

THE DEVELOPMENT AND EVALUATION OF THE SLOVENIAN VERSION OF THE EARLY CHILDHOOD ORAL HEALTH IMPACT SCALE (ECOHIS-SVN)

OVREDNOTENJE SLOVENSKE RAZLIČICE VPRAŠALNIKA ZA OCENJEVANJE VPLIVA OTROKOVEGA ORALNEGA ZDRAVJA NA KVALITETO ŽIVLJENJA (ECOHIS-SVN)

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ABSTRACT

Keywords:

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Validity

Reliability

Introduction: There has been no valid and reliable instrument available to measure the impact of oral health on the quality of life of Slovenian preschool children. The main aim of this study was to develop and evaluate the validity and reliability of the first Slovenian instrument assessing Oral Health-Related Quality of Life (OHRQoL) preschool children: the ECOHIS-SVN.

Methods: The ECOHIS-SVN was developed using forward-backward translations and with the participation of children aged under six and their parents. The children's teeth were examined, and parents were asked to complete questionnaires, including the ECOHIS-SVN. The internal consistency of ECOHIS-SVN was evaluated through the calculation of Cronbach's alpha (α), test-retest reliability with an intra-class-correlation coefficient (ICC), convergent validity with Spearman's rank correlation (r) and criterion validity with the Mann-Whitney test. The association between the ECOHIS-SVN score and parents' age, educational level, self-reported oral health and OHIP-SVN14 was estimated using multiple linear regression.

Results: In the study, 255 children participated, with a mean age of 4.8 years (± 0.8). The ECOHIS-SVN questionnaire was completed by the parents of all 255 children and re-filled by 71 parents. The results of the total ECOHIS-SVN scale include $\alpha=0.85$, $ICC=0.85$, and $r=0.6-0.75$. A statistically significant association was found between the ECOHIS-SVN and parents' age and between the ECOHIS-SVN and parents' OHIP-SVN14 in the whole group and in the subgroup of children with no teeth affected by cavitated caries ($dmft=0$) ($p=0.025$, $p=0.028$), respectively.

Conclusion: ECOHIS-SVN enables further studies to assess the OHRQoL of preschool children in the Slovenian-speaking population.

IZVLEČEK

Ključne besede:

ustno zdravje

predšolski otroci

kvaliteta življenja,

povezana z ustnim

zdravjem

vprišalniki

veljavnost

zanesljivost

Uvod: Za merjenje vpliva ustnega zdravja na kakovost življenja slovenskih predšolskih otrok doslej nismo imeli veljavnega in zanesljivega instrumenta. Glavni namen študije je bil razviti in ovrednotiti veljavnost in zanesljivost prvega slovenskega vprašalnika za ocenjevanje z ustnim zdravjem povezane kakovosti življenja predšolskih otrok, poimenovanega ECOHIS-SVN.

Metode: ECOHIS-SVN smo razvili s prevodom vprašalnika ECOHIS. K sodelovanju smo povabili vse otroke, stare do šest let, in njihove starše. Otrokom staršev, ki so pristali na sodelovanje, smo pregledali zobe, starše pa prosili, da izpolnijo vprašalnike, vključno z ECOHIS-SVN. Notranja konsistentnost ECOHIS-SVN je bila ovrednotena s Cronbach alfa (α), zanesljivost s koeficientom intraklasne korelacije (ICC), konvergentna in kriterijska veljavnost pa s Spearmanovim koeficientom korelacije rangov (r) in s testom Mann-Whitney. Z multiplo linearno regresijo smo ocenili povezave med rezultatom ECOHIS-SVN in starostjo, izobrazbeno stopnjo, ustnim zdravjem, medtem ko so bile OHIP-SVN14 staršev ocenjene z multiplo linearno regresijo.

Rezultati: V raziskavi je sodelovalo 255 otrok, povprečno starih 4,8 ($\pm 0,8$) let. Starši vseh 255 otrok so izpolnili vprašalnike, 71 staršev je izpolnilo ECOHIS-SVN vprašalnik dvakrat. Rezultati veljavnosti in zanesljivosti ECOHIS-SVN vključujejo $\alpha = 0,85$, $ICC = 0,85$ in $r = 0,6-0,75$. V celotni preiskovani skupini smo ugotovili statistično značilno povezavo med ECOHIS-SVN in starostjo staršev ($p = 0,025$), v podskupini otrok s $kep = 0$ pa med ECOHIS-SVN in OHIP-SVN14 staršev ($p = 0,028$).

Zaključek: ECOHIS-SVN omogoča nadaljnje študije ocenjevanja z oralnim zdravjem povezane kvalitete življenja predšolskih otrok v slovensko govoreči populaciji.

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1 INTRODUCTION

Oral health affects an individual's overall health and quality of life (1). For many years, deviations in oral health were described only by oral clinical signs and symptoms, without assessing the actual impact of oral diseases on the quality of patients' daily lives (2). Oral Health-Related Quality of Life (OHRQoL) is influenced by various factors, including the presence of oral pain (3), malocclusions and dental diseases (4), as well as many other factors (e.g. socio-economic status) (5).

In adults, several instruments have been in use to measure the impact of oral health on quality of life (6). One of the most frequently used is the Oral Health Impact Profile (OHIP) (7) and its short version (OHIP-14) (8). The original OHIP-14 has also been translated into Slovenian and validated for use in the Slovenian population (9).

In children, especially in the preschool population, only a few instruments are available to assess OHRQoL. In 2007, the Early Childhood Oral Health Impact Scale (ECOHIS) questionnaire was introduced to assess the impact of OHRQoL on pre-schoolers and their families (10). Since then, ECOHIS has been translated and validated in several languages (11-18). To date, no valid and reliable instrument for assessing OHRQoL in preschool children has been available in the Slovenian language. The development of the Slovenian version of the ECOHIS questionnaire will enable further research studies that will measure and compare the impact of oral health-related quality of life of Slovenian preschool children in relation to various diseases and/or treatments, as well as comparison of the results of such studies with similar studies conducted around the world.

This study aimed to translate and validate the Slovenian version of the ECOHIS questionnaire (i.e. the ECOHIS-SNV). Due to the children's immaturity, including their cognitive and linguistic limitations, which prevent them from disclosing past events and self-reporting OHRQoL, children's OHRQoL assessments are usually based on their parents' reports. Since studies have found that their subjective perceptions are also influenced by socioeconomic characteristics (5), the researchers sought a possible correlation between the ECOHIS-SNV results and parents' age, level of education, self-reported oral health status and OHIP-SVN14 score.

2 METHODS

The original English ECOHIS questionnaire was translated into Slovenian using the forward-backwards translation method by two native Slovenian speakers. Both translations were compared and merged into a single ECOHIS-SVN version (Figure 1). The Slovenian version was back-translated into English by two independent native English speakers. Both versions were compared and synthesised, and the English translation of the ECOHIS-SVN was compared with the original English version.

1. Kako pogosto je imel vaš otrok bolečine zaradi zob, ali bolečine v področju ustne votline ali željstnega sklepa?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
2. Kako pogosto je imel vaš otrok zaradi težav z zobmi ali zobozdravniškega zdravljenja težave s pitjem toplih ali mrzlih pijač?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
3. Kako pogosto je imel vaš otrok zaradi težav z zobmi ali zobozdravniškega zdravljenja težave z žvečenjem hrane?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
4. Kako pogosto je imel vaš otrok zaradi težav z zobmi ali zobozdravniškimi zdravljenjem težave z izgovorjavo določenih besed?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
5. Kako pogosto je vaš otrok zaradi težav z zobmi ali zobozdravniškega zdravljenja izostal iz vrtca ali šole?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
6. Kako pogosto je imel vaš otrok zaradi težav z zobmi ali zobozdravniškega zdravljenja težave s spanjem?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
7. Kako pogosto je bil vaš otrok zaradi težav z zobmi ali zobozdravniškega zdravljenja razdražljiv ali nerazpoložen?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
8. Kako pogosto se vaš otrok zaradi težav z zobmi ali zaradi zobozdravniškega zdravljenja ni želel nasmehnjati ali smejeti?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
9. Kako pogosto se je vaš otrok zaradi težav z zobmi ali zaradi zobozdravniškega zdravljenja izogibal govorjenju?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
10. Kako pogosto ste bili vi ali drugi člani vaše družine razburjeni zaradi težav z zobmi ali zdravljenja zob vašega otroka?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
11. Kako pogosto ste imeli vi ali drugi člani vaše družine občutek krivde zaradi težav z zobmi ali zdravljenja zob vašega otroka?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
12. Kako pogosto ste bili vi ali drugi člani vaše družine odsotni z dela zaradi težav z zobmi ali zdravljenja zob vašega otroka?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem
13. Kako pogosto ste občutili finančen vpliv na vašo družino zaradi težav z zobmi ali zdravljenja zob vašega otroka?	1. Nikoli	2. Redko	3. Včasih	4. Pogosto	5. Zelo pogosto	6. Ne vem

Figure 1. ECOHIS-SVN questionnaire.

The ECOHIS questionnaire, inquiring about the frequency of particular events in the child's life thus far, is divided into two main parts: the section on the impact on the child (9 items) and the section on the impact on the family (4 items). The child impact section contains four subscales: symptom (1 item), child-related function (4 items), psychology (2 items) and self-image/social interaction (2 items). The family impact section comprises two subscales: parental distress (2 items) and family-related function (2 items) (10). The total score of the completed ECOHIS questionnaire is the sum of the responses to all 13 questions. For each question, the selected response is scored as follows: 1=never, 2=hardly ever, 3=occasionally, 4=often, 5=very often. The ECOHIS summary score ranges from 13 to 65; the scores for the child and family sections

may range from 9 to 45 and 4 to 20, respectively. A higher total score means a lower quality of life. An alternative response, "I do not know", was also available. Parents responding to one or more questions with "I do not know" were excluded from the analysis.

To participate in the study, the researchers invited all children under six years of age from two kindergartens in Ljubljana and their parents. The researchers thoroughly explained to the parents the aim and the course of the study and its voluntary nature. The study included only children with no systemic disease, motor or cognitive impairment, children who were willing to take part in the dental examination, and whose parents had given written informed consent for participation. The study was conducted in accordance with the Helsinki Declaration and approved by the Slovenian National Committee for Medical Ethics (Act No. 0120-484/2019/14).

All children underwent a clinical dental examination by a trained and calibrated examiner. In each child, dental caries and caries-affected teeth were recorded according to the WHO criteria for visual assessment of dental caries (19). The entire group of children was divided into two subgroups: children with dentine caries lesions ($dmft > 0$) and children without dentine caries lesions ($dmft = 0$). A modified plaque assessment scoring system (PASS) was used to assess plaque accumulation (20). As suggested by the authors, the presence or absence of dental plaque was recorded on 20 surfaces; instead of the first permanent molars, the researchers checked for the presence of plaque on the second deciduous molars and one upper central incisor. If the second deciduous molar was absent, the presence of plaque was assessed on the first deciduous molar. In the presence of dental plaque at one or more sites, the subject was categorised into the group with dental plaque ($DP > 0$), while a child without detected dental plaque was classified into the group without dental plaque ($DP = 0$).

During the visit, parents were asked to complete ECOHIS-SVN. Three weeks later, parents of the first 30% of children in whom dental examinations were performed were invited to re-complete the ECOHIS-SVN questionnaire. The ECOHIS-SVN internal consistency was tested using Cronbach's alpha coefficient (21). Test-retest reliability was assessed by the intra-class correlation coefficient (ICC) according to Shrout and Fleiss (22); more specifically the ICC (3,1). This calculation, based on a two-way mixed-effect model, as the two consecutive measurements (test-retest setting) were not randomized samples and it is built on the assumption of absolute agreement between measurements of the two consecutive time points.

The convergent validity of the ECOHIS-SVN was assessed according to Pahel and co-authors (10). The researchers compared the results of each of the ECOHIS-SVN sections (the child and the family) with the responses to either of

two questions relating to the child's overall and dental health ("In general, how would you rate the overall health of your child?" and "In general, how would you rate the dental health of your child?"). For each of the two questions, parents selected one of the following responses: 1=excellent, 2=very good, 3=good, 4=fair, and 5=poor (10). Convergent validity was assessed with Spearman's rank correlation.

Criterion validity was tested between groups of children who differed in two oral health indicators: tooth affection due to dentine caries lesions ($dmft = 0$ and $dmft > 0$) and dental plaque presence ($DP = 0$ and $DP > 0$). Differences in the scale score distributions between the groups of children on the two indicators were tested with the Mann-Whitney test. The magnitude of the statistical difference was assessed by calculating the effect size (23).

In the second part of the study, the researchers examined the relationships between some characteristics of the parents (age, educational level, self-reported oral health and OHIP-SVN 14) on the responses they gave in the ECOHIS-SNV questionnaire. For this purpose, parents indicated their age and level of education (primary, secondary school or university). Education was included in the form of dummy variables. They also answered with "yes" (scored as 1) or "no" (scored as 0) to each of four questions: "Do you have tooth fillings?", "Do you have a tooth or multiple teeth replaced with a prosthetic substitute (i.e. crown, bridge, denture)?", "Do you have periodontal disease?", and "Have you had any teeth extracted due to caries or periodontal disease?". In addition, each parent also completed the OHIP-SVN14 questionnaire, which asks about the parent's oral health-related quality of life (9). For each of the OHIP-SVN14 questions, one of the following responses could be selected: 0=never, 1=hardly ever, 2=occasionally, 3=often, 4=very often. Multiple linear regression analysis was used to assess the association between ECOHIS-SVN results and the parents' age, level of education, self-reported oral health status and the parents' OHIP-SVN14 score. Due to the heteroscedasticity and non-normal distribution of residuals, the bootstrapping method was used to obtain reliable confidence intervals for regression coefficients. The same analysis was also conducted on the $dmft = 0$ subgroup. Statistical analysis was performed using SPSS for Windows, version 25.0 (IBM Corporation, Armonk, NY, USA) and R Statistical Software (version 4.1.3). A p-value ≤ 0.05 was considered statistically significant.

3 RESULTS

The original ECOHIS questionnaire was translated without major adaptations. Minor adaptation in the ECOHIS-SVN was required, as the term "kindergarten" replaced both terms used in the original ECOHIS questionnaire (i.e. "preschool" and "daycare").

Of 462 invited children, 255 children, 130 boys (51%) and 125 girls (49%), with a mean age of 4.8 years±0.8 (boys 4.9±0.8 and girls 4.8±0.8) participated in the study (Figure 2).

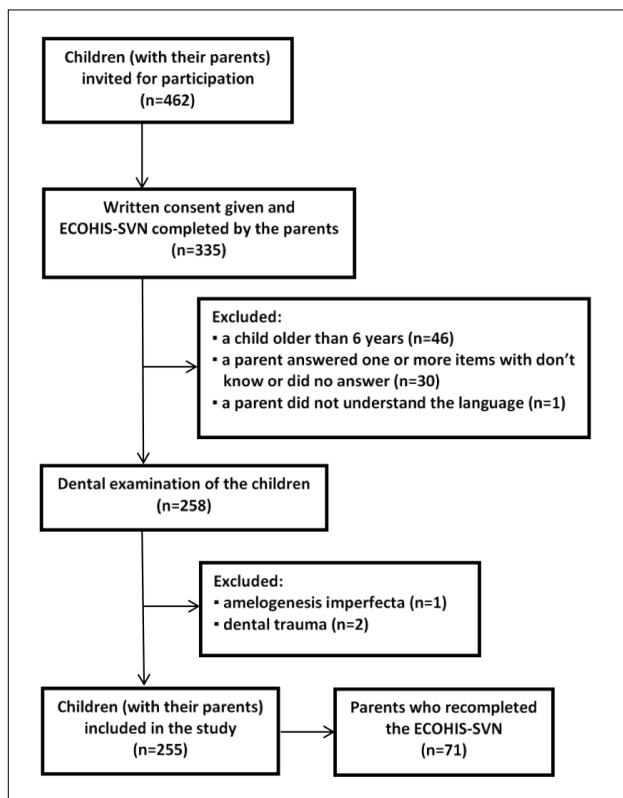


Figure 2. Participants' flowchart.

In the entire study group, 115 children had at least one tooth affected with dentine caries (45.1%). In the entire group of children, the mean dmft was 2.34±3.61, and in the dmft>0 subgroup, the mean dmft was 5.19±3.75. The total number of teeth affected with dentine caries lesions (n=597) and proportions of decayed, missing and filled teeth were 82.8%, 1.5%, and 15.7%, respectively.

For each child, the ECOHIS-SVN questionnaire was fully completed by her/his parent; 205 mothers (80.4%) and 50 fathers (19.6%). For the entire group, the mean ECOHIS-SVN total score was 15.3 (15.1 for boys and 15.6 for girls). The distribution of responses to ECOHIS-SVN is presented in Table 1. In the child impact section, oral/dental pain was the most frequently reported problem (10.2% answered "occasionally", "often", and "very often"), while in the family impact section, feelings of guilt (10.2%) was ranked highest. However, it should be emphasised that 50.3% of parents reported not noticing the problems described in the ECOHIS-SVN questionnaire, indicating a strong floor effect, while the ceiling effect was negligible (Table 2).

Table 2. Ranges and floor effect of ECOHIS-SVN items (child, family and total).

Domain	Number of items	Possible range	Range	Floor effect (% of minimum score)
Child impact	9	9-45	9-31	58.0
Family impact	4	4-20	4-16	63.5
Total score	13	13-65	13-40	50.2

Table 1. Distribution of responses to individual questions of the ECOHIS-SVN questionnaire.

	Never		Hardly ever		Occasionally		Often		Very often	
	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)
Child impact										
Oral/dental pain	180	70.6	49	19.2	21	8.2	5	2.0	0	0.0
Difficulty drinking	229	89.8	20	7.8	4	1.6	1	0.4	1	0.4
Difficulty eating	220	86.3	26	10.2	6	2.4	2	0.8	1	0.4
Difficulty pronouncing words	230	90.2	14	5.5	4	1.6	5	2.0	2	0.8
Missed kindergarten, day care, school	233	91.4	17	6.7	5	2.0	0	0.0	0	0.0
Trouble sleeping	239	93.7	10	3.9	6	2.4	0	0.0	0	0.0
Irritable, frustrated	220	86.3	30	11.8	4	1.6	1	0.4	0	0.0
Avoided smiling, laughing	246	96.5	8	3.1	1	0.4	0	0.0	0	0.0
Avoided talking	251	98.4	3	1.2	1	0.4	0	0.0	0	0.0
Family impact										
Been upset	181	71.0	49	19.2	16	6.3	6	2.4	3	1.2
Felt guilty	196	76.9	33	12.9	20	7.8	5	2.0	1	0.4
Time off from work	225	88.2	29	11.4	0	0.0	1	0.4	0	0.0
Financial impact	244	95.7	6	2.4	1	0.4	1	0.4	3	1.2

The ECOHIS-SVN score reliability in the study sample is shown in Table 3. Cronbach's alpha was 0.85 (the lower limit of the 95% CI is 0.82) and therefore considered to be satisfactory for a reliable comparison between groups (24). Parents of 71 children (28%) re-completed the ECOHIS-SVN questionnaire three weeks later. In this subgroup, the mean ECOHIS-SVN scores of the baseline and of the additional completion of the questionnaire were 14.79 ± 3.28 and 14.41 ± 2.89 , respectively. The ICC was 0.85 (95% CI ranging from 0.76 to 0.91).

As for the ECOHIS-SVN validity, a statistically significant correlation was confirmed between ECOHIS-SVN and general health, as well as the dental health-rating question (Table 4). The Spearman correlation coefficients for the

total ECOHIS-SVN scores and the general or dental health question were 0.60 and 0.75, respectively. This moderate-to-high correlation confirms the convergent validity of the ECOHIS-SVN. Testing criterion validity, a statistically significant difference was found between the groups of children affected with dentine caries and children without dental caries lesions ($p < 0.001$). Regarding the plaque accumulation status of the children, score differences were statistically significant in the child impact section and the total ECOHIS-SVN. The effect size of the total ECOHIS-SVN scores between children with and without caries was 0.76 (child impact section=0.74, family impact section=0.52), and regarding the plaque accumulation status, 0.40 (child impact section=0.49, family impact section=0.21).

Table 3. ECOHIS-SVN score reliability of the study sample.

	Number of items	Internal consistency (n=255)		Test-retest reliability (n=71)	
		Cronbach's alpha (lower limit of 95% CI)	Average inter-item correlation	ICC (95% CI)	Mean ECOHIS score difference examination time 1-time 2 (95% CI)
Child impact	9	0.81 (0.77)	0.38	0.85 (0.76-0.91)	0.13 (-0.28-0.54)
Family impact	4	0.76 (0.71)	0.46	0.79 (0.65-0.87)	0.25 (0.06-0.44)
Total score	13	0.85 (0.82)	0.34	0.85 (0.76-0.91)	0.38 (-0.14-0.90)

Legend: ICC=intraclass correlation coefficient; CI=confidence interval

Table 4. ECOHIS-SVN score validity: correlations with parental-reported oral and general health as well as caries and plaque accumulation.

	(n)	Child impact (9 items)		Family impact (4 items)		Total score (13 items)	
		Mean (SD)	r (95% CI)	Mean (SD)	r (95% CI)	Mean (SD)	r (95% CI)
General health rating							
Excellent	108	9.3 (1.3)	0.56	4.1 (0.6)	0.52	13.5 (1.9)	0.60
Very good	116	10.6 (2.4)	(0.46-0.64)*	5.5 (2.3)	(0.41-0.61)*	16.1 (4.0)	(0.50-0.68)*
Good	25	13.2 (4.9)		6.4 (2.2)		19.6 (6.4)	
Fair	5	10.0 (1.2)		5.0 (1.0)		15.0 (2.1)	
Poor	1	15.0 (/)		7.0 (/)		22.0 (/)	
Dental health rating							
Excellent	93	9.1 (0.3)	0.69	4.1 (0.3)	0.65	13.2 (0.5)	0.75
Very good	89	9.6 (1.0)	(0.61-0.76)*	4.7 (1.3)	(0.56-0.72)*	14.3 (1.8)	(0.68-0.80)*
Good	43	11.6 (2.0)		5.7 (2.1)		17.3 (3.2)	
Fair	22	14.1 (5.6)		7.8 (3.0)		22.0 (7.2)	
Poor	8	15.0 (4.1)		8.4 (2.3)		23.4 (4.7)	
		Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Dmft							
dmft=0	140	9.5 (1.0)	9 (9-9)	4.6 (1.3)	4 (4-4)	14.0 (2.0)	13 (13-14)
dmft>0	115	11.4 (3.5)	10 (9-12)*	5.6 (2.4)	5 (4-6)*	17.0 (5.2)	15 (13-19)*
Dental plaque							
no	131	9.7 (1.5)	9 (9-10)	4.8 (1.9)	4 (4-5)	14.6 (3.0)	13 (13-15)
yes	124	11.0 (3.4)	10 (9-11)*	5.2 (1.9)	4 (4-6)	16.2 (4.8)	14 (13-17)*

* $p < 0.001$

Legend: r=Spearman correlation coefficient; SD=standard deviation; CI=confidence interval; IQR=interquartile range; dmft=decayed, missing, filled teeth

In the framework of the second part of the study, the researchers found that the majority of parents belonged to the age group between 20 and 40 years of age (67.5%), had a university degree or some level of higher education (61.2%), and the most common number of points on self-reported oral health was one (53.3%). The mean OHIP-SVN14 score of the parents of the entire group of children was low (4.61 ± 5.09).

Multiple linear regression models confirmed a statistically significant association only between ECOHIS-SVN and parents' age (Table 5). The education, self-reported oral health and OHIP-SVN14 were non-significant in all three ECOHIS-SVN sections. In the subgroup of children with $dmft=0$, higher OHIP-SVN14 values of parents were statistically significantly accompanied by higher values of ECOHIS-SVN of children (Table 6).

Table 5. Associations between ECOHIS-SVN (total, child and family) and the parent's age, education level, self-reported oral health status and OHIP-SVN14 score.

	B	SE	95 % CI	Std. B	p-value
ECOHIS-SVN child score					
Parent's age	-0.068	0.036	-0.140-0.005	-0.118	0.068
Parent's education					
Primary	Ref.				
Secondary	0.278	1.003	-2.592-3.182	0.105	0.842
University	-0.578	0.993	-3.337-2.210	-0.218	0.691
Self-reported oral health	0.330	0.197	-0.149-0.812	0.109	0.177
OHIP-SVN14	0.076	0.034	-0.013-0.168	0.146	0.096
R ² =0.072, F=4.916 (p<0.001)					
ECOHIS-SVN family score					
Parent's age	-0.043	0.026	-0.088-0.001	-0.103	0.044
Parent's education					
Primary	Ref.				
Secondary	-0.341	0.748	-2.497-1.934	-0.177	0.804
University	-0.374	0.740	-2.536-1.912	-0.194	0.784
Self-reported oral health	0.02	0.147	-0.244-0.308	0.009	0.822
OHIP-SVN14	0.065	0.025	-0.004-0.133	0.171	0.065
R ² =0.022, F=2.156 (p=0.059)					
ECOHIS-SVN total score					
Parent's age	-0.111	0.055	-0.213-0.015	-0.126	0.025
Parent's education					
Primary	Ref.				
Secondary	-0.063	1.540	-5.267-4.878	-0.016	0.941
University	-0.952	1.524	-6.091-3.927	-0.236	0.673
Self-reported oral health	0.350	0.303	-0.298-1.034	0.076	0.279
OHIP-SVN14	0.141	0.052	-0.002-0.279	0.177	0.054
R ² =0.06, F=4.259 (p<0.001)					

Legend: OHIP-SVN14=Slovenian version of the 14-item Oral Health Impact Profile; B=unstandardised beta; SE=standard error; Std. B=standard error for the unstandardised beta; CI=confidence interval; R²=coefficient of determination; F=test statistic

Table 6. In the subgroup of children with dmft=0, associations between ECOHIS-SVN (child, family and total) and the parent's age, level of oral health status education, self-reported and OHIP-SVN14 score.

	B	SE	95 % CI	Std. B	p-value
ECOHIS-SVN child score					
Parent's age	0.03	0.02	-0.005-0.066	0.132	0.097
Parent's education					
Primary	Ref.				
Secondary	0.119	0.73	-0.416-0.635	0.119	0.684
University	0.199	0.723	-0.195-0.579	0.199	0.332
Self-reported oral health	-0.203	0.111	-0.432-0.045	-0.165	0.112
OHIP-SVN14	0.047	0.017	0.003-0.089	0.234	0.038
R2=0.040, F=2.168 (p=0.061)					
ECOHIS-SVN family score					
Parent's age	0.023	0.025	-0.018-0.063	0.079	0.275
Parent's education					
Primary	Ref.				
Secondary	-0.296	0.9	-1.427-0.867	-0.235	0.633
University	-0.215	0.891	-1.308-0.927	-0.171	0.739
Self-reported oral health	-0.205	0.137	-0.486-0.082	-0.132	0.163
OHIP-SVN14	0.086	0.021	0.008-0.167	0.343	0.032
R2=0.082, F=3.494 (p=0.005)					
ECOHIS-SVN total score					
Parent's age	0.052	0.039	-0.009-0.115	0.116	0.093
Parent's education					
Primary	Ref.				
Secondary	-0.177	1.421	-1.533-1.150	-0.089	0.780
University	-0.017	1.408	-1.328-1.315	-0.008	0.993
Self-reported oral health	-0.408	0.217	-0.870-0.075	-0.166	0.099
OHIP-SVN14	0.132	0.034	0.014-0.250	0.334	0.028
R2=0.086, F=3.629 (p=0.004)					

Legend: OHIP-SVN14=Slovenian version of the 14-item Oral Health Impact Profile; B=unstandardised beta; SE=standard error; Std. B=standard error for the unstandardised beta; CI=confidence interval; R2=coefficient of determination; F=test statistic

4 DISCUSSION

The main goal of this study was to develop the Slovenian version of the ECOHIS questionnaire: the ECOHIS-SNV. The development of the questionnaire in the local language enables further research studies that will measure and compare the impact of the quality of life of Slovenian preschool children in the case of various diseases of the oral cavity and/or treatments (e.g. comparisons of different treatments methods, choices of different materials). Furthermore, it also enables comparisons of the results of such studies in the preschool population in Slovenia with similar studies conducted around the world. To achieve this goal, the researchers assessed its internal consistency, test-retest reliability, and its convergent and criterion validity. In this way the researchers obtained the first questionnaire in the Slovenian language that enables the appraisal of the quality of life of preschool children concerning their oral health.

The selection of the sample size and corresponding power was based on previous ECOHIS validation studies, which were conducted on groups ranging between 111 and 492 participants (10-18, 25) and are consistent with recommendations for assessing construct validity, ceiling/floor effects, internal consistency and factorial analysis (26). The results of ECOHIS-SVN validation are in accordance with previously published studies evaluating this OHRQoL measure. Cronbach's alpha was 0.85, which is comparable to results between 0.82 and 0.95, as found in the previous studies (10-14, 16, 18). Another measure of the scores' internal consistency (mean inter-item correlation) ranged between 0.15 and 0.50, as recommended (27). ICC of 0.85 was also comparable to the previously reported ICC values between 0.81 and 0.86 (10, 11, 15, 17, 18) and indicates good test and retest agreement (28). The researchers have confirmed a strong correlation between the ECOHIS-SVN scores and the general and dental health rating questions, whereas it was weak to moderate in the previous studies (10, 14, 18). The ECOHIS-SVN scores discriminated between

children with and without cavitated caries, as well as between children with or without accumulated dental plaque ($p < 0.001$), as in previous studies (10, 15, 18).

The mean ECOHIS-SVN total score of the whole group was 15.34. Parents most repeatedly answered questions related to “pain” (10.2%), “guilt” (10.2%), and “upset” (9.9%) with “very often”, “often”, or “occasionally”. Furthermore, they reported their child’s difficulty in “pronouncing words” (4.4%) and “eating” (3.6%). While “pain” and “difficulty eating” are often reported in studies (10, 14, 18), difficulty in pronouncing words was highlighted only in this study.

The limitation of this study was that no pilot study with at least a dozen subjects included had been previously conducted (29). A further limitation was a strong floor effect observed, with 70-98% of parents (depending upon the item) reporting that their children “never” experienced oral health problems. Other validation studies reported similar findings (10, 12, 14, 15). This may have been due to the low level of oral health problems experienced by the participating children and/or the fact that parents did not pay attention to their children’s oral diseases until pain was present. Indeed, in this study, only 15.7% of teeth affected with cavitated dentine caries lesions were filled.

5 CONCLUSION

With this study, a reliable and valid instrument has been developed for assessing the OHRQoL of preschool children in the Slovenian-speaking population. Although ECOHIS is primarily intended for use in epidemiological research and with limited use in clinical practice, it is used by health professionals to assess preschool children who can have a variety of dental, orthodontic and craniofacial conditions (30). The ECOHIS-SVN enables further studies to assess the effects of oral diseases and their treatment modalities on the OHRQoL of preschool children.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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