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Abstract: Until recently, no disease-specific health-related quality of life (HRQoL) instrument existed for pediatric traumatic brain injury (TBI). In this revalidation study, the psychometric properties and the validity of the final German version of the 35-item QOLIBRI-KID/ADO questionnaire were examined in 300 children and adolescents. It is the first self-reported TBI-specific instrument for measuring pediatric HRQoL in individuals aged 8–17 years. The six-factor model fits the data adequately. Internal consistencies were excellent for the total score and satisfactory to excellent for the scale scores. Intraclass correlations indicated good test-retest reliability. Construct validity was supported by overlaps between the QOLBRI-KID/ADO and the PedsQL, which measures generic HRQoL. Discriminant validity indicated that HRQoL was significantly lower in older children and girls, and in those with anxiety, depression, and post-concussion symptoms than in comparison groups, replicating the results of the questionnaire's first development study. Our results suggest that the QOLIBRI-KID/ADO is a valid and reliable multidimensional instrument for assessing disease-specific HRQoL after pediatric TBI in clinical and research settings, which can additionally be used across the lifespan in combination with the adult version. This may help to improve care, treatment, daily functioning and HRQoL after TBI.

Keywords: health-related quality of life (HRQoL); pediatric traumatic brain injury (TBI); QOLIBRI-KID/ADO

1. Introduction

Pediatric traumatic brain injury (TBI) is a leading cause of disability worldwide [1,2], affecting between 47 and 280 children and adolescents per 100,000 every year [3]. Impairment after TBI may persist for months or even years after the injury, affecting physical [4], cognitive [5], emotional [6], and social functioning [4]. These impairments significantly impact quality of life, which the World Health Organization has defined as "the individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [7]. Health-related quality of life (HRQoL) describes an individual's subjective physical and mental health status and can classified as generic [8] or disease-specific HRQoL [9]. While generic HRQoL encompasses a wide range of parameters related to a variety of health conditions [8], disease-specific HRQoL focuses on a specific group of patients with specific health conditions and addresses particular disease-specific symptoms [9]. Thus, disease-specific measures of HRQoL are tailored and particularly sensitive to impairments resulting from a certain health condition and can more sensitively capture HRQoL in a patient population [10,11].

The recently developed Quality of Life after Brain Injury – Kid/Adolescent (QOLIBRI-KID/ADO) questionnaire is the first self-reported disease-specific HRQoL instrument for children and adolescents (8–17 years) after TBI [12]. It was developed from a specifically created item pool based on focus group interviews, national and international Delphi panels, adaptations of items from questionnaires in use in the field of TBI, and cognitive debriefings. It was tested in a German multicenter pilot study in 300 pediatric individuals who had suffered a TBI three months to ten years previously [12]. The pilot version of the QOLIBRI-KID/ADO consisted of 35 items covering six domains (i.e., Cognition, Self, Daily Life & Autonomy, Social Relationships, Emotions, and Physical Problems). It was found to be reliable and valid for assessing HRQoL in children and adolescents after TBI [12,13]. Its psychometric properties were examined using methods referred to as classical test theory (i.e., reliability and validity), supplemented by differential item functioning (DIF) analyses for the age groups. Satisfactory reliability was reported for both the total score (Cronbach's α = .89)

and for the scales (Cronbach's α = 0.70–0.80) in groups of children and adolescents with and without multiple symptom burden [12]. Its test-retest reliability was acceptable (intraclass correlation coefficients: 0.42–0.64). Satisfactory construct validity was demonstrated using the Pediatric Quality of Life Inventory (PedsQL) [14] as a reference measure of generic HRQoL. The results of the psychometric analyses using the item response theory framework indicate that the scales are largely unidimensional, there was no evidence of the assumptions of monotonicity and local independence being violated, and predominantly no DIF occurred in the various patient groups [13].

Few studies have examined the influence of sociodemographic and clinical variables on HRQoL after pediatric TBI. According to the findings, reduced pediatric HRQoL is associated with older age [10,12], being female [15], suffering from adverse emotional states [12,16,17], a more severe TBI [18], a lower level of recovery [12,19], a higher burden of post-concussion symptoms, and a comparatively recent TBI [12,17].

The present study aims to revalidate this 35-item version of the questionnaire, with four items reworded, by replicating the structure and design of the developmental study in a different TBI sample. Several factors associated with impaired HRQoL after pediatric TBI were examined to ensure its construct, discriminant, and convergent validity. We expected lower HRQoL to be associated with older age [20], being female [15], higher TBI severity [18,21], mental health problems such as anxiety [22] and depression [23], and a higher number of post-concussion symptoms [17]. The final validation of the QOLIBRI-KID/ADO will contribute to assessing the quality of the instrument and its ability to capture the impact of pediatric TBI sequalae on the HRQoL of children and adolescents. By providing a psychometrically robust instrument for measuring TBI-specific HRQoL, we aim to improve diagnosis, treatment, monitoring, and research efforts to reduce the burden of TBI in children and adolescents.

2. Materials and Methods

2.1. Ethical Approval

The study was conducted in accordance with all relevant German and Austrian laws while taking into account the ICH Harmonized Tripartite Guideline for Good Clinical Practice and the World Medical Association Declaration of Helsinki. The study was granted ethical clearance at each of the recruiting centers and informed consent was obtained from all participants in accordance with the German and Austrian laws on data protection. The Ethics Committee of the University Medical Center Goettingen approved the study (application no. 19/4/18).

2.2. Participants

For the statistical analyses, we met the requirements for the statistical power, which suggested a sample size of approximately 140 individuals per age group based on a simulation study [24]. Patients were eligible for participation if they were aged 8 to 17 years at the time of study enrollment (February 2022 until February 2023), had been diagnosed with TBI (at least three months but no more than ten years post injury), were able to understand and answer the questions, and were outpatients (or had recently resumed inpatient treatment). Participants were excluded if the severity of their TBI was not available in their medical records, if they were in a current vegetative state, had a spinal cord injury, had a severe mental illness (e.g., psychosis, autism) or epilepsy prior to the TBI, had diseases leading to death, or very severe polytrauma. All participants and their legal guardians gave written informed consent. The interviews were conducted face-to-face, either online or in person. Parental reports were collected in writing by email, post, or at the medical centers and hospitals. Details of the sample composition are shown in Figure 1.
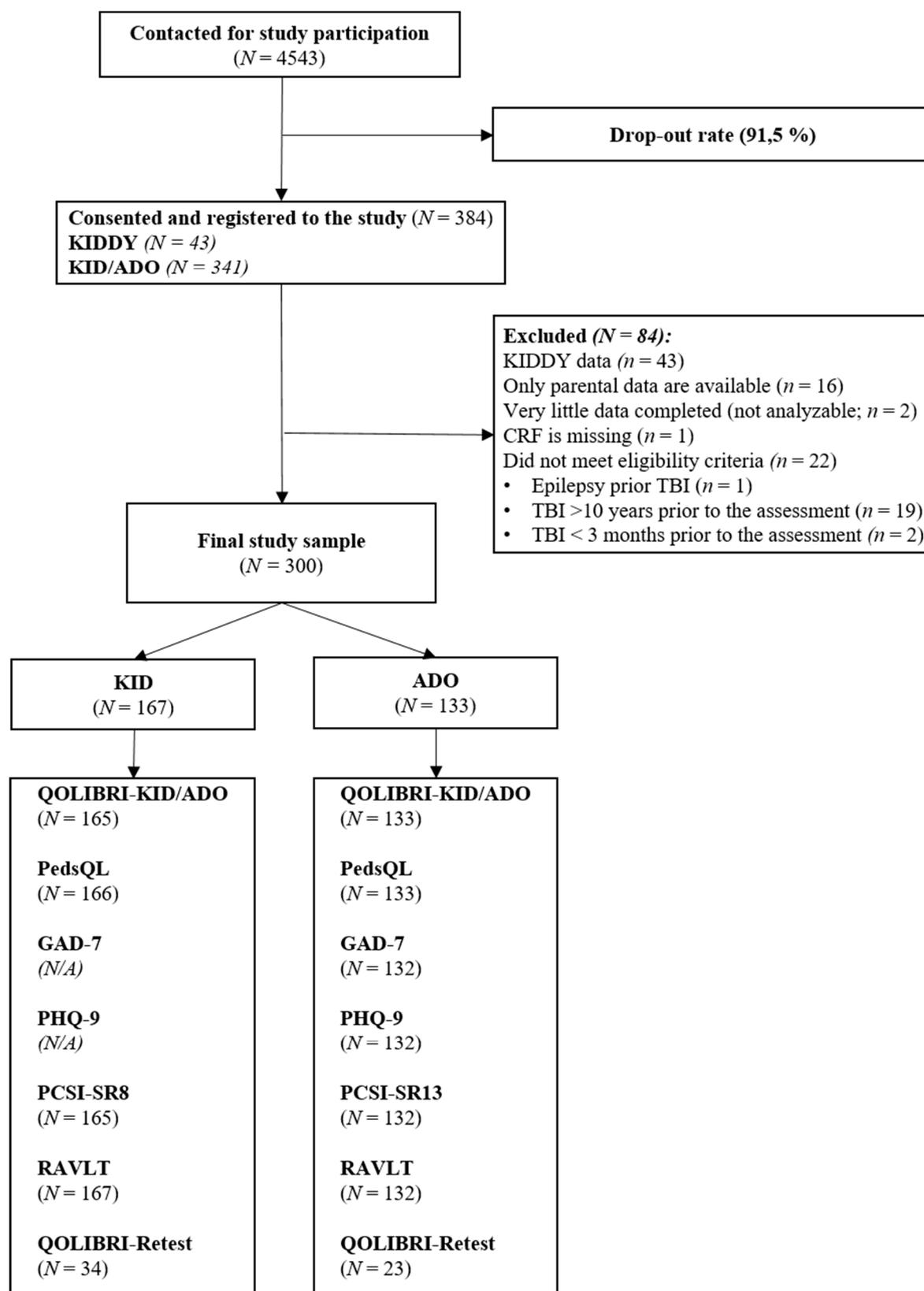
Figure 1. Flow Chart of the Recruitment Process and the Number of Participants per Instrument. Note. TBI = Traumatic brain injury; QOLIBRI-KID/ADO = Quality Of Life after Brain Injury in Children and Adolescents; PedsQL = Pediatric Quality of Life Inventory; GAD-7 = Generalized Anxiety Disorder 7; PHQ-9 = Patient Health Questionnaire 9; PCSI-SR8/13 = Postconcussion Symptom Inventory; RAVLT = Rey Auditory Verbal Learning Test.

2.3. Sociodemographic and Clinical Data

The sociodemographic and clinical information was comparable to that collected in the QOLIBRI adult studies [25,26] and the QOLIBRI-KID/ADO pilot study [12]. Parents provided information about themselves and their participating children, including age and gender, as well as their education and occupation.

Clinical data covering findings from imaging procedures (CT or MRI), cause, date and severity of the TBI, and loss of consciousness were collected from medical records. The TBI severity (mild, moderate, severe) was derived either from the Glasgow Coma Scale (GCS) [27] or the International Statistical Classification of Diseases and Related Health Problems (ICD-10) diagnosis code (S06.*) [28] or from the clinical description of the TBI, such as post-traumatic amnesia, need for ventilation and resuscitation, post-traumatic epilepsy, presence of lesions (according to MRI/CT findings), or the need for surgical intervention.

In addition, the time since TBI was obtained from the medical records and subgroups of participants were created using a median split on this time. Additional clinically relevant data were obtained from parental reports. Using a dichotomous scale ("Yes" or "No"), they reported whether the children experienced headaches, other pain, physical impairment, or mental health problems after TBI. To further investigate the presence of persistent symptoms, the mean time since TBI was analyzed and compared between participants with and without these symptoms (parent-reported problems with headaches, other pain, physical impairment, and mental health problems, mild to severe depression or anxiety, and self-reported above-average post-concussion symptoms; for more details see the subsection "Instruments").

2.4. Instruments

The QOLIBRI-KID/ADO questionnaire tested in the final validation study included 35 items assessing self-reported TBI-specific HRQoL in children and adolescents aged 8–17 years on four "satisfaction" scales ("How satisfied are you with…") dealing with cognitive abilities, self-concept, perceived autonomy, and social life, and two "bothered" scales ("How bothered are you with…") describing physical and emotional problems. Responses are provided on a five-point Likert-type scale ranging from "Not at all" to "Very", supplemented by smileys, using today and the past week as the time frame. As the responses for the two "bothered" scales are worded negatively, they need to be recoded before being aggregated with the satisfaction scales for analysis. The responses for each QOLIBRI-KID/ADO scale are linearly transformed to values ranging from 0 to 100, with higher scores indicating better HRQoL. Scale scores are calculated as the average of the item scores in each scale, and the total score is computed as the average of all scales. Compared with the pilot study, four questions were rephrased and/or misleading or unnecessary examples were removed to improve the comprehensibility of the item content (see Appendix A, Table A1).

The Pediatric Quality of Life Inventory (PedsQL™) [14] is a 23-item generic HRQoL questionnaire covering physical, emotional, social, and school functioning domains. Scale scores can be aggregated to form a total, a physical health, and a psychosocial health score. Participants answer on a five-point Likert-type scale ranging from 0 to 4 ("Never" to "Almost always"). To compute scores, responses are first inverted and then linearly transformed to a scale of 0 to 100, with higher scores indicating better HRQoL.

Anxiety and depression symptoms were rated using the proxy versions of the Generalized Anxiety Disorder 7 (GAD-7) [29] and the Patient Health Questionnaire 9 (PHQ-9) [30], respectively, as clinical ratings could not be obtained within the study and self-report questionnaires have not been validated for children younger than twelve years of age [31,32]. The GAD-7 captures generalized anxiety disorder as characterized by the DSM-IV [33]. It assesses the occurrence of seven anxiety symptoms in children or adolescents. Parents rated participants' symptoms on a four-point Likert-type scale ranging from 0 to 3 ("Not at all" to "Nearly every day"). The sum score of all items, ranging from 0 to 21, represents the severity of the anxiety disorder as assessed by the proxies: minimal (1–4), mild (5–9), moderate (11–14), and severe (15–21) anxiety symptoms [34]. The PHQ-9 captures the presence and severity of symptoms related to major depression in children and adolescents as

characterized by the DSM-IV [33] criteria. Respondents rate nine depression symptoms on a four-point Likert-type scale from 0 to 3 ("Not at all" to "Nearly every day"). The sum score of the items can range from 0 to 27, with the following severity categories for proxy reports: minimal (1–4), mild (5–10), moderate (11–14), and severe (15–27) depression symptoms [35].

The German version of the Postconcussion Symptom Inventory (PCSI-SR8 for children and PCSI-SR13 for adolescents) [36,37] was used for self-reporting post-concussion symptoms after TBI. For children (aged 8–12 years), 16 items are answered on a three-point Guttman scale ranging from zero to two ("No problem" to "A lot of a problem"). For adolescents, 21 items have to be answered on a seven-point Guttman scale with three anchor categories (0: "Not a problem", 3: "Moderate problem", and 6: "Severe problem"). In both age versions, items cover four domains (i.e., physical, emotional, cognitive, and sleep/fatigue), and a total score can be calculated as a sum across all items. Due to the lack of reference values, total scores are categorized as being below, above, or within the average range (M ± 1 SD) of participants who completed the age-appropriate version of the PCSI.

Examiners and clinicians rated functional recovery after pediatric TBI using the King's Outcome Scale for Closed Head Injury (KOSCHI) [38] on disability/recovery levels of TBI (3a: "lower severe disability", 3b: "upper severe disability", 4a: "lower moderate disability", 4b: "upper moderate disability", 5a: "good recovery", 5b: "intact recovery").

Verbal learning and memory was assessed using the Rey Auditory Verbal Learning Test (RAVLT) [39,40]. Fifteen words are read out loud by the examiners, and these have to be repeated by the children in eight trials. The RAVLT's learning rate was calculated by subtracting the number of words recalled in Trial I from those in Trial V. They were categorized as being above, below, or within the average range (M ± 1SD) for the respective age group.

2.5. Statistical Analyses

Descriptive statistics at the item, scale, and total score levels included means (*M*), standard deviations (*SD*), skewness (*SK*), and floor and ceiling effects. Skewness was considered absent for values from -0.5 to 0.5; values from ±0.5 to ±1 were considered moderately, and values beyond ±1 heavily skewed, respectively [41]. Ceiling effects are reported in terms of the percentage of responses in the most satisfied/least bothered category and conversely floor effects in terms of the percentage of responses in the least satisfied/most bothered category [42].

Using differential item functioning (DIF) analyses, we investigated whether participants' responses to the final version of the QOLIBRI-KID/ADO were independent of their age. This was analyzed using a logistic ordinal regression of differential item functioning (LORDIF) [43] based on the age category (children aged 8–12 years, adolescents aged from 13–17 years). For each item as a dependent variable, DIF was evaluated by comparing a LORDIF model including scale scores with a model including scale scores, age category, and an age category-scale score interaction. Whenever the comparison of the models revealed a significant difference (α = 0.01) and the associated effect exceeded a very small effect (McFadden's pseudo R^2 > 0.05) [44], response behavior was assumed to differ between age categories.

Reliability analyses of the final version of the QOLIBRI-KID/ADO took the form of tests for internal consistency and test-retest reliability. Cronbach's α and McDonald's ω were calculated for the total and scale scores as indicators of internal consistency. In line with findings from pediatric outcome research, Cronbach's $\alpha \geq 0.60$ [8] and McDonalds's $\omega \geq 0.70$ [45] were regarded as satisfactory. It has been reasoned in the past that the internal consistency of HRQoL measures may be lower in individuals with cognitive impairment [12,46]. We therefore conducted subgroup analyses based on the RAVLT learning rate. To further investigate the reliability of the questionnaire for different TBI-related symptoms, internal consistency was calculated and stratified by severity and symptom groups (for a list and classification, see the subsection "Computational Software, Classification, and Cut-Off Values"). In addition, corrected item-total correlations (CITC) were calculated for individual items and their corresponding scales, with a criterion of CITC > 0.40.

Test-retest reliability was assessed in a subsample of participants who filled in the final version of the QOLIBRI-KID/ADO twice, with an interval of 10 to 20 days between completions. Intraclass

correlation coefficients (ICC) were calculated based on a two-way random effects model for the total score and each scale. ICC values > 0.60 [47] were considered satisfactory. In addition, the standard error of measurement (SEm) [48] and the minimal detectable change (MDC) were calculated based on the ICC of the total and scale scores. Since there are no clear criteria for acceptable MDC and SEm values, SEm was considered as the total possible uncertainty range of the instrument. A percentage less than 10%, corresponding to a variation of 10 points on the 0 to 100 scale score, was considered satisfactory [49].

The factorial structure of the final version of the QOLIBRI-KID/ADO was analyzed by means of a confirmatory factor analysis (CFA). A six-factor model representing the six scales of the QOLIBRI-KID/ADO was assumed. Given the ordinal nature of the response categories, diagonally weighted least squares with mean and variance adjustment (WLSMV) was used as the estimation approach for model identification [50]. As the cut-off values were established for estimating maximum likelihood and not for the estimation method, the following cut-offs for the model fit indices must be interpreted with caution [51]. The indices used, with their respective desirable cut-offs in parentheses, were: χ^2-test statistics (p > 0.01) [52], χ^2/df ratio ($\leq$ 2) [52], comparative fit index (CFI > 0.95) [53,54], Tucker-Lewis index (TLI > 0.95) [54,55], root mean square error of approximation and its 90-percent confidence interval (RMSEA < 0.06, CI90%) [56], as well as the standardized root mean square residual (SRMR < 0.08) [54].

To examine whether the final version of the QOLIBRI-KID/ADO measures the construct of HRQoL, its convergent validity was investigated using correlation analyses against an established measure of generic HRQoL in children and adolescents, the PedsQL. Pearson correlations were calculated between all the scales, the QOLIBRI-KID/ADO total score, the physical functioning score (equal to the Physical Problems scale), and the psychosocial functioning score (mean of Cognition, Self, Social Relationships, and Emotions scales) with the corresponding PedsQL scale scores.

Discriminant validity was analyzed using correlational analyses with constructs presumed to be less closely related. The association of the construct and relevant sociodemographic and clinical characteristics was investigated using correlational analyses as well as known-groups analyses [57]. The associations between the QOLIBRI-KID/ADO total and scale scores and the self-reported PCSI-SR8/13 as well as the proxy-reported GAD-7 and PHQ-9 scores were examined using Pearson correlations. The GAD-7, PHQ-9, and PCSI-SR8/13 were assumed to have negative correlations corresponding to a small to medium effect (i.e., r between -0.10 and -0.30) [58], demonstrating some overlap across the domains and pointing to a possible relationship between lower HRQoL and increased symptom burden. To determine the amount of variance explained, the coefficient of determination (R^2) was calculated.

2.6. Missing Values

The occurrence of missing values was not considered a problem if missing values did not exceed five percent of responses to an item. QOLIBRI-KID/ADO scale scores were computed if no more than a third of a scale's responses were missing and total scores only if all scales yielded a score. Following the manual for the PedsQL [59], mean scale scores were computed as long as no more than half of a scale's responses were missing. Similarly, GAD-7 and PHQ-9 mean scores and the PCSI-SR8/13 sum scores were calculated if no more than one third of the items per instrument were missing.

2.7. Computational Software, Classification, and Cut-Off Values

The software R (version 4.3.0) [60] was used for all the analyses, using the packages psych [61] for calculating reliability measures, lavaan [62] for the CFA, and lordif [63] for DIF analyses.

The following TBI-related symptoms were considered when analyzing the symptom burden: low functional recovery (expressed as a KOSCHI scores below 5), parent-reported post-TBI problems (headache or other aches, physical impairments, or mental health problems: if at least one is reported by a parent), depression and anxiety symptoms (expressed by PHQ-9 and GAD-7 scores above 4, respectively), post-concussion symptoms (expressed as PCSI-SR8/13 scores equal to or greater than 1 SD above the age-adjusted mean), and a low learning rate (expressed as corresponding RAVLT scores

equal to or less than 1 SD below the age-adjusted mean). The symptom burden was first examined for the total sample and then in TBI severity groups (i.e., mild vs. moderate/severe).

Cohen's cut-off criteria were used to assess the strength of associations, indicating a small (0.10), moderate (0.30), or large (0.50) effect [58]. For the comparisons presented, moderate correlations ($r \geq 0.30$) were determined to ascertain the convergent validity; small to medium correlations were expected to indicate sufficient discrimination between the constructs. The mean comparisons for the known-groups validity analyses used one-tailed Student's t-tests. The correlation analyses used Pearson correlation coefficients.

For statistical comparisons, a *p*-value less than 0.05 was considered significant for the total score. For the scale comparisons, the *p*-value was adjusted using the Bonferroni correction (i.e., 0.05/6 = 0.008).

3. Results

3.1. Participants

A total of 300 children and adolescents completed the final version of the QOLIBRI-KID/ADO. Data from 41 participants had to be excluded because only parental data were available, insufficient data was provided, or the inclusion criteria had been violated (one participant was diagnosed with epilepsy prior to TBI, and 22 participants completed the questionnaire outside the allotted time frame of 3 months to 10 years after TBI).

Participants were interviewed face-to-face, either online (60%) or in person (40%). Participants interviewed online exhibited higher QOLIBRI-KID/ADO total scores than those assessed in-person (M_{online} = 75.67 vs. $M_{in\text{-}person}$ = 79.49, t(296) = -2.73, p = .005, d = 0.33). Ninety-four (31%) participants had also taken part in the pilot study, however, prior participation had no effect on the QOLIBRI-KID/ADO total scores in the present study ($M_{repeated}$ = 77.78 vs. $M_{naïve}$ = 76.95, t(296) = 0.56, p = 0.574, d = 0.07).

Table 1 summarizes the sociodemographic and clinical data. The mean age was 12.6 years (*SD* = 2.67, *Min* = 8.00, *Max* = 17.90) and 54% were male. Mild TBI was the most common type of severity (80%), of which 21 participants (9%) sustained complicated mild TBI [64] (i.e., mild TBI with brain lesion identified on CT or MRI). Overall, lesions were present in 24% of all participants. The most common onset of TBI was four to ten years prior to study enrollment (67%). The majority of participants displayed favorable functionality (5a/b) based on their KOSCHI score (94%). The parents of half the participants (49%) reported their children as having post-TBI problems. Participants' self-rated post-concussion symptoms were mostly within the average range for their age group (75%). Most participants showed no or minimal signs of anxiety (71%) or depression (70%). We also examined the symptom characteristics of participants having parent-reported headaches or other pain, physical impairment, and mental health problems, mild to severe anxiety and depression, and above-average post-concussion symptoms in relation to the time since TBI. Only participants with parent-reported problems after TBI differed significantly from those without, with a shorter mean time since injury ($M_{problems}$ = 5.06, $M_{no\ problems}$ = 5.71, t(296) = 2.09, p = 0.038, d = 0.24; see Appendix B, Table B1).

Table 1. Descriptive Statistics for Demographic and Clinical Characteristics of Participants of the Final Validation Study.

Variable	Group	N (%)
Sex	Female	137 (46%)
	Male	163 (54%)
Age	Children (8–12 years)	167 (56%)
	Adolescents (13–17 years)	133 (44%)
Parents' highest education	Primary school	1 (0%)

	Secondary school	51 (17%)
	Vocational school	54 (18%)
	College/university	193 (64%)
	Unknown or missing	1 (0%)
TBI Severity	Mild	240 (80%)
	Moderate	30 (10%)
	Severe	30 (10%)
Cerebral Lesion(s) Found in Neuroimaging	No	227 (76%)
	Yes	73 (24%)
KOSCHI Disability/ Recovery Score	4b	15 (5%)
	5a	21 (7%)
	5b	261 (87%)
	Missing	3 (1%)
Time Since TBI	<1 Year	15 (5%)
	1–<2 Years	30 (10%)
	2–<4 Years	55 (18%)
	4–10 Years	200 (67%)
Head-/aches, Physical Impairments, or Mental Health Problems after TBI	No	151 (50%)
	Yes	147 (49%)
	Missing	2 (1%)
Learning Rate (RAVLT)	Below average ($\leq M - 1SD$)	57 (19%)
	Average	177 (59%)
	Above average ($\geq M + 1SD$)	65 (22%)
	Missing	1 (0%)
GAD-7	No anxiety (0)	46 (15%)
	Minimal anxiety (1–4)	166 (55%)
	Mild to severe anxiety (> 4)	87 (29%)
	Missing	1 (0%)
PHQ-9	No depression (0)	34 (11%)
	Minimal depression (1–4)	176 (59%)
	Mild to severe depression (≥ 5)	89 (30%)
	Missing	1 (0%)
PCSI-SR8/13	Below average ($\leq M - 1SD$)	26 (9%)
	Average	224 (75%)
	Above average ($\geq M + 1SD$)	47 (16%)
	Missing	3 (1%)

Note. TBI = traumatic brain injury, KOSCHI = King's Outcome Scale for Closed Head Injury, RAVLT = Rey Auditory Verbal Learning Test, GAD-7 = Generalized Anxiety Disorder 7 (proxy-report), PHQ-9 = Patient Health Questionnaire 9 (proxy-report), PCSI-SR8/13 = Postconcussion Symptom Inventory (age adapted M/SD; self-report), M = mean, SD = standard deviation.

3.2. Item analyses of the final QOLIBRI-KID/ADO questionnaire: Item Properties, Internal Consistency, and Differential Item Functioning

The item characteristics and distributions are shown in Table 2. Given the low number of missing values per item ($\leq 1\%$), we assumed these rare cases would not affect the assumption that missingness is completely random. The means of all the items exceeded three on the five-point Likert-type scale, and all items were skewed to the left. Similarly, most responses displayed ceiling effects, a common observation in this kind of HRQoL assessment [65].

Regarding the contribution of individual items to internal consistency, two items from the Cognition scale ("Decision between two things", "Orientation") had corrected item-total correlations below 0.40. The item "Loneliness" from the Emotion scale also led to a slight increase (+0.01) in Cronbach's α when omitted (see Table 2).

The DIF analysis did not detect any meaningful differences in the response pattern for individual items between children and adolescents. Although three items ("Planning", "Sadness", "Other injuries") showed significant differences when comparing models with and without assumed age-group effects, the differences found were not sufficiently large to be considered to have an impact. For details, see the right side of Table 2.

The internal consistency for the total score of the QOLIBRI-KID/ADO was excellent, with Cronbach's α = 0.92 and McDonald's ω = 0.92. The individual QOLIBRI-KID/ADO scales showed good to excellent internal consistency (Cronbach's α 0.69–0.77; McDonald's ω 0.76–0.85, see Table 2 for details) which matches the findings from the pilot study. Subgroup analyses of the internal consistencies for individual scales and subgroups with lower learning rates showed for the most part satisfactory to excellent results (Cronbach's α 0.65–0.85; McDonald's ω 0.76–0.89). This was also the case for other subgroups stratified by sociodemographic and clinical characteristics (Cronbach's α 0.87–0.94; McDonald's ω 0.89–0.96), except for the group with present post-concussion symptoms on the Cognition scale (Cronbach's α = 0.52). For details, see Appendix B, Table B2.

Table 2. Item and Scale Statistics of the QOLIBRI-KID/ADO questionnaire: Descriptive Statistics, Internal Consistency Parameters, and DIF-Analyses.

Scale	Item Abbreviation	Items	M	SD	% Missing	SK	% Floor	% Ceiling	α	Changes in α if Omitted	ω	CITC	p	R^2
									Descriptive Statistics				**Internal Consistency**	**DIF Analyses**
Cognition									0.69		0.79			
	A1	Concentration	3.91	0.85	1	-0.63	5	72		-0.07		0.64	0.754	
	A2	Talking to Others	4.45	0.69	0	-0.99	1	90		-0.03		0.46	0.153	
	A3	Remembering	3.91	0.92	1	-0.57	8	70		-0.03		0.49	0.035	
	A4	Planning	4.06	0.96	0	-0.90	7	75		-0.04		0.51	0.003*	0.015
	A5	Decision Between Two Things	3.45	1.06	0	-0.41	17	51		-0.01		0.37	0.016	
	A6	Orientation	4.79	0.49	0	-2.70	1	97		0.00		0.27	0.212	
	A7	Thinking Speed	3.97	0.81	0	-0.55	3	74		-0.08		0.70	0.164	
Self									0.76		0.81			
	B1	Energy	3.95	0.94	0	-0.88	8	74		-0.03		0.58	0.815	
	B2	Accomplishment	4.07	0.69	0	-0.45	2	83		-0.03		0.58	0.820	
	B3	Appearance	4.12	0.85	1	-0.88	4	78		-0.08		0.71	0.216	
	B4	Self-Esteem	4.26	0.87	1	-1.16	3	82		-0.06		0.67	0.098	
	B5	Future	4.13	0.9	1	-0.94	5	78		-0.02		0.53	0.163	
Daily Life & Autonomy									0.73		0.80			
	C1	Daily Independence	4.76	0.51	0	-2.17	0	97		-0.02		0.47	0.096	
	C2	Getting Out and About	4.64	0.62	0	-1.66	1	94		-0.05		0.62	0.028	

	Item	Name	M	SD		SK		%	α	α	Changes in α if Omitted	CITC	p
	C3	Manage at school	4.22	0.82	1	-1.00	3	83			-0.04	0.55	0.503
	C4	Social Activities	4.56	0.73	0	-1.60	2	90			-0.04	0.56	0.485
	C5	Decision Making	4.12	0.85	0	-0.76	4	79			-0.02	0.50	0.739
	C6	Support from Others	4.32	0.78	0	-0.96	3	86			-0.02	0.47	0.560
	C7	Ability to Move	4.7	0.7	0	-2.87	2	93			-0.03	0.52	0.161
Social Relationships									0.77	0.85			
	D1	Open up to Others	4.07	0.89	0	-0.81	5	77			-0.05	0.68	0.132
	D2	Family Relationship	4.42	0.75	0	-1.05	1	87			0.00	0.42	0.152
	D3	Relationship with Friends	4.45	0.71	0	-1.41	1	91			-0.05	0.65	0.039
	D4	Friendships	4.53	0.69	0	-1.44	2	92			-0.03	0.57	0.103
	D5	Attitudes of Others	4.22	0.76	0	-0.75	2	84			-0.04	0.63	0.359
	D6	Demands from Others	4.01	0.84	0	-0.95	4	78			-0.04	0.60	0.080
Emotions									0.73	0.76			
	E1	Loneliness	4.01	1.13	1	-0.89	13	70			0.01	0.46	0.028
	E2	Anxiety	3.83	1.13	0	-0.81	13	67			-0.07	0.64	0.326
	E3	Sadness	3.39	1.24	0	-0.44	24	53			-0.15	0.77	< 0.016 0.001*
	E4	Anger	3.41	1.25	0	-0.28	27	51			-0.04	0.57	0.230
Physical Problems									0.71	0.83			
	F1	Clumsiness	3.55	1.21	0	-0.62	21	60			-0.01	0.44	0.028
	F2	Other Injuries	4.13	1.24	0	-1.24	13	73			-0.05	0.57	0.007* 0.014
	F3	Headaches	3.49	1.41	0	-0.58	26	60			-0.05	0.57	0.222
	F4	Pain	3.74	1.15	0	-0.64	15	62			-0.05	0.58	0.601
	F5	Seeing/Hearing	4.25	1.11	0	-1.41	11	80			-0.05	0.57	0.019
	F6	TBI Effects	4.34	1.01	0	-1.57	7	81			-0.03	0.50	0.380
Total score									0.91	0.92			

Note. M = mean, SD = standard deviation, % = percent, SK = skewness. Negative values indicate left-skewed distributions. R^2 = McFadden's R^2. CITC = corrected item-total correlations, Negative values in "Changes in α if Omitted" indicate a decrease in a scale's Cronbach's α if this item is omitted. p refers to a χ^2-test between LORDIF models including scale scores for an item only, to models including the scale score, the age category as well as the age category and scale score interaction. McFadden's R^2 is only reported for items with significant differences in model comparison. * = p-value < .01.

3.3. Scale analyses of the QOLIBRI-KID/ADO questionnaire: Descriptive Statistics, Test-Retest Reliability, and Factorial Validity

Table 3 summarizes the descriptive statistics for the QOLIBRI-KID/ADO, PedsQL, PHQ-9, GAD-7, and PCSI-SR8/13. The QOLIBRI-KID/ADO mean scale scores were higher than 60, as often observed in HRQoL studies [65], especially in children and adolescents [66]. Almost all scales of the QOLIBRI-KID/ADO and the PedsQL were skewed to the left, except for the Cognition and Emotions scales of the QOLIBRI-KID/ADO, which only showed a tendency to be skewed in this direction. On average, the levels of anxiety, depression, and post-concussion symptoms reported were low.

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Table 3. Descriptive Statistics of the QOLIBRI-KID/ADO, PedsQL, PHQ-9, GAD-7, and PCSI-SR8/13 Questionnaires.

Instrument	Scoring	Scale	N	M	SD	Min	Max	SK
QOLIBRI-KID/ADO	0–100	Cognition	300	76.98	12.55	42.86	100.00	-0.47
		Self	298	77.63	15.24	15.00	100.00	-1.03
		Daily Life & Autonomy	300	86.85	11.18	42.86	100.00	-1.30
		Social Relationships	300	82.09	13.27	29.17	100.00	-0.98
		Emotions	300	66.47	22.00	6.25	100.00	-0.40
		Physical Problems (= Physical Functioning Score)	300	72.96	19.16	8.33	100.00	-0.83
		Psychosocial Functioning Score	298	75.82	12.51	26.82	100.00	-0.63
		Total Score	298	77.21	11.71	32.46	100.00	-0.68
PedsQL	0–100	Emotional Functioning	300	72.13	18.21	28.13	100.00	-0.73
		Social Functioning	299	88.23	12.53	0.00	100.00	-1.28
		School Functioning	299	76.90	15.34	40.00	100.00	-0.73
		Physical Functioning (= Physical Health Summary Score)	300	84.98	12.33	25.00	100.00	-1.39
		Psychosocial Health Summary Score	299	79.11	12.55	41.67	100.00	-0.77
		Total Scale score	299	81.15	11.60	36.96	100.00	-0.98
GAD-7	0–21	Total Score	299	3.77	3.30	0.00	17.00	1.87
PHQ-9	0–27	Total Score	299	3.39	3.19	0.00	22.00	1.44
PCSI-SR8	0–32	Total Score	165	5.48	4.92	0.00	25.00	1.46
PCSI-SR13	0–126	Total Score	132	20.37	18.64	0.00	82.00	1.05

Note. *N* = absolute frequencies, *M* = mean, *SD* = standard deviation, *Min* = Minimum, *Max* = Maximum, *SK* = skewness. QOLIBRI-KID/ADO = Quality Of Life after Brain Injury in Children and Adolescents (self-report); PedsQL = Pediatric Quality of Life Inventory (self-report); GAD-7 = Generalized Anxiety Disorder 7 (proxy-report); PHQ-9 = Patient Health Questionnaire 9 (proxy-report); PCSI-SR8/13 = Postconcussion Symptom Inventory (self-report).

For the test-retest analysis, 57 participants completed the QOLIBRI-KID/ADO questionnaires twice with the specified delay of 10–20 days. The indicitual scale ICCs ranged from 0.57 to 0.74, the total scale ICC was 0.78 and thus almost all ICCs were above the 0.60 criterion, except for the Physical Problems scale (see Table 4 for details). Expressed as a percentage of the total possible range of the instrument, almost all the SEm values were below the 10% criterion. The MDC of the total score and the scales ranged from 13.35 to 34.91.

Table 4. Test-Retest Reliability of the QOLIBRI-KID/ADO questionnaire for 57 Participants after 10–20 Days.

Scale	ICC(2,1)	SEm	MDC
Cognition	0.74 (0.59–0.84)	6.37	17.65
Self	0.76 (0.62–0.85)	7.03	19.50
Daily Life & Autonomy	0.62 (0.43–0.76)	5.68	15.74
Social Relationships	0.62 (0.44–0.76)	6.95	19.26
Emotions	0.67 (0.45–0.80)	12.59	34.91
Physical Problems	0.57 (0.33–0.73)	10.55	29.25
Total score	0.78 (0.60–0.87)	4.82	13.35

Note. ICC(2,1) = intraclass correlation coefficient with 95% confidence interval, SEm = standard error of measurement, MDC = minimal detectable change.

For the factorial validity, an inspection of the response categories revealed that the lowest response categories were seldom chosen by the participants, which made it necessary to collapse the response categories "not at all" and "slightly" for the "satisfaction items" as well as "very" and "quite" for the "bothered scales" for CFA analyses. The six-factor model exhibited fit indices that fulfill the requirements for an excellent fit (CFI = 0.99, TLI = 0.99, RMSEA = 0.03, CI$_{90\%}$ [0.03, 0.04], SRMR = 0.07), with the $\chi^2(545) = 729.20$ index being the sole exception ($p < 0.01$). The significant p-value can be attributed to the high number of degrees of freedom (545). However, the ratio between χ^2 and df was 1.34, which did not exceed the acceptable cut-off of 2. These findings match those obtained during the pilot study. The resulting factor loadings are shown in Figure 2.
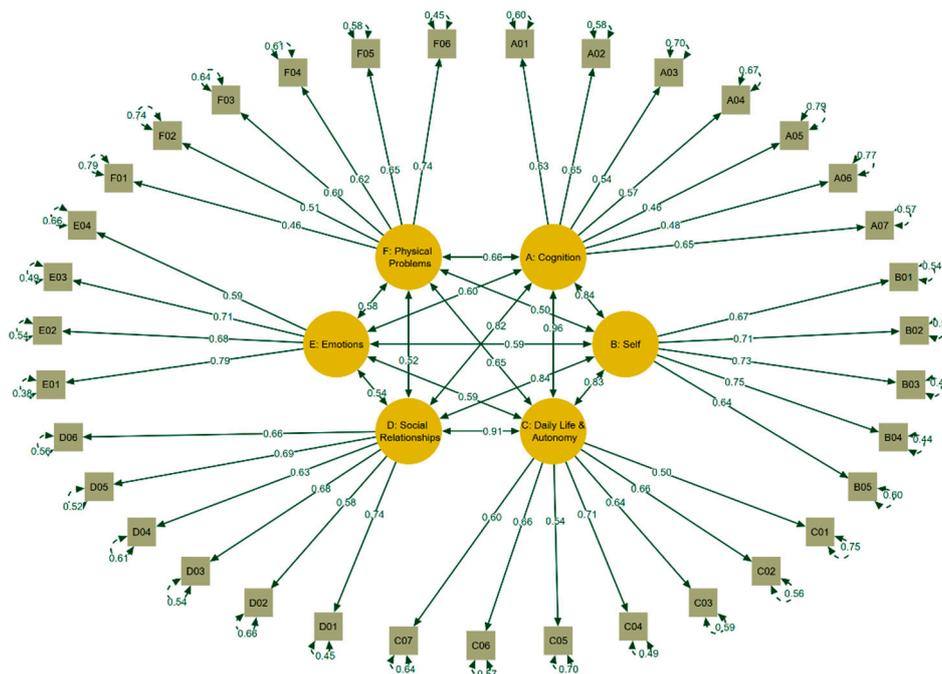
Figure 2. Results of the Confirmatory Factor Analysis of the QOLIBRI-KID/ADO Questionnaire. Note: Standardized coefficients. A1–7: Cognition (6 items: Concentration, Talking to Others, Remembering, Planning, Decision Between Two Things, Orientation, Thinking Speed), B1–5: Self (5 items: Energy, Accomplishment, Appearance, Self-Esteem, Future), C1–7: Daily Life and Autonomy (7 items: Daily Independence, Getting out and About, Manage at School, Social Activities, Decision Making, Support from Others, Ability to Move), D1–6: Social Relationships (6 items: Open up to Others, Family Relationship, Relationship with Friends, Attitudes of Others, Demands from Others), E1–4: Emotions (4 items: Loneliness, Anxiety, Sadness, Anger), F1–6: Physical Problems (6 items: Clumsiness, Other Injuries, Headaches, Pain, Seeing/Hearing, TBI Effects).

Figure 3 summarizes the Pearson correlation coefficients for the construct validity, and Appendix B, Table B3 shows the corresponding explained variance obtained from correlating the QOLIBRI-KID/ADO total and scale scores with the PedsQL total and scale scores, and with the total scores of the GAD-7, the PHQ-9, and the PCSI-SR8/13. The constructs of the QOLIBRI-KID/ADO and PedsQL that were compared included the emotional, social, physical, and psycho-social dimension as well as the total scores. Correlations between the QOLIBRI-KID/ADO and PedsQL scales ranged from $r = 0.43$ (Emotions and Emotional Functioning), $r = 0.5$ (Social Relationships and Social Functioning), $r = 0.56$ (Physical Problems and Physical Functioning), $r = 0.69$ (Psychosocial Functioning scale scores) to $r = 0.75$ (total scores of QOLIBRI-KID/ADO and PedsQL). The corresponding explained variances were between 18% (emotional), 25% (social), 31% (physical), 48% (psychosocial), and 56% (total), supporting construct validity.
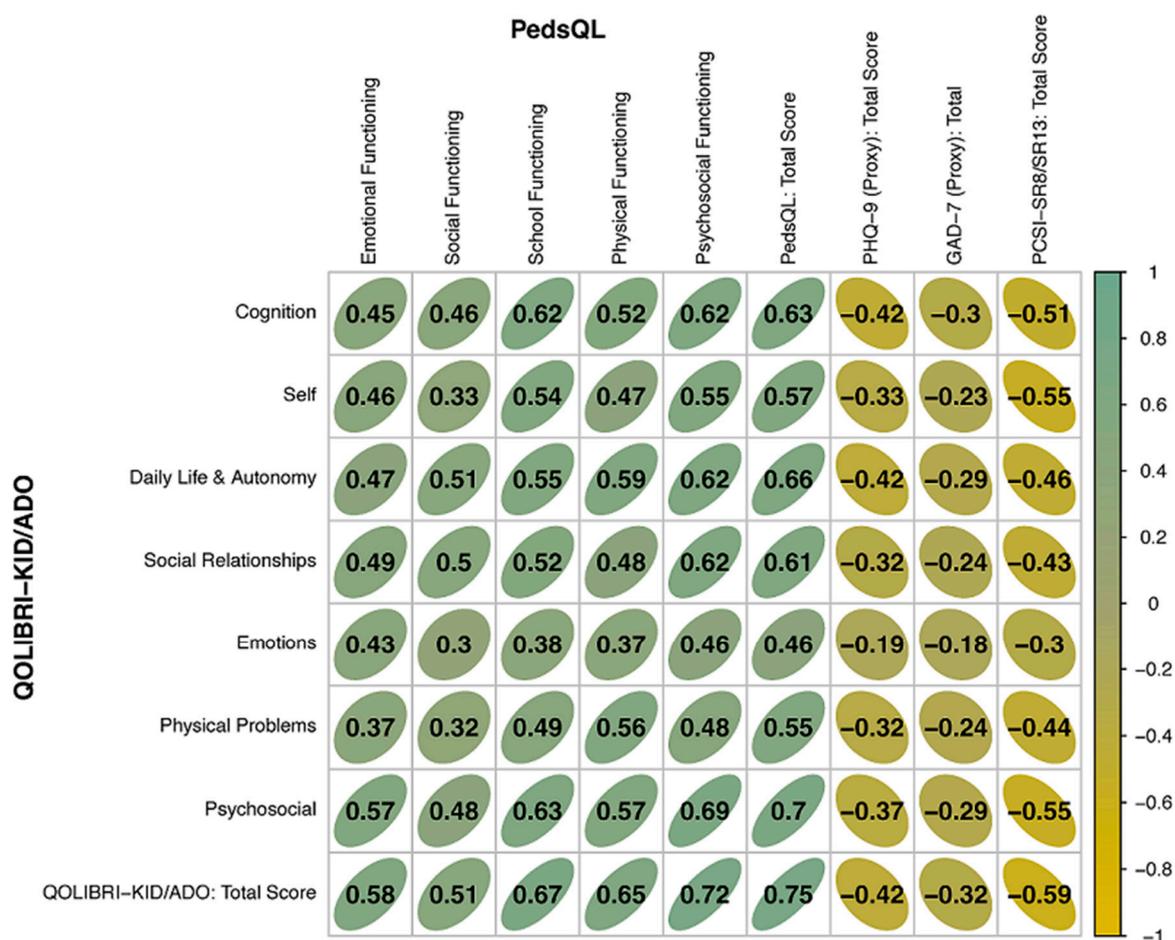
Figure 3. Correlation Results of Convergent and Divergent Validity Analyses. Note: Pearson correlation coefficients.

The results of the divergent validity analyses tested against instruments measuring anxiety, depression, and post-concussion symptoms revealed the hypothesized negative correlations. The scales of the QOLIBRI-KID/ADO were in the range of r = -0.42 to r = -0.18 against the GAD-7 and PHQ-9 and in the range of r = -0.3 to r = -0.55 against the PCSI-SR8/13, explaining 3% to 18% of the variability of the scores. The correlations of the total scores were r = -0.42, r = -0.32, and r = -0.59, with an explained variance of 17%, 10%, and 34%, respectively, indicating good discriminant validity of the QOLIBRI-KID/ADO questionnaire compared to the emotional states and post-concussion symptom measures.

Table 5 summarizes the results of known group comparisons that were hypothesized to differ in TBI-related HRQoL, providing further indication of construct validity. Children were found to

exhibit significantly higher QOLIBRI-KID/ADO total scores than adolescents. Looking more closely at the scales for which children reported higher HRQoL than adolescents, a significant difference was found for the Self scale ($t(296) = -5.21$, $p < .001$, $d = -0.61$). The total scores of the QOLIBRI-KID/ADO were significantly higher for male participants than the scores of female participants. When examining the individual scales on which males reported higher HRQoL than females, a significant difference was also found on the Self scale ($t(296) = -2.89$, $p < .001$, $d = -0.34$).

Table 5. Results of Known-Group Validity Analyses of the QOLIBRI-KID/ADO total Score Sociodemographic and Clinical Characteristics.

Known Groups	n	M	SD	t	df	p	d
Children	165	78.61	10.62	-2.32	296	.01*	-0.27
Adolescents	133	75.47	12.76				
Female	137	76.02	12.76	-2.26	296	.01*	-0.14
Male	161	78.61	10.96				
TBI within the last four years	100	76.19	11.89	-1.07	296	.14	-0.13
TBI more than four years ago	200	77.72	11.61				
Moderate-severe TBI	60	76.67	12.24	-0.40	296	.35	-0.06
Mild TBI	238	77.34	11.59				
Low Functional Recovery[1]	15	-	-	-	-	-	-
High Functional Recovery[1]	280	77.61	11.34				
Post-Concussion Symptoms[2]	47	63.98	11.81	-10.03	293	<.001*	-1.60
No Post-Concussion Symptoms[2]	248	79.92	9.62				
Head-/aches, Physical Impairments, or Mental Health Problems[3]	146	74.93	11.67	-3.28	294	<.001*	-0.38
No Aches, Impairments, or Problems[3]	150	79.33	11.41				
Low Learning Rate[4]	57	77.73	12.99	0.41	295	.66	0.06
Higher Learning Rate[4]	240	77.02	11.38				
Mild to Severe Anxiety[5]	87	72.14	13.07	-4.96	295	<.001*	-0.63
No Anxiety[5]	210	79.28	10.46				
Mild to Severe Depression[6]	88	71.46	12.74	-5.76	295	<.001*	-0.73
No Depression[6]	209	79.61	10.39				

Note. n = sample size (only groups with n > 30 included in the analyses), M = mean, SD = standard deviation, df = degrees of freedom, t = t-value, p = p-value (* = p < 0.05) were adapted for one-tailed testing, d = Cohen's d. [1] KOSCHI (low = 3a/b, 4a/b, high = 5a/5b; no further statistical analyses were performed for the KOSCHI due to the small sample of participants with low functional recovery; [2] PCSI-SR8/13 (symptoms = impaired: $\geq M + 1SD$, not impaired $\leq M$; [3] based on parent-report, [4] RAVLT (low learning rate $\leq M - 1SD$, not impaired: $\geq M$); [5] GAD-7 (mild to severe ≥ 5, no < 5); [6] PHQ-9 (mild to severe ≥ 5, no < 5).

Looking at TBI-related characteristics, the QOLIBRI-KID/ADO total and scale scores were unaffected by time since TBI or TBI severity ($p > 0.05$). Participants without post-concussion symptoms had significantly higher QOLIBRI-KID/ADO total scores ($p < 0.05$) and scores on all individual scales ($p_{adjusted} < 0.008$) than those with symptoms. Similarly, participants whose parents reported no headaches, other pain, physical impairment, or mental health problems after TBI had significantly higher QOLIBRI-KID/ADO total, Cognition, and Physical Problems scale scores than did participants whose parents reported these problems. Furthermore, participants with a low learning rate did not differ significantly from participants with an average to high learning rate in terms of their QOLIBRI-KID/ADO scores. Regarding emotional states, the absence of depression and anxiety symptoms was associated with higher QOLIBRI-KID/ADO total and all scale scores as compared to the presence of depression and anxiety symptoms, respectively.

4. Discussion

The QOLIBRI-KID/ADO questionnaire was developed as the first disease-specific instrument to assess HRQoL specifically in children and adolescents after TBI. Our results indicate that the final version of the QOLIBRI-KID/ADO is a valid and reliable measure of pediatric TBI-specific HRQoL

which can be used in research, diagnostic, and therapeutic contexts. The questionnaire covers six relevant dimensions of life that may play an important role for children and adolescents following TBI [67]: Cognition, Self, Daily Life and Autonomy, Social Relationships, Emotions, and Physical Problems.

The internal consistency for the total score was high, and satisfactory to good for the six subscales. The internal consistency was also shown to be largely sufficient and satisfactory in different subgroups of children/adolescents with anxiety or depression symptoms or lower learning rates. This underlines the use of the questionnaire in populations with different symptom burdens, which is particularly important for the assessment of HRQoL in diagnostic and therapeutic processes [68].

Furthermore, the revalidation of the QOLIBRI-KID/ADO questionnaire confirms that it is a reliable, valid, and stable measure over the test-retest interval. The total score displayed very good reliability as indicated by the ICC, and the scales demonstrated a fair to good agreement between test and retest [47]. The SEm values of less than 10% for the total score and for all scales, except the Emotions and Physical Problems scales, reflect some variability in the data. The MDC values indicate that a change of more than 13 points in the QOLIBRI-KID/ADO total score and a change of 15 points or more in the scale scores can be considered a "true" change [49] in disease-specific HRQoL after TBI. Longitudinal treatment or therapy studies are recommended to further address the issue of the QOLIBRI-KID/ADO's sensitivity to change and meaningful clinical change.

The factorial validity analyses replicated the one-level six-factor structure with excellent fit indices, comparable to the findings of both the pilot study [12] and the adult QOLIBRI assessment [25]. The one-level six-factor structure supports the notion that the six factors of the multidimensional HRQoL construct should also be considered in research and clinical practice [69].

There were no meaningful item differences between the two age groups, supporting the use of the same questionnaire from 8 to 17 years of age, allowing aggregated analyses and long-term follow-up using the QOLIBRI-KID/ADO and underscoring the suitability of the questionnaire for comparing children (8–12 years) and adolescents (13–17 years).

The majority of children and adolescents expressed rather high satisfaction with their HRQoL on the Cognition, Self, Daily Life and Autonomy, Social Relationships dimensions and did not report feeling bothered very much by Emotions or Physical problems (QOLIBRI-KID/ADO scores > 62). This observation may be partially explained by the composition of the study sample. Other studies have reported a decrease in HRQoL in individuals after moderate and severe TBI [18], with chronic health conditions [70], or with cognitive impairment [71]. In our sample, anxiety and depression symptoms were reported for more than 30% of the participants, 19% had a low learning rate, and 18% suffered from post-concussion symptoms. Furthermore, 50% of parents reported that their children/adolescents had at least one problem after the TBI: headaches, other pain, physical impairment, or mental health problems.

We observed an unexpected difference in the total score between those tested online and those tested in person. There was a small effect with a significantly lower HRQoL in the online group, which can be attributed to the fact that the online group included more participants who had experienced TBI within the first year (8.4% vs. 0%) and had a higher incidence of moderate/severe TBI (23.4% vs. 14.8%) compared with the group tested face-to-face. Previous study participation (31.3%) had no significant effect on HRQoL.

We replicated all the results of the pilot study regarding the validity of the QOLIBRI-KID/ADO. Evidence of construct validity was obtained by comparing the total score, the physical functioning and the psychosocial functioning scores with the corresponding scales of the generic HRQoL measure, the PedsQL. The correlations of the total scores and both physical and psychosocial functioning scales were fairly high, explaining up to 56% of variance and supporting the construct validity of the new measure. The moderate negative correlations of the total score of the QOLIBRI-KID/ADO with anxiety and depression symptoms are similar to the correlations observed between these concepts in other studies [22,23] indicating that higher levels of symptom burden correspond to lower levels of HRQoL and vice versa. However, the construct overlap given by the explained

variance is relatively low, which was also hypothesized in terms of the divergent validity. Previous research observed that 11 to 45% of children face the risk of developing mental health issues following pediatric TBI [72]. In our study, one third of participants exhibited mild to severe symptoms of anxiety and depression, even years after TBI, with a noteworthy decline in HRQoL. Similar mental health outcomes have been documented for children and adolescents coping with chronic health conditions [16]. Given that the adverse effects of TBI, including mental health problems, may manifest years after injury, early identification of emotional problems in the children and adolescents concerned could improve rehabilitation for the affected children and adolescents and their families.

It is known from reviews of pediatric TBI studies that several factors may influence HRQoL [18]. As in the developmental pilot study [12], we found a higher total HRQoL score, and especially a higher score on the Self scale, in the current study in children aged 8–12 years compared with adolescents aged 13–17 years. Other pediatric studies also report increasing health complaints [73,74] and lower HRQoL with increasing age [20,75–78]. This may be explained by the fact that adolescence and puberty is a period of major developmental, physical, and social transitions due to the maturation process [79], and individuals often face challenges in coping with their environment [80]. It could be also explained by the fact that the younger the children, the less dramatic they experience life changes after TBI as being, because they may have limited memory of their lives before the injury occurred [23].

Our sample included only slightly more boys (54%), which is relatively more balanced in terms of sex compared with other QOLIBRI studies [12,26,81]. In general, males have a higher incidence of TBI [82] and report fewer health complaints than females, at least in industrialized countries [73,83], resulting in higher HRQoL [15]. Accordingly and as in the pilot study [12], boys reported a significantly higher total HRQoL, and the Self scale in particular was rated more positively than among girls. This may be due to a conglomerate of genetic, cultural, and social factors [83]. Different societal expectations [76] regarding roles and positions [84] may explain why girls in general have a less optimistic view of happiness [78] and are generally more worried [83]. They tend to internalize problems and negative emotions [85], which makes them more vulnerable to later mental health problems [85]. They may therefore benefit from engaging in greater reflection and more communication about their feelings [78].

As observed in previous research [18] and in our pilot study [12], the current study found no association between moderate and severe TBI and lower HRQoL, possibly because TBI severity and HRQoL are not linearly correlated [86]. In contrast to other studies reporting that longer time since TBI is associated with better HRQoL [23], we found no significant effect of time since injury on HRQoL. However, when the TBI was more recent we observed a negative effect on HRQoL in those with more post-concussion and depression symptoms. This contrasts with other research suggesting that persistent symptoms and adverse outcomes following early pediatric TBI may not manifest until later in life [87]. In our study, we found only minimal symptoms reported several years after TBI. This may be due to the predominantly mild severity of the TBI experienced by our study participants. Existing studies have suggested that the persistence of symptoms may be more closely related to TBI severity than to time since TBI or the age of the child [88]. This issue should be further explored in future studies by additionally controlling for potential confounders [89] (e.g., other health conditions, comorbidities, or also considering developmental stages leading to depressive symptoms) that may affect adolescents between the time of injury and the assessment of post-concussion, depression symptoms, and HRQoL in the post-acute injury phase.

In line with the pilot study [12] and other research findings [23,90], we found small but significant effects indicating that more post-concussion, anxiety and depression symptoms, as well as parent-reported problems, are associated with lower HRQoL. In general, children who have suffered a TBI are at a higher risk of developing anxiety [91], depression [72], and persistent post-concussion symptoms [17,92]. It is known from the adult literature [93] that persistence of symptoms and emotional states compromise HRQoL even years after TBI. Early identification and treatment of emotional challenges in children and adolescents following TBI could enhance and improve the rehabilitation and HRQoL for patients and their families.

Overall, compared with the pilot study, we were able to replicate the robust psychometric structure, the construct validity, and the significant impact of age, sex, anxiety, depression, and post-concussion symptoms on HRQoL assessed using the first disease-specific QOLIBRI-KID/ADO after pediatric TBI. The only effects found in the pilot study but not in the validation study are the impact of low recovery (not analyzable in the present study due to the small sample size) and the very small impact of time since injury on HRQoL. It is important to note that severity did not affect HRQoL in either study, but caution should be exercised in interpreting this finding due to the characteristics of the sample, with children and adolescents predominantly having mild TBI.

4.1. Limitations

This study complements the development and validation of the QOLIBRI-KID/ADO [12], the first disease-specific questionnaire to assess HRQoL after pediatric TBI. However, some limitations should be mentioned. Concerning the study sample, less than 10% of those originally contacted decided to participate in the study. The reasons for non-participation in pediatric clinical studies are formally unknown, but self-selection bias [94] may potentially explain the high drop-out rate observed. Other reasons for non-participation may involve parental concerns. Before participating in the study, some parents expressed concern that their children might be too healthy to participate or that they might not remember the accident, while others were concerned that their children might be retraumatized by participating in the study, as is also mentioned in other studies [95,96].

Furthermore, like in many observational studies [18], most participants had experienced a mild TBI and in most cases the injury dated back four to ten years. The sample composition may therefore explain why especially the lower response categories, indicating low satisfaction, were rarely selected by participants. This in turn caused some problems with model estimation, solved by subsequently merging the two lower response categories. This limited variability in the sample could pose challenges in interpreting our results.

A potential limitation may be also the use of parent ratings to assess depression and anxiety in children and adolescents. Discrepancies in agreement between self-reports and parent ratings, particularly in younger children, may limit the validity of parent ratings as proxies for child self-reports [97,98].

5. Conclusions

The QOLIBRI-KID/ADO questionnaire is the first validated, disease-specific instrument for measuring disease-specific HRQoL after pediatric TBI. The psychometric properties of this comprehensive 35-item self-report instrument demonstrate the necessary feasibility and measurement characteristics in six dimensions of HRQoL in children and adolescents after TBI. The QOLIBRI-KID/ADO successfully captures the expected theoretical links between the construct of HRQoL and other constructs and aspects, thereby supporting its construct validity. The findings emphasize the importance of implementing prevention strategies that are sensitive to age and sex differences, as well as to anxiety, depression and other symptoms, such as post-concussion or cognitive symptoms, which occur after pediatric TBI. The QOLIBRI-KID/ADO can therefore be applied in research and clinical practice to assess HRQoL after pediatric TBI in order to plan and ameliorate interventions and subsequently outcome after TBI.

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Appendix A

Table A1. Changes in Wording of the German Items in the Pilot and Final Validation Study translated into English.

Item	Wording*	
	Pilot Study	**Final Validation Study**
	How satisfied are you with…	
Orientation	… how you find your way around (for example, **at home or** how you can find the way to school)?	… how you **are able to** find your way around (for example, finding your way to school)?
Daily Independence	… being able to do **everyday things** without assistance (for example, using the toilet, getting dressed)?	… being able to do **things you do every day** without **help** (for example, getting dressed)?
Social Activities	KID: … how you are able to play with your friends **(for example, at school, at birthday parties)**? ADO: … how you are able **to join in with adolescents (for example, hobbies, parties, sport clubs)**?	… how you are able to play/ **do things** with your friends?

Family Relationship	… how you get along with your family (parents, siblings)?	… how you get along with your family?

Note. * The English questionnaires were linguistically validated in the pilot and again for the changed items in the final validation study, therefore slight differences are possible in comparison to the German versions. Bold text refers to the removed/rephrased parts.

Appendix B

Table B1. Mean Time in Years Since TBI of Participants with and without Neuropsychiatric Symptoms.

Symptoms	Symptoms Present		Symptoms Absent		t-Test Parameters			
	n	*M* (*SD*)	*n*	*M* (*SD*)	*t*	*df*	*p*	*d*
Problems after TBI	147	5.06 (2.64)	151	5.71 (2.76)	2.09	296	0.04*	0.24
Mild to Severe Anxiety	87	5.15 (2.66)	212	5.47 (2.74)	0.93	297	0.35	0.12
Mild to Severe Depression	89	4.99 (2.79)	210	5.55 (2.67)	1.64	297	0.10	0.21
Post-concussion Symptoms	47	5.13 (2.56)	250	5.41 (2.76)	-0.64	295	0.52	-0,10

Note. Post-concussion symptoms refer to a PCSI score that is one *SD* above the respective age average (see "Instrument" section). *M* = mean time since TBI in years, *SD* = standard deviation, *df* = degrees of freedom, *t* = *t*-value, *p* = *p*-value (* = $p < 0.05$), *d* = Cohen's *d*.

Table B2. Internal Consistency of the QOLIBRI-KID/ADO Scales for Groups of Participants Stratified by Sociodemographic and Clinical Characteristics.

Group	*n*	Cognition		Self		Daily Life & Autonomy		Social Relationships		Emotions		Physical Problems		Total score	
		α	*ω*	*α*	*ω*	*α*	*ω*	*α*	*ω*	*α*	*ω*	*α*	*ω*	*α*	*ω*
Moderate/Severe TBI	60	0.68	0.76	0.71	0.82	0.76	0.84	0.80	0.86	0.64	0.84	0.69	0.81	0.91	0.93
Mild TBI	240	0.70	0.80	0.77	0.83	0.72	0.81	0.76	0.86	0.74	0.76	0.72	0.83	0.91	0.92
Problems Post TBI[1]	147	0.68	0.73	0.74	0.80	0.70	0.78	0.76	0.85	0.69	0.82	0.70	0.80	0.90	0.92
No Problems Post TBI	151	0.69	0.78	0.78	0.83	0.75	0.80	0.78	0.85	0.77	0.83	0.69	0.80	0.91	0.93
Mild to Severe Anxiety	87	0.68	0.78	0.78	0.84	0.74	0.82	0.81	0.86	0.67	0.74	0.73	0.83	0.91	0.93
No Anxiety[2]	212	0.66	0.75	0.73	0.80	0.70	0.80	0.72	0.82	0.74	0.80	0.68	0.80	0.89	0.91
Mild to Severe Depression	89	0.67	0.75	0.83	0.88	0.73	0.82	0.78	0.84	0.62	0.77	0.73	0.85	0.91	0.93
No Depression[3]	210	0.65	0.75	0.69	0.81	0.70	0.80	0.75	0.84	0.76	0.82	0.68	0.81	0.89	0.91
Post-Concussion Symptoms[4]	47	0.52	0.71	0.73	0.85	0.63	0.77	0.71	0.85	0.64	0.75	0.70	0.82	0.87	0.89
No Post-Concussion Symptoms	250	0.64	0.77	0.70	0.80	0.69	0.78	0.73	0.80	0.73	0.81	0.63	0.79	0.87	0.90
Low Learning Rate[5]	57	0.75	0.85	0.82	0.89	0.79	0.84	0.78	0.84	0.65	0.76	0.75	0.87	0.93	0.95
High Learning Rate	242	0.67	0.76	0.74	0.80	0.71	0.79	0.77	0.86	0.74	0.79	0.71	0.83	0.90	0.92

Note. *α* = Cronbach's Alpha, *ω* = McDonald's Omega, [1] based on parent-report, [2] GAD-7 (mild to severe ≥ 5, no < 5), [3] PHQ-9 (mild to severe ≥ 5, no < 5), [4] PCSI-SR8/13 (symptoms = impaired: *M* + 1*SD*, not impaired = *M* and *M* − 1*SD*), [5] RAVLT (low learning rate= *M* − 1*SD*, not impaired: *M* and *M* + 1*SD*).

Table B3. Correlations of the QOLIBRI-KID/ADO with the PedsQL, PHQ-9, GAD-7, and PCSI-SR8/SR13: Convergent and Divergent Validity Results (Variance Explained).

	PedsQL						PHQ-9	GAD-7	PCSI-SR8/SR13
	Emotional Functioning	Social Functioning	School Functioning	Physical Functioning	Psychosocial Functioning	Total Score	Total Score	Total Score	Total Score
Cognition	20%	21%	39%	27%	39%	40%	18%	9%	26%
Self	21%	11%	29%	22%	31%	32%	11%	5%	31%
Daily Life & Autonomy	22%	26%	30%	34%	39%	43%	17%	8%	22%
Social Relationships	24%	25%	27%	23%	38%	37%	10%	6%	18%
Emotions	18%	9%	14%	14%	21%	21%	4%	3%	9%
Physical Problems	14%	10%	24%	31%	23%	30%	10%	6%	20%
Psychosocial Functioning	33%	23%	39%	32%	48%	49%	14%	8%	30%
Total Score	34%	26%	44%	42%	52%	56%	17%	10%	34%

(QOLIBRI-KID/ADO rows)

Note. The determination coefficient R^2 is presented in percent (%); 0% = no variance explained, 100% = variance is perfectly explained. The shading represents a range from lowest (yellowish cells) to highest (greenish cells) amount of variance explained per row (i.e., from the perspective of QOLIBRI-KID/ADO total and scale score).

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