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The Impact of Dental Caries and its Treatment by Conventional or Biological Approaches on the Oral Health-Related Quality of Life of Children and Carers.

Summary

Background. The effect of untreated dental caries and the approaches taken to its treatment have not been extensively elucidated in children.

Aim. To investigate the impact of untreated dental caries on children aged 4-9 years and whether its treatment with either a conventional or a biological approach influenced the oral health related quality of life (OHRQoL) of the children and their carers.

Design. Children (n=110) and their carers attending two specialist centres for treatment of carious primary teeth completed the Early Childhood Oral Health Impact Scale and the Self-reported Scale of Oral Health Outcomes for 5 year old Children at baseline prior to dental treatment, and at 3-6 months following completion of dental care. Dental treatment was provided using either a conventional or a biological approach.

Results. Dental caries showed a negative impact on the child and family`s OHRQoL (p= 0.001). Children reported difficulty eating (55.5%), sleeping (40%), and avoiding smiling because of how the teeth looked (27.3%). More than half of the parents reported their child had toothache. Parents perceived difficulty eating (40.9%), being irritable (38.2%) and difficulty drinking (30.9%) as being impacts of caries on their child's OHRQoL. In addition, approximately half the parents reported feeling a sense of guilt because of their child's dentall disease. Following dental treatment, participants reported significant improvement in their overall health status (p= 0.001). Children`s age, gender or the treatment approach were not statistically significantly associated with changes in OHRQoL of the child or carer. Children

and parents who initially reported greater impacts of untreated dental caries demonstrated greater improvements in their overall oral health status ($p < 0.0001$).

Conclusion. Dental caries was associated with negative impacts on children and parents` quality of life. Treatment of caries improved the quality of life of children and families significantly, irrespective of whether the treatment was provided by a conventional or a biological approach.

Author contributions: A.B., M.D. and C.D. conceived the ideas; A.B. collected the data; A.B. and T.M. analysed the data; A.B., M.D., C.D., T.M. and J.T. all contributed to the writing.

Introduction

Children with untreated dental caries often suffer from a reduced oral health-related quality of life (OHRQoL) when contrasted with their caries-free peers[1, 2, 3, 4, 5, 6, 7]. Many also have other associated health problems such as infection and pain. Dental caries significantly negatively impacts on the social and psychological functioning in children. Impacts reported include school absences, inability to concentrate in school, reduced self-esteem, poor social relationships, impaired speech development, difficulty sleeping, and inadequate diet[1]. The most common impacts reported by parents in the literature are “pain in teeth, mouth or jaws”, “irritation or frustration”, “difficulty eating” and “trouble sleeping” [3, 4, 5, 6, 7].

Poor dental health has a significant impact on the growth, as well as the cognitive development of the child in the long term by interfering with nutrition. It can result in lower body weight and height [8, 9, 10, 11, 12]. Untreated dental caries also impacts on the family, resulting in sleepless nights, lost workdays for caregivers or time and cost of accessing dental care also causes distress for the carer and financial impact on the family [4, 5, 6, 7].

Currently, two treatment approaches are proposed for the restoration of carious primary teeth in the UK; the conventional and the biological [13, 14]. Conventional restoration includes complete removal of carious tissue followed by placing a suitable filling material with or without pulp therapy, whereas the biological approach involves the isolation of the carious lesion from the biofilm using for example sealants, the Hall Technique and indirect pulp capping.

Although some data are available on the impact of untreated dental caries on the child and family`s quality of life, the impact of the two treatment approaches, conventional and biological, on children and families' quality of life has not been explored. In young children the way care is provided could also have an impact on both the child and the carer. Therefore, the aim of this prospective clinical trial (cohort study) was to investigate the impact of dental caries on children and their families` quality of life and to assess whether its treatment and the approach taken to treatment, either conventional or biological, influenced the OHRQoL of the children and their carers.

Material and methods

Study population and ethical approval

The study was conducted in two specialist dental hospitals in the North of England, UK; Leeds Dental Institute (LDI) and School of Clinical Dentistry, University of Sheffield (SCD). Differing treatment approaches are practiced in these two dental centres. In LDI, a conventional approach is predominantly practiced, whereas a biological approach is the mainstay of dental treatment of the carious primary dentition in SCD. For the conventional treatment, children had complete removal of carious tissue with or without pulp therapy of primary teeth using local anaesthetic (LA). Pulp therapy included both a pulpotomy and a

pulpectomy. For the biological treatment, restorations were placed without the use of LA and were either an indirect pulp cap (IPC) or preformed metal crown using the Hall Technique. No participants had teeth extracted.

Approval was obtained from the Dental Research Ethics Committee (DREC), University of Leeds, and the National Research Ethics Service (NRES). All carers gave written consent and children gave assent.

Participants were selected from English speaking patients aged 4-9 years and their parents/caregivers attending LDI and SCD for the treatment of carious primary teeth between September-2013 to May-2015. Patients were included in the study if they met the following criteria:

- No significant health problem (ASA Physical Status-1 and 2).
- At least one primary tooth (molar or anterior) with the carious lesion extending into dentine requiring treatment with either approach.
- The tooth to be treated had no history of infection or swelling and no evidence of periapical pathology.
- The tooth to be treated was asymptomatic or showed signs of reversible pulpitis.
- Pre-operative radiographs were available.

Sample size calculation

The sample size was calculated based on comparing OHRQoL scores between the conventional and biological treatment approaches**.** Assuming a large effect size of 0.7, power 90%, significance level 0.05, 46 subjects were required for each group[15]. This was increased to 55 per group to allow for drop outs. Gpower software version 3.1 was used to determine the power for a Mann Whitney U test[16].

Oral health related quality of life measures

The impact of oral health on the child and their parents` quality of life was measured using the Early Childhood Oral Health Impact Scale (ECOHIS) for parents/carers and Self-reported Scale of Oral Health Outcomes for 5 year old Children (SOHO-5) for children[17, 18]. Participants completed the questionnaires at baseline prior to dental treatment using a face-to-face interview and again at 3-6 months' following the completion of the treatment by telephone interview.

The Early Childhood Oral Health Impact Scale (ECOHIS)

ECOHIS measured the impact of dental caries on children and their parents` quality of life based on parental reports. It consisted of two domains; the child impact section (CIS) and family impact section (FIS) with total of 13 questions.

The CIS had four subscales: child symptoms, child function, child psychology, and child self-image/social interaction. The FIS had two subscales: parental distress and family function. The scale had five response options for recording how often an event has occurred in the child's life.

The CIS and FIS scores were calculated through a simple sum of the scores on all items in each section, ranging from 0 to 36 (CIS) and 0 to 16 (FIS). The total score ranged from 0 to 52, with a higher scores denoting greater oral health impact and poorer OHRQoL.

Self-reported Scale of Oral Health Outcomes for 5 year old Children (SOHO5)

The SOHO-5 is a child self-reported scale that assesses their perception of oral health impacts. It consisted of 7 questions and responses were given through a 3-point scale

facilitated by an explanation card with relevant faces. The total score ranged from 0 to 14 and was calculated through adding the individual item scores, with a higher score denoting greater degree of oral impact on children's quality of life.

Data analysis

The SOHO-5, and ECOHIS scores including change in scores from baseline were summarised using medians and range. Median scores of SOHO-5 and ECOHIS were compared among the two treatment approaches using Mann-Whitney test as data was not normally distributed.

Changes in scores of SOHO-5 and ECOHIS from baseline to the 3-6 months follow-up, following dental intervention within a treatment approach, conventional or biological, were compared using Wicoxon Signed Ranks test. In addition, median change in scores of SOHO-5 from baseline to follow-up between the conventional and biological treatment approaches were compared using Mann-Whitney test as data was not normally distributed. Finally the mean change in scores of ECOHIS from baseline to follow-up between the two treatments approaches was compared using an Independent t-test as data was found to be normally distributed.

Multivariable linear regression analysis was used to determine the effect of factors such as age of patients, gender, treatment approach, baseline SOHO-5 score, and baseline ECOHIS scores to the changes in SOHO-5 and ECOHIS scores at 3-6 months following dental intervention. The outcome for the linear regression model was a change score (dental intervention's impact on children and parents' quality of life; SOHO-5 and ECOHIS score at 3-6 months following dental treatment), and the predictors were age of patients, gender, treatment approach, baseline SOHO-5 score, and baseline ECOHIS scores.

Descriptive statistics and univariate analysis were conducted using SPSS (Statistical Package for the Social Sciences) version 22 and regression analysis was conducted in STATA version 12 (StataCorp, 2011.). A probability values of $p<0.05$ was considered statistically significant.

Results

Baseline characteristics

A total of 110 children and their carers were enrolled in the study; 55 children received treatment with the conventional approach and 55 with the biological approach. The age range of the children was 4-9 years and the median age of children was 7.0 ± 1.4 years (6.0 ± 1.33 and 7.0 ± 1.53 years in the conventional and biological approaches, respectively), with slightly more than half of the patients being males (50.9%).

More than two thirds (n= 83, 75.5%) of the participants completed the SOHO-5 and ECOHIS questionnaires 3-6 months following the completion of dental treatment; 42 from the conventional approach and 41 from the biological approach (Figure 1).

OHRQoL prior to and following dental intervention

The majority of children (71.8%) and their carers (95.5%) reported impact on their quality of life due to dental disease (i.e. SOHO-5 and ECOHIS > score of 0). The highest baseline Soho-5 score was 12 whereas the maximum baseline total ECOHIS score was 38 with maximum scores of 28 and 15 were reported on the CIS and FIS, respectively (Table 1).

Tables 2 and 3 display the distribution of SOHO-5 and ECOHIS responses at baseline according to each question. From a child`s perception, items related to difficulty eating

(55.5%), sleeping (40%), avoiding smiling because of the way the teeth looked (27.3%) and because they hurt (25.5%) were most frequently reported by the children. On the CIS of ECOHIS, the greatest impacts were recorded for items related to pain (55%), difficulty eating (40.9%), irritation (38.2%), and difficulty drinking (30.9%). In the FIS, the most frequently reported items were feeling guilty (50.9%) and having to take time off work due to problems with their children teeth, mouth or jaw (46.4%). Carers of children who had received conventional restoration reported higher total ECOHIS scores at baseline ($p= 0.009$), including the child and family impact sections ($p= 0.03$), compared to carers of children who attended for the biological restoration.

Following dental intervention with either approach, conventional or biological, the majority of the children and their carers reported a significant improvement in their overall health status. In total, 90.4% and 35% of the children and their carers, respectively, reported no impacts of dental caries on their quality of life following the dental intervention. The maximum highest score of SOHO-5 following dental treatment was 2.0 while the maximum highest score of total ECOHIS was 35 (28 and 8.0 on CIS and FIS, respectively) (Table 1). A statistical significant improvement was found between the mean scores of SOHO-5 and total ECOHIS at baseline and at 3-6 months whichever treatment approach had been adopted ($p < 0.001$).

Children and carers responses to SOHO-5 and ECOHIS at follow-up after dental treatment are summarised in Tables 4 and 5. Responses indicated significant improvements in children and carers` quality of life following dental intervention with both approaches, conventional and biological. Improvement in the ability to eat was the predominant outcome reported by children (described by 90.4%) followed by the ability to sleep (95.2%). In addition, all children reported an increase in smiling as the overall look of their teeth was improved and

because their teeth were no longer causing any pain. On CIS of ECOHIS, improvement in pain (95.2%) was the main outcome reported by carers, followed by improved ability to eat (92.8%), being less irritable or frustrated (93.9%), and improved habits of drinking (94%) and sleeping (96.4%). On FIS of ECOHIS, the number of carers who were feeling upset and/or guilty about their children dental problems prior to the dental treatment dropped by half following dental intervention. Similar decreases were seen in items related to “taken time off work” and” whether dental problems or treatments had financial impact on the family”.

Factors affecting the changes in children and their carers’ quality of life following dental intervention

From child`s (SOHO-5) and carers` (total ECOHIS, CIS of ECOHIS) perspectives, age of patient, gender and treatment approach, conventional or biological, were not found to be statistically significantly associated with the changes in SOHO-5, total ECOHIS and CIS of ECOHIS quality of life scores after adjusting for all factors using multivariable linear regression analysis (Table 6).

The multivariable linear regression analysis of change in FIS of ECOHIS scale showed that unlike for the age of the patient and gender, the conventional approach in compared to the biological was associated with a larger improvement in all aspects of the family`s quality of life, from a pooer baseline ($p= 0.02$) (Table 6). In addition, children and carers who reported higher baseline SOHO-5 and ECOHIS scores showed greater improvements in their overall oral health status and wellbeing following dental intervention ($p < 0.001$).

Discussion

The current study has provided the opportunity to assess the impact of oral health problems and related treatment experience on the quality of life of the child and family. In addition, it is the first study to explore the impact of the two treatment approaches, conventional and biological, on children and families` quality of life.

Conventional restorations have been the traditional approach for restoring carious primary teeth for decades[19, 20] but the biological approach which is less invasive[19, 20, 21] is gaining popularity. Few studies have directly compared the conventional and the biological approaches for the treatment of carious primary teeth in children[14, 22, 23, 24]. We have previously reported similar clinical outcomes, with both approaches when carried out by specialists for management of carious lesions in the primary dentition[14]. However, this is the first study to report the impact of the conventional and biological restorations on the child and family's quality of life.

This study`s principal findings were that dental caries adversely impact OHRQoL of children as well as their families, and that both treatment approaches, conventional and biological, were associated with significant improvement in the overall children`s oral health status ($p < 0.0001$). Prior to dental treatment, 71.8% and 95.5% of the children and their carers, respectively, reported adverse impact on their quality of life. However, these proportions dropped significantly to 9.6% and 65.1%, respectively, at 3-6 months following dental intervention with either approach, which is in agreement with previous studies, reporting conventional treatment ($p < 0.0001$) [1, 2, 3, 5]. These studies assessed the impact of early childhood caries on children aged 2-5 years and their families' quality of life, whereas the current study assessed the impact of untreated dental caries on an older age group of children (4-9 years). Items related to difficulty eating, trouble sleeping, and avoidance of smiling because of the appearance of the teeth and pain were the difficulties most frequently reported by children in this study. More than half of the carers in the study reported their

child had pain from their teeth, mouth or jaw at some point in their life. Items related to difficulty eating, irritation, difficulty drinking and trouble sleeping were the most frequent on the CIS. These symptoms were related to untreated dental caries and are frequently reported in the literature[1, 2, 4, 5, 6, 7, 25].

In agreement with other studies, more negative impacts were reported on the child's symptoms (pain), function (difficulty eating and drinking) and psychological domains (trouble sleeping and irritability) of OHRQoL than child self-image/social interaction (avoidance of smiling, playing or talking) [4, 5, 6, 25]. This is likely to be because abstract thinking, and self-image and concept only begin to manifest in children at the age of six years. Children at this age, start to pay attention to their physical features and personal traits as well as to compare them with those of other children or against a norm[4]. Although the age range of the children in the current study was 4 to 9 years, the majority were 6 years old and therefore just at an age where they had started to develop abstract thinking, and self-image and concept.

The present study's findings also showed that dental caries was related to negative impacts on the family`s quality of life again in agreement with the literature[4, 5, 6, 7, 25]. More impact was seen in the carer distress domain (feeling guilty and upset) rather than in carer function domain (taken time off from work and having financial impact) of the FIS of ECOHIS. Children`s oral health particularly dental pain reflect on carers` quality of life negatively. Having toothache can keep the child awake at night, which results in less sleep for the carers. Additionally, oral health problems can result in systemic manifestations with associated visits to medical practitioners and general dental practitioners. The latter might lead again to a financial burden, missed workdays and disturbed sleep for carers. Interestingly, only 9.1% of the carers reported that their children's dental treatment or dental problems had financial impact on their families. This could be explained by the fact that children under the age of 18

are entitled to free National Health Service (NHS) dental treatment in the UK, therefore, reducing the financial burden to carers.

Among the two treatment approaches, significant higher ECOHIS scores at baseline were reported by carers in the conventional approach compared to carers in the biological approach ($p= 0.009$). This suggests that carers of children who attended for the conventional restoration exhibited a more adverse impact of untreated dental caries on the child and their quality of life than carers of children who attended for the biological restoration. The reason for this difference is unclear but is not related to the treatment choice. In the current study, the impact of dental treatment on OHRQoL of the child and his family was measured at 3-6 months following the dental intervention. This was done to allow for any changes associated with dental treatment on OHRQoL to occur whether these changes were positive or negative as well as to give participants enough time to realise and feel these changes.

Following dental intervention, the median scores of SOHO-5 and total ECOHIS significantly decreased by more than half suggesting an overall improvement in the child and family's quality of life from child and carer`s perception. In the current study, both treatment approaches, conventional and biological, were associated with substantial improvement in the overall children's oral health status and family`s quality of life ($p <0.0001$). Within SOHO-5, the greatest improvement was seen in the child ability to eat, followed by the ability to sleep and smile as the overall appearance of the teeth was improved and their teeth were no longer causing any pain. Within the CIS, the greatest reduction was noted in the oral symptoms and child function domains. Improvement in pain was the main outcome described by nearly half of the carers, followed by improved ability to eat, being less irritable, and improved habits of drinking and sleeping. In the FIS, the proportion of carers who were feeling upset and/or guilty as well as items related to "taken time off work" and" whether dental problems or treatments had a financial impact on the family" had decreased by more than half as the

primary cause of oral health problems in children was eliminated. The majority of the carers in our study reported feeling satisfied with themselves for taking their child to the dentist for the treatment of his carious teeth. Seeking dental treatment for children with decayed teeth contributed significantly to the reduction in the carer distress domain of the ECOHIS questionnaire.

A greater decrease was observed in the FIS than the CIS. This is because it is likely that carers would feel guilty and upset about their child`s oral health problems especially if the child is in pain.

Improvement in OHRQoL in the current study was not associated with patients` age, gender or type of treatment approach (conventional vs biological). From the child and carer perspectives, the conventional and biological approaches were equally associated with significant improvement in the child and family`s oral health related quality of life in the current study. This can be explained by the fact that the two treatment approaches demonstrated similar successful outcomes as demonstrated in several specialist based RCTs and cohort studies[14, 23, 24]. A recent study reported 95.8% and 95.3% of the primary teeth that were restored using the conventional and biological approaches, respectively, remained asymptomatic over 6 years follow up[14]. This high success rate would contribute to the improvement of the overall health status and quality of life of the participants reported in the current study.

The conventional restorative approach was significantly associated with larger improvements in the FIS of ECOHIS compared with the biological approach. This could be attributed to the fact that carers in the conventional approach reported higher significant scores in the FIS of ECOHIS at baseline (6.0 ± 3.9 and 3.0 ± 2.9 for conventional and biological restorations, respectively) and does not reflect a superiority of one approach over the other. These carers are more likely to feel guilty and upset about their child`s oral health

problems with many of them might need to take time off work to look after the child especially if he/she is in pain. However, the guilt and upset feeling subside greatly following seeking dental care for their child`s carious teeth.

The current study has provided further evidence that children with untreated dental caries and their families experience significant quality of life issues because of the child's oral health problems. However, following dental intervention with either treatment approach, conventional or biological, the majority of these patients and their carers reported significant improvement in their overall health status and wellbeing. The greatest improvement in the present study occurred among those who were more seriously affected by their condition prior to dental intervention.

Conclusion

Untreated dental caries in the present study was associated with significant adverse impacts on the child and family`s quality of life. This is the first study to demonstrate that dental intervention with either a conventional or biological approach was associated with significant improvement in the child and family`s oral health related quality of life.

Why this paper is important for paediatric dentistry

- The current study has provided further evidence that untreated dental caries is associated with negative impact on children and parents` quality of life.
- However, treatment of caries with either approach, conventional or biological, can significantly improve the overall health status and wellbeing of children and their families.

- This study demonstrated the significance of training clinicians in primary care in both the conventional and biological treatment approaches to improve children and parents` quality of life especially among those who are more seriously affected by their condition prior to dental intervention.

The authors have no conflict of interest to declare

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Figure Legends

Figure 1: Flowchart showing the description of the number of participants who completed SOHO-5 and ECOHIS at baseline and at 3-6 months following dental intervention.

Table-1: Descriptive analysis of SOHO-5 and ECOHIS questionnaires including ECOHIS total, child (CIS) and family impact sections (FIS) for the two treatment approaches and for the total sample at baseline (n=110) and at 3-6 months following dental intervention (n= 83)

Variable	Conventional approach		Biological		Total sample	
	At baseline	At follow-up	At baseline	At follow-up	At baseline	At follow-up
Total SOHO-5 score						
Range	0.0-12	0.0-2.0	0.0-10	0.0-2.0	0.0-12	0.0-2.0
Median	2.0± 3.5	0.1± 0.6	1.0± 2.3	0.01± 0.3	2.0 ± 3.01	0.01± 0.5
Total ECOHIS score						
Range	0.0-38	0.0-30	0.0-34	0.0-35	0.0-38	0.0-35
Median	15 ± 9.6	8.5 ± 6.9	9.0 ± 7.6	2.0 ± 7.3	11.5 ± 9.0	4.0 ± 7.2
CIS of ECOHIS						
Range	0.0-24	0.0-22	0.0-28	0.0-28	0.0-28	0.0-28
Median	8.0 ± 6.5	6.0 ± 5.1	6.0 ± 6.4	0.01 ± 5.7	7.0 ± 6.7	0.01 ± 5.5
FIS of ECOHIS						
Range	0.0-15	0.0-8.0	0.0-9.0	0.0-8.0	0.0-15	0.0-8.0
Median	6.0 ± 3.9	3.1 ± 2.5	3.0 ± 2.9	0.01 ± 2.4	4.0 ± 3.6	2.0 ± 2.6

Table-2: Distribution of children responses to SOHO-5 questionnaire at baseline in the study sample (n= 110). Similar trend of responses was seen among the two treatment approaches; conventional and biological.

Impact	SOHO-5 response, n (%)		
	No	A little	A lot
▪ Has it ever been hard for you to eat because of your teeth?	49 (44.5%)	40 (36.4%)	21 (19.1%)
▪ Has it ever been hard for you to drink because of your teeth?	84 (76.4%)	15 (13.6%)	11 (10%)
▪ Has it ever been hard for you to speak because of your teeth?	89 (80.9%)	16 (14.5%)	5.0 (4.5%)
▪ Has it ever been hard for you to play because of your teeth?	89 (80%)	16 (15.5%)	5.0 (4.5%)
▪ Have you ever not smiled because your teeth were hurting?	82 (74.5%)	18 (16.4%)	10 (9.1%)
▪ Have you ever not smiled because of how your teeth look?	80 (72.7%)	23 (20.9%)	7.0 (6.4%)
▪ Has it ever been hard for you to sleep because of your teeth?	66 (60%)	32 (29.1%)	12 (10.9%)

Table-3: Distribution of responses to ECOHIS questionnaire by parents/caregivers in both treatment approaches (n= 110) at baseline. Similar trend of responses was seen among the two treatment approaches; conventional and biological.

Impact	ECOHIS response, n (%)				
	Never	Hardly ever	Occasionally	Often	Very often
Child impact					
1. How often has your child had pain in the teeth, mouth or jaw?	23(20.9%)	26(23.6%)	39(35.5%)	17(15.5%)	5.0(4.5%)
How often has your child...because of dental problems or dental treatments:					
2. Had difficulty drinking hot or cold beverage?	47(42.7%)	29(26.4%)	19(17.3%)	8.0(7.3%)	7.0(6.3%)
3. Had difficulty eating some foods	32(29.1%)	33(30%)	27(24.6%)	14(12.7%)	4.0(3.6%)
4. Had difficulty pronouncing any words	83(75.5%)	13(11.8%)	6.0(5.5%)	4.0(3.6%)	4.0(3.6%)
5. Missed preschool, day-care or school	52(47.3%)	35(31.8%)	18(16.4%)	2.0(1.8%)	3.0(2.7%)
6. Had trouble sleeping	53(48.1%)	28(25.5%)	20(18.2%)	6.0(5.5%)	3.0(2.7%)
7. Been irritable or frustrated	45(40.9%)	23(20.9%)	25(22.7%)	14(12.8%)	3.0(2.7%)
8. Avoided smiling or laughing	81(73.6%)	17(15.5%)	7.0(6.4%)	3.0(2.7%)	2.0(1.8%)
9. Avoided talking	86(78.2%)	16(14.5%)	6.0(5.5%)	1.0(0.9%)	1.0(0.9%)
Family impact					
How often have you or another family member… because of dental problems or dental treatments?					
10. Been upset	44(40%)	17(15.5%)	26(23.6%)	14(12.7%)	9.0(8.2%)
11. Felt guilty	41(37.3%)	13(11.8%)	28(25.5%)	14(12.7%)	14(12.7%)
12. Taken time off from work	47(42.7%)	12(10.9%)	29(26.4%)	13(11.8%)	9.0(8.2%)
13. How often has your child					

	had dental problems or dental treatments that had a financial impact on your family?	88(80%)	12(10.9%)	6.0(5.5%)	2.0(1.8%)	2.0(1.8%)

1 = Child symptom domain; 2, 3, 4, 5 = child function domain; 6, 7 = child psychological domain; 8, 9 = child self-image/social interaction domain; 10, 11 = parent distress domain; 12, 13 = family function domain

Table-4: Distribution of responses to SOHO-5 questionnaire following dental intervention by children for both treatment approaches (n= 83). Similar trend of responses was seen among the two treatment approaches; conventional and biological.

Impact	**SOHO-5 response following dental intervention**

	No	A little	A lot
▪ Has it ever been hard for you to eat because of your teeth?	75 (90.4%)	8.0 (9.6%)	-
▪ Has it ever been hard for you to drink because of your teeth?	78 (94%)	5.0 (6.0%)	-
▪ Has it ever been hard for you to speak because of your teeth?	83 (100%)	-	-
▪ Has it ever been hard for you to play because of your teeth?	83 (100%)	-	-
▪ Have you ever not smiled because your teeth were hurting?	83 (100%)	-	-
▪ Have you ever not smiled because of how your teeth look?	83 (100%)	-	-
▪ Has it ever been hard for you to sleep because of your teeth?	83 (100%)	-	-

Table 5: Distribution of responses to ECOHIS questionnaire by parents of children who received both treatment approaches in the study at 3-6 months following dental treatment (n=83). Similar trend of responses was seen among the two treatment approaches; conventional and biological.

Impact	ECOHIS response, n (%)				
	Never	Hardly ever	Occasionally	Often	Very often
Child impact					
1. How often has your child had pain in the teeth, mouth or jaw?	44(53%)	35(42.2%)	1.0(1.2%)	2.0(2.4%)	1.0(1.2%)
How often has your child...because of dental problems or dental treatments:					
2. Had difficulty drinking hot or cold beverage?	44(53%)	34(41%)	3.0(3.6%)	1.0(1.2%)	1.0(1.2%)
3. Had difficulty eating some foods	42(50.6%)	35(42.2%)	2.0(2.4%)	3.0(3.6%)	1.0(1.2%)
4. Had difficulty pronouncing any words	51(61.4%)	30(36.2%)	1.0(1.2%)	-	1.0(1.2%)
5. Missed preschool, day-care or school	51(61.4%)	30(36.2%)	1.0(1.2%)	1.0(1.2%)	-
6. Had trouble sleeping	49(59%)	31(37.4%)	2.0(2.4%)	1.0(1.2%)	-
7. Been irritable or frustrated	49(59%)	29(34.9%)	4.0(4.9%)	1.0(1.2)%	-
8. Avoided smiling or laughing	51(61.4%)	30(36.2%)	1.0(1.2)%	1.0(1.2)%	-
9. Avoided talking	51(61.4%)	30(36.2%)	2.0(2.4%)	-	-
Family impact					
How often have you or another family member… because of dental problems or dental treatments?					

10.	Been upset	37(44.6%)	28(33.7%)	12(14.5%)	4.0(4.8%)	2.0(2.4%)
11.	Felt guilty	37(44.6%)	27(32.5%)	13(15.7%)	4.0(4.8%)	2.0(2.4%)
12.	Taken time off from work	57(68.7%)	22(26.5%)	3.0(3.6%)	1.0(1.2%)	-
13.	How often has your child had dental problems or dental treatments that had a financial impact on your family?	59(71.1%)	22(26.5%)	1.0(1.2%)	1.0(1.2)	-

1 = Child symptom domain; 2, 3, 4, 5 = child function domain; 6, 7 = child psychological domain; 8, 9 = child self-image/social interaction domain; 10, 11 = parent distress domain; 12, 13 = family function domain

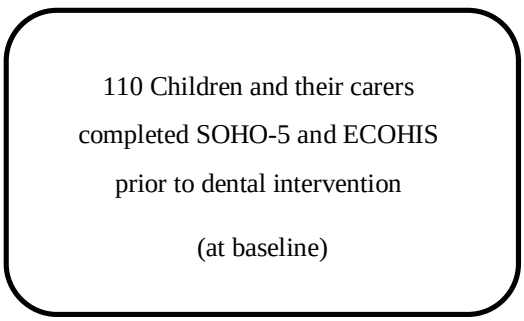
Table 6: Association between the changes in SOHO-5 and ECOHIS scores (total ECOHIS, CIS and FIS of ECOHIS) before and after dental intervention with treatment approach, gender, age, SOHO-5 and ECOHIS (total ECOHIS, CIS and FIS of ECOHIS) scores at baseline.

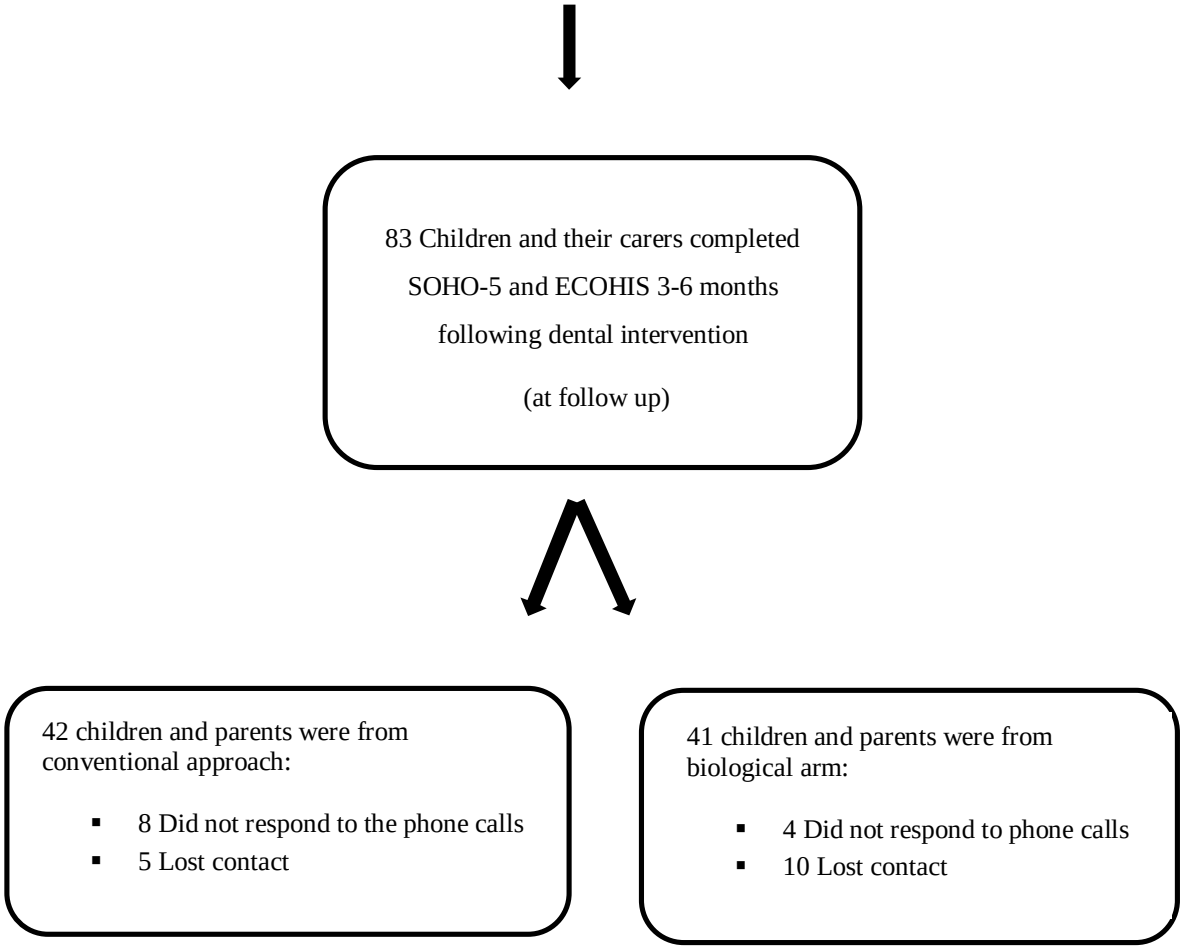
variable	**B**	**Std.Err**	**t**	**p-value**	**95% CI**
Changes in Soho-5 scores					
Treatment approach:					

Conventional approach	0.55	0.34	1.65	0.10	-0.11- 1.23
Biological approach					
Age	0.11	0.11	1.02	0.31	-0.11-0.34
Gender:					
Male	-0.14	0.34	-0.40	0.69	-0.81- 0.53
Female					
Soho-5 score at baseline	-0.9	0.06	-14.2	0.001*	-1.03- (-0.79)
Changes in Total ECOHIS scores					
Treatment approach:					
Conventional approach (ref)	2.80	1.65	1.72	0.09	-0.44- 6.13
Biological approach					
Age	0.50	0.54	0.91	0.36	-0.58- 1.56
Gender:					
Male	0.60	0.37	0.37	0.71	-2.57- 3.77
Female					
Total ECOHIS score at baseline	-0.90	0.09	-9.67	0.001*	-1.09- (-0.72)
Changes in ECOHIS-CIS scores					
Treatment approach:					
Conventional approach					
Biological approach	1.39	1.22	1.15	0.25	-1.03- 3.82
Age	0.40	0.41	0.99	0.32	-0.41- 1.22
Gender:					
Male					
Female	0.59	1.18	0.50	0.62	-1.7- 2.96
ECOHIS-CIS score at baseline					
Changes in ECOHIS-FIS scores	-0.83	0.09	-8.45	0.001*	-1.03 - (-0.63)
Treatment approach:					

Conventional approach	1.40	0.58	2.43	0.02*	0.22 - 2.55
Biological approach					
Age	0.01	0.08	0.08	0.93	-0.30 - 0.38
Gender:					
Male	-0.02	0.56	-0.03	0.97	-1.13 - 1.09
Female					
ECOHIS-FIS score at baseline	-0.99	0.07	-12.49	0.001*	-1.15 - (-0.83)

Figure 1: Flowchart showing the description of the number of participants who completed SOHO-5 and ECOHIS at baseline and at 3-6 months following dental intervention.




83 Children and their carers completed SOHO-5 and ECOHIS 3-6 months following dental intervention
(at follow up)
42 children and parents were from conventional approach:
8 Did not respond to the phone calls
5 Lost contact
41 children and parents were from biological arm:
4 Did not respond to phone calls
10 Lost contact