ORAL HEALTH RELATED QUALITY OF LIFE OF PRESCHOOL CHILDREN PARTICIPATING IN A RANDOMIZED CLINICAL TRIAL OF DIFFERENT TREATMENT REGIMENS OF SILVER DIAMINE FLUORIDE

by

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ABSTRACT

Objective: To investigate the oral health-related quality of life (OHRQoL) of young children in a randomized clinical trial of silver diamine fluoride (SDF) with 5% fluoride varnish (FV) to manage early childhood caries (ECC).

Methods: Children < 72 months of age with active dentinal caries lesions (ICDAS 5 or 6) in primary teeth received two applications of 38% SDF and 5% FV as part of a randomized clinical trial testing three different frequency regimes (1, 4 and 6 months apart). The early childhood oral health impact scale (ECOHIS) questionnaire was completed at each study visit. Statistical analyses included descriptive and parametric methods. A p-value ≤ 0.05 was statistically significant.

Results: Eighty-two children (58.5% male) were recruited with a mean age of 44.3±14.2 months. Statistically significant improvement in total ECOHIS scores for all children was observed following treatment (baseline mean scores 4.64±4.74 vs. second visit score 3.26±4.36 vs. third visit score 3.25±3.77, p=0.006 and p=0.01, respectively). The following domains showed the most improvement with SDF treatment: parental distress, and family function. No statistically significant difference in ECOHIS scores were observed between the three frequency groups at baseline, second visit, and final visit (p=0.24, p=0.71 and 0.26)

Conclusions: Children exhibited improved overall OHRQoL following two applications of 38% SDF and 5% FV, although there were no significant differences observed between the treatment groups. The results from our study demonstrate that SDF is a suitable non-restorative caries management option for children with ECC as it is associated with improved oral health related quality of life.

Table of Contents

INTRODUCTION

Early Childhood caries (ECC) is the most common dental problem in the pediatric dental population. The American Academy of Pediatric Dentistry (AAPD) defines ECC as one or more decayed, missing or filled tooth surfaces in any primary tooth in a child under six.[1] ECC impacts dental health and overall health and well-being.[2] Unfortunately, many children with severe ECC (S-ECC) are subject to dental rehabilitation under general anesthesia, which is considered the most frequent hospital day surgery procedure for preschoolers in Canada.[3] It has been reported that Manitoba has some of the highest rates of day surgery to treat ECC in Canada.[4]

Silver diamine fluoride (SDF) is a topical agent that has been shown to be effective in arresting cavitated enamel and dental carious lesion in children.[5–7] SDF was first approved for use in Canada as a non-restorative approach to managing caries in 2017 as Advantage Arrest™ 38% SDF Since that time, there has been gradual acceptance by the dental profession in Canada. A recent Canadian study reported arrest rates of 96.2% following two applications of SDF.[8] Studies have shown no toxic effects on serum after using SDF.[9] The major disadvantage of using SDF is the dark discolouration that appears on the caries affected areas of the teeth.[10–12] The penetration of the silver ions from SDF leaves a permanent black stain on the caries-affected tooth structure.[9] Although SDF is a minimally invasive dental procedure with promising results for the dentist, it is important to understand whether this treatment has any influence on oral health related quality of life (OHRQoL).

According to the definition of OHRQoL, it is a multidimensional concept that includes subjective evaluation of the individual's oral health, functional well-being, sense of self, and how they feel about the care they receive. [13,14]

INTRODUCTION

OHRQoL in children has been studied before and after using various restorative materials by Elheeny & Abdelmotelb, Paula et al., and Araujo et al.[15–17] Pre-and post-treatment changes in OHRQoL of children after dental rehabilitation under general anesthesia have been studied by Jankauskiene & Narbutaite, Gaynor & Thomson and Grant et al.[3,18,19]

The Early Childhood Oral Health Impact Scale (ECOHIS) is a widely accepted and the most validated tool for assessing the OHRQoL in preschool children.[20] Studies by Duangthip et al, Rodrigues et al, Sihra et al and Jiang et al have all found that OHRQoL remains unaffected or is improved after SDF application to arrest caries in preschool children.[8,10,21,22]

To our knowledge, no studies have compared the OHRQoL of children receiving SDF treatment at different frequency regimens. The aim of the study was to investigate changes in OHRQoL of children receiving two applications of 38% SDF followed by 5% sodium fluoride varnish (NaFV) according to three different frequency regimens and to compare OHRQoL between the treatment groups.

METHODS

This study was part of a randomized control trial (RCT) on the use of SDF to arrest cavitated caries lesions in primary teeth at three different application regimens (1-month group, 4-month group and 6-month group), which included measures of OHRQoL at each study visit.

Ethics approval for this study was obtained from the University of Manitoba's Biomedical Research Board. The interested parents and caregivers were contacted by the research staff to inform them of the study objectives, eligibility criteria, and procedures. Study visits took place at one of the community-based dental clinics or the Children's Hospital Research Institute of Manitoba (CHRIM). A total of 84 participants were recruited initially from community clinics in Winnipeg (Access Downtown, Mount Carmel Clinic, and SMILE plus) between October 2019 and June 2020. The patients were randomly allotted to three different groups with N=28 of each group initially but two of the participants left the study at different stages and hence were excluded from the study. The final participant size was 82 and the randomized allotment of patients in 1-month group, 4-month group and 6-month group was N=28, 27 and 27 respectively.

Inclusion Criteria: 1) Child who were < 72 months of age with ECC with active caries lesions; 2) Child living in the Winnipeg region or within a one-hour drive of Winnipeg to minimize the risk of loss-to-follow-up; and 3**)** Child had ≥ 1primary tooth with caries that was eligible to receive SDF. Eligible primary teeth had: a) soft cavitated caries lesions extending into dentin [ICDAS 5 or 6]; b) the cavitated lesions that allowed for direct application of SDF. Teeth that met any of the PUFA criteria (i.e., spontaneous pain due to caries, pulp exposure, mobility, signs of pulpal infection such as abscess, fistula, or swelling) were excluded. However, a child was still eligible even if they had at least one tooth that met PUFA criteria, but other eligible teeth with caries did not.

METHODS

Exclusion Criteria: 1) Child who had allergy or sensitivity to silver or other heavy metal ions; 2) Child who had hereditary generalized developmental defects of teeth (e.g., Amelogenesis Imperfecta, Dentinogenesis Imperfecta); 3) Child had severe medical problems that limit participation; 4) Child required immediate rehabilitation under GA because of severe infection or pain; 5) Antibiotic use within the last 2 weeks (because there was a separate objective to assess the oral microbiome).

Children were randomized to receive two applications of SDF followed by 5% NaFV according to three different frequency regimens. Those randomized to the 4-month group received two applications of SDF four months apart, which is the protocol frequency adopted by the Winnipeg Regional Health Authority's (WRHA) Clinical Guideline on SDF.[23] The 6-month group received two applications of SDF six months apart (ADA recommendation). The 1-month group received two applications of SDF one month apart, which is proposed in the AAPD's clinical practice guideline [which recommends monitoring 2-4 weeks (i.e. 1 month) after first application of SDF and consider reapplication at that point] and is also suggested by Horst et al.[24–26] This RCT did not include a control group to receive fluoride varnish as this is considered unethical and substandard care for cavitated caries lesions.

Arrest of caries lesion was determined by assessing clinical hardness, colour change, and size of lesions at baseline, at second visit, and at the final study visit. Children were recruited over eight months. Performance of block randomization by site was done to achieve equal proportions in each group by clinic site of recruitment. Study visits happened at the CHRIM or at community-based dental clinics.

Following informed consent, the child's parent/caregiver completed a short questionnaire (via interview) on general and dental health, oral hygiene, dietary intake of sugars, and family

demographics along with the Early Childhood Oral Health Impact Scale (ECOHIS) to assess OHRQoL. Children lost to follow-up were excluded from our assessment for OHRQoL (two lost to follow-up). SDF was applied on the day of recruitment to cavitated lesions involving dentin followed by 5% NaFV. During this second visit, caries lesions treated with SDF at baseline was assessed to see if caries is arrested as determined through measures of hardness, colour change, and size. At this same visit a second application of SDF was done to these initially treated caries lesions followed by 5% NaFV. The child's parent/caregiver completed a short questionnaire (via interview) on Early Childhood Oral Health Impact Scale (ECOHIS) to assess OHRQoL in this second visit. Children and parents returned for the third and final study visit according to the schedule of their randomized grouping. Parents/caregivers completed a follow-up questionnaire like the baseline tool and the ECOHIS. Caries lesions previously treated by SDF was assessed for clinical hardness, colour change and size to determine if they had been arrested.

ECOHIS is a validated questionnaire which uses caregiver responses to assess the OHRQoL in preschool children and their families.[27] This was administered by an interview in this study. ECOHIS consists of 13 questions and is divided into 2 sections; the child impacts section (CIS) which has 4 domains (symptoms, function, psychological, self-image/social interaction) and the family impacts section (FIS) which has 2 domains (parent distress, family function).[27] Responses were coded according to ECOHIS protocol: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = often, 4 = very often, 5 = don't know.(27) Total scores were calculated as a simple sum of the responses. The CIS score can range from 0 to 36 and the FIS from 0 to 16, with the total possible score ranging from 0 to 52. A higher score indicates a greater impact and a lower OHRQoL , and a lower score indicates a lesser impact and a higher OHRQoL.[27]

METHODS

Data were entered into a REDCap database followed by saving on the secure server at CHRIM. Statistical analyses included descriptive statistics (frequencies, means, standard deviations (SD)) and Parametric Tests (Paired T-test, one way analysis of variance (ANOVA), and one way analysis of covariance (ANCOVA)) were carried out on NCSS version 22.0.3. A p value ≤ 0.05 was significant.

Results

A total of 82 children (58.5% male) with a mean age of 44.3±14.2 months were recruited. Table 1 presents the characteristics of the recruited children with a mean dmft score of 6.7±4.5.

The baseline scores across all the groups for total ECOHIS was 4.64±4.74, with an overall FIS of 3.13 ±3.01 and overall CIS of 1.60 ± 3.07 (Table 2).

Table 2 presents the mean total ECOHIS scores along with mean CIS and FIS scores for all children and within each of the three groups. Paired t-test analysis revealed significant improvements in the total ECOHIS score (baseline mean scores 4.64 ± 4.74 vs. third visit mean scores 3.25 ± 3.77, p=0.01) and FIS score (baseline mean scores 3.13 ± 3.01 vs. third visit mean scores 1.78 ± 2.20, p=0.001) for all children. However, no significant change in the mean CIS score was observed among all the children (p=0.97).

Paired t-test analyses was performed to compare within group differences in total ECOHIS and section scores (Table 3). Analyzing the data for each group showed a significant improvement in the total ECOHIS scores within the 1-month group (baseline mean scores 5.71 ± 4.75 vs. third visit mean scores 2.89 ± 2.92, p=0.004), but not among the 4-month and the 6-month groups (p=0.24 and p=0.69, respectively).

Significant improvement in CIS scores was observed among children in the 1-month group (baseline mean scores 2.25±3.09 vs. third visit mean scores 0.96 ± 1.85, p=0.04). However, no significant improvements were found in the CIS scores in either the 4-month or 6-month group when baseline visits were compared to third visit (p=0.43 and 0.35, respectively). Meanwhile, significant improvement in FIS scores were observed among all of the groups (p=0.02, 0.01, and 0.03, respectively) (Table 3). Overall, while the total ECOHIS scores and sections improved in the

1-month group, only the FIS changed over time in two of the study groups, namely the 4-month and 6-month group.

Comparisons between the baseline and third visit were made for three individual domains (Child psychology, parental distress, and family function) within the total study population (Table 3). No significant differences between baseline and final visit for the remaining domains was observed (data not reported). Among all children participating and completing the study significant improvements were found in two domains, the parental distress (baseline mean scores 2.04 ± 2.47 vs. third visit mean scores 1.19 ± 1.84, p=0.002) and family function domains (baseline mean scores 1.01 ± 1.55 vs. third visit mean scores 0.48 ± 0.98, p=0.005). However, no significant improvement in the overall study population was observed in the child psychology domain (baseline mean scores 0.35± 1.10 vs. third visit mean score 0.24±0.91, p=0.52). Within each group, the family function domain in 4-month group showed significant improvement (baseline mean scores 0.77 ± 1.73 vs. third visit mean scores 0.07 ± 0.26, p=0.04) and in 1-month group parental distress domain showed significant improvement (baseline mean scores 2.21 ± 2.31 vs. third visit mean scores 1.07 ± 1.90, p=0.02).

Lastly, comparisons were made between the groups. Results from one-way ANOVA revealed that there were no statistically significant differences in total ECOHIS scores between all three groups (1-month group, 4-month group, and 6-month group) at baseline, 2nd visit, and 3rd visit (Table 4). Similarly, no significant differences were observed for the CIS and FIS scores between groups at any stage of the study. The results of one-way ANCOVA revealed that there were no significant differences when comparisons were done between the 4-month group vs. 6-month group, 4-month group vs. 1-month group, and the 6-month group vs. 1-month group for total ECOHIS, FIS, and CIS scores (Table 5).

Discussion

This study investigated the OHRQoL of children with ECC randomized to three different treatment frequencies for two applications of SDF followed by 5% NaFV. Overall, significant improvement in OHRQoL was observed from the time of enrollment through to the completion of the study. Specifically, we observed an overall improvement of ECOHIS scores in the range of 30% in this urban Canadian cohort, which is in contrast to the findings by Duangthip et al., Jiang et al., and Ruff et al. Those authors reported that overall OHRQoL was not affected after SDF application. Meanwhile, OHRQoL findings from this present RCT are consistent with the findings by Altner et al. and Renugalakshmi et al, who found that SDF application significantly improved OHRQoL.[10,22,28–30]

Our study found that the overall CIS scores were not affected for all the children. This is consistent with studies carried out in Hong Kong by Duangthip et al. on preschool children aged 4-5 years old and Jiang et al. who carried out a study on preschool children aged 3-4 years but in contrast with Renugalakshmi et al. as they reported improvements in CIS scores of approximately 64.3%.[10,22,29]

Our study also demonstrated statistically significant improvement in the FIS for all children at the second and third visits compared to the baseline visit. This finding is consistent with findings by Renugalakshmi et al. who reported improvement in FIS scores after SDF application, but in contrast with findings by Altner et al. and Jiang et al. who reported no improvement in FIS after SDF application.[22,28,29] The FIS focuses on four questions, including parental guilt and stress. The reduction in FIS that we observed may suggest that parents were accepting of SDF, which is again consistent with the finding by Sihra et al., Crystal et al., and Kyoon-Achan et al. who reported acceptance of SDF treatment by parents.[8,31,32]

Discussion

Under the FIS for all children, we found that the feeling of guilt after SDF application decreased compared to a prior study of SDF and 5% NaFV conducted by our team prior to COVID-19.[8] Part of the reason behind this is that during COVID-19, health facilities were open for urgent and emergent care only, restricting access to care. This in turn helped change parents' perspectives towards SDF as a form of non-restorative treatment of caries. Having a way to manage their child's caries during the pandemic with SDF might have also reduced their stress levels. Given the challenges in accessing regular dental care during the pandemic, it is appearing that parents view SDF as an acceptable treatment modality despite its side effect. Despite the openness to SDF, the black discolouration from SDF becomes a potential barrier to its use.[32,33] This side effect makes it essential to know the OHRQoL after SDF application. Since parents are the primary decision-makers for preschoolers, it is vital to understand their acceptance of SDF treatment.[31]

Among the 1-month group, we not only observed a statistically significant improvement in the total ECOHIS score but also with the CIS and FIS scores when baseline visit values were compared to those at visit 3 ($p=0.004$,0.04 and 0.02). Although the mean total ECHOIS scores for the 4-month and 6-month groups showed improvement of approximately 25% and 8% when visit 3 was compared to the baseline visit, scores were not significantly different.

Our study was a part of a larger comprehensive RCT of SDF in children with ECC in which caries arrest rates were also measured. The findings of the larger study revealed significant differences in arrest rates between treatment groups with the 6-month group having lower arrest rates than the 4-month and 1-month groups (59.3% vs. 89.2% vs. 88.5%). Similar to these arrest rates, we also observed more significant improvement in total ECOHIS, CIS, FIS, and parental distress domain scores in the 1-month group when baseline visits were compared to the third visit's mean scores within each group.

Discussion

To our knowledge, this is the first RCT investigating differences in OHRQoL between different groups on different timing intervals between SDF reapplications. We did not find any statistical difference in OHRQoL between these groups. However, it should be noted that the RCT's original calculated sample size was not based upon the OHRQoL outcomes, so we may be underpowered to detect changes in total ECOHIS and section scores.

The prevalence of ECC has been significantly high even in developed countries like the USA and Canada.[34,35] There has been an unequal distribution of ECC among the population, with the urban population disproportionately affected by it. Every one in six preschoolers in the USA is found to have caries.[34,35] To deliver dental treatment to preschool children, especially those who are uncooperative, the dentist is left with very limited treatment modalities, which results in a high cost of treatment.[36] General Anesthesia (GA) is the most common treatment modality for treating ECC in preschool children.[3,4,36] However, due to the high incidence of ECC, there has been a significant increase in the wait time for GA to complete their dental treatment. Additionally, the recent pandemic of COVID-19 has overloaded the already exhaustive healthcare system.[37] This has further lengthened the wait times for dental treatment under GA.

A study conducted by Grant et al. at our centre, assessed changes in OHRQoL in preschoolers before and after dental treatment under GA reported statistically significant improvement in mean ECHOIS scores (6.3 ± 5.3 vs. 3.4 ± 2.9), which is comparable end of study final ECOHIS scores found in this present study (4.6 ± 4.7 and 3.3 ± 3.8) for all children.[3] This suggests that SDF may produce similar EOCHIS scores as surgical management of caries. However, further research is needed to confirm whether SDF has similar improvement in OHRQoL as compared to children receiving dental treatment under GA.

Discussion

This study has some strengths. We overcame several shortcomings of the pilot study completed by Sihra et al. by conducting a RCT with an increased sample size.[8] Our study was able to compare both follow-up visit data to the baseline visit, which was not done in the pilot study. Further strengths of our study were that we had a high acceptance to response and retention rate of participants throughout the COVID-19 pandemic. A limitation of the study was that our sample size was moderate. The study could have been more comprehensive if high income group had participated in our study.

This study can inform general and pediatric dentists about OHRQoL after SDF application. The study was carried out during the COVID-19 pandemic and demonstrates how SDF can be an effective tool in caries prevention. SDF can be utilized in a vast array of situations due to its low cost, simple application, and minimal requirement for special equipment. Patients who may not otherwise receive dental care due to financial or geographic barriers could benefit significantly from SDF treatment. Furthermore, SDF may be used as a definitive treatment in situations where the tooth is expected to exfoliate shortly, and the loss of tooth structure does not severely compromise function.

Scully et al. noted that there has been an increase in the use of SDF in recent times among both general and pediatric dentist.[38] Moreover, in the year 2021, World Health Organization (WHO) included SDF as one of the most efficacious, safe and cost-effective medicines for meeting the most critical needs in a health system for adults and children.[39] Thus, consideration should be given to routinely employing SDF as an adjunct to surgical treatment to slow or halt disease progression while children wait for GA.

By making SDF a standard of care in one's practice we can reduce extractions and pulp treatment of deciduous teeth and increase, children's overall quality of life. SDF can also be used to manage

Discussion

ECC until the child's age and cooperation allows for conventional treatment in a clinical setting. This would, thereby reduce the dependence on GA, alleviate the risk of sedation, and decrease strain on the healthcare system.

Conclusion

Based on the findings of our study, the following conclusions have been made:

1. Two applications of SDF followed by 5% NaFV application appears to improve OHRQoL in young children with ECC.
2. Parental distress significantly improved for children participating in this SDF RCT.
3. There are no significant differences in OHRQoL irrespective of the timing interval between SDF applications, but this may also result from being underpowered.
4. Further research is needed with a larger sample size to assess the various timings of application and its impact on OHRQoL.

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TABLES

Table 1: Baseline characteristics and oral health status of recruited participants

Variable	OVERALL TOTAL (82) N (%)	4 MONTHS APART (27) N (%)	6 MONTHS APART (27) N (%)	1 MONTH APART (28) N (%)
Mean age ± SD (months)	44.3 ± 14.2	40.0 ± 12.4	49.4 ± 14.1	43.7 ± 15.0
Sex				
Male	48 (58.5)	12 (44.4)	17 (63.0)	19 (67.9)
Female	34 (41.5)	15 (55.6)	10 (37.0)	9 (32.1)
Dental Insurance				
Yes	57 (69.5)	19 (70.3)	19 (70.3)	19 (67.8)
No	23 (28.0)	8 (29.6)	7 (25.9)	8 (28.5)
Unsure	2 (2.4)	0 (0.0)	1 (3.7)	1 (3.5)
Frequency of tooth brushing				
Twice daily	50 (60.9)	16 (59.2)	16 (59.2)	18 (64.2)
Once daily	24 (29.2)	8 (29.6)	10 (37.0)	6 (21.4)
Every other day	6 (7.32)	2 (7.4)	0 (0.0)	4 (14.2)
Seldom/rarely	2 (2.4)	1 (3.7)	1 (3.7)	0 (0.0)
Never	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Uses fluoridated toothpaste				
Yes	66 (80.4)	21 (77.7)	21 (77.7)	24 (85.7)
No	5 (6.1)	1 (3.7)	2 (7.4)	2 (7.1)
Unsure	11 (13.4)	5 (18.5)	4 (14.8)	2 (7.1)
Baseline dmft, mean ± SD	6.7 ± 4.5	6.5 ± 4.7	6.2 ± 3.8	7.4 ± 5.0

TABLES

Table 2: Summary of comparison for baseline and follow-up ECOHIS scores

Groups	Total ECOHIS Score Mean ±SD	P Value for Baseline Visit vs. Third Visit	Child Impact Section Total (CIS) Mean ±SD	P Value for Baseline Visit vs. Third Visit	Family Impact Section Total (FIS) Mean ±SD	P Value for Baseline Visit vs. Third Visit
All groups **BASELINE VISIT (N= 82)** **SECOND VISIT (N= 82)** **THIRD VISIT (N= 82)**	**4.64 ±4.74** **3.26 ±4.36** **3.25 ±3.77**	**0.01**	**1.60 ±3.07** **1.13 ±2.30** **1.62 ±2.84**	**0.97**	**3.13 ±3.01** **2.18 ±2.92** **1.78 ±2.20**	**0.001**
4-Months Interval Group **BASELINE VISIT (N= 27)** **SECOND VISIT (N= 27)** **THIRD VISIT (N= 27)**	**3.55 ±3.26** **2.70 ±4.72** **2.66 ±3.57**	**0.24**	**0.96 ±1.50** **1.03 ±2.78** **1.33 ±2.09**	**0.43**	**2.59 ±2.51** **1.62 ±2.64** **1.25 ±1.74**	**0.01**
6-Months Interval Group **BASELINE VISIT (N= 27)** **SECOND VISIT (N= 27)** **THIRD VISIT (N= 27)**	**4.62 ±5.79** **3.59 ±4.71** **4.22 ±4.61**	**0.69**	**1.59 ±4.03** **1.29 ±2.50** **2.59 ±3.97**	**0.35**	**3.03 ±3.32** **2.29 ±3.06** **1.85 ±2.08**	**0.03**
1-Months Interval Group **BASELINE VISIT (N= 28)** **SECOND VISIT (N= 28)** **THIRD VISIT (N= 28)**	**5.71 ±4.75** **3.50 ±3.70** **2.89 ±2.92**	**0.004**	**2.25 ±3.09** **1.07 ±1.53** **0.96 ±1.85**	**0.04**	**3.53 ±3.06** **2.42 ±2.68** **1.92 ±2.19**	**0.02**

TABLES

Table 3: Paired t-test comparison of ECOHIS and its subgroups for baseline and follow up visits

Groups	T- statistics	CI (95%) of difference		p – value
		Lower Limit	Upper Limit	
All Children				
Total ECOHIS (All groups)				
Visit 3 vs. Baseline visit	-2.63	-2.44	-0.33	0.01
Visit 2 vs. Baseline visit	-2.80	-2.35	-0.39	0.006
Visit 3 vs. Visit 2	-0.02	-0.95	0.92	0.97
Child Impact Section Total (All groups)				
Visit 3 vs. Baseline visit	0.02	-0.86	0.89	0.97
Visit 2 vs. Baseline visit	-1.24	-1.23	0.28	0.21
Visit 3 vs. Visit 2	1.40	-0.20	1.17	0.16
Family impact Section Total (All groups)				
Visit 3 vs. Baseline visit	-4.22	-2.02	-0.72	0.001
Visit 2 vs. Baseline visit	-3.29	-1.50	-0.37	<0.001
Visit 3 vs. Visit 2	-1.41	-1.05	0.17	0.16
Child Psychology Domain (All groups)				
Visit 3 vs. Baseline visit	-0.63	-0.40	0.20	0.52
Parental Distress Domain (All groups)				
Visit 3 vs. Baseline visit	-3.18	-1.38	-0.31	0.002
Family function Domain (All groups)				
Visit 3 vs. Baseline visit	-2.85	-0.89	-0.15	0.005
4-Month Group				
Total ECOHIS (4-month group)				
Visit 3 vs. Baseline visit	-1.18	-2.43	0.65	0.24
Visit 2 vs. Baseline visit	-1.02	-2.56	0.86	0.31
Visit 3 vs. Visit 2	-0.04	-1.85	1.78	0.96
Child Impact Section Total (4-month group)				
Visit 3 vs. Baseline visit	0.79	-0.58	1.32	0.43
Visit 2 vs. Baseline visit	0.11	-1.23	1.38	0.90
Visit 3 vs. Visit 2	0.50	-0.91	1.51	0.62
Family impact Section Total (4-month group)				

TABLES

Visit 3 vs. Baseline visit	-2.69	-2.35	-0.31	0.01
Visit 2 vs. Baseline visit	-1.98	-1.95	0.03	0.06
Visit 3 vs. Visit 2	-0.70	-1.45	0.71	0.48
Child Psychology Domain (4-month group)				
Visit 3 vs. Baseline visit	0.00	-0.21	0.21	1.00
Parental Distress Domain (4-month group)				
Visit 3 vs. Baseline visit	-1.54	-1.41	-1.41	0.16
Family function Domain (4-month group)				
Visit 3 vs. Baseline visit	-2.11	-1.38	-0.02	0.04
6-Month Group				
Total ECOHIS (6-month group)				
Visit 3 vs. Baseline visit	-0.39	-2.54	1.72	0.69
Visit 2 vs. Baseline visit	-1.07	-3.02	0.95	0.29
Visit 3 vs Visit 2	0.67	-1.28	2.54	0.50
Child Impact Section Total (6-month group)				
Visit 3 vs. Baseline visit	0.93	-1.19	3.19	0.35
Visit 2 vs. Baseline visit	-0.37	-1.91	1.32	0.70
Visit 3 vs Visit 2	1.67	-0.29	2.88	0.10
Family impact Section Total (6-month group)				
Visit 3 vs. Baseline visit	-2.26	-2.26	-0.10	0.03
Visit 2 vs. Baseline visit	-1.54	-1.72	0.24	0.13
Visit 3 vs. Visit 2	-0.73	-1.69	0.80	0.47
Child Psychology Domain (6-month group)				
Visit 3 vs. Baseline visit	-0.21	-0.76	0.61	0.82
Parental Distress Domain (6-month group)				
Visit 3 vs. Baseline visit	-1.64	-1.74	0.19	0.11
Family function Domain (6-month group)				
Visit 3 vs. Baseline visit	-1.65	-0.91	0.09	0.10
1-Month Group				
Total ECOHIS (1-month group)				
Visit 3 vs. Baseline visit	-3.14	-4.66	-0.97	0.004
Visit 2 vs. Baseline visit	-2.93	-3.76	-0.66	0.006
Visit 3 vs. Visit 2	-0.95	-1.90	0.69	0.34
Child Impact Section Total (1-month group)				
	-2.15	-2.51	-0.06	0.04

TABLES

Visit 3 vs. Baseline visit Visit 2 vs. Baseline visit Visit 3 vs. visit 2	-2.15 -0.28	-2.30 -0.87	-0.05 0.65	0.04 0.77
Family impact Section Total (1-month group) Visit 3 vs. Baseline visit Visit 2 vs. Baseline visit Visit 3 vs. Visit 2	 -2.40 -2.09 -1.01	 -2.98 -2.19 -1.50	 -0.23 -0.02 0.50	 0.02 0.04 0.31
Child Psychology Domain (1-month group) Visit 3 vs. Baseline visit	 -0.72	 -0.82	 0.39	 0.47
Parental Distress Domain (1-month group) Visit 3 vs. Baseline visit	 -2.34	 -2.14	 -0.14	 0.02
Family function Domain (1-month group) Visit 3 vs. Baseline visit	 -1.25	 -1.22	 0.29	 0.21

**P-Value ≤ 0.05 is Significant

TABLES

Table 4: One-way analysis of variance (ANOVA) comparison of ECOHIS for baseline and follow up visits.

	Baseline visit P-value (DF)	Visit 2 P-value (DF)	Visit 3 P-value (DF)
Family Impact Section Total	0.50 (2)	0.53 (2)	0.89 (2)
Child Impact Section Total	0.30 (2)	0.90 (2)	0.08 (2)
Total ECOHIS	0.24 (2)	0.71 (2)	0.26 (2)

**P-Value ≤ 0.05 is significant

TABLES

Table 5: One-way analysis of covariance (ANCOVA) Comparison of ECOHIS for baseline and follow up visits.

	Visit 3 to baseline visit Adjusted P- Value*	Visit 2 to baseline visit Adjusted P-Value*
Family Impact Section Total		
4-month group vs. 6-month group	0.61	0.77
4-month group vs. 1-month group	0.66	0.88
6-month group vs. 1-month group	0.98	0.94
Child Impact Section Total		
4-month group vs. 6-month group	0.26	0.93
4-month group vs. 1-month group	0.79	0.94
6-month group vs. 1-month group	0.07	0.84
Total ECOHIS		
4-month group vs. 6-month group	0.40	0.91
4-month group vs. 1-month group	0.86	0.94
6-month group vs. 1-month group	0.40	0.80

* Adjusted p-values are computed using the number of comparisons (3) and the adjustment type (Tukey-Kramer). **P-Value $\leq$ 0.05 is significant

TABLES

Supplemental Table 1: Baseline and follow-up ECOHIS scores for all groups

CHILD IMPACT SECTION	**BASELINE VISIT (N= 82) SECOND VISIT (N = 82) THIRD VISIT (N= 82)**						
	Mean ±SD	Never N (%)	Hardly ever N (%)	Occasionally N (%)	Often N (%)	Very Often N (%)	Don't Know N (%)
Child Symptoms: Question one	**0.57 ±1.11** **0.35 ±0.83** **0.53 ±1.02**						
1) Oral/dental pain		59(71.9) 65(79.2) 61(74.3)	9(10.9) 9(10.9) 5(6.0)	9(10.9) 6(7.3) 11(13.4)	1(1.2) 1(1.2) 3(3.6)	3(3.6) 0(0.0) 2(2.4)	1(1.2) 1(1.2) 0(0.0)
Child Functions: Questions two through five	**0.62 ±1.40** **0.48 ±1.21** **0.74 ±1.66**						
2) Difficulty drinking		71(86.5) 74(90.2) 76(92.6)	2(2.4) 4(4.8) 2(2.4)	5(6.0) 3(3.6) 3(3.6)	4(4.8) 1(1.2) 1(1.2)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
3) Difficulty eating		71(86.5) 74(90.2) 68(82.9)	1(1.2) 2(2.4) 3(3.6)	7(8.5) 4(4.8) 6(7.3)	3(3.6) 2(2.4) 4(4.8)	0(0.0) 0(0.0) 1(1.2)	0(0.0) 0(0.0) 0(0.0)
4) Difficulty pronouncing words		81(98.7) 78(95.1) 79(96.3)	1(1.2) 2(2.4) 0(0.0)	0(0.0) 2(2.4) 1(1.2)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 2(2.4)	0(0.0) 0(0.0) 0(0.0)
5) Missed preschool or school		80(97.5) 77(93.9) 77(93.9)	2(2.4) 4(4.8) 2(2.4)	0(0.0) 1(1.2) 2(2.4)	0(0.0) 0(0.0) 1(1.2)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Psychological: Questions six and seven	**0.34 ±1.10** **0.23 ±0.80** **0.24 ±0.91**						
6) Trouble sleeping		74(90.2) 77(93.9) 80(97.5)	5(6.0) 1(1.2) 0(0.0)	2(2.4) 4(4.8) 0(0.0)	0(0.0) 0(0.0) 1(1.2)	1(1.2) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 1(1.2)
7) Irritable or frustrated		74(90.2) 77(93.9) 76(92.6)	4(4.8) 3(3.6) 1(1.2)	2(2.4) 1(1.2) 4(4.8)	1(1.2) 0(0.0) 1(1.2)	1(1.2) 0(0.0) 0(0.0)	0(0.0) 1(1.2) 0(0.0)
Child Self Image/Social Interaction: Questions eight and nine	**0.07 ±0.37** **0.06 ±0.39** **0.09 ±0.53**						
8) Avoid smiling or laughing		80(97.5) 80(97.5) 79(96.3)	1(1.2) 0(0.0) 0(0.0)	0(0.0) 1(1.2) 3(3.6)	1(1.2) 1(1.2) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
9) Avoid talking		80(97.5) 82(97.5) 81(98.7)	2(2.4) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 1(1.2)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Section Total Questions one through nine	**1.60 ±3.07** **1.13 ±2.30** **1.62 ±2.84**						
FAMILY IMPACT SECTION							
Parental Distress: Questions ten and eleven	**2.04 ±2.47** **1.64 ±2.41** **1.19 ±1.84**						
10) Been upset		47(57.3) 58(70.7) 58(70.7)	5(6.0) 0(0.0) 4(4.8)	16(19.5) 14(17.0) 14(17.0)	12(14.6) 6(7.3) 6(7.3)	2(2.4) 4(4.8) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
11) Felt guilt		45(54.8) 51(62.1) 58(70.7)	4(4.8) 6(7.3) 7(8.5)	18(21.9) 12(14.6) 11(13.4)	13(15.8) 9(10.9) 5(6.0)	2(2.4) 4(4.8) 1(1.2)	0(0.0) 0(0.0) 0(0.0)
Family Function: Questions twelve and thirteen	**1.01 ±1.55** **0.47 ±1.04** **0.48 ±0.98**						
12) Time off work		66(80.4) 68(82.9) 69(84.1)	8(9.7) 9(10.9) 4(4.8)	5(6.0) 5(6.0) 9(10.9)	3(3.6) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
13) Financial impact		61(74.3) 70(85.3) 71(86.5)	2(2.4) 5(6.0) 5(6.0)	9(10.9) 6(7.3) 5(6.0)	5(6.0) 1(1.2) 1(1.2)	4(4.8) 0(0.0) 0(0.0)	1(1.2) 0(0.0) 0(0.0)
Family Section Total Questions ten through thirteen	**3.13 ±3.01** **2.18 ±2.92** **1.78 ±2.20**						
Total ECOHIS Score Questions one through thirteen	**4.64 ±4.74** **3.26 ±4.36** **3.25 ±3.77**						

TABLES

Supplemental Table 2: Baseline and follow-up ECOHIS scores for 4-Month group (Regime 1)

CHILD IMPACT SECTION	BASELINE VISIT (N= 27) SECOND VISIT (N = 27) THIRD VISIT (N= 27)						
	Mean ±SD	Never N (%)	Hardly ever N (%)	Occasionally N (%)	Often N (%)	Very Often N (%)	Don't Know N (%)
Child Symptoms: Question one	**0.44 ±1.05** **0.37 ±1.04** **0.55 ±0.89**						
1) Oral/dental pain		20 (74.0) 22 (81.4) 18(66.6)	5 (18.5) 3 (11.1) 4 (14.8)	1 (3.7) 1(3.7) 4(14.8)	0 (0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	1(3.7) 1(3.7) 0(0.0)
Child Functions: Questions two through five	**0.37 ±0.88** **0.40 ±0.97** **0.51 ±1.36**						
2) Difficulty drinking		23(85.1) 25(92.5) 26(96.2)	2(7.4) 1(3.7) 1(3.7)	1(3.7) 1(3.7) 0(0.0)	1(3.7) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
3) Difficulty eating		25(92.5) 24(88.8) 23(85.1)	1(3.7) 1(3.7) 2(7.4)	1(3.7) 2(7.4) 1(3.7)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
4) Difficulty pronouncing words		27(100.0) 25(92.5) 26(96.2)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)
5) Missed preschool or school		27(100.0) 26(96.2) 26(96.2)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Psychological: Questions six and seven	**0.11 ±0.32** **0.25 ±1.02** **0.11 ±0.42**						
6) Trouble sleeping		25(92.5) 26(96.2) 27(100.0)	2(7.4) 0(0.0) 0(0.0)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
7) Irritable or frustrated		26(96.2) 26(96.2) 25(92.5)	1(3.7) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 1(3.7) 0(0.0)
Child Self Image/Social Interaction: Questions eight and nine	**0.03 ±0.19** **0 ±0** **0.14 ±0.76**						
8) Avoid smiling or laughing		26(96.2) 27(100.0) 26(96.2)	1(3.7) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
9) Avoid talking		27(100.0) 27(100.0) 26(96.2)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Impact Section Total Questions one through nine	**0.96 ±1.50** **1.03 ±2.78** **1.33 ±2.09**						
FAMILY IMPACT SECTION							
Parental Distress: Questions ten and eleven	**1.81 ±2.25** **1.48 ±2.39** **1.18 ±1.68**						
10) Been upset		15(55.5) 20(74.0) 16(59.2)	4(14.8) 0(0.0) 2(7.4)	4(14.8) 4(14.8) 7(25.9)	4(14.8) 2(7.4) 2(7.4)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
11) Felt guilt		16(59.2) 18(66.6) 21(77.7)	1(3.7) 2(7.4) 3(11.1)	6(22.2) 2(7.4) 2(7.4)	4(14.8) 4(14.8) 1(3.7)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Family Function: Questions twelve and thirteen	**0.77 ±1.73** **0.14 ±0.60** **0.07 ±0.26**						
12) Time off work		24(88.8) 26(96.2) 26(96.2)	1(3.7) 1(3.7) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	2(7.4) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
13) Financial impact		23(85.1) 25(92.5) 26(96.2)	0(0.0) 1(3.7) 1(3.7)	1(3.7) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	3(11.1) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Family Impact Section Total Questions ten through thirteen	**2.59 ±2.51** **1.62 ±2.64** **1.25 ±1.74**						
Total ECOHIS Score Questions one through thirteen	**3.55 ±3.26** **2.70 ±4.72** **2.66 ±3.57**						

TABLES

Supplemental Table 3: Baseline and follow-up ECOHIS scores for 6-Month group (Regime 2)

CHILD IMPACT SECTION	BASELINE VISIT (N= 27) SECOND VISIT (N = 27) THIRD VISIT (N=27)						
	Mean ±SD	Never N (%)	Hardly ever N (%)	Occasionally N (%)	Often N (%)	Very Often N (%)	Don't Know N (%)
Child Symptoms: Question one	**0.55 ±1.15** **0.33 ±0.73** **0.70 ±1.32**						
1) Oral/dental pain		20(74.0) 21(77.7) 20(74.0)	3(11.1) 4(14.8) 1(3.7)	2 (7.4) 1(3.7) 2(7.4)	0(0) 1(3.7) 2(7.4)	2(7.4) 0(0.0) 2(7.4)	0(0.0) 0(0.0) 0(0.0)
Child Functions: Questions two through five	**0.48 ±1.50** **0.59 ±1.67** **1.37 ±2.25**						
2) Difficulty drinking		24(88.8) 24(88.8) 23(85.1)	0(0.0) 2(7.4) 1(3.7)	2(7.4) 0(0.0) 2(7.4)	1(3.7) 1(3.7) 1(3.7)	0(0.0) 0(0.0) 0(0)	0(0.0) 0(0.0) 0(0.0)
3) Difficulty eating		25(92.5) 25(92.5) 20(74.0)	0(0.0) 0(0.0) 1(3.7)	2(7.4) 1(3.7) 3(11.1)	0(0.0) 1(3.7) 2(7.4)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)
4) Difficulty pronouncing words		27(100.0) 25(92.5) 25(92.5)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 1(3.7) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)
5) Missed preschool or school		25(92.5) 24(88.8) 24(88.8)	2(7.4) 3(11.1) 1(3.7)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 1(3.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Psychological: Questions six and seven	**0.44 ±1.52** **0.18 ±0.78** **0.37 ±1.14**						
6) Trouble sleeping		26(96.2) 26(96.2) 26(96.2)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 1(3.7)	1(3.7) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
7) Irritable or frustrated		24(88.8) 25(92.5) 24(88.8)	1(3.7) 1(3.7) 0(0.0)	0(0.0) 1(3.7) 2(7.4)	1(3.7) 0(0.0) 1(3.7)	1(3.7) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Self Image/Social Interaction: Questions eight and nine	**0.11 ±0.57** **0.18 ±0.68** **0.14 ±0.53**						
8) Avoid smiling or laughing		26(96.2) 25(92.5) 25(92.5)	0(0.0) 0(0) 0(0.0)	0(0.0) 1(3.7) 2(7.4)	1(3.7) 1(3.7) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
9) Avoid talking		27(100.0) 27(100.0) 27(100.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Impact Section Total Questions one through nine	**1.59 ±4.03** **1.29 ±2.50** **2.59 ±3.97**						
FAMILY IMPACT SECTION							
Parental Distress: Questions ten and eleven	**2.11 ±2.90** **1.59 ±2.70** **1.33 ±1.98**						
10) Been upset		17(62.9) 20(74.0) 20(74.0)	0(0.0) 0(0.0) 1(3.7)	3(11.1) 3(11.1) 5(18.5)	5(18.5) 1(3.7) 1(3.7)	2(7.4) 3(11.1) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
11) Felt guilt		16(59.2) 19(70.3) 17(69.2)	2(7.4) 1(3.7) 2(7.4)	3(11.1) 3(11.1) 5(18.5)	4(14.8) 1(3.7) 2(7.4)	2(7.4) 3(11.1) 1(3.7)	0(0.0) 0(0.0) 0(0.0)
Family Function: Questions twelve and thirteen	**0.92 ±1.17** **0.70 ±1.10** **0.51 ±0.89**						
12) Time off work		19(70.3) 19(70.3) 22(81.4)	5(18.5) 4(14.8) 1(3.7)	3(11.1) 4(14.8) 4(14.8)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
13) Financial impact		21(77.7) 22(81.4) 24(88.8)	1(3.7) 3(11.1) 2(7.4)	3(11.1) 2(7.4) 0(0.0)	1(3.7) 0(0.0) 1(3.7)	1(3.7) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Family Impact Section Total Questions ten through thirteen	**3.03 ±3.32** **2.29 ±3.06** **1.85 ±2.08**						
Total ECOHIS Score Questions one through thirteen	**4.62 ±5.79** **3.59 ±4.71** **4.22 ±4.61**						

TABLES

Supplemental Table 4: Baseline and follow-up ECOHIS scores for 1-Month group (Regime 3)

CHILD IMPACT SECTION	BASELINE VISIT (N=28) SECOND VISIT (N= 28) THIRD VISIT (N= 28)						
	Mean ±SD	Never N (%)	Hardly ever N (%)	Occasionally N (%)	Often N (%)	Very Often N (%)	Don't Know N (%)
Child Symptoms: Question one	**0.71 ±1.15** **0.35 ±0.73** **0.35 ±0.78**						
1) Oral/dental pain		19(67.8) 22(78.5) 23(82.1)	1(3.5) 2(7.1) 0(0.0)	6(21.4) 4(14.2) 5(17.8)	1(3.5) 0(0.0) 0(0.0)	1(3.5) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Functions: Questions two through five	**1.00 ±1.65** **0.46 ±0.92** **0.35 ±0.98**						
2) Difficulty drinking		24(85.7) 25(89.2) 27(96.4)	0(0.0) 1(3.5) 0(0.0)	2(7.1) 2(7.1) 1(3.5)	2(7.1) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
3) Difficulty eating		21(75.0) 25(89.2) 25(89.2)	0(0.0) 1(3.5) 0(0.0)	4(14.2) 1(3.5) 2(7.1)	3(10.7) 1(3.5) 1(3.5)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
4) Difficulty pronouncing words		27(96.4) 28(100.0) 28(100.0)	1(3.5) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
5) Missed preschool or school		28(100.0) 27(96.4) 27(96.4)	0(0.0) 0(0.0) 1(3.5)	0(0.0) 1(3.5) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Psychological: Questions six and seven	**0.46 ±1.10** **0.26 ±0.58** **0.25 ±1.00**						
6) Trouble sleeping		23(82.1) 25(89.2) 27(96.4)	3(10.7) 1(3.5) 0(0.0)	2(7.1) 2(7.1) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 1(3.5)
7) Irritable or frustrated		24(85.7) 26(92.8) 27(96.4)	2(7.1) 2(7.1) 0(0.0)	2(7.1) 0(0.0) 1(3.5)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Self Image/Social Interaction: Questions eight and nine	**0.07 ±0.26** **0 ±0.0** **0 ±0.0**						
8) Avoid smiling or laughing		28(100.0) 28(100.0) 28(100.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
9) Avoid talking		26(92.8) 28(100.0) 28(100.0)	2(7.1) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Child Impact Section Total Questions one through nine	**2.25 ±3.09** **1.07 ±1.53** **0.96 ±1.85**						
FAMILY IMPACT SECTION							
Parental Distress: Questions ten and eleven	**2.21 ±2.31** **1.85 ±2.20** **1.07 ±1.90**						
10) Been upset		15(53.5) 18(64.2) 22(78.5)	1(3.5) 0(0.0) 1(3.5)	9(32.1) 7(25.0) 2(7.1)	3(10.7) 3(10.7) 3(10.7)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
11) Felt guilt		13(46.4) 14(50.0) 20(71.4)	1(3.5) 3(10.7) 2(7.1)	9(32.1) 7(25.0) 4(14.2)	5(17.8) 4(14.2) 2(7.1)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
Family Function: Questions twelve and thirteen	**1.32 ±1.70** **0.57 ±1.25** **0.85 ±1.32**						
12) Time off work		23(82.1) 23(82.1) 21(75.0)	2(7.1) 4(14.2) 2(7.1)	2(7.1) 1(3.5) 5(17.8)	1(3.5) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0)
13) Financial impact		17(60.7) 23(82.1) 21(75.0)	1(3.5) 1(3.5) 2(7.1)	5(17.8) 3(10.7) 5(17.8)	4(14.2) 1(3.5) 0(0.0)	0(0.0) 0(0.0) 0(0.0)	1(3.5) 0(0.0) 0(0.0)
Family Impact Section Total Questions ten through thirteen	**3.53 ±3.06** **2.42 ±2.68** **1.92 ±2.19**						
Total ECOHIS Score Questions one through thirteen	**5.71 ±4.75** **3.50 ±3.70** **2.89 ±2.92**						

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