suitable for factor analysis. The total explained variance was 68%. The larger the percentage of explained variability, the stronger the factor structure is. In social science studies, explained variance ratios of 50–60% are commonly considered fairly high[25]. Hence, the total explained variance in the current study was considered satisfactory.

The factor loadings are expected to be between 0.30 and 0.40. Results of the confirmatory factor analysis of the Pediatric Quality of Life in Children with Type 1 Diabetes Mellitus Module showed that the factor distributions of items complied with the original scale; that the factor loading of the diabetic symptom sub-dimension ranged between 0.27 and 0.61, that of obstacle to treatment sub-dimension between 0.32 and 0.54, that of compliance to treatment sub-dimension between 0.03 and 0.86, that of anxiety sub-dimension between 0.52 and 0.74, and that of communication 0.10 and 0.80. In the study conducted with Iranian children, the factor loading of the diabetic symptom sub-dimension was found between 0.37 and 0.66, that of obstacle to treatment between 0.63 and 0.75, that of compliance to treatment sub-dimension between 0.58 and 0.82, that of anxiety sub-dimension between 0.70 and 0.85, and that of communication 0.76 and 0.87. Our study found the factor loadings of items 8, 18, 19, 20 and 28 lower than 0.30.

The fit indices of the study were ascertained as $\chi^2 = 346$, df = 336, RMSEA = 0.017, GFI = 0.82, CFI = 0.95, IFI = 0.96 and NNFI = 0.94. The result of confirmatory factor analysis showed that NFI, NNFI and CFI were > 0.90, and that RMSEA was < 0.05. Another parameter for model fit is calculated by dividing its χ^2 value by its degree of freedom. If the outcome is under the value of five, the model fit is satisfactory[19]. This calculation was less than five (1.03) in the current analysis, indicating that the data were compatible with the scale, the items and sub-scales were related, and items in each sub-scale could define the corresponding factor sufficiently. These results support the construct validity of the original questionnaire and indicate that the instrument is a valid tool that can be used in Turkish population.

The total Cronbach alpha was 0.71 for the original version of the scale, and the Cronbach alpha of the present scale was above 0.80. The Cronbach alpha of the sub-scales of the original scale varied between 0.63 and 0.81. The Cronbach alpha of the sub-scales for versions translated into Swedish[26], Hungarian[27], Persian[28] have been found to vary more, ranging between 0.49 and 0.80, 0.69 and 0.79, 0.60–0.72 and 0.65 and 0.78. In our Turkish sample, the Cronbach alpha of the sub-scales tended to fall within these values (i.e. 0.66 to 0.71) with the exception of treatment barriers and communication, which was 0.32, 0.48.

The split-half correlation between the two halves of the test was the first measure of internal consistency. The scale was divided into two equal parts, and the scores of the two halves were calculated. The correlation between the scores on the two halves provided the split-half reliability[20]. Use of the Spearman–Brown prophecy formula permits extrapolation from the obtained reliability coefficient to the original length of the test, typically raising the reliability of the test[20]. In psychological measurement, experts cite reliability of 0.70 or 0.80 as being acceptable for research purposes[21]. The split-half reliability was 0.71 in the first and second halves of the instrument respectively, and the correlation between the halves was 0.55.

Item-total correlations varied between –122 and 0.86 and were statistically significant. The standard advice is to eliminate items whose correlation with the total scale is less than 0.30 (Ref. 17).

The reliability and validity studies of the PedsQL™ 3.0 Diabetes Module in different cultures, such as Swedish children with diabetes[26], Hungarian children with diabetes[27], Iranian children with diabetes[28], Greek children with diabetes[29] also showed that the instrument was reliable. The current work showing the reliability of the Turkish version of the instrument will make further international comparisons possible.

Limitations. The study has several limitations. The first is its use of a convenience sample, which limits the generalisation of the findings. Another limitation is the study relatively small size sample. This was because that it was difficult to reach who had children with diabetes within the 8–12 age groups who also met the inclusion criteria. Some of the factor loadings for the items on the sub-scales were also low. While the sample size was adequate to conduct the analyses, a larger sample would increase confidence in the findings. Although the Cronbach alphas were of sufficient magnitude, they were not ideal, and the alpha for treatment barriers and communication was quite low (0.32, 0.48). Retesting the scale with a large sample should eliminate the concerns associated with these preliminary findings.

CONCLUSIONS

This scale is the first diabetes-specific quality of life scale, by which quality of life of children with diabetes can be measured in Turkey, and the validity and reliability of which have been proved and the validity and reliability results support its use in practice and future research. The data on quality of life to be attained from children using the scale may serve as a guidance for health professionals. By using this scale, how diabetes affects quality of life of children can be measured, and can enable necessary actions to be recommended.

ABBREVIATIONS

PedsQL™, Pediatric Quality of Life Inventory™; RMSEA – Root mean square error of approximation; NNFI – Non-normed fit index; CFI – Comparative fit index; IFI – Incremental fit index; GFI – Good-

ness of fit index; KMO – the Kaiser–Meyer–Olkin coefficient; DM – Diabetes mellitus; T1DM – Type 1 diabetes mellitus; EFA – Exploratory factor analysis; CFA – Confirmatory factor analysis.

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