

**Oral health-related quality of life of preschool children after receiving silver diamine fluoride treatment**

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1 **Oral health-related quality of life of preschool children receiving silver diamine fluoride**  
2 **therapy**

3

4 **Abstract**

5 **Objectives:** The aim of the study was to investigate the effect of silver diamine fluoride (SDF)  
6 therapy on the oral health-related quality of life (OHRQoL) of preschool children and their families  
7 in a school-based setting. **Methods:** A prospective study was conducted in six kindergartens in  
8 Hong Kong. Parents of the children were invited to complete an oral health questionnaire and to  
9 have their child undergo a dental examination. The decayed, missing and filled teeth (dmft) index  
10 was adopted for recording oral health status. The Chinese Early Childhood Oral Health Impact  
11 Scale (C-ECOHIS) was used to evaluate the OHRQoL of the children and their families. Children  
12 with untreated caries were treated with SDF. The Wilcoxon Signed Ranks Test was used to  
13 determine the changes in C-ECOHIS scores before and after SDF treatment for six months.  
14 **Results:** At baseline, 117 preschool children aged 4-5 years received SDF treatment for caries  
15 arrest. Their mean(SD) dmft score at baseline was 4.9(3.8). After six months, 113(96.6%) returned  
16 a completed questionnaire. Their mean(SD) C-ECOHIS scores at baseline and follow-up were  
17 7.4(6.6) and 7.8(6.4), respectively. The overall differences between pre- and post-treatment scores  
18 were not significant ( $p=0.301$ ). Concerning parent section, a negative impact was found ( $p=0.014$ ),  
19 whereas no significant impact was found in the child section ( $p=0.831$ ).  
20 **Conclusion:** The SDF treatment conducted in a school setting did not affect the overall OHRQoL  
21 of preschool children and families.  
22 **Clinical significance:** These results can provide important information to dental professionals  
23 regarding the use of SDF for caries control.

24 **Introduction:**

25 Tooth decay is the most prevalent chronic disease in childhood [1]. In Hong Kong, approximately  
26 half of kindergarten children in Hong Kong have tooth decay, and most of them (93%) are left  
27 untreated [2]. Children with untreated dental caries may suffer from dental infection, orofacial pain  
28 or the inability to chew and eat. Studies revealed that untreated caries is associated with worse oral  
29 health-related quality of life (OHRQoL) [3]. This may affect the quality of life of their family  
30 members and eventually impact their communities. A restorative approach alone is insufficient for  
31 improving oral health inequality, especially in deprived communities [4]. Therefore, non-invasive  
32 treatment, such as caries-arresting treatment, has gained more attention in community dental care.

33

34 Recently, several systematic reviews concluded that silver diamine fluoride (SDF) therapy can be  
35 a therapeutic option for controlling tooth decay in children due to its safety, efficacy and cost-  
36 effectiveness [5]. However, most of the clinical outcomes in caries arrest studies were based on  
37 clinicians' judgements [6, 7]. As commonly known, a side effect of SDF is the blackening of  
38 carious lesions [8]. It remains unknown if tooth discoloration on carious lesions may affect a  
39 child's social and psychological aspects. In the US, the use of SDF has recently gained more  
40 interest among pediatric and general dental practitioners [9]. To date, limited information exists  
41 regarding the effect of SDF treatment on patient-reported outcomes. The assessment of OHRQoL  
42 has been proved to be a valuable tool in assessing adult patients' needs and patient-based outcomes  
43 [10]. However, preschool children are incapable of abstract thinking, which most likely underlies  
44 health perceptions; thus, parents must be their representatives in reporting the impacts of any dental  
45 disease or treatments. The Early Childhood Oral Health Impact Scale (ECOHIS) was proposed  
46 and validated to assess the impact of dental health problems and treatment experiences on the

47 quality of life of children aged 3 to 5 years old and their families [11]. A recent Chinese version  
48 of the ECOHIS (C-ECOHIS) demonstrated good reliability and validity [12].

49

50 As of now, no information exists regarding the OHRQoL (individual's physical, social, and  
51 psychological wellbeing) of children after participating and using SDF in a school oral health  
52 program. The aim of this study was to assess the changes of the OHRQoL of preschool children  
53 and their families using the C-ECOHIS questionnaire on 4- to 5-year old children who had dental  
54 caries and received SDF treatment for caries control in a school oral health program. The results  
55 of this study can provide important information to dentists and to dental public health professionals,  
56 as well as to parents in making decisions regarding the use of SDF for caries control in the school  
57 setting.

58

## 59 **Methods**

60 Ethics approval was obtained from the Institutional Review Board of the University of Hong  
61 Kong/Hospital Authority Hong Kong West Cluster (UW 17-414). Six kindergartens that were not  
62 involved in any research study were selected. An invitation letter was sent to the parents of the  
63 children in the selected schools, explaining the purpose and procedures of the study. Written  
64 parental consent was sought and received before the children participated. This study was  
65 conducted from November 2017 to June 2018. Eligibility criteria were preschool children aged  
66 4-5 years old who have had at least one dentin caries and had never previously received SDF  
67 treatment, and whose parents or guardians were able to read and write in Chinese. Exclusion  
68 criteria included children who were uncooperative, refused examination or had major systemic  
69 illnesses. The study children were examined and followed up in their kindergarten classrooms.

70

71 *Sample size calculation:*

72 The sample size calculation was estimated using the software G\*Power 3.1.9.2 (University of  
73 Düsseldorf, Germany) based on these assumptions: 1) the mean Chinese ECOHIS score before  
74 treatment was approximately 15 (SD=7) [13]; 2) the minimal important difference (MID) would  
75 be around 3 for those reporting that their conditions at least ‘improved a little’ [14], and thus, the  
76 anticipated mean Chinese ECOHIS score after treatment would be 12 (SD=7); and 3) the power  
77 of the study was set at 90% ( $\beta=0.10$ ) and with the two-sided test at the 0.05 statistical significance  
78 level. With an anticipated 20% dropout rate, the minimum sample size to be recruited at baseline  
79 would be 83 children. Based on our previous results [7], the caries prevalence of Hong Kong  
80 children aged 4-5 years old was approximately 40%; therefore, 216 children were screened. With  
81 an anticipated 70% response rate, at least 309 parent-child dyads were invited to join the study.

82

83 *Clinical examination*

84 One examination team, which consisted of one examiner and one assigned recorder, conducted a  
85 clinical oral examination and recorded the caries experience and oral hygiene status in a chart at  
86 baseline and at six-month follow-up. Clinical examinations of the children were performed in  
87 kindergarten classrooms mainly through careful visual inspections with the aid of World Health  
88 Organization Community Periodontal Index (CPI) probes (405/WHO probe, Otto Leibinger,  
89 Mühlheim, Germany) and dental mirrors attached to handles with light-emitting diodes for intra-  
90 oral illumination (MirrorLite, Kudos Crown Limited, Hong Kong, China).

91 Children were examined in the supine position. The decayed, missing and filled teeth index (dmft)  
92 was used for recording the caries status. Caries was diagnosed at the cavitation level following the

93 criteria of the WHO [15]. The oral hygiene status was measured using the visible plaque index  
94 (VPI)[16]. The buccal and lingual surfaces of six index teeth (55, 51, 63, 71, 75 and 83) were  
95 examined, and the presence or absence of visible plaque on caries surfaces was recorded. The  
96 modified 'pufa' is used to assess the presence of oral conditions resulting from untreated caries  
97 [17, 18]. The index is recorded separately from the dmft and scores the presence of either a visible  
98 pulp (p) or an abscess, (a) including the ulceration (u) of the oral mucosa due to root fragments  
99 and a fistula (f). Thus, for an individual preschool child, the dmft and modified 'pufa' score can  
100 range from 0 to 20.

101

102 Regarding lesion activity, carious lesions were explored with a CPI probe. All surfaces of each  
103 tooth were assessed. A lesion was recorded as active if softness was detected upon gentle probing,  
104 and it was classified as arrested caries if the dentine surface was hard to probe [6, 7]. Duplicate  
105 examinations on 10% of the preschool children were carried out to assess intra-examiner  
106 agreement regarding the caries assessments. After each examination, an individual oral health  
107 report stating the number of decayed teeth and the oral hygiene status of the examined child was  
108 given to his or her parents, and the parents could seek dental treatment with their own financial  
109 means.

110

### 111 *Questionnaire survey*

112 A parental questionnaire was administered before and after the parents joined the program for six  
113 months. At baseline, information on the children's demographic background and OHRQoL were  
114 collected via a self-completed parental questionnaire. At the six-month follow-up examination, the  
115 same parent was asked to complete the questionnaire survey. The Chinese version of the ECOHIS

116 (C-ECOHIS), which is a validated tool for measuring the OHRQoL of preschool children, was  
117 adopted [12]. It contained 13 items corresponding to two sections: a 1) child impact section (nine  
118 items) consisting of four descriptive domains (symptoms – one item; function – four items;  
119 psychological –two items; self-image/social interaction – two items) and 2) parent impact section  
120 consisting of two domains (parent distress – two items and family function – two items). The  
121 response categories for the C-ECOHIS were coded: 0 = never; 1 = hardly ever; 2 = occasionally;  
122 3 = often; 4 = very often; 5 = don't know. The total C-ECOHIS scores and scores for individual  
123 domains were calculated as a simple sum of the response codes, after all 'Don't know' responses  
124 were recoded to missing. The total scores ranged from 0 to 52, with higher scores indicating greater  
125 degrees of oral impact on the quality of life of the child.

126

### 127 *Intervention*

128 Participating children with dentin caries were treated with 38% silver diamine fluoride (SDF)  
129 (Saforide, Toyo Seiyaku Kasei Co. Ltd., Japan) in a school-based setting. Steps of the SDF  
130 treatment were as follows: 1) position the child supine on the bench; 2) isolate the child's decayed  
131 teeth with dental gauze; 3) apply SDF on each caries surface with a micro applicator for  
132 approximately one minute; and 4) after the application, inform a class teacher that the child should  
133 not eat or drink, or rinse his or her mouth for at least 30 minutes. After the intervention, an  
134 individual report on the child's oral health status was sent to his or her parents.

135

### 136 **Statistical analysis**

137 Data were analyzed using the software SPSS 24.0 for Windows (IBM Corp. Armonk, NY, USA).  
138 Intra-examiner agreement in the diagnosis of dental caries was assessed by using Cohen's Kappa

139 statistics. The McNemar-Bowker test was used to compare the distribution of the C-ECOHIS  
140 before and after SDF treatment. Changes in C-ECOHIS scores were generated by subtracting the  
141 post-treatment score (T1) from the pre-treatment score (T0). A positive change or an improvement  
142 of OHRQoL was indicated if the post-treatment score was lower than the pre-treatment score,  
143 whereas a negative change or a deterioration of OHRQoL was indicated if the post-treatment C-  
144 ECOHIS score was higher than the pre-treatment score. Children could have zero change or the  
145 level of impacts on OHRQoL would remain unchanged. Due to the non-normal distribution of the  
146 mean differences of the ECOHIS scores, the Wilcoxon Signed Rank Test was adopted. An  
147 indication of the magnitude of the statistical change was assessed by determining the effect size  
148 (ES) (mean change [T0—T1]/standard deviation) [13]. The level of statistical significance for all  
149 tests was set at 0.05. Multiple logistic regression models were adopted to determine if other family-  
150 and child-related factors were associated with the negative impact of SDF. The backward stepwise  
151 procedure was performed until only variables demonstrating a statistically significant association  
152 ( $p < 0.05$ ) remained in the final model.

153

## 154 **Results**

155 Among the 434 preschool children invited, 388 (89.4%) provided informed consent and returned  
156 their baseline questionnaires. On the day of the baseline examination, 36 children were absent.  
157 Thus, 362 children were screened. Among these, 117 children had dentin caries ( $dt > 0$ ) and were  
158 then treated with SDF. The value of the Kappa statistics for caries assessment was 0.96. After six  
159 months, all (100%) remained in the study; however, four participants who missed more than two  
160 missing items were excluded from the analysis. Therefore, 113 (96.6%) study dyads were included  
161 in the analysis. Among the 113 questionnaires, eight missing values were computed using the mean

162 of the remaining items of the ECOHIS score in each participant. Their mean (SD) age was 4.6  
163 (0.3) years. The demographic and clinical characteristics of the children are displayed in Table 1.  
164 Among these, 54 children (47.8%) were boys. Their mean (SD) dmft and dt scores were 4.9 (3.8)  
165 and 4.6 (3.6), respectively. Most (69.9%) of the children had 1-5 decayed teeth. A majority (86.7%)  
166 of them had dental caries on their upper anterior teeth. The prevalence of oral conditions resulting  
167 from untreated caries (modified pufa score>0) was 10.6%. Their VPI score was 0.47 (0.19). A  
168 majority of the respondents (77.9%) were mothers. Around half of the fathers (51.3%) and mothers  
169 (45.1%) had completed secondary education.

170  
171 The frequency of ECOHIS responses (%) at baseline and follow-up examinations are displayed in  
172 Table 2. At baseline, ‘difficulty pronouncing any words’ (56.6%), ‘pain in the teeth or mouth’  
173 (54%), and ‘had difficulty eating’ (54%) were the most frequently reported items in the child  
174 impact section. Regarding the family impact section, the items of ‘feeling guilty’ (57.5%) and  
175 ‘upset’ (55.8%) were the most frequently reported regarding parental distress. After SDF treatment,  
176 there was a higher proportion (66.4%) of the item of ‘feeling guilty’ compared with that reported  
177 at the baseline examination (p=0.044, McNemar-Bowker test). For other items, no differences  
178 were found between the distribution of ECOHIS responses before and after SDF treatment  
179 (p>0.05).

180  
181 After six months, the mean of the caries arrest rates was 46.4%. No significant differences were  
182 found in the changes of C-ECOHIS scores between children with arrested caries and those with  
183 active caries (p=0.736, Mann-Whitney U test). Some parents (23%) had brought their children to

184 visit their own dentists during the six months. No significant differences were found between the  
185 C-ECOHIS scores regarding the dental visit experience ( $p=0.735$ , Mann-Whitney U test).

186  
187 Table 3 displays the mean (SD) of the overall C-ECOHIS scores at baseline and follow-up, which  
188 are 7.4(6.6) and 7.8(6.4), respectively. The mean changes of the C-ECOHIS score were not  
189 normally distributed ( $p=0.001$ , Shapiro-Wilk normality test). The results of the Wilcoxon Signed  
190 Ranks Test indicated that no significant differences were found between the changes of the overall  
191 C-ECOHIS ( $p=0.301$ ) and the child impact section's C-ECOHIS scores ( $p= 0.831$ ). Therefore,  
192 multiple logistic regression analysis was not further performed. However, in the section regarding  
193 parent impact, a negative change of the C-ECOHIS scores was found ( $p=0.014$ , Wilcoxon Signed  
194 Ranks Test). The effect size was small (0.28). In the parent impact section, a significantly negative  
195 change was observed only in the domain of 'parent distress' ( $p=0.010$ , Wilcoxon Signed Ranks  
196 Test), whereas no changes were found in the domain of 'family function ( $p=0.060$ , Wilcoxon  
197 Signed Ranks Test).

198  
199 Table 4 displays the number and percentage of the children and families who had positive, zero or  
200 negative impacts on OHRQoL following SDF therapy. Multiple logistic regression analysis on the  
201 section of parent impact was performed. All potential variables, namely sex, the relationship of the  
202 respondent to a child, the father's and mother's education levels, caries involving the upper  
203 anterior teeth, previous dental experience, the caries arrest rate, the dmft, the modified pufa and  
204 the VPI score, were also included in the base model. The results of the final model indicated that  
205 the dmft score was the only significant variable associated with the parent impact, whereas the  
206 other factors were not. Children with higher dmft scores had a higher chance of having negative

207 impacts on their families after receiving SDF treatment at six months (OR=1.12, 95% CI:1.01-  
208 1.25, p=0.035).

209

## 210 **Discussion**

211 SDF treatment has recently been regarded as an evidence-based effective measure for caries  
212 management for children and those with special needs [19]. Several clinical trials and systematic  
213 reviews reported the positive clinical outcomes on caries prevention and caries arrest [5, 20].  
214 Although SDF has several advantages, such as effectiveness, ease of use and the fact that it is safe  
215 [6, 8], the known side effects of black staining on carious lesions may hinder the adoption of SDF  
216 treatment [21]. Psycho-social impact cannot be determined by using clinical parameters alone.  
217 Information regarding changes in quality of life after joining a community-based oral health  
218 program is limited. Based on our search in PubMed on 13th September 2018, the present study is  
219 the first study investigating the impacts of non-invasive treatment with SDF treatment on the  
220 OHRQoL of preschool children in the school-based setting. This information allows oral health  
221 professionals to choose the appropriate care and treatment when implementing school oral health  
222 programs.

223

224 Our results indicated that the overall OHRQoL of preschool children had been unchanged or  
225 stabilized after non-invasive treatment with SDF at the six-month follow-up examinations. This  
226 might be explained in various ways. First, the baseline or pre-treatment ECOHIS scores were  
227 relatively low (seven out of 52). In other words, a low level of need for any changes existed.  
228 Despite having untreated decay teeth, a majority of the children (83.2%%) seldom or never had  
229 dental pain experience prior to SDF treatment. Compared with the previous study, the pre-

230 treatment ECOHIS scores of children who had sought dental treatment in clinics were higher (13  
231 out of 52) [19]. As previously alluded to, the impacts of ECC on OHRQoL were low in the study  
232 population; therefore, the effects or consequences of any treatment may be subtle to detect.  
233 Furthermore, it should be noted that the results of SDF treatment on children's OHRQoL were  
234 based on the school-based setting without parental involvement. Patient communication and  
235 empathy may affect clinical outcomes and quality of life [22]. In other settings, where a dentist-  
236 child-parent relationship is established, or where there is a high level of dental treatment need, the  
237 impact of SDF treatment on OHRQoL of children may be different.

238  
239 The parental acceptance of black staining was reported as the most-cited obstacle to adopting SDF  
240 treatment [21]. Contradictorily, the present study revealed that SDF treatment had no significant  
241 impact on child psychology, self-image and social interaction. Similar findings were found that  
242 dental aesthetic issues did not influence the self-confidence of the preschool children [23]. This  
243 may be explained by the fact that body image awareness had not fully developed at their very  
244 young ages. Despite the dark staining on carious lesions, studies revealed that the parental  
245 impression of SDF application was favorable compared with advanced pharmacological  
246 approaches involving conscious sedation or general anesthesia [24, 25]. When choosing caries  
247 management methods, dental esthetics may not be a priority for their young children.

248  
249 Interestingly, the impact of SDF treatment is more remarkable on parental distress, particularly in  
250 the item of 'felt guilty'. Presumably, some existing carious lesions, that had been unnoticeable,  
251 became more apparent after SDF application. Thus, parents may acknowledge the unfavorable oral  
252 health statuses of their children late, which leads to higher levels of emotional distress. The present

253 study found that a negative impact of SDF on parent distress was significantly related to higher  
254 dmft scores. An epidemiological survey also reported that parents often felt guilty with the  
255 increased severity of ECC in their children [26]. Care must be taken to parents whose children  
256 have multiple decayed teeth, as they may tend to have higher levels of distress following SDF  
257 treatment. The parent-child relationship is a complex and dynamic interaction. Most dental  
258 research focused on the relationship between ECC and socioeconomic factors [27], whereas less  
259 is known about parental perceptions toward child oral health. Although ‘felt guilty’ is thought to  
260 be one of the negative consequences of SDF treatment, it, in fact, may positively help to change  
261 behaviors. Parents of the SDF-treated children with increased levels of guilt may be more strongly  
262 motivated to change. Possibly, dental professionals may take this opportunity to reinforce proper  
263 oral care practices for children.

264

265 The present study had several strengths, including a high response rate (89%), high retention rates  
266 (100%) and a sufficient sample size following the sample size estimation. The distribution of  
267 children’s sex and demographic background were as estimated, representing kindergarten children  
268 in Hong Kong. Nevertheless, the limitations of the present study should also be addressed. Due to  
269 the ethical issue, the so-called baseline-controlled study was designed, in which children’s  
270 OHRQoL after SDF treatment was compared with their baseline statuses. Thus, possible bias  
271 would occur due to a lack of blinding and randomization. In addition, the present study was  
272 conducted among Chinese dyads (preschool children and their parents). These results may not be  
273 generalizable to other ethnic populations or to other age groups with different cultures and different  
274 caries severity levels. It should be noted that the present conclusion was derived from the short-

275 term results (six months). Thus, long-term prospective studies are required to confirm or refute  
276 these findings.

277

## 278 **Conclusions**

279 In summary, the difference of C-ECOHIS scores between pre- and post-SDF treatment are not  
280 significant, indicating that the overall OHRQoL level of preschool children is not affected  
281 following SDF therapy at six months. However, the subgroup analysis revealed that the impact of  
282 SDF treatment on parental side is remarkable. Parents whose children have higher caries  
283 experience are more likely to have increased levels of parental distress following SDF treatment.

284

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1 Table 1 Demographic characteristics of children with dental caries and their oral health status (n  
 2 = 113)

<b>Parent and child characteristics</b>	<b>Frequency</b>	<b>Percentage</b>
<b>Sex</b>		
Male	54	47.8
Female	59	52.2
<b>Relationship of respondent to the child</b>		
Mother	88	77.9
Other family member	25	22.1
<b>Mother's education level</b>		
Up to junior secondary school	34	30.1
Secondary school	51	45.1
Post secondary school/ University	28	24.8
<b>Father's education level</b>		
Up to junior secondary school	30	26.5
Secondary school	58	51.3
Post secondary school/ University	25	22.1
<b>Dental caries in upper anterior teeth</b>		
Yes	98	86.7
No	15	13.3
	<b>Mean</b>	<b>SD</b>
Caries experience (dmft index)	4.9	3.8
Consequence of untreated caries (modified pufa)	0.2	0.8
Visible plaque index (VPI)	0.47	0.19

3

4

5 Table 2 Frequency of ECOHIS response (%) at baseline and follow-up examination (n=113)

6

Items	Baseline					6-month follow-up					p-value <sup>c</sup>
	Never	Hardly ever	Occasion-ally	Often	Very often	Never	Hardly ever	Occasion-ally	Often	Very often	
<b>Child impact section<sup>a</sup></b>											
<b>Symptom</b>											
a) had pain in the teeth, mouth or jaws?	46.0	37.2	13.3	2.7	0.9	45.1	34.5	19.5	0.9	0.0	0.869
<b>Function</b>											
b) had difficulty drinking beverages?	50.4	40.7	8.8	0.0	0.0	54.9	33.6	10.6	0.9	0.0	0.444
c) had difficulty eating some foods?	46.0	38.1	15.0	0.9	0.0	54.0	37.2	7.1	0.9	0.9	0.077
d) had difficulty pronouncing any words?	43.4	34.5	18.6	2.7	0.9	49.6	33.6	14.2	1.8	0.9	0.100
e) missed school?	75.2	23.0	1.8	0.0	0.0	77.9	20.4	1.8	0.0	0.0	0.942
<b>Child psychology</b>											
f) had trouble sleeping?	63.7	31.9	4.4	0.0	0.0	69.9	25.7	4.4	0.0	0.0	0.399
g) been irritable or frustrated?	58.4	37.2	3.5	0.9	0.0	61.1	30.1	8.0	0.9	0.0	0.343
<b>Social interaction</b>											
h) avoided smiling or laughing?	69.0	26.5	4.4	0.0	0.0	66.4	30.1	2.7	0.9	0.0	0.886
i) avoided talking?	71.7	26.5	1.8	0.0	0.0	71.7	24.8	3.5	0.0	0.0	0.545
<b>Parent impact section<sup>b</sup></b>											
<b>Parent distress</b>											
j) been upset?	44.2	35.4	15.9	3.5	0.9	38.9	30.1	20.4	8.8	1.8	0.156
k) felt guilty?	42.5	36.3	15.0	3.5	2.7	33.6	31.9	23.9	8.8	1.8	<b>0.044</b>
<b>Family function</b>											
l) had to take hours or days off work?	61.1	31.0	6.2	0.9	0.9	54.9	32.7	12.4	0.0	0.0	0.470
m) affected the family's economic situation?	61.1	31.9	5.3	0.9	0.9	49.6	37.2	9.7	2.7	0.9	0.054

7 <sup>a</sup> How often has your child ..... because of dental problems or the need for dental treatments?

8 <sup>b</sup> How often have you or another family member ..... because of your child's dental problems or dental  
9 treatments?

10 <sup>c</sup> McNemar-Bowker test

11 Table 3 Total and individual domain of the C-ECOHIS score before and after SDF therapy  
 12 (n=113)

	Mean(SD) Baseline (T0)	Mean(SD) Follow up (T1)	Mean (SD) Difference (T0-T1)	Effect size	p-value <sup>a</sup>
<b>Total score</b>	7.4(6.6)	7.8(6.4)	-0.5(6.0)	-0.08	0.301
<b>Child impact</b>	4.7(4.3)	4.4(4.1)	0.3(4.2)	0.07	0.831
Symptoms	0.8(0.9)	0.8(0.8)	0.0(0.8)	0.0	0.822
Function	2.4(2.1)	2.1(2.1)	0.3(2.1)	0.14	0.172
Child psychology	0.9(1.1)	0.8(1.1)	0.0(1.2)	0.0	0.816
Social interaction	0.7(1.0)	0.7(1.1)	0.0(1.2)	0.0	0.979
<b>Parent impact</b>	2.7(2.9)	3.4(3.1)	-0.8(2.9)	-0.28	<b>0.014</b>
Parent distress	1.7(1.8)	2.2(2.0)	-0.5(1.9)	-0.26	<b>0.010</b>
Family function	1.0(1.4)	1.3(1.4)	-0.3(1.4)	-0.21	0.060

13 <sup>a</sup> Wilcoxon Signed Ranks Test

14

15 Table 4 Number (%) of the children who had changes (positive or negative) or had no changes of the C-  
 16 ECOHIS scores in total and in each domain

	<b>Positive change<sup>a</sup></b> <b>no. (%)</b>	<b>No change<sup>b</sup></b> <b>no.(%)</b>	<b>Negative change<sup>c</sup></b> <b>no.(%)</b>
<b>Total score</b>	45(39.8)	20(17.7)	48(42.5)
<b>Child impact</b>	46(40.7)	21(18.6)	46(40.7)
Symptoms	23(20.4)	67(59.3)	23(20.4)
Function	46(40.7)	36(31.9)	31(27.4)
Child psychology	26(23.0)	63(55.8)	24(21.2)
Social interaction	19(16.8)	71(62.8)	23(20.4)
<b>Parent impact</b>	27(23.9)	35(31.0)	51(45.1)
Parent distress	26(23.0)	42(37.2)	45(39.8)
Family function	19(16.8)	61(54.0)	33(29.2)

17 <sup>a</sup> Positive change = C-ECOHIS score of the follow up was lower than that of the baseline (positive impact  
 18 on OHRQoL)

19 <sup>b</sup> No change = C-ECOHIS score of the follow up was equal to that of the baseline

20 <sup>c</sup> Negative change = C-ECOHIS score of the follow up was higher than that of the baseline (negative  
 21 impact on OHRQoL)

22