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Psychometric analysis of the cross-cultural Spanish version of the diabetes management questionnaire

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ABSTRACT

Evaluation of the degree of adherence to self-care among Spanish type 1 diabetes (T1DM) pediatric population lacks of a validated tool.

Purpose: To cross-culturally adapt and determine the psychometric properties of the Spanish version of the Diabetes Management Questionnaire to assess the degree of adherence to self-care among children with T1DM.

Methods: Translation, back-translation, and patient suggestions, were considered to obtain the Spanish version (DMQ-Sp). A cross-sectional study was conducted with 323 children (aged 8–18 years) with T1DM and their parents to determine internal reliability, structural validity, and external validity. Responsiveness to change was analyzed through a prospective longitudinal study involving 102 newly diagnosed T1DM patients. Psychometrics were evaluated for the entire sample and stratified by age (8–12 and 13–18 years).

Results: A total of 323 children with T1DM [49.8% female; age 13.3 ± 2.8 years; 155 aged 8–12; glycated hemoglobin (HbA1c) value 7.7 ± 1.0%] answered the Spanish final version. The internal consistency Cronbach's alpha was 0.76 and intraclass correlation coefficient 0.84. Test-retest reliability was $r = 0.84$ ($p < 0.001$). Fit index of structural validity was >0.7. External validity correlated inversely with HbA1c ($r = -0.39$; $p < 0.001$). The DMQ-Sp score increased significantly after 6 months of receiving the full therapeutic education program (TEP) (baseline 57.07 ± 10.81 vs. 6 months 78.80 ± 10.31; $p < 0.001$).

Conclusion: The DMQ-Sp is reliable, valid, and sensitive to change in a large sample of children (aged 8–18 years) with T1DM and their parents.

Practice implications: DMQ-Sp can be a useful tool for diabetes teams to identify adherence to different tasks and to evaluate TEPs.

Type 1 diabetes (T1DM) management is complex for both patients and families. Many self-care activities to balance insulin regimens with glucose values and glucose trends, diet, exercise as well as other daily activities are required. Over the last decades, there have been developed several pharmacological advances with new insulin analogs and remarkable technological improvements. That includes continuous subcutaneous insulin delivery systems (CSII), continuous glucose monitoring (CGM), and advanced diabetes devices that combined CSII and CGM systems with algorithms to adjust insulin delivery in response to CGM values in real time. Nonetheless, difficulties achieving good diabetes control and diabetes burden persists in patients' daily life (Holmes-Walker et al., 2021).

Education for diabetes self-management is considered essential for integrating treatment into daily life and to help people with diabetes improve their outcomes (American Diabetes Asociation, 2021) and avoid secondary complications. Such education is necessary for all patients including the ones using the most advanced technology (Cardona-Hernandez et al., 2021). Adherence is described as an outcome of therapeutic patient education (Golay et al., 2008) together with quality of life and metabolic control. Hence, patient self-care

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management adherence should be periodically evaluated. Adherence to good diabetes self-care has consistently been related to achieving better-glycated hemoglobin (HbA1c) values, while poor adherence has been associated with increased morbidity and mortality, and higher costs has been allied with hospitalizations for acute complications (Galler et al., 2021; Liu et al., 2018; Shrivastava et al., 2013). Therefore, promoting treatment adherence and self-care autonomy is one of the key objectives of educational interventions. The American Association Diabetes Educators (AADE) describes seven essential self-care behaviors to achieve good metabolic control: medication compliance, healthy coping, healthy and balanced eating habits, physical activity, monitoring, problem-solving, and reducing risk (Moss-Barnwell et al., 2020). In addition, good family support improves adherence in adolescents with T1DM (Hsin et al., 2010). Different complementary methods to assess T1DM treatment adherence have been used: semi-structured interviews (Lewin et al., 2010), patient self-report questionnaires (Kristensen et al., 2012; Schmitt et al., 2013), direct observation, and downloading device data. Although there are several questionnaires available to evaluate self-care management in T1DM, specific scales for pediatric population are scarce (Harris et al., 2000; Iannotti et al., 2006; Kristensen et al., 2012). The Diabetes Self-Management Profile (DSMP-Parent-Sp) to assess diabetes self-care among parents of children with T1DM was developed and adapted (Valenzuela et al., 2010) into Spanish-speaking families living in the United States. However, it was never adapted for the Spanish child population. The Self-Care Inventory-Revised Version (SCI-R) (Jansà et al., 2013) for Spanish adults with T1DM lacks a pediatric version. On the other hand, the Diabetes Management Questionnaire (DMQ) (Mehta et al., 2015) addressed to children and adolescents with T1DM treated with MDI or CSII seems to be a useful tool that covers all the self-care behaviors defined by the AADE (Moss-Barnwell et al., 2020). Providing a cross-cultural tool adapted to the Spanish pediatric population with T1DM is crucial for assessing adherence to self-care among these patients.

Purpose

The purpose of this study was to cross-culturally adapt the Diabetes Management Questionnaire (DMQ) to children and adolescent with T1DM in Spain and then determine psychometric properties of the adapted version to assess the degree of adherence to self-care among children and adolescents with T1DM in Spain.

Methods

Design and ethics

The design of this study involved three phases: 1) translation, back-translation, and cultural adaptation from the English to the Spanish version of the questionnaire; 2) a cross-sectional study to analyze psychometric properties: internal reliability, structural validity, and external validity, and 3) responsiveness to change through a prospective longitudinal analysis. Consent to use the original survey was obtained from the authors.

The study was approved by the Ethics and Clinical Research Committee of the Pediatric Hospital (PIC-22-16). Informed consent from parents and assent from children and adolescents were obtained. Patients and their parents were included through a consecutive non-probability sampling method during their regular visits to a pediatric diabetes center in Spain. None of the participants received economic compensation for their participation.

Characteristics of the survey

The Spanish DMQ version (DMQ-Sp) is a self-reported survey of 20 questions assessing patient perceptions of their adherence to diabetes self-management recommendations over the previous month. All participants required 5–10 min to complete the questionnaire. The survey encompasses five dimensions: physical activity (items 1, 2 and 3), diet (items 4 to 11), low glucose levels (items 12, 13 and 14), high glucose levels (items 15, 16 and 17), and preventive/routine aspects of self-care (items 18, 19 and 20). Each question was graded on a five-point Likert scale and scored from 0 (almost-never) to 4 (almost-always). Six of the 20 items were reverse scored. The mean of all the completed items was calculated and was then multiplied by 25 for normalization to a 0–100 scale to facilitate interpretation as in the original survey (Mehta et al., 2015). Higher total DMQ-Sp scores defined greater adherence to diabetes-related tasks. The questionnaire was aimed at children from the age of eight with T1DM following MDI or CSII treatment.

Study population

The study participants included children and adolescents aged 8 to 18 with T1DM treated with MDI or CSII and their parents (with 'parent' referring to a parent or legal guardian) seen in the Diabetes Unit of the tertiary hospital in Spain. The exclusion criteria were patients not willing to participate or sign the informed consent and assent form and individuals with difficulties in language comprehension. Sample sociodemographic and clinical characteristics are summarized in Table 1 and Table 2 respectively. All patients were attended by the National Health System of Spain.

Sample size calculation

To estimate a Cronbach's alpha population coefficient with a confidence interval of +/− 0.1 and a significance level of 0.05 in a 20-item questionnaire and an expected coefficient of 0.8, a sample of 133 subjects was needed. Therefore, it was calculated that 133 patients from 8 to 12 years of age and 133 aged 13–18 years as well as 133 parents would be necessary to carry out the study.

Procedures of the study phases

Translation, back-translation and cultural adaptation from the English to the Spanish version of the questionnaire

The original English version of the questionnaire was translated into Spanish by one pediatric endocrinologist, three diabetes advanced practice nurses, and one registered dietician followed by group discussion and unification of the version. The Spanish version was back-translated into English by two independent native English speakers also fluent in Spanish without previous knowledge of the original version of the questionnaire and later compared with the original questionnaire. Expert committee review: five diabetes specialists, along with the two translators of this study, reviewed the original version and the translated one, synthetized and back-translated versions, and defined the second unified Spanish version of the DMQ-Sp.

Thirty children with T1DM and their parents (Tables 1, 2) answered the questionnaire in the presence of a member of the research team in order to detect and register any word that would difficult to understand. Patients' suggestions were collected and discussed in another group discussion. Lastly, the final Spanish version was created.

Psychometric properties analysis: internal reliability, structural validity, and external validity

A cross-sectional study was conducted between 2018 and 2019. Patients and their parents were recruited at their regular follow-up visits to the Diabetes Unit through a consecutive non-probability sampling method. We invited 326 patients. One of them declined to participate. Two patients were excluded because they did not complete all the answers. The remaining 323 participants (155 aged 8–12 years and 168 aged 13–18 years) were included in the analysis. *Re*-test survey was obtained from 279 subjects (136 aged 8-12y and 143 aged 8-13y) (Tables 1, 2). All surveys were provided on a paper-based format. First

Table 1
Patients and family socioeconomic characteristics according to study phase.

	Phase 1		Phase 2		Phase 3	
Participants scholar level [a]						
Primary School	11 (36.6)		118 (36.4)		36 (35.3)	
Secondary School	14 (46.7)		144 (44.4)		46 (45.1)	
Pre-university of High School	4 (13.4)		43 (13.6)		13 (12.8)	
Bachelor	1 (3.3)		18 (5.6)		7 (6.8)	
Family structure [a]						
Nuclear	21 (70.0)		229 (71.7)		71 (69.7)	
Separated parents	5 (16.7)		60 (18.5)		19 (18.6)	
Mono-parental	1 (3.3)		13 (4)		3 (2.9)	
Reconstituted	1 (3.3)		11 (3.4)		5 (4.9)	
Other	2 (6.7)		8 (2.4)		4 (3.9)	
Diabetes self-care responsibility [a]						
Father and mother	18 (60.0)		194 (60.1)		61 (59.9)	
Mother	11 (36.6)		118 (36.5)		37 (36.3)	
Father	1 (3.4)		10 (3.1)		3 (2.9)	
Others	0		1 (0.3)		1 (0.9)	
	Fathers	mothers	Fathers	mothers	Fathers	mothers
Studies level [a]						
High education	14 (46.6)	16 (53.3)	148 (47.6)	175 (54.9)	47 (46.6)	55 (53.9)
Secondary	11 (36.7)	10 (33.3)	111 (35.7)	105 (32.9)	36 (35.2)	33 (32.4)
Primary	5 (16,7)	4 (13.4)	49 (15.8)	36 (11.3)	17 (16.7)	13 (12.8)
Without studies	0	0	3 (1.0)	3 (0.9)	2 (1.9)	1 (0.9)
Does not respond	0	0	12 (3.7)	12 (3.7)	1 (0.9)	1 (0.9)

Note: Phase 1 of the study corresponds to cross-cultural adaptation ($n = 30$). Phase 2 of the study corresponds to psychometric properties analysis: internal reliability, structural validity, and external validity ($n = 323$). Phase 3 of the study corresponds to responsiveness to change ($n = 102$).
[a] Values are presented as number (%).

time survey was provided at the clinic while the second one was requested to be filled at home and returned to the clinic. A reminder phone call for the second request was performed six days after the first response.

Cronbach's alpha was computed for the DMQ-Sp scale to evaluate internal consistency. To study the contribution that each item had in the consistency scale, the effect of the remaining items in the Cronbach's alpha without the item of interest was analyzed. Correlation between the item of interest and the total score with the remaining items was also calculated. Cronbach's $\alpha \geq 0.70$ (Cicchetti, 1994) was considered acceptable.

Table 2
Clinical of study participants according to study phase.

	Phase 1	Phase 2	Phase 3
Age (years)[a]	12.9 ± 2.6	13.3 ± 2.8	12.3 ± 2.4
Gender, females (%)	49.7	49.8	49.1
Time of T1DM duration (years)[a]	5.1 ± 3.6	5.3 ± 3.3	0
HbA1c (%)[a]	7.8 ± 1.1	7.7 ± 1.0	
Treatment regimen (%)			
MDI	80.3	79.5	100
CSII	19.7	20.5	0
Use of CGM	29.6	30.1	-
At baseline	-	-	0%
6 moths after complete TEP	-	-	90.1%
Number of total daily glucose measures[a]	6.8 ± 4.5	6.9 ± 4.6	7.9 ± 2.3
Other chronic diseases (%)			
Celiac disease	-	8.1	-
Autoimmune thyroiditis	-	12.2	-
Number of new T1DM diagnosed (%)	0	0	100

Abbreviations: CGM, Continuous Glucose Monitoring; CSII, Continuous Subcutaneous Insulin Infusion; HbA1c, Glycated hemoglobin; MDI, Multiple Daily Injections; TEP, Therapeutic Education Program; T1DM, Type 1 Diabetes.
Note: Phase 1 of the study corresponds to cross-cultural adaptation (n = 30). Phase 2 of the study corresponds to psychometric properties analysis: internal reliability, structural validity, and external validity (n = 323). Phase 3 of the study correspond to responsiveness to change (n = 102).
[a] Values presented as mean ± standard deviation.

Three hundred and twenty-three patients and parents independently completed the survey. Pearson correlation and intraclass correlation coefficient (ICC) were calculated to evaluate test-retest reliability, with an ICC ≥0.70 being considered acceptable.

A confirmatory factorial analysis to confirm the structure suggested by the dimensions of the survey was performed to analyze structural validity. DMQ-Sp scores and HbA1c values obtained in the clinic using point of care that same day, were correlated to analyze external validity. Predictive validity was based on an inverse association between survey scores and children's HbA1c values. In addition, survey scores correlation with HbA1c was evaluated according to patients' treatment regimen (MDI or CSII) and according to glucose monitoring method (blood glucose or CGM). Also, DMQ-Sp scores were correlated with glucose monitoring frequency and glucose time in range (TIR) in patients wearing CGM.

Responsiveness to change

A prospective longitudinal analytical single-center study with patients' ages 8 to 18 newly diagnosed with T1DM was conducted during the period 2018–2020. A total of 104 patients were successively invited at the moment of diabetes diagnosis. Two subjects did not answer the survey at the last visit and were excluded. The remaining 102 participants were included in the analysis. Sociodemographic and clinical characteristics are summarized in Table 1 and Table 2 respectively. We selected this cohort of patients because they had not done any activity related to diabetes self-management before diabetes onset. Patients and parents receive education at diagnosis to acquire knowledge, abilities, and attitudes toward diabetes self-management.

All patients followed MDI treatment and together with their parents underwent a structured therapeutic education program (TEP) aimed to provide competencies to achieve good self-management and diabetes control. This program consisted of 12 individual intervention sessions of at least one hour, using a motivational interviewing and cognitive-behavioral approach facilitated by diabetes advanced practice nurses and registered dietitian, during the first 3 months of T1DM onset. The program was divided into two steps: first) four initial sessions during

inpatient hospitalization aimed at addressing the "safety level" of diabetes management; second) eight more outpatient sessions after discharge aimed to acquire the basic level of diabetes management. After discharge, patients and their parents could contact the team by telephone or using an online encrypted platform (Patient Portal) for any questions they might have. At the end of the TEP, additional appointments were scheduled as necessary. Patients answered DMQ-Sp first in the clinic, at the end of the first step of the TEP, and a second time at home, after receiving a reminder phone call, six months after completing the entire program. Both measures were compared.

Additional measures

HbA1c was analyzed using high-performance liquid chromatography [Afinion™ 2 device; Abbott Diagnostics Technologies AS, Oslo Norway; reference range 4.0–6.0% (20-42 mmol/mol)]. Current treatment regimen was collected from electronic health records. Frequency of glucose monitoring was collected by downloading glucose meter devices and was assessed by medical chart review. Time per day within the TIR, defined as the time of glucose between 70 and 180 mg/dl (3.9–10 mmol/ml) (Battelino et al., 2019), was collected by downloading the CGM system and was assessed by chart review.

Flesch-Szigriszt Index (FSZI), available on the INFLESZ program, was calculated to evaluate survey readability (Barrio-Cantalejo et al., 2008). INFLESZ Scale establishes five sections: "very difficult" (<40), "somewhat difficult" (40–55), "normal" (55–65), "quite easy" (65–80), and "very easy" (>80). In the case of texts on health, there is a greater probability of being read and understood if the score is >55.

Families' demographic characteristics were obtained through a self-report questionnaire elaborated ad hoc. Content of the form included: children's scholar level, family structure, diabetes self-care responsibility, education level, parents' employment situation, and annual family income. Clinical data were obtained from the medical record of each patient.

Statistical analysis

Statistical analysis was performed using SPSS 19.0 (Armonk, NY: IBM Corp.) except for the confirmatory factor analysis that used R 3.5.1 with the lavaan 0.6.2 library. Statistical significance was set at $p < 0.05$.

Descriptive statistics were used to describe demographic variables. Data was expressed as mean ± standard deviation (SD) or a percentage. DMQ-Sp psychometrics were assessed for patients' and parents' surveys, and additionally stratified according to the age of the children (8–12 vs. 13–18 years) to assess psychometrics for children and adolescent participants and their parents.

Cronbach's alpha coefficient was used to assess internal consistency of the DMQ-Sp.

Pearson's coefficient was used to analyze test-retest reliability and DMQ-Sp association with HbA1c and TIR. Because of the discrete distribution of the number of blood glucose determinations, Spearman's coefficient was used to analyze its correlation with DMQ-Sp. ICC (95% CI) was used to assess test-retest reliability at 6–8 days and parent-child agreement. Student's *t*-test was used for comparisons.

A confirmatory factorial analysis was carried out to confirm the structure suggested by the dimensions of the DMQ-Sp: physical activity, diet, low glucose levels, high glucose levels, and routine aspects of self-care. Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), and Root Mean Square Error of Approximation (RMSEA) were calculated to evaluate the model. For CFI and TLI, the maximum value is 1.0 (the higher, the better), with values greater than or equal to 0.90 suggesting a good fit for the model. With RMSEA, values below 0.08 indicate an acceptable model fit, with an ideal value being <0.05 (Hu & Bentler, 1999).

Results

Cultural adaptation and pilot-scale understanding

After translation to Spanish and back-translation to English, seven words were modified. The most relevant one was the replacement of *blood sugar* by the word *just sugar* as, at the time of the study, patients started progressively using CGM (both real-time CGM and intermittently scanned CGM) instead of finger prick blood glucose measurements. Finally, we obtained the unified Spanish version (Appendix 1). Survey DMQ-Sp showed a readability FSZI of 73.725 on the INFLESZ Scale.

Internal reliability, structural validity, and external validity

Three hundred twenty-three patients with T1DM duration of 5.3 ± 3.3 years (155 aged 8–12 years and 168 aged 13–18 years) and parents (Tables 1, 2) answered the final Spanish version.

Cronbach's alpha was 0.76 for children and 0.75 for parents. Cronbach's alpha was higher for children 13–18 years old (0.76) than for children younger than 13y (0.69). Two items, both negative-weighted, "give all of the insulin doses after you have finished eating" and "over-treat a low sugar value with more carbohydrates than were needed" had a low item-to-total correlation of <0.10, thereby giving the scale less reliability. A total of 279 participants completed the retest. Test-retest reliability for all patients was $r = 0.84$ ($p < 0.001$) being higher for adolescents aged 13–18 years than for children 8–12 years old ($r = 0.85$, $p < 0.001$ vs. $r = 0.79$, $p < 0.001$). ICC for all children was 0.84. It was also higher in older than for younger children [ages 13–18 $r = 0.85$ ($p < 0.001$) and ages 8–12 $r = 0.79$ ($p < 0.001$), respectively].

Confirmatory factorial analysis showed an acceptable model fit, obtaining a CFI =0.78, a TLI =0.74 and an RMSEA =0.06. All the items were positively associated with the dimension they represent except for items 8, 14, and 20, which had an influence of close to zero and were not statistically significant. Item 14 had a negative-weighted influence (Table 3).

Children DMQ-Sp scores correlated inversely with HbA1c $r = -0.39$ ($p < 0.001$). Survey scores correlation with HbA1c according to patients' treatment regimen were $r = -0.37$ ($p < 0.001$) for MDI and $r = -0.43$, ($p < 0.001$) for CSII users. This correlation taking in account the glucose monitoring method was $r = -0.55$ ($p < 0.001$) for patients using blood glucose determination and $r = -0.33$ ($p < 0.001$) for CGM users. Results of all subjects and stratified by age are summarized in Table 4.

Responsiveness to change

One hundred two patients aged 8–18 years old (52 aged 8–12 and 50 aged 13–18 years) with newly diagnosed T1DM were included (Tables 1, 2). There was a marked increase in the DMQ-Sp score between the test at baseline and the retest answered 6 months after completing the TEP (57.07 ± 10.81 vs. 78.80 ± 10.31, $p < 0.0001$, respectively). DMQ-Sp score in children aged 8–12 years increased by a mean of 25.7 (baseline 54.64 ± 10.39 to 80.38 ± 9.88; $p < 0.001$). Adolescents aged 13–18 years raised by a mean of 17.3 (baseline 59.49 ± 10.83 to 76.84 ± 10.52; $p < 0.001$).

Parent-child agreement

Parents of adolescents discussed the relevance of answering the survey because their sons and daughters had greater diabetes self-management autonomy. Parents felt that they did not have control over their children diabetes management. Six parents of children younger than 15 years and 128 parents of children older than 15 years refused to complete the questionnaire. Finally, a hundred and eighty-seven parent-child dyads were recruited. Children showed a lower

Table 3
Influence of items in the dimension they represent.

Latent Variables	Estimate	Std.Err	z-value	P(>z)
Physical Activity = ~				
1. To adjust food or insulin before long periods of PhA	0.689	0.079	8.673	<0.001
2. Check sugar before PhA	0.949	0.088	10.732	<0.001
3. Check sugar within 2 to 3 h after PhA	0.933	0.089	10.433	<0.001
Meal and snack = ~				
4. Use a sugar value to help decision making on amount of insulin to give for a meal	0.297	0.057	5.187	<0.001
5. Use the amount of CH to help decision making on amount of insulin to give for a meal	0.617	0.076	8.170	<0.001
6. Use food labels to help counting CH	0.955	0.079	12.090	<0.001
7. Measure or weigh food to help counting CH, when eating at home	0.946	0.077	12.292	<0.001
8. Give all of an insulin dose after finishing eating. (NEG)	0.143	0.081	1.773	0.076
9. Eat meals without knowing the amount of CH. (NEG)	0.504	0.052	9.723	<0.001
10. Eat meals without checking a sugar. (NEG)	0.168	0.038	4.425	<0.001
11. Check sugar within 2 h after a meal	0.608	0.102	5.941	<0.001
Low sugar = ~				
12. Check sugar before treating low sugar	3.393	0.067	5.871	<0.001
13. Check sugar after treating low sugar	0.904	0.116	7.784	<0.001
14. Over-treat low sugar with more CH than needed. (NEG)	−0.173	0.1081	−1595	0.111
High sugar = ~				
15. Give a dose of insulin right away based on a correction/ sensitivity factor or sliding scale	0.341	0.083	4.123	<0.001
16. *Re*-check sugar about 2 h after giving insulin for high sugar	1.165	0.137	8.514	<0.001
17. Check ketones when 2 blood sugar results in a row above 250–300	0.404	0.087	4.632	<0.001
Checking sugar = ~				
18. Go >8 h without checking sugar, except for overnight (NEG)	0.137	0.050	2.776	0.005
19. Check sugar at bedtime	0.751	0.175	4.299	<0.001
20. Miss or forget an insulin dose (NEG)	0.086	0.045	1.904	0.057

Abbreviations: CH: Carbohydrates; NEG: negative-weighted; PhA: physical Activity; Std.Err: Standard Errors.
Note: All items have a significant and positive influence on the dimension they represent, except item 8, 14 and 20 (negative-weighted). These three items have a near-zero power and are non-significant. In the case of item 14, influence is even negative, that is, in the opposite direction to what is expected according to the rest of the items in its dimension.

DMQ-Sp score than parents (74.94 ± 13.08 vs. 76.97 ± 12.59; $p < 0.01$). ICC for the DMQ-Sp scores of children and their parents was similar for both age groups of 8–12 and 13–18 years (0.78 vs. 0.76 respectively). Test-retest reliability for all patients $r = 0.84$ ($p < 0.001$) and parents $r = 0.80$ ($p < 0.001$) was similar.

Regarding HbA1c targets established by the International Society of Pediatric Adolescent Diabetes (ISPAD), only 21.7% achieved an HbA1c value <7%. The DMQ-Sp score was significantly higher in subjects who achieved this target than in those who did not (77.09 ± 11.38 vs. 72.30 ± 13.37; $p = 0.007$). However, no difference was observed in their parents' DMQ-Sp score (76.96 ± 12.57 vs.76.90 ± 12.65; non-significant).

Table 4
DMQ-Sp scores and results of external validity, and for all subjects and children in each age group.

	Total children sample	Children 8-12y	Children 13-18y
DMQ-Sp scores [a]	74.94 ± 13.08	82.54 ± 9.23	75.05 ± 10.34
Correlation DMQ-Sp scores with HbA1c	−0.39*	−0.39*	−0.38*
Glucose monitoring frequency [b]	0.52*	0.40*	0.52*
TIR (only in patients wearing CGM)	0.32*	–	–

Abbreviations: CGM, Continuous Glucose Monitoring; DMQ-Sp, Diabetes Management Questionnaire Spanish version; HbA1c, Glycated hemoglobin; TIR, Time in Range.
Notes: *P* value: * $p < 0.001$. P value <0.05 is considered significant. Data are presented by mean ± Standard deviation [a]; Spearman coefficient [b]. Values for each of the analysis are shown for the total children simple (n = 323), for the children 8-12y ($n = 155$), and for the children 13-18y ($n = 168$). Correlation between DMQ-Sp scores and TIR was analyzed for children of the total sample only in those wearing CGM system ($n = 100$).

Discussion

We developed a cross-cultural Spanish version of the DMQ, which was reliable, valid, and sensitive to change in a large sample of Spanish children (aged 8–18 years) with T1DM and their parents. Recruited simple size was higher than that calculated to carry out the study. That conferred sufficient statistical power to detect small differences and we have considered this issue a strength of the study.

In the cultural adaptation phase, only few participants used CGM. However, this has changed dramatically over the years and currently most children with T1DM use CGM. Therefore, the term *blood sugar* by *sugar* was replaced in all the questions to adapt to the new reality of glucose measuring. Readability FSZI obtained was "quite easy", thereby indicating a high probability of being understood by patients (Barrio-Cantalejo et al., 2008). DMQ-Sp items were well understood and acceptable for children. None of them required assistance answering the questions, indicating a good applicability.

In the second study phase, psychometric properties of the DMQ-Sp were analyzed. This is a self-administered survey that assess diabetes self-management adherence in children older than eight years of age with T1DM. The evaluation indicated adequate item characteristics, reliability, and suitable validity based on the standard (Nunnally & Bernstein, 1994). Results were consistent with the original version (Mehta et al., 2015). Internal consistency was sufficiently good, although Cronbach's alpha value was better for children and parents in the original version than in DMQ-Sp. In addition, the original version obtained better Cronbach's alpha values for older (13-18y) than for younger (8–12y) children. Items 8 and 14, both negative-weighted, were identified as elements that reduce Cronbach's alpha value and fit index, conferring less reliability to the scale. Nevertheless, children and their parents reported to understand the meaning of these two

items in the cross-cultural adaptation (first phase of the study). In order to improve patients' attention answering the questionnaire, a reminder may be necessary. However, these items were retained because of their clinical relevance, as in the original version. Results were consistent with previously published measures of diabetes adherence (Wysocki et al., 2012). The DMQ-Sp demonstrated excellent test-retest reliability, being better in adolescents than in children under 13 years of age, similar to the original version. Moreover, younger children showed better ICC for DMQ-Sp than in the original version, with similar results for the older children.

Structural construct was acceptable, although other authors consider it a good fit from 0.9 (Hu & Bentler, 1999). The approximation error of RMSEA 0.06 could be valued as relatively good; although some authors have considered it an ideal fit when <0.05 (Hu & Bentler, 1999).

HbA1c is considered the gold standard measure of diabetes metabolic control (Klein & Buse, 2020; Moscardó et al., 2020; Vigersky, 2019). The survey focuses on relevant behaviors of the previous month allowing a more reliable assessment of self-management and better prediction of glycemic outcome. As in the original version, DMQ-Sp scores of both children and parents demonstrated good external validity showing an inverse correlation with HbA1c levels. Although most children were on MDI treatment during the study, the survey demonstrated similar good external validity for patients wearing CSII as for those on MDI therapy. This is important as CSII therapy is increasing. A positive association between a high frequency of blood glucose monitoring and good HbA1c values has been demonstrated (Davey & Segal, 2015). In our study, survey scores also showed good correlation with glucose determinations frequency, confirming result consistency. In addition, the increase use of CGM systems adds new parameters of metabolic control measures such as TIR (Battelino et al., 2019). TIR also showed good correlation with DMQ-Sp scores.

Parent-child agreement was acceptable, mainly for parents of children under 15 years of age. Children showed lower DMQ-Sp scores compared to parents, similar to what reported in the original version.

To improve the psychometric validation of the DMQ original version, responsiveness to change analysis was included as the Plevinsky systematic review recommendations (Plevinsky et al., 2020). Good responsiveness to change was found in children and adolescents with T1DM after six months of completing the TEP.

Patients are required to spend only 5–10 min answering the survey and it was easy to score. Further, a self-report survey is considered the most economical tool to evaluate adherence. For these reasons, DMQ-Sp could be useful in daily clinical practice, helping health professionals to evaluate how patients follow their self-care counseling. The use of this questionnaire could also help health professionals guide the visit with patients and their parents in their self-care behavior.

We included participants of minority ethnic groups who understood the Spanish language well. However, in contrast to what was done in the original version, DMQ-Sp scores by ethnic group was not analyzed.

Practice implications

The DMQ-Sp could be a useful tool in clinical practice for Spanish diabetes medical teams to assess adherence to self-care in their T1DM patients aged 8–18 years. In addition, the DMQ-Sp could be valid for detecting the degree of individual adherence to each self-management task in order to individualize educational strategies to improve patient adherence. Furthermore, the DMQ-Sp could be a meaningful tool to evaluate outcomes of structured therapeutic education programs.

Limitations

This study has some limitations. Only one center of pediatric diabetes care participated in the study. Nevertheless, this hospital covers a massive referral area including different socioeconomic neighborhoods and it could be representative of many different pediatric patients with T1DM. Despite including TIR, in addition to HbA1c value, in order to analyze external validity, at the time, only 30.1% of patients used sensors to determine glucose values.

We did not analyze the impact of suffering additional chronic diseases in DMQ-Sp scores. That could be considered another limitation. Even though the scale measures specific diabetes behaviors, it is unknown if suffering another chronic disease, such as celiac disease and autoimmune thyroiditis, could influence the result.

Another limitation of this study was the lack of a control group to compare the TEP. This was not included for ethical reasons. It is known that children and adolescents with T1DM and their parents must optimize metabolic control from diabetes onset in order to prevent the development of diabetes chronic complications. The lack of a gold standard adherence measure for comparison was another study limitation. Adherence is a personal behavior. Consequently, it may be possible to show partial or total adherence to all activities of self-care and treatment. Patients answer questionnaire subjectively. Nevertheless, survey questions are formulated to obtain the most objective answer regarding whether they do or do not carry out self-care activity. A review (Monnette et al., 2018) on the concordance of self-reported adherence with medication monitoring devices demonstrated moderate to a high correlation between both ones.

Conclusion

The DMQ-Sp is reliable, valid, and sensitive to change in a large sample of children (aged 8–18 years) with T1DM and their parents. This survey can be used in patients following both MDI and CSII treatment, and using CGM systems.

Authors contribution

Carmen Yoldi Vergara, Ignacio Conget Donlo, and Marta Ramon-Krauel contributed to the study conception and design conceptualization of the study. Translation and decision of finally survey version was performed by Carmen Yoldi Vergara, Marina Llobet Garcés, María Teresa Rouco Gómez, Irune Goicoechea Manterola, Roque Cardona-Hernandez. Data collection were performed by Carmen Yoldi Vergara, María Teresa Rouco Gómez, Irune Goicoechea Manterola, Marina Llobet Garcés, Roque Cardona-Hernandez, and Marta Ramon-Krauel. Carmen Yoldi Vergara performed data curation and got funding acquisition. The original draft preparation, written review, and editing were performed by Carmen Yoldi Vergara, Marta Ramon-Krauel, and Ignacio Conget Donlo. All authors have read and approved the final manuscript.

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Declaration of Competing Interest

The authors declare no actual or potential conflicts of interest on this work.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pedn.2022.11.015.

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