

Assessing Paediatric Hrql in Diabetes: Semantic and Pilot Validation Study of the Portuguese Versions of DISABKIDS-DM Condition-Specific Module

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Introduction

Type 1 diabetes mellitus (T1DM) is a chronic medical condition defined by the autoimmune destruction of pancreatic cells that produce insulin – a hormone that allows the human body to use food energy. This leads to a total or partial insulin deficit and to subsequent hyperglycemia – too much sugar in the bloodstream (1, 2). This disease has in-

Objective – This study aimed to semantically validate the Portuguese versions of the diabetes module of a pediatric health-related quality of life assessment instrument – DISABKIDS-DM – and to preliminarily explore their main psychometric properties. **Materials and Methods** – Two samples of children (8-12 yo) and adolescents (13-18 yo) with Type 1 diabetes and their caregivers participated in the semantic validation (n=36) and in the pilot study (n=160) and filled out the DISABKIDS-DM, the semantic validation questionnaires and the Strengths and Difficulties Questionnaire. Using classical statistical validation procedures, the reliability, interrater consistency, and construct, discriminant, convergent and divergent validity were analyzed. **Results** – The findings support the relevance, comprehensibility and adequacy of the Portuguese versions. Both the self and proxy versions exhibited adequate levels of reliability; interrater consistency; and convergent, divergent and discriminant validity. The instrument differentiated between HbA1c groups, with children/adolescents with lower levels reporting better HRQoL, and between groups with and without comorbidity, with participants with other chronic diseases showing worse HRQoL. The instrument did not discriminate between the gender and time of diagnosis categories. Children and adolescents tended to report higher levels of HRQoL than their parents. **Conclusion** – These results reinforce the importance of cross-cultural validation procedures to ensure the equivalence of pediatric HRQoL measures, particularly in the context of diabetes-specific instruments. More research is needed, with a larger and more diverse sample, to study the factorial structure. The use of the questionnaires should be encouraged in both pediatric clinical settings and research.

creased significantly worldwide (3, 4) and is one of the most frequent chronic pediatric conditions (5, 6). New cases in Portugal have increased from 160 per 100,000 inhabitants in 2000 to 195 in 2015 (7).

Diabetes is a complex condition demanding multiple daily self-care behaviors – glycaemia checking, insulin administration, diet control, prevention and correction of extreme

blood glucose levels, complementary medication and physical activity (8, 9). The treatment demands, symptom interference in social activities and the impact of the disease on daily life, along with the physiological, social and emotional changes occurring during childhood and youth, constitute significant challenges to youngsters with diabetes, who are therefore at greater risk for emotional and behavioral problems (8, 10), with considerable repercussions for their quality of life (11, 12).

Health-related quality of life (HRQoL) assessment is particularly salient to identify the need for clinical interventions (13, 14), to ease the experience of the disease and reduce its negative impact (15), and to evaluate the efficacy of those interventions (16, 17). HRQoL may be defined as the impact of a medical condition on the individual's physical, emotional and social functioning and well-being. This construct includes patients' perception of their health status (18, 19) and is related to the individual experience of the disease and associated treatments, affecting most life domains, such as family, friends, school, hobbies, sports, religion, mental attitude, and future career (20).

In contrast to the progress in adult HRQoL research over the last decades, the pediatric HRQoL domain has evolved more slowly due to conceptual and operational difficulties linked to younger subjects' development and the need to use different informants (21, 22). Initially, HRQoL dimensions assessed in adults were directly transformed into the pediatric version, and a higher value was attributed to the external evaluator's opinion rather than to the child/ adolescent's own perspective, thus disregarding the need to adapt the item content to the developmental specificities of this population (23, 24).

The development of pediatric HRQoL assessment procedures has led to the international spread of instruments that were initially developed for a specific language and

culture (25, 26). The DISABKIDS project – Quality of life in children and adolescents with disabilities and their families – Assessing patients' views and patients' needs for comprehensive care – (27, 28) was developed under the scope of a cross-cultural perspective, gathering the input of experts from several European countries. Following a developmental perspective from the beginning of the project, as well as a simultaneous approach in their construction and validation, these instruments encompassed transcultural specificities, both generic and specific quality of life dimensions, and a wide age range, along with representations of physical, mental and social well-being appropriate for youth (29, 30).

The present study focuses on the diabetes-specific module of the DISABKIDS and is the first to use this instrument in Portugal. According to the recommended transcultural procedures in adapting pediatric HRQoL assessment instruments within a sequential approach (26, 31), our aim was to semantically validate the experimental Portuguese versions of the DISABKIDS-DM and to preliminarily explore their main psychometric properties.

Method

The DISABKIDS Methodology

The adaptation of the T1DM-specific module to the Portuguese language and culture followed the guidelines established by the international group (32), encompassing three steps: (i) the translation, aiming to reach conceptual equivalence of the two versions of the instrument; (ii) the semantic validation, aiming to assess the instrument's content, based on the opinion of the respondents, in terms of the items' acceptance, comprehensibility and relevance while considering any wording issues or item modification that might clarify their meaning; and (iii) the psychometric study, aiming to conduct a preliminary anal-

ysis of the main psychometric properties of both the self and proxy versions.

Participants

Following the sampling frames indicated by the European DISABKIDS Group (32), the sample collection was carried out between December 2017 and December 2018 at the diabetes pediatric outpatient service of the Portuguese Diabetes Association (APDP). The inclusion criteria were as follows: (i) children and adolescents between 8 and 18 years of age; (ii) clinical diagnosis of T1DM without severe psychiatric comorbid disorder or development delay; (iii) illness duration of at least one year; and (iv) patients accompanied by at least one adult caregiver. In agreement with the aforementioned cross-cultural adaptation guidelines, two samples were recruited: one for semantic validation – nine children (aged 8-12 years), nine adolescents (aged 13-18 years) and their respective caregivers (total of 36 participants) – and another for the pilot study – 31 children (aged 8-12 years), 49 adolescents (aged 13-18 years) and their respective caregivers (total of 160 participants).

Measures

The *DISABKIDS-DM diabetes-specific module* (32) (Portuguese experimental versions) assesses HRQoL in children and adolescents (8-18 years old) with T1DM, concerning their global functioning and well-being during the last four weeks. The questionnaire includes 10 items, which are similar in both versions for patients and caregivers, grouped into two subscales: impact (6 items), assessing the functional and emotional impact of the disease (e.g., “Does diabetes stop you from doing the things that you like to do?”), and treatment (4 items), assessing the burden of carrying the equipment and planning

the treatment (e.g., “Do you get fed up with measuring your blood sugar levels?”). Items are scored on a five-point Likert scale (1 = never; 2 = seldom; 3 = quite often; 4 = very often; 5 = always) and inverted, with higher total scores representing better HRQoL. The instrument also includes three specific questions (e.g., “How severe have your problems with your diabetes been during the last year?”) assessing symptom severity during the last 12 months.

The *DISABKIDS general impression sheet* (DISABKIDS group document, s/d.). This document aims to obtain the participant's overall impression of the questionnaire. It includes seven questions covering the following: (i) global quality of the questionnaire; (ii) item comprehensibility; (iii) understanding and usability of the response scale; (iv) relevance of the questions for the chronic condition; (v) a wish to change something in the questionnaire; (vi) a wish to add something; and (vii) items that the young person/caregiver might not want to answer.

The *DISABKIDS cognitive debriefing sheet* (DISABKIDS group document, s/d.). This is the core instrument of the semantic validation process. For each item, the respondent is asked to indicate (i) whether the item is relevant for the child/adolescent condition; (ii) whether the item is difficult to understand; and (iii) whether the response scale is simple and in agreement with the question posed. Respondents are also asked to paraphrase each of the items using their own words in order to explain their perceived meaning.

The *DISABKIDS-12 chronic generic measure* (27) – Portuguese versions (33) – is the brief version of the DISABKIDS-37 and assesses the HRQoL of children and adolescents (aged 8-18 years) with any chronic condition, referring to the general aspects of those conditions. Items were based on mental, social and physical factors to yield a single global result. The questionnaire includes 12

items answered on a five-point Likert scale (1 = never; 2 = seldom; 3 = quite often; 4 = very often; 5 = always), with higher results indicating better HRQoL. The internal reliability for the global score of the DISABKIDS-12 was good for both the self ($\alpha=0.88$) and proxy ($\alpha=0.90$) versions.

The *SDQ – Strengths and Difficulties Questionnaire* – Portuguese versions (34) – assesses adjustment difficulties in children and adolescents (aged 3-18 years) by identifying symptoms and their impact. It comprises 25 items divided into five dimensions: (i) emotional symptoms, (ii) conduct problems, (iii) hyperactivity/inattention, (iv) peer relationship problems, and (v) prosocial behavior. The questionnaire is scored on a three-point scale (0 = not true; 1 = somewhat true; 2 = certainly true). A global score can be obtained by summing the first four dimensions, which may otherwise be clustered into internalizing (emotional symptoms and peer relationship problems) and externalizing (conduct problems and hyperactivity/inattention) problems (35). Higher scores indicate greater psychological adjustment difficulties. The internal reliability for the SDQ was acceptable for the global result (*Self*: $\alpha=0.66$; *Proxy*: $\alpha=0.64$) and for externalization (*Self*: $\alpha=0.64$; *Proxy*: $\alpha=0.71$) but weak for internalization (*Self*: $\alpha=0.58$; *Proxy*: $\alpha=0.56$).

Procedure

Formal authorization was obtained from the Ethical Committee of Portuguese Diabetes Association (APDP) and the Ethics Commission of Faculty of Psychology, University of Lisbon (FPUL). In conformity with the Portuguese legal framework, after elucidation of the research goals and procedures, informed consent was obtained from participants younger than 14 years old, and informed consent forms were signed by adolescents (>14 years old) and their caregivers prior to

each phase of the study. Permission to access clinical data (insulin administration mode and HbA1c level) from the patients' clinical files was obtained. Prior to the administration of the questionnaires, demographic data (child's and caregiver's age and sex and caregivers' educational level) were collected. Participants were recruited on a consecutive basis when waiting for a medical consultation, according to a previous selection of participants who met the inclusion criteria by the responsible physician, and they filled out the questionnaires in a room that ensured total privacy in the presence of a research team member for any occasional assistance needed.

Translation

Translation of the self and proxy versions of the DISABKIDS-DM original questionnaire was performed according to the recommended procedures of the DISABKIDS European Group, which included the following: (i) item and instructions translated from English to Portuguese by two members of the research team fluent in English; (ii) conciliation of those two independent translations into a single version; (iii) retroversion by a third research member; (iv) retroversion-original comparison; (v) review of reconciled versions and problematic item harmonization by a member of the international DISABKIDS team; and (vi) stabilization of the self and proxy experimental versions.

Semantic Validation

Participants were recruited through a convenience sample in order to obtain a homogeneous sample regarding age group and gender. After the questionnaire was filled out, the cognitive debriefing was individually led by a research member (one child asked for the presence of his mother; therefore, the proxy version was administered to the oth-

er parent). Participants were asked to make an overall assessment of the questionnaire (general impression phase) and of a specific number of items (specific semantic validation phase). To prevent fatigue among the respondents, this last phase was divided into three item clusters, each one of them answered by six youth and six caregivers. The procedure lasted an average of 12 minutes for each respondent. The final versions were approved by the DISABKIDS research group.

Pilot Study

Participants were sequentially recruited. The administration of the questionnaires was conducted by three team members separately for each dyad (child/adolescent – caregiver). Participants filled out the questionnaires by themselves, and attention was given to the goal of preventing information exchange between respondents. The procedure lasted an average of 10 minutes for each dyad.

Statistical Analysis

Data analysis was performed using SPSS Statistics version 25.0. The information considered the probability associated with a confidence interval – in this case, 95% – in order to facilitate the reliable interpretation of results. Item frequencies were calculated to assess the pattern of responses obtained in the semantic validation procedure, considering a minimum frequency of three subjects in a negative response category for an item to be considered problematic and thus require additional revision. Internal reliability was assessed with Cronbach's alpha and mean interitem correlations. Pearson's and Spearman's coefficients were computed to evaluate construct validity (DISABKIDS-DM), convergent validity (DISABKIDS-DM and DISABKIDS-12) and divergent validity (DISABKIDS-DM and SDQ). Following the

suggestions of Nunnally and Bernstein (36), alpha values ≥ 0.70 were considered acceptable and ≥ 0.80 were optimal; correlation coefficients between 0.1 and 0.3, those between 0.31 and 0.5, and those superior to 0.5 were classified as indicators of weak, moderate and strong associations, respectively. Regarding discriminant validity, the Kruskal-Wallis test was used to assess differences among the HbA1c level and age of diagnosis groups, and U-Mann-Whitney tests were used to assess differences among the gender, age and comorbidity groups. Caregiver-patient agreement was assessed with interclass correlations for average measurements within a two-way mixed model (absolute agreement) and the median Wilcoxon signed-rank test for paired samples. Student's t-tests were used for the comparison of the HRQoL self and proxy mean results. Cohen's d test was used to assess the effect size of the differences between HRQoL mean scores.

Results

Sample Characteristics

For the semantic validation phase, children and adolescents were distributed to achieve homogeneity with respect to age group and gender. One adolescent presented comorbidity with other chronic disease. In the pilot study phase, participants were sequentially recruited. One child and nine adolescents presented comorbidity with other chronic diseases. Most children/adolescents had an HbA1c level $>7.5\%$, the time of diagnosis was greater than three years, and most caregivers were women (Tables 1 and 2).

Semantic Validation – General Impression Phase

All parents and children/adolescents rated their general impression of the questionnaires as “good” or “very good”. The major-

Table 1. Demographic and Clinical Characteristics of Children/Adolescents and Caregivers (Semantic Validation Sample)

Characteristics		Children (8-12 yr) (n=9)	Adolescents (13-18 yr) (n=9)	Caregivers (n=18)
Demographic				
Age	Mean (SD)	10.33 (1.32)	15.11 (1.90)	46.39 (8.02)
Gender	Male (n/%)	4/44.4	5/55.6	6/33.3
	Female (n/%)	5/55.6	4/44.4	12/66.7
Clinical				
Blood sugar level (HbA1c)	Mean (SD)	8.10 (0.83)	8.39 (1.01)	-
	7.5% or less (n/%)	2/22.2	2/22.2	-
	7.6% to 9.9% (n/%)	7/77.8	7/77.8	-
Time of diagnosis (in months)	Mean (SD)	60.56 (37.83)	56.22 (27.38)	-
	12 to 35	2/22.2	3/33.3	-
	36 to 59	3/33.3	1/11.1	-
	60 or more	4/44.4	5/55.6	-

Table 2. Demographic and Clinical Characteristics of Children/Adolescents and Caregivers (Pilot Study Sample)

Characteristics		Children (8-12 yr) (n=31)	Adolescents (13-18 yr) (n=49)	Caregivers (n=80)
Demographic				
Age	Mean (DP)	10.77 (1.02)	14.69 (1.52)	44.12 (6.04)
Gender	Male (n/%)	13/41.9	20/40.8	14/17.5
	Female (n/%)	18/58.1	29/59.2	66/82.5
School grade ¹	1 st Cycle (n/%)	5/16.1	-	1/1.3
	2 nd Cycle (n/%)	22/71.0	2/4.1	3/3.8
	3 rd Cycle (n/%)	4/12.9	24/49.0	8/10.0
	High School (n/%)	-	22/44.9	25/31.3
	Superior (n/%)	-	1/2.0	39/48.8
	ND (n/%)	-	-	4/5.0
	Clinical			
Blood sugar level (HbA1c)	Mean (SD)	8.05 (1.05)	8.37 (1.11)	-
	7.5% or less (n/%)	11/35.5	7/14.3	-
	7.6% to 9.9% (n/%)	18/58.1	36/73.5	-
	10% or higher (n/%)	2/6.5	6/12.2	-
Time of diagnosis (in months)	Mean (SD)	49.06 (33.96)	87.51 (38.76)	-
	12 to 35 (n/%)	15/48.4	1/2.0	-
	36 to 59 (n/%)	6/19.4	10/20.4	-
	60 or above (n/%)	10/32.3	38/77.6	-
Insulin administration mode	Infusing pump	16/51.6	29/59.2	-
	Pen	15/48.4	20/40.8	-
Comorbidity with other chronic disease	Yes	1/3.2	9/18.4	-
	No	30/96.8	40/81.6	-

¹School grades in Portugal: 1st Cycle (6-9 years old); 2nd Cycle (10-11 years old); 3rd Cycle (12-14 years old); High school (15-17 years old); Superior (18 years old and above); ND=Non-defined.

Table 3. Results of the Semantic Validation General Impression Phase (Children/Adolescents and Caregivers)

Questions	Multiple choice answers	Children / Adolescents (8-18 yr) (n=18)	Caregivers (n=18)
1. What is your overall opinion of the questionnaire? (n/%)	Very good	7/38.89	3/16.67
	Good	11/61.11	15/83.33
2. Are the questions easily understandable? (n/%)	Easy to understand	17/94.44	18/100.0
	Sometimes hard to Understand	1/5.56	-
3. And what about the response scale? Was it hard to understand? (n/%)	Not hard at all	17/94.44	16/88.89
	A bit hard	1/5.56	2/11.11
4. Are the questions important for your health issue? / Are the questions important for your son's/daughter's health issue? (n/%)	Very important	17/94.4	17/94.44
	Sometimes important	1/5.56	1/5.56
5. Would you like to change anything in the questionnaire? (n/%)	Yes	-	-
	No	18/100.0	18/100.0
6. Would you like to add something to the questionnaire? (n/%)	Yes	-	4/22.22
	No	18/100.0	14/77.78
7. Was there any question you didn't want to answer? (n/%)	Yes	-	1/5.56
	No	18/100.0	17/94.44

ity of participants globally rated items as very important and perceived the items and the response scale as easily understandable and usable (Table 3). Nevertheless, four youngsters questioned the comprehensibility of item 2 (“O teu dia-a-dia é dominado pela diabetes?” – *Does diabetes rule your day?*), being unsure about its meaning, and one child questioned item 10 (“Incomoda-te teres que planear tudo?” – *Are you bothered that you have to plan everything?*), not knowing exactly what the expression *planear tudo* (plan everything) was referring to (Table 3). One caregiver suggested changing the term *irritado* (annoyed) for *aborrecido* (fed up) in item 9 (“Ficas irritado por teres de andar com o aparelho de medição de glicose contigo?” – *Are you annoyed that you have to carry the testing equipment with you?*). Another caregiver answered item 2 reluctantly, claiming not to know what her daughter thought about that specific issue. Four caregivers expressed their wish to add something: one more point in the response scale between *nunca* (never) and *raramente* (seldom); an opportunity to allow

parents to express their feelings about the child's disease; a question about whether children with T1DM feel different from other children; and the inclusion of an additional section to explain their answers.

Semantic Validation – Cognitive Debriefing Phase

Participants considered most items relevant to the diabetes condition. The items considered less relevant were item 2 (“Does diabetes rule your day?”) by one child; item 4 (“Is it difficult for you to stick to your diet?”) by one caregiver; item 6 (“Does it bother you that others can always eat and drink as much as they like?”) by two children and two caregivers; and item 9 (“Are you annoyed that you have to carry the testing equipment with you?”) by one caregiver.

All caregivers considered all of the questions to be easily understandable, and most questions were considered easy to understand by all children and adolescents. Item 8 (“Do you get fed up with measuring your blood

sugar levels?”) was found to be difficult to understand by one child, who asked if it was related to the measurement of glycaemia.

However, three children and one adolescent found it hard to understand item 2 (“Does diabetes rule your day?”). Due to this issue, a subsample of 33 youngsters and their caregivers responded to questionnaires where an alternative version of item 2 was added with slightly different wording to assess whether this new version would change the results. Because the answers to these two versions were highly correlated (Self: $r=0.69$; $P>0.01$; Proxy: $r=0.59$; $P>0.01$), all further analyses were conducted with the initial version of the item.

The paraphrasing method did not reveal discrepancies between the meaning given to the questions by the participants and the meaning intended by the research team. Nonetheless, it is interesting that this method highlighted differences in the tone or intensity of meanings attributed by children/adolescents and their parents. Consider the following: concerning item 2: *If diabetes controls my life on a daily basis* (children/adolescents) versus *It feels like the sword of Damocles is hanging over my son’s head, we cannot alienate ourselves from that concern, and we can’t ever forget* (parents); concerning item 6: *If it bothers me that I have diabetes and other people don’t, and I have to do certain things and other people don’t* (children/adolescents) versus *That is my major frustration, as a parent, not being able to give her all that she wants to eat or drink, that’s what bothers me the most* (parents); concerning item 8: *If I get bored constantly having to*

measure glycaemia (children/adolescents) versus *It’s her daily routine, it’s a daily challenge* (parents); concerning item 9: *If I get angry for carrying the (testing) equipment with me* (children/adolescents) versus *It’s very boring having to carry one more piece of equipment that makes her different from others* (parents).

Pilot Study

Descriptive Analysis

Descriptive statistics for the DISABKIDS-DM (self and proxy versions) are presented in Table 4. Both parents and children/adolescents most often used the response scale points corresponding to higher HRQoL levels (“never” and “seldom”). The exception was for item 5 (“Do you worry about your blood sugar level?”), which the majority of subjects answered with the lowest points on the scale (“often” and “always”). Item 2 (“Does diabetes rule your day?”) had the highest frequency of responses on the highest point of the scale (Self version). The mean results for children/adolescents were apparently higher than those for caregivers in both subscales (impact and treatment) and total scores and in the majority of items, with caregivers having lower scores on the scale.

Reliability

Both versions of the questionnaire showed reasonable to good internal consistency values for each subscale and for the total score (Table 5). The elimination of item 5 would

Table 4. Descriptive Statistics of HrQoL Perception Results (Total Score and Subscales) of DISABKIDS-DM (Self and Proxy Versions)

Participants (n=80)	Mean	SD	Median	Minimum	Maximum
Impact (Self / Proxy)	21.48 / 20.51	3.96/3.52	22.00 / 21.00	10/13	27/27
Treatment (Self / Proxy)	15.84 / 14.11	3.44/3.52	17.00 / 14.00	6/4	20/20
Total score (Self / Proxy)	37.31 / 34.63	6.66/ 6.39	39.00/34.50	17/17	46/45

Table 5 Internal Consistency Values for Portuguese, Swedish, Danish and International Versions (Self and Proxy) of DISABKIDS-DM

Internal Consistency Analysis	Cronbach's α				IIC	
	Portuguese (n=80)	Swedish (Self: n=116; Proxy: n=113)	Danish (Self: n=99)	International (Self: n=204)	Portuguese (n=80)	Number of items
Impact (Self/Proxy)	0.72 / 0.71	0.79 / 0.84	0.78 / -	0.84 / -	0.50 / 0.58	6/6
Treatment (Self/Proxy)	0.81 / 0.90	0.79 / 0.79	0.84 / -	0.85 / -	0.79 / 0.89	4/4
Total score (Self/Proxy)	0.84 / 0.86	0.85 / 0.87	- / -	- / -	0.73 / 0.81	10/10

IIC=Inter-Item Correlation.

increase internal consistency values (Total score: Self: $\alpha=0.86$; Proxy: $\alpha=0.90$; Impact: Self: $\alpha=0.78$; Proxy: $\alpha=0.81$). This item showed an extremely biased distribution, with 92.5% of youngsters and 57.5% of caregivers choosing answers on the scale corresponding to lower HRQoL levels. The interitem correlation analysis (IIC) showed good internal consistency values for both subscales and for the total score in both versions (Table 5).

Construct Validity

Moderate correlations between the two subscales were observed (Self: $r_s=0.55$, $P<0.01$; Proxy: $r_s=0.64$, $P<0.01$). Strong associations were found between the subscales and the total HRQoL score (Self: Impact: $r_s=0.90$, $P<0.01$; Treatment: $r_s=0.85$, $P<0.01$; Proxy: Impact: $r_s=0.91$, $P<0.01$; Treatment: $r_s=0.90$, $P<0.01$). In the original study (27), there was a moderate correlation between the subscales (Self: $r_s=0.66$, $P<0.01$).

Parent-child Agreement

The intraclass correlation coefficients (ICC) showed reasonable consistency between children/adolescents and their caregivers (Total score: $p_1=0.65$; Impact: $p_1=0.64$; Treatment: $p_1=0.57$). Significant differences were found between the two groups of raters, with children and adolescents showing higher HRQoL scores (Total score: $r_s=0.57$, $P<0.01$; Impact: $r_s=0.49$, $P<0.01$; Treatment: $r_s=0.52$,

$P<0.01$). These scores are similar to the original study ($r_s=0.50$, $P<0.01$ in both subscales).

Discriminant Validity

The DISABKIDS-DM child version differentiated between HbA1c groups, with children/adolescents with lower levels reporting better HRQoL in the impact subscale, and between groups with and without comorbidity, with participants with other chronic diseases showing worse HRQoL scores in the treatment subscale. The proxy version showed differences in both subscales and in the total scores, with groups with lower HbA1c levels reporting better HRQoL and groups with comorbidity showing worse HRQoL, and in the impact subscale for different age groups, with children showing worse HRQoL than adolescents. Finally, the self and proxy versions did not discriminate between the gender and time of diagnosis categories (Tables 6 and 7).

Convergent Validity

Moderate to strong positive associations were observed between the total DISABKIDS-DM and DISABKIDS-12 scores (Self: $r_s=0.69$, $P<0.01$; Proxy: $r_s=0.85$, $P<0.01$). The strength of the associations was similar between the two genders ($r_s=0.70$, $P<0.01$ for boys and $r_s=0.68$, $P<0.01$ for girls).

Divergent Validity

Significant but weak to moderate negative associations were found between the total

Table 6. HrQoL Results by Hba1c Level and Time of Diagnosis for DISABKIDS-DM (Self/Proxy)

HbA1c level		Favourable (7.5% or less) (n=18) Median (IQR)	Unfavourable I (7.6% to 9.9%) (n=54) Median (IQR)	Unfavourable II (10% or more) (n=8) Median (IQR)	chi ²	P
Impact subscale	Self	23.00 (17)	21.50 (12)	21.50 (17)	0.500	0.779
	Proxy	23.00 (13)	20.00 (13)	21.50 (9)	6.286	0.043
Treatment subscale	Self	19.00 (13)	16.00 (14)	17.00 (9)	7.237	0.027
	Proxy	16.00 (16)	13.00 (13)	14.50 (8)	7.481	0.024
HrQoL Total score	Self	42.00 (29)	38.50 (26)	38.00 (24)	3.760	0.153
	Proxy	39.50 (28)	32.00 (22)	35.00 (17)	8.159	0.017
Time of diagnosis		1 to 3 years (n=16) Median (IQR)	3 to 5 years (n=16) Median (IQR)	>5 years (n=48) Median (IQR)	chi ²	P
Impact subscale	Self	21.00 (14)	22.00 (17)	22.00 (17)	0.943	0.624
	Proxy	18.50 (11)	20.50 (13)	21.00 (11)	4.246	0.120
Treatment subscale	Self	16.00 (12)	16.50 (13)	17.00 (14)	1.191	0.551
	Proxy	13.00 (15)	14.50 (11)	14.00 (12)	0.735	0.692
HrQoL Total score	Self	37.00 (24)	40.00 (26)	39.00 (29)	1.389	0.499
	Proxy	31.00 (25)	35.00 (22)	35.50 (21)	2.355	0.308

Table 7. HrQoL Results by Gender, Comorbidity and Age Group for DISABKIDS-DM (Self/Proxy)

Gender		Male (n=33) Median (IQR)	Female (n=47) Median (IQR)	Z	P
Impact subscale	Self	24.00 (15)	21.00 (17)	-1.788	0.074
	Proxy	21.00 (14)	21.00 (12)	-0.579	0.562
Treatment subscale	Self	17.00 (14)	16.00 (13)	-1.402	0.161
	Proxy	14.00 (16)	14.00 (13)	-0.265	0.791
HrQoL Total score	Self	41.00 (26)	37.00 (29)	-1.895	0.058
	Proxy	36.00 (27)	34.00 (23)	-0.450	0.652
Comorbidity		With (n=10) Median (IQR)	Without (n=70) Median (IQR)	Z	P
Impact subscale	Self	20.50 (14)	22.00 (17)	-0.395	0.693
	Proxy	17.50 (11)	21.00 (13)	-1.447	0.148
Treatment subscale	Self	14.00 (8)	17.00 (14)	-2.541	0.011
	Proxy	9.50 (16)	14.50 (13)	-2.913	0.004
HrQoL Total score	Self	36.00 (22)	40.00 (29)	-1.538	0.124
	Proxy	27.50 (25)	35.50 (23)	-2.412	0.026
Age group		Children (8-12 yr) (n=31) Median (IQR)	Adolescents (13-18 yr) (n=49) Median (IQR)	Z	P
Impact subscale	Self	21.00 (17)	23.00 (17)	1.345	0.179
	Proxy	20.00 (12)	22.00 (13)	2.277	0.023
Treatment subscale	Self	17.00 (14)	17.00 (13)	0.313	0.754
	Proxy	14.00 (16)	14.00 (12)	-0.426	0.670
HrQoL Total score	Self	38.00 (29)	39.00 (26)	1.079	0.281
	Proxy	33.00 (27)	36.00 (23)	0.984	0.325

Table 8. HrQoL Results (0-100) of the Child Version of DISABKIDS-DM (Portuguese, International, Norwegian and Swedish Studies) by Subscales

Subscale	Portuguese (n=80) Mean (SD)	International (n=205) Mean (SD)	Norwegian (n=102) Mean (SD)	Swedish (n=115) Mean (SD)	Cohen's d	r
Impact	64.48 (16.49)	62.73 (22.22)	70.00 (16.90)	70.42 (17.71)	0.089 -0.331 -0.347	0.045 -0.163 -0.171
Treatment	73.98 (21.50)	58.94 (23.41)	62.00 (20.70)	65.42 (21.98)	0.669 0.567 0.394	0.317 0.273 0.193

DISABKIDS-DM score and the total problems identified by the SDQ (Self: $r_s = -0.32$, $P < 0.01$; Proxy: $r_s = -0.23$, $P < 0.05$), the internalizing problems dimension (Self: $r_s = -0.29$, $P < 0.05$) and the externalizing problems dimension (Self: $r_s = -0.23$, $P < 0.05$).

Comparison with HRQoL Results of International Studies

The mean results for both subscales of the child version in the Portuguese study were higher than those in the international study (29), which had a sample of 205 children and adolescents from seven European countries, with ages ranging from 8 to 16 years old and with most (96.3%) having mild to moderately severe HbA1c levels. Our results were lower in the impact subscale and higher in the treatment subscale in comparison with the results of both the Norwegian study (39), with a sample of 102 subjects ranging from 8 to 19 years old, and the Swedish study (37), with a sample of 115 youngsters aged 8 to 18 with mildly severe HbA1c levels (Table 8).

Discussion

This study aimed to semantically validate the Portuguese versions of the DISABKIDS-DM according to the procedures outlined by the original European project (27) in order to ascertain their adequacy for pediatric HRQoL assessment in Portugal, based on a cross-cultural perspective.

Additionally, some preliminary results on basic psychometric properties were explored. The findings from this study indicate that the Portuguese versions of the DISABKIDS-DM are reliable and constitute valid measures to assess the pediatric HRQoL of children and adolescents with T1DM and their parents.

The items on the Portuguese versions of the questionnaires were generally rated as important, easily understandable and adequate by children/adolescents and their caregivers, thereby supporting the importance of the items for HRQoL assessment, in line with the results of the semantic validation of the Portuguese versions of the DISABKIDS-37 (40).

Although a few participants reported difficulties in understanding item 2, we chose to maintain the initial wording, supported by the high correlation between the initial translation and an alternative version and by previous results of the semantic validation of the DISABKIDS-37, in which item 9 ("Is your life ruled by your condition?") had similar wording in the Portuguese version and did not raise significant issues. However, considering that this item also obtained the highest frequency of answers with the highest points in the self version, its specific wording should be explored in further studies given an in-depth psychometric performance analysis (e.g., item response theory).

The paraphrasing method revealed that although all participants showed a good under-

standing of the items, the youngsters tended to attribute a more literal and casual meaning to the items (with wording closer to the originally intended meaning), and this was even more evident in the group of children (8-12 years). This finding may be linked to their concrete operational stage of cognitive development. On the other hand, caregivers tended to attribute a more intense emotional meaning to the items, focusing on the disease burden, which might be partially explained by their personal burden of treatment issues and their awareness of the potential consequences of diabetes. These differences in interpretation are consistent with the tendency for parents to rate their child's HRQoL as worse than the child does (41, 42).

The fact that children and adolescents gave answers with fewer points on the response scale for most items, corresponding to higher HRQoL levels, suggests they have a good perception of their HRQoL. In contrast, the fact that the answers to item 5 ("Do you worry about your blood sugar levels?") mainly corresponded to lower HRQoL levels suggests that these answers might have been affected by a desire to show compliance with the medical instructions they had been given on the need to regularly measure and control their glycemia levels. This interpretation was reinforced by the frequent verbal comments, made by both the youngsters and the parents, concerning the importance of adhering strictly to the routine of measuring blood sugar levels.

The exploratory psychometric results in terms of internal consistency, construct validity and parent-child agreement are within the desirable standards and in accordance with the original study (27). The level of consistency with the results in other countries and languages (27, 37, 38) may be seen as a positive outcome of the rigorously structured translation and adaptation protocol.

Regarding the discriminant validity of the questionnaires, significant differences were found among the HbA1c groups, confirming previous studies showing that youngsters with good glycemia control report higher HRQoL levels in the dimension of treatment (43, 44). Differences among the HbA1c groups were also found in the parent version (total scores and individual dimensions), suggesting that caregivers also associate better glycemia control with higher HRQoL levels.

Additionally, we found differences between the groups with and without comorbidity for the treatment dimension (in both versions) and for the total HRQoL score (in the proxy version), suggesting that both children/adolescents and caregivers perceive the additional weight of having to care for another disease in the overall treatment burden. However, only parents emphasized the impact of multiple conditions on the overall child's quality of life.

We found that caregivers of adolescents reported higher HRQoL scores than the children's caregivers. This result is contrary to those of previous studies showing the opposite tendency (20, 45) and the more general observation of worse HRQoL in adolescents with chronic conditions when compared to younger patients (46, 47). One possible explanation is that these adolescents' caregivers may be deemphasizing the chronic condition, considering that as children grow older, they are more able to cope with the impact of the disease.

Our results also did not confirm previous studies accounting for significantly worse HRQoL among girls in comparison with boys (44, 45). In our sample, no differences were found among the distinct "age of diagnosis" groups, despite some previous studies showing a positive correlation between a longer time of diagnosis and lower HRQoL levels (48). However, we must take in account that all children and adolescents in this sam-

ple had received their diagnosis more than a year ago. It is possible that the inclusion of youngsters with a more recent diagnosis would result in the detection of such specific differences.

Concerning convergent validity, the strong association between the scores for the DISABKIDS-DM (specific condition) and DISABKIDS-12 (generic condition) suggests that the present version of the condition-specific module represents the original HRQoL construct well. Regarding divergent validity, we found lower HRQoL levels associated with higher levels of general behavioral and internalizing problems. These results are consistent with previous studies highlighting that children and adolescents with diabetes usually have more internalizing problems (49, 50). However, these results need to be considered cautiously given the low reliability levels for the internalization dimension of the SDQ.

Satisfactory results were found regarding the parent-child agreement for pediatric HRQoL assessment in terms of total scores, with caregivers perceiving lower HRQoL (both generic and specific) than their children. Similar results were found for both subscales, although agreement was lower for the impact dimension, which is more related to the emotional and social aspects of the disease. Previous studies suggest that agreement levels vary according to the dimensions considered, with good agreement levels usually reported in domains related to physical activity, functioning and symptoms and lower levels reported in social and emotional domains (41, 44). These results highlight the need to consider both sources of information when assessing pediatric HRQoL (51, 52). Understanding the differences between these two sources may be of major importance when, for instance, a decision concerning clinical intervention is at stake. The differences found in this study may result from a

true discrepancy between raters, with caregivers feeling more affected by the disease than their children. It is interesting to recall that when paraphrasing, parents tended to give a more emotionally loaded interpretation of the items, as opposed to the more literal and moderate meanings attributed by youngsters. It is possible that parents overprotect their children, the youngest ones in particular, by not exploring diabetes-related issues with them in depth or by providing vague and softer information about the disease in an attempt to relieve the child from the burden of the chronic condition (42). By indicating what they think about their children's perception of HRQoL, parents may be having trouble differentiating their own and their child's perspectives (43). Our results confirm previous studies with diabetes and other pediatric chronic conditions showing that caregivers tend to report lower child HRQoL levels than their children (41, 44).

In comparison with the original international study (29), the Norwegian study (39) and the Swedish study (37), the moderate to large effect differences that were found (with the exception of the impact dimension relative to that in the original study) suggest the need for further research with a larger Portuguese sample in order to assess whether resulting differences are related to cultural specificities regarding diabetes management.

Limitations of the Study

Despite the exploratory nature of this study, the small sample size is nonetheless an important limitation, thus narrowing the use of more complex statistical procedures and the power of the tests used. Recruitment of children and adolescents in only one diabetes pediatric service may hinder the extension of the results to other clinical contexts (e.g., general hospitals). Additionally, the fact that the majority of the caregivers had a relatively

high educational level in the context of the Portuguese population may affect the generalization of results. Future research with a larger and more diverse sample is needed to further explore the impact of other clinical and demographic variables on the HRQoL of Portuguese youth with T1DM.

Conclusions

The Portuguese experimental versions of the DISABKIDS-DM showed cross-cultural adequacy, as well as satisfactory internal consistency and validity, thus being adequate for use in larger HRQoL studies. Overall, the results support the use of the DISABKIDS-DM as a reliable and useful assessment tool with a developmental scope for children and adolescents with T1DM. The use of this instrument should be encouraged for both scientific research and clinical pediatric care. Children and adolescents' perspectives about their HRQoL should be considered when adjusting clinical and educational interventions to their needs. The DISABKIDS-DM questionnaire is easy and brief to administer and interpret and can be an important resource to detect the occurrence of changes in HRQoL over time that may not be observable in generic instruments, favoring the adoption of more targeted clinical strategies and interventions and thus contributing to enhancing the quality of life of these children and adolescents.

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Conflict of Interest: The authors declare that they have no conflict of interest.

Data Availability: The questionnaires filled out by the participants can be found at Health and Disease Psychology Unit, Faculty of Psychology, University of Lisbon, Alameda da Universidade, 1649-013 Lisboa, Portugal.

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