Comparison of Oral Health Education and Fluoride Varnish to Prevent Early Childhood Caries: A Randomized Clinical Trial

Mahtab Memarpour, Shorangize Dadayein, Ebrahim Fakhraei, Mehrdad Vossoughi

Oral and Dental Disease Research Center, Department of Pediatric Dentistry, Student Research Committee and Oral and Dental Disease Research Center, Department of Dental Public Health, School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran

Key Words
Dental caries · Early childhood caries · Fluoride varnish · Oral health education · Primary teeth

Abstract
Early childhood caries, a serious health problem among young children, can be prevented with effective intervention. The aim of this study was to evaluate the efficacy of oral health education and a fluoride varnish in the prevention of caries in children under the age of 3 years. For this single-blind randomized parallel group 1-year clinical trial in Shiraz, 300 children aged 12–24 months with sound primary teeth were selected and randomly divided into three groups (n = 100): (1) control: no preventive intervention; (2) oral health counseling, and (3) oral health counseling and fluoride varnish at baseline and 6 months later. At baseline and 4, 8 and 12 months after the intervention, caries risk reduction was recorded as the primary outcome. The mothers’ knowledge and performance regarding oral health in children was used as a secondary outcome. A total of 260 children (mean age: 20.49 ± 7.33 months) completed the study. Compared to group 1, caries risk reduction in group 2 was 28% (95% CI: –39.05 to –17.45) and 31% in group 3 (95% CI: –41.88 to –21.73). However, there was no significant difference between groups 2 and 3 (95% CI: –8.58 to 1.47). In all groups, mothers’ knowledge and performance at baseline were low; however, they increased significantly in follow-up appointments in groups 2 and 3 (p < 0.001). Oral health education increased mothers’ knowledge and performance regarding oral health in children. Oral health counseling alone or associated with the use of fluoride varnish reduced the caries incidence in young children.

Early childhood caries (ECC) is a common problem among preschool children and may lead to pain, infection, and functional disorders as well as increased expenditures for parents and the government. Caries may begin to appear shortly after tooth eruption and even before the primary dentition is complete by the age of 3 years. The term severe ECC (SECC) has been used to describe ‘any signs of caries on the smooth surface of primary teeth in children younger than 3 years’ [AAPD, 2011]. The prevalence of SECC depends on socioeconomic status and ethnicity, and has been reported to be 9.5% in Germany [Bissar et al., 2014], 32.19% in Sri Lanka [Kumarahamy et al., 2011], and 26–33% in Iran [Mohebbi et al., 2006, 2008].
Methods to prevent SECC include oral health education on regular toothbrushing, dietary counseling, avoiding prolonged feeding with milk or sweet liquids, particularly during sleep, and limiting the consumption of cariogenic foods. The use of fluoride products is one method that reduces dental caries [Davies et al., 2005; Kagihara et al., 2009; Douglass, 2011; Ng and Chase, 2013; Skrivele et al., 2013; Medeiros et al., 2015].

A number of studies have shown that oral health in children is directly related to mothers’ knowledge of oral health and performance of oral health activities. Hence, oral health counseling (OHC) for mothers is necessary [Skrivele et al., 2013; Azevedo et al., 2014; Begzati et al., 2014].

The effectiveness of fluoride varnish (FV) to prevent caries in preschool children has been documented [AAPD, 2011; Ramos-Gomez et al., 2012; Marinho et al., 2013]. The mechanisms of action of fluoride include inhibiting the demineralization of sound enamel, increasing enamel remineralization, and interfering with the metabolic activity of microorganisms [AAPD, 2011]. Hence, fluoride therapy may be associated with oral health education [Douglass, 2011].

Access to free dental treatment service is limited in some countries; therefore, the importance of the role of caregivers needs to be considered in efforts to study oral health in children and the effectiveness of FV in preventing dental caries. The present study was designed to investigate the clinical effectiveness of oral health education and FV in reducing dental caries among children younger than 3 years.

**Participants and Methods**

This research protocol was approved by the Human Ethics Review Committee of the Faculty of Dentistry, Shiraz University of Medical Sciences, and was registered in the Iranian Registry of Clinical Trials under code IRCT201508127402N5. The study was conducted in Shiraz over a 12-month period at 5 local public health care centers. Recruitment began in December 2012 and was completed within 4 months. This study was a parallel, single-blind randomized controlled clinical trial that enrolled 300 children whose parents were blind to the study group their child was randomized to. The children were enrolled by employees at health care clinics.

All dental examinations were performed by 2 dentists. Before the beginning of the study, the children were enrolled by employees at health care clinics and examined by the dentists, who determined that all children enrolled had a dmft = 0. A staff member randomly assigned 100 children from the list of children with dmft = 0 to each group using a block randomization method (total n = 300), with a block length of B = 6. Random allocation sequences were generated by a statistician with a random number table and were concealed from the two examiners until the start of the study.

**Inclusion Criteria**

The main inclusion criterion was age between 12 and 24 months at the beginning of the study. All children had resided since birth in Shiraz, where water fluoridation levels are similar (<0.7 ppm) in all areas. All participants had at least 4 erupted primary teeth. None of the teeth showed signs of noncavitated or cavitated caries (dmft = 0).

The parents did not use any oral hygiene methods such as toothbrushing or any fluoride products at home or in other clinics. All parents were interviewed to explain the aim of the study, and all parents provided their informed consent in writing. A schedule of appointments was provided and parents were asked to attend the health care center to receive both free health and dental care service during the study period.

**Exclusion Criteria**

The exclusion criteria were medical history of systemic diseases, drug allergies, congenital physical or mental disabilities, oral or dental anomalies or disabilities, and unwillingness to participate due to lack of time.

**Sample Size**

A sample size of 60 persons per group was estimated to be sufficient to detect a clinically significant difference of 20% between groups in caries incidence using a two-tailed test of proportions between two groups with 80% power and a 5% level of significance. This difference represents a 30% incidence of caries in the control group [Mohebbi et al., 2006, 2008; Kumanlhamy et al., 2011] and a 10% incidence of caries in the FV group 12 months after the start of the study. However, because of the long study period, a sample size of 300 children (100 in each group) was finally selected at baseline to compensate for the high rate of probable withdrawal (>50%).

**Dental Examinations**

The primary outcome was the influences of the interventions on the incidence of caries. The children’s teeth were examined by two trained dentists with the arm-craddling or knee-to-knee positions. First the dentists were given instructions by a senior author (M.M.) with a role-playing technique on how to perform the oral examination, interview the mothers, provide oral health instructions, and complete the questionnaire. To ensure consistency, under supervision by the senior author, both examiners assessed 15 children as part of the training for this research (pilot study) during 1 week. The examiners used disposable dental mirrors, a head light and ball-ended World Health Organization CPI probes according to their criteria for the diagnosis of dental caries [World Health Organization, 1997]. Initially the teeth were cleaned with a toothbrush, then wiped with a cotton roll and allowed to air dry. We used the dmft index to record the presence of any caries. This index is defined by ‘d’ indicating a decayed tooth, ‘m’ indicating a missing tooth due to decay, and ‘i’ indicating a filled tooth. Both dentists were present at the follow-up appointments. The Kappa values for caries detection showed a high level of agreement between the two examiners at all three follow-up time points (range 0.940–1.0). In case of disagreement during the evaluations, consensus evaluations were obtained between the examiners. The data were collected and recorded at each follow-up period.
Study Design

The children were randomly divided into three equal groups of 100 participants each. The study was performed in two steps as follows. In step 1, parents’ knowledge and performance regarding oral health was assessed as the secondary outcome. A 2-page, self-reporting questionnaire was administered to parents in all three groups. The questionnaire was completed in the presence of the researchers, who provided face-to-face explanations of the aim of the study to the mothers or caregivers and answered any questions raised by parents while they were completing the forms.

The two questionnaires were designed for the knowledge and performance areas. A total of 5 pediatric dentists evaluated the questionnaires, and any necessary changes were made based on their comments. Both questionnaires had an acceptable to good level of internal consistency in a pilot test with 30 mothers (10 from each group) at the first meeting. Cronbach’s α was 78.6% for the knowledge questionnaire and 66.8% for the performance questionnaire. Knowledge and performance were evaluated with a 5-point Likert scale.

The questionnaire addressed (1) demographic information of the child, i.e. age, gender, place of birth, general health status, and dental history; (2) parents’ information, including level of education, employment, family income, and mother’s age; (3) parents’ knowledge, evaluated as their knowledge about factors that contribute to SECC, the role of brushing and fluoride in caries prevention, bottle feeding of milk or sweet liquids, and the importance of caring for primary teeth; and (4) parents’ performance on activities to ensure the child’s oral health, including brushing the child’s teeth, frequency of brushing, frequency of snacking, method of milk feeding, sharing utensils with the child during meals and checking the child’s teeth.

In the second step, intervention methods were used in the experimental groups as follows.

Group 1 (Control). Mothers completed the questionnaires, and the children’s teeth were examined at baseline. Control group participants did not receive any oral health care intervention. The placebo, a water-based colored solution similar to FV, was painted applied to all primary teeth at baseline. The parents were advised to brush the child’s teeth, frequency of brushing, frequency of snacking, method of milk feeding, sharing utensils with the child during meals and checking the child’s teeth. The baseline procedure for placebo application was repeated at the follow-up appointment 6 months later.

Group 2 (OHC). At the first appointment, parents in group 2 completed the questionnaires and received a free gift bag that contained an educational pamphlet and a toothbrush. The pamphlet explained the importance of caring for primary teeth, the factors that influence SECC, instructions on how to prevent SECC with a noncariogenic diet and feeding methods, and instructions for oral hygiene. Parents received face-to-face oral health instructions that were included in the pamphlet and were trained in the proper use of a toothbrush [Kagihara et al., 2009]. Children in this group received a placebo FV as previously described. Subsequent appointments were scheduled until the end of the follow-up period, and the placebo varnish was applied at baseline and at the 6-month follow-up appointment.

Group 3 (OHC + FV). The parents received oral health instruction as described for group 2. The dentist cleaned the children’s teeth by brushing and isolated them with cotton rolls. FV that contained 5% sodium fluoride (DuraShield, Sultan Healthcare, Hackensack, N.J., USA) was applied with a disposable brush to all tooth surfaces and left for 1 min. A small amount of varnish was applied to all primary teeth at baseline. The parents were advised not to allow the child to eat rough (abrasive) foods for the remainder of the day [Holve, 2008] and not to brush until the following day [Weyant et al., 2013]. The FV was applied again 6 months later.

All procedures including completion of the questionnaires, oral hygiene instruction and performing the intervention took about 30–40 min for each child in all groups.

Follow-Up

Parents were blinded to the study groups. They were not aware which group their child had been randomized to regarding the use of FV or a placebo. Follow-up appointments were scheduled at 4, 8, and 12 months after the initial dental appointment for each child. The incidence of caries was recorded as the primary outcome according to the dmft index. Also at each follow-up appointment, the parents completed the questionnaires which determined whether their knowledge and performance had changed after the baseline appointment. Each child received a new toothbrush every 3 months. In cases where preventive treatment failed, the children were referred for caries treatment. The children in group 1 (control) and group 2 (OHC) received OHC and FV after the study period had ended.

Statistical Analysis

All data are reported as frequencies and percentages, in terms of the mean ± standard deviation. Differences between groups in quantitative and qualitative variables were identified with one-way ANOVA and χ² tests. Repeated-measure ANOVA and Tukey post hoc tests were used to evaluate changes in the mean knowledge and performance score during the study period. One-way ANOVA and Tukey tests were used for between-group comparisons of knowledge and performance scores at each follow-up time point. One-sample repeated-measure ANOVA and Sidak post hoc tests were used for within-group comparisons. Incidence rate difference (risk difference, RD), the corresponding 95% confidence interval (95% CI) and the p value of Fisher’s exact test were calculated for dental caries experience (dmft ≠ 0) at each follow-up time point. Values of p < 0.05 were considered statistically significant.

Results

A total of 300 children (54.3% males) with no dental caries (dmft = 0) were enrolled in this 1-year design study. Of these, 260 completed the study. Figure 1 shows the flow diagram of study participants according to the CONSORT checklist [Moher et al., 2010]. Recruitment began in December 2012 and was completed within 4 months. The mean age of children was 20.49 ± 7.33 months, and ages ranged from 12 to 24 months. The mean age and demographic variables such as sex, maternal age and education level at baseline for all groups are presented in table 1. Table 2 shows the demographic variables of those who were lost to follow-up and those who completed the study.
Table 3 displays the total numbers and numbers of children with dental caries (dmft ≠ 0) in addition to the risk of caries and RD (with 95% CI) indices. The RD values in this table comprise the risk (incident rate) of dental caries in the OHC and OHC + FV groups minus the control group (in the preceding column) and the risk in the OHC + FV group minus that in the OHC group.

Caries Incidence at Follow-Up

Table 3 displays the total numbers and numbers of children with dental caries (dmft ≠ 0) in addition to the risk of caries and RD (with 95% CI) indices. The RD values in this table comprise the risk (incident rate) of dental caries in the OHC and OHC + FV groups minus the control group (in the preceding column) and the risk in the OHC + FV group minus that in the OHC group.

Four-Month Follow-Up. After 4 months of follow-up, we observed dental caries in 6 children: 3 in the control group, 2 in the OHC group and 1 in the OHC + FV group. The risk for caries in the OHC group was statistically similar to that of the control group (RD = –1.06%; 95% CI: –5.55 to –3.42; p = 0.642). There was no statistically significant difference in risk between the OHC + FV and control groups (RD = –2.07%; 95% CI: –6.11 to 1.97; p =
0.317). The difference in risk of caries between the OHC + FV and OHC groups was not statistically significant either (RD = –1.01%; 95% CI: –4.50 to 2.48; p = 0.573).

Eight-Month Follow-Up. At this follow-up, 15 children in the control group had dental caries compared to 3 in the OHC group and 1 in the OHC + FV group. The OHC group showed a significant reduction in caries risk (12.77%) compared to the control group (95% CI: –20.98 to –4.55; p = 0.005). The OHC + FV group had a caries risk reduction of 14.88% compared to the control group (95% CI: –22.58 to –7.19; p < 0.001). However, the risk values for caries in the OHC + FV and OHC groups did not differ significantly (RD = –2.12%; 95% CI: –6.24 to 2.01; p = 0.621).

End of Follow-Up (12 Months). The control group had the greatest number of children (n = 29) with dental caries. There were 4 children in the OHC and 1 child in the OHC + FV group that had dmft ≠ 0. The OHC program resulted in a risk reduction of 28.25% compared to the control group (95% CI: –39.05 to –17.45; p < 0.001). The OHC + FV program reduced the risk of dental caries by 31.80% compared to the control group (95% CI: –41.88 to –21.73; p < 0.001). The OHC + FV program did not yield a significant risk reduction compared to the OHC program (RD = –3.56%; 95% CI: –8.58 to 1.47; p = 0.165). No side effects or unexpected effects were reported or observed in any of the experimental groups.

Most mothers had low levels of knowledge and performance at baseline, with scores less than half the highest possible questionnaire score in 92.9% (knowledge) and 98.1% (performance) of the participants. The trend for the change in mean knowledge score showed a significant group-by-time interaction effect (p < 0.001). Table 4 shows the mean values ± SD for mothers’ knowledge and performance scores as well as between-group and within-group comparisons. There was no statistically significant difference in mean knowledge score between the control (31.11 ± 3.18, range: 23–45), OHC (31.97 ± 3.83, range: 24–46), and OHC + FV (32.42 ± 3.94, range: 24–42) groups at baseline (p = 0.070). However, mean knowledge scores in the OHC and OHC + FV groups were significantly higher than in the control group 4, 8, and 12 months after baseline. Within-group comparisons showed that the mean knowledge score tended to remain constant during the study period in the control group (p = 0.744). However, the mean knowledge score increased with time in both intervention groups (all p < 0.05) (fig. 2). We obtained similar results for the mothers’ mean performance score. The mean performance scores in the control, OHC, and OHC + FV groups were 21.66 ± 3.70 (range: 12–30), 22.96 ± 4.24 (range: 11–33) and 22.67 ± 4.30 (range: 9–35), respectively. All groups performed similarly at baseline; however, we noted significant differences at all three follow-up time points (all p < 0.05; table 4). Although the mean performance score increased in groups OHC and OHC + FV during the follow-up period (all p < 0.05), it tended to remain the same and sometimes decreased in the control group (fig. 3). Table 5 displays mean between-group differences in knowledge and performance scores and the corresponding 95% CI.

Table 3. Reduction in caries incidence during the follow-up period

<table>
<thead>
<tr>
<th>Follow-up time</th>
<th>Group</th>
<th>n</th>
<th>dmft ≠ 0</th>
<th>Risk</th>
<th>RD1</th>
<th>RD2</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 months</td>
<td>Control</td>
<td>96</td>
<td>3</td>
<td>3.12 (0.00–6.60)</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>97</td>
<td>2</td>
<td>2.06 (0.00–4.92)</td>
<td>–1.06 (–5.55, 3.42)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>OHC + FV</td>
<td>95</td>
<td>1</td>
<td>1.05 (0.00–3.10)</td>
<td>–2.07 (–6.11, 1.97)</td>
<td>–1.01 (–4.50, 2.48)</td>
</tr>
<tr>
<td>8 months</td>
<td>Control</td>
<td>94</td>
<td>15</td>
<td>15.96 (9.01–22.91)</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>94</td>
<td>3</td>
<td>3.19 (0.00–6.74)</td>
<td>–12.77 (–20.98, –4.55)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>OHC + FV</td>
<td>93</td>
<td>1</td>
<td>1.08 (0.00–3.16)</td>
<td>–14.88 (–22.58, 7.19)</td>
<td>–12.12 (–6.24, 2.01)</td>
</tr>
<tr>
<td>12 months</td>
<td>Control</td>
<td>88</td>
<td>29</td>
<td>32.95 (23.13–42.77)</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>85</td>
<td>4</td>
<td>4.71 (0.21–9.21)</td>
<td>–28.25 (–39.05, –17.45)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>OHC + FV</td>
<td>87</td>
<td>1</td>
<td>1.15 (0.00–3.39)</td>
<td>–31.80 (–41.88, –21.73)</td>
<td>–3.56 (–8.58, 1.47)</td>
</tr>
</tbody>
</table>

RD1 = Risk of caries experience for OHC or OHC + FV groups minus that of the control group; RD2 = risk of caries experience for OHC + FV group minus that of the OHC group. RD = 0 indicates that this group was considered the reference group. Figures in parentheses indicate 95% CI.
Discussion

Oral health can be favored by providing healthy, non-cariogenic feeding in addition to routine oral hygiene such as toothbrushing and flossing, and scheduled regular dental appointments [Daly et al., 2010]. Approaches to achieving oral health involve 3 factors: individual, family, and community [Fisher-Owens et al., 2007]. There is some controversy regarding the positive effect of oral health instructions in reducing dental caries or periodontal diseases [Cascaes et al., 2014]. Caregivers or mothers of young children who are responsible for the child’s gen-

Table 4. Evaluation of mean knowledge and performance scores in mothers in all groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>Follow-up time</th>
<th>p1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>4 months</td>
<td>8 months</td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>31.11±3.18&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>31.19±3.37&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>31.16±3.31&lt;sup&gt;A,a&lt;/sup&gt;</td>
</tr>
<tr>
<td>OHC</td>
<td>31.97±3.83&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>39.78±3.70&lt;sup&gt;B,b&lt;/sup&gt;</td>
<td>42.42±3.29&lt;sup&gt;B,c&lt;/sup&gt;</td>
</tr>
<tr>
<td>OHC + FV</td>
<td>32.42±3.94&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>40.42±3.43&lt;sup&gt;B,b&lt;/sup&gt;</td>
<td>43.27±2.28&lt;sup&gt;B,c&lt;/sup&gt;</td>
</tr>
<tr>
<td>p2</td>
<td>0.070</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Performance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>21.66±3.70&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>21.25±2.95&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>20.27±2.83&lt;sup&gt;A,b&lt;/sup&gt;</td>
</tr>
<tr>
<td>OHC</td>
<td>22.96±4.24&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>27.28±4.17&lt;sup&gt;B,b&lt;/sup&gt;</td>
<td>27.05±2.14&lt;sup&gt;B,b&lt;/sup&gt;</td>
</tr>
<tr>
<td>OHC + FV</td>
<td>22.67±4.30&lt;sup&gt;A,a&lt;/sup&gt;</td>
<td>26.81±2.88&lt;sup&gt;B,b&lt;/sup&gt;</td>
<td>27.16±2.41&lt;sup&gt;B,b&lt;/sup&gt;</td>
</tr>
<tr>
<td>p2</td>
<td>0.081</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

p1 = One-sample repeated-measure ANOVA F test; p2 = one-way ANOVA F test. In each column, different superscript capital letters indicate significant differences between groups (Tukey HSD test, p < 0.05). In each row, different superscript lower-case letters indicate significant differences between follow-up periods (Sidak test, p < 0.05).

Fig. 2. Changes in mean knowledge score in all experimental groups during 12 months: group 1 (control), group 2 (OHC), and group 3 (OHC + FV).

Fig. 3. Changes in mean performance score in all experimental groups during 12 months: group 1 (control), group 2 (OHC), and group 3 (OHC + FV).
eral health should also provide oral health care. Therefore, an increase in parent’s knowledge and performance of children’s oral health measures can lead to the prevention of ECC in children, in addition to shaping children’s attitudes toward oral health as they mature [Blinkhorn, 1991; Begzati et al., 2014].

In the present study, the mothers in all groups showed a lack of knowledge and performance skills in oral health at baseline, which is consistent with results from a previous study [Azevedo et al., 2014]. In addition, our results showed increased mean knowledge and performance scores over time after receiving oral health instruction, which led to a reduction in dental caries or severity of caries in the children who participated in this study. This finding has been reported previously [Kay et al., 1996; Harrison et al., 2007, 2012; Masumo et al., 2012; Wagner et al., 2014; Medeiros et al., 2015]. However, some have reported few changes or modest changes in parents’ behaviors regarding their child’s oral health and subsequently in the incidence of caries [Freudenthal and Bowen, 2010; Ismail et al., 2011]. In the present study, the effectiveness of oral health education was observed in mothers from groups 2 and 3, who were of different ages and had different levels of education and family income. However, some studies have shown that education is influenced by the mother’s age [Niji et al., 2010], family income, parent’s level of education, and socioeconomic background [Chu et al., 2012]. The differences may be attributed to regular education and motivational counseling of mothers during the period when children experience eruption of their primary teeth, in addition to differences in sample size and study design. Further research on oral health education and counseling interventions is recommended [Cascaes et al., 2014; Habbu and Krishnappa, 2015].

A number of factors influence increased oral health knowledge and performance in children, such as the time of the first dental appointment, the dentist who provides primary dental care, regular face-to-face instruction for caregivers [Kowash et al., 2000; Ammari et al., 2007], and the method of parental education in the prevention of ECC [Kagihara et al., 2009; AAPD, 2011]. The intervention we tested in the present study attempted to achieve all of the goals noted above for oral health programs. Two dentists participated in the initial dental appointment and provided motivational face-to-face counseling with parents individually regarding oral health instruction, as in other studies [Weinstein et al., 2006; Naidu et al., 2012; Batliner et al., 2014]. Despite the role of dentists in educating parents about oral health, education can also be initiated by midwives during the mother’s pregnancy and by health care professional groups such as pediatric nurses and pediatricians after childbirth [Ehlers et al., 2014]. Health care professionals should also receive instruction about dental caries and become comfortable with delivering oral health services for children, e.g. the use of fluoride therapy [Naidu et al., 2012; Ehlers et al., 2014; Ruiz et al., 2014].

A strength of the present study was the nature of the oral health interventions, which comprised repeated instruction as well as a pamphlet and free toothbrush [Kowash et al., 2000; Ammari et al., 2007] in addition to the free health and dental care given to the children at public health centers [Holve, 2008].

| Table 5. Between-group differences (Δ, with 95% CI) in knowledge and performance scores |
|---------------------------------|---------------------------------|-----------------|-----------------|
| Δ                               | Follow-up time                  | Mean Δ knowledge | performance     |
| OHC – control                   | baseline                        | 0.86 (–6.04 to 9.10) | 1.30 (–6.50 to 9.10) |
|                                 | 4 months                        | 8.59 (1.65 to 15.53) | 6.03 (0.47 to 14.65) |
|                                 | 8 months                        | 11.26 (4.79 to 17.73) | 6.78 (1.97 to 11.81) |
|                                 | 12 months                       | 12.95 (7.09 to 18.81) | 7.56 (–5.26 to 4.32) |
| (OHC + FV) – control            | baseline                        | 1.31 (–5.71 to 8.33) | 1.01 (–1.83 to 13.89) |
|                                 | 4 months                        | 9.23 (2.57 to 15.89) | 5.56 (–4.70 to 6.72) |
|                                 | 8 months                        | 12.11 (6.53 to 17.69) | 6.89 (3.25 to 12.19) |
|                                 | 12 months                       | 13.90 (8.22 to 19.58) | 7.72 (–4.90 to 5.12) |
| (OHC + FV) – OHC                 | baseline                        | 0.45 (–7.17 to 8.07) | –0.29 (–1.59 to 15.15) |
|                                 | 4 months                        | 0.64 (–6.36 to 7.64) | –0.47 (–1.48 to 12.60) |
|                                 | 8 months                        | 0.85 (–4.70 to 6.40) | 0.11 (–5.44 to 4.86) |
|                                 | 12 months                       | 0.95 (–3.77 to 5.67) | 0.16 (–4.38 to 4.70) |
The use of FV is a professional care approach for the prevention of dental caries in young children. This material is safe and easy to use with children [Carvalho et al., 2010; Weyant et al., 2013]. However, fluoride is released slowly from the varnish [Rošin-Grget et al., 2013]. Our results showed a significant reduction in the number of caries in the OHC and OHC + FV groups compared to the control group. After 12 months, children in the OHC group had 28% less caries, whereas those in the OHC + FV group had 31% less caries compared to the control group. In agreement with our results, a number of studies reported that the combination of an oral health education program and the use of FV in public health programs reduced ECC [Weintraub et al., 2006; Holve, 2008; Lawrence et al., 2008; Sundell et al., 2013; Memarpour et al., 2015]. However, some studies found that the application of FV failed to reduce caries in high-risk preschool children [Anderson et al., 2016; Oliveira et al., 2014]. Our results showed that both intervention methods were important in reducing SECC, and should be considered by health care staff when designing free health care services for young children in public health centers. However, there was no significant difference between the OHC and OHC + FV groups in the numbers of caries. The differences between the results may have been influenced by the sample size and duration of the study. The sample size in the present study was determined based on comparison of the control and FV groups. However, a larger sample size would be needed to detect a statistically significant difference between the oral health education and FV groups. Moreover, the two intervention groups may be different in a study with a longer follow-up period.

Potential limitations of our study included the limited sample size and geographic location of the participants, as well as the lack of knowledge regarding risk factors for caries in children. In addition, the present study did not include children from different socioeconomic backgrounds, i.e., living in rural areas or receiving care from a private pediatrician, and these factors may influence the characteristics of oral health education programs, yet may not be feasible in all clinical settings. It is also possible that some of the parents may not have followed our instructions completely or correctly. Another limitation of the study was that the same dentists who performed the research also provided the dental care, i.e., oral examination, oral health instruction and clinical interventions. However, to reduce their judgment bias at each follow-up appointment, the dentists first examined the teeth and recorded the dmft index on page 2 of the questionnaire. Then the parents completed their part of the questionnaire, and the dentist was informed by the health center staff member which group the child belonged to so that the dentist could use the appropriate group intervention and then complete the child’s group section on page 1 of the questionnaire. This procedure ensured that the examiner remained unaware of which group each child had been randomized to so that the data were not influenced by examiner bias or assumptions. We note that our analysis in this study was not an intention-to-treat analysis, given that children who did not follow the instructions were not included in the analysis. We recommend additional studies with larger sample sizes and analyses based on intention to treat. It should be noted that although 40 participants withdrew from the study, we believe this is not an issue of concern. As mentioned in the sample size section, the required sample size was calculated assuming a withdrawal rate which was higher than the actual withdrawal rate in this study. Moreover, there were no obvious differences in the characteristics of participants who withdrew and those who completed the study.

The results of the present study show that oral health education programs in public health care centers can enhance parents’ knowledge and performance in children’s oral health. Education in oral health, either with or without the use of FV, was an effective method that reduced caries in younger children. The results of our study have been reported to the Vice-Chancellery of Health and the Health System Research Department of the Vice-Chancellery of Research of our university, in preparation for a program to prevent ECC among young children. Further clinical studies are necessary to evaluate the effectiveness of preventive methods in children over longer periods of time, and to investigate the influence of additional factors on the development of dental caries.

Acknowledgments

The authors wish to thank the Vice-Chancellery of Research of Shiraz University of Medical Sciences, Shiraz, Iran, for supporting this research (grant No. 92-6158). The authors also thank the Dental Research Development Center of Shiraz Dental School for the statistical analysis. We also thank K. Shashok (AuthorAID in the Eastern Mediterranean) for improving the use of English in the manuscript.

Author Contributions

Dr. Memarpour: conceived and designed the study, supervised data collection, critically reviewed the manuscript, and approved the final manuscript as submitted. Dr. Dadaein, Dr. Fakhraei: de-
signed the data collection instrument, participated in the study design, reviewed the manuscript, and approved the final manuscript as submitted. Dr. Vossoughi: supervised data collection, carried out the initial analyses, drafted the initial manuscript, and reviewed the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

References


Disclosure Statement

There are no conflicts of interest.


