Optimizing oral health: Towards a tailored, effective and cost-effective dental care

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Chapter 2

Three-year outcomes of a randomized controlled clinical trial in 6-year-old children on caries-prevention programs
Three-year outcomes of a randomized controlled clinical trial in 6-year-old children on caries-prevention programs.

Introduction

According to current standards, the daily use of fluoridated toothpaste is the most effective measure for caries prevention (Marinho et al., 2003). Besides the use of occlusal sealants (Ahovuo-Saloranta et al., 2008), professional application of fluorides (gels, varnishes) is also considered to contribute largely to reduction of caries incidence (Marinho et al., 2002). A meta-analysis of 14 placebo-controlled trials concluded that a higher decayed, missing or filled surfaces (DMFS) prevented fraction was associated with increased frequency and intensity of application (Marinho et al., 2002). In the Netherlands, a frequently used approach of caries-prevention is to maintain a dental check-up interval of 6 months, apply 1.23% fluoride gel at these visits and routinely seal the occlusal surfaces of erupted permanent molars. Despite continuing efforts and concomitant expenses, a large number of children still experience caries. A study in 11-year-olds in the Netherlands reported an increase of decayed, missing or filled surfaces in permanent dentition (DMFS) from 1.4 (± 2.3) in 1999 to 1.7 (± 2.8) in 2005 (Poorterman & Schuller, 2006); this study also showed an increase in primary dentition (dmfs) in children aged 5: 4.0 (± 7.4) in 1999 vs. 4.6 (± 8.0) in 2005.

An alternative strategy, implementing the concept of non-operative caries treatment and prevention (NOCTP), based on parental homecare, has been the subject of several studies. Although results to the contrary have been found (Arrow, 2000), most studies investigating delivering individualized preventive care report good efficacy and effectiveness (Carvalho et al., 1992; Ekstrand et al., 2000; Ekstrand & Christiansen, 2005; Hausen et al., 2007; Evans & Dennison, 2009).

Most studies on caries prevention strategies with NOCTP are performed in high-risk populations. But also for populations with relatively low caries prevalence rates it is important to identify the feasibility of these strategies and to determine which strategy is most effective in preventing caries. Therefore, it is of interest to investigate to what extent different caries preventive strategies are effective in daily practice in a mixed-SES population in a country with a relatively low caries incidence.
The aim of this study was to test the hypothesis that, compared to regular care (routinely twice a year a dental check-up with professional topical fluoride application and sealing newly erupting permanent molars) a larger caries-preventive effect can be achieved by following a non-operative caries treatment and prevention strategy (NOCTP) or by following the regular approach with an increased professional topical fluoride application frequency of 4 times a year (IPFA). All participants (from a mixed SES population) followed the respective programmes in the same general dental clinic in the Netherlands.

**Material & Methods**

**Procedure**

From September 2006 to September 2008, all parents of 6-year-old children (± 3 months) – all regular patients of a large dental clinic in ’s-Hertogenbosch, the Netherlands – were asked to allow their child to participate in this trial. ’s-Hertogenbosch is a city with approximately 150,000 inhabitants. This city can be considered, in terms of demographic indicators, to be representative of the Netherlands (Schuller, 2009). The study team sent a letter to inform the parents about the study and of the possibility of participation in the study, approximately two weeks prior to the planned dental check-up around the child’s sixth birthday. After informed consent was obtained, parents were asked to fill out a questionnaire to provide information on socioeconomic variables, oral hygiene habits, dietary habits, and knowledge on dental topics. The questionnaire also asked parents to indicate the objections they might have of investing in preventive oral health treatments for their child. If the parent decided against participation, the reason for non-participation was recorded and the parent was still asked to fill out the same questionnaire.

**Sample size estimation**

The interventions aimed at the reduction of caries progression. Therefore, caries increment in permanent dentition (first three years after eruption) was considered the main outcome measure. Caries increment in primary dentition, the level of oral hygiene and the number of pit and fissure sealants were also recorded. A sample size of 181 was determined to be sufficient to observe a difference of 1 DMFS with 80% of power using a two sided test at $\alpha = 0.05$. An anticipated dropout percentage of 20% was taken into account. Therefore, a total of 230 children, aged 6.0 year (± 3 months) were included in this study. After inclusion, children were randomly assigned to one of three treatment groups using research randomizer: www.randomizer.org/form.htm.
Interventions

Children receiving the practice’s regular caries treatment and prevention served as the control group. The regular protocol comprised preventive visits (dental check-ups) twice a year, professional 1.23% fluoride gel application twice a year, routinely sealing pits and fissures of newly erupted molars with a resin-based material and restoration of caries at the dentine-threshold (d3/D3-level).

In experimental group 1, the standard protocol was abandoned and replaced by a non-operative caries treatment and prevention protocol (NOCTP); an individual, tailored approach, which was copied from the protocol used in Nexø, Denmark (Ekstrand & Christiansen, 2005) and applied to the situation in this specific dental practice. The main difference was that all children in this study started the programme at the age of 6 years (and not already at 6 months). The dental personnel involved in this project followed a 1-day training course that was run by former staff of the Nexø-clinic. The protocol was based on the understanding caries being a localized process that can be prevented by tooth brushing with fluoride toothpaste. Recall intervals were individualized using the criteria described by Carvalho et al. (1992): the cooperation of the parents, the activity of caries lesions within the dentition, the eruption stage of permanent first molars, and caries activity in the occlusal surfaces of the first permanent molars. Each of these criteria was assigned either one (favourable) or two (unfavourable) points. With a maximum score, the recall interval was set at 1 month, with a minimum score at 9 months. Oral hygiene and dietary instructions were supported with written information, based on the leaflets used by the staff in the Nexø study. Professional fluoride applications were restricted to those situations where caries initiation or progression was recorded. Placement of pit and fissure sealants was also restricted to situations where intensified brushing with fluoride toothpaste and additional professional fluoride application were not able to inhibit caries progression. A checklist was completed by dental staff during each visit so that the dental staff could maintain accurate and up-to-date records of all preventive and restorative actions that were taken with each subject. Like in the control group, caries was restored at d3/D3-level in this group as well.

Children in experimental group 2 followed the same approach as the control group but the children in this second group had two additional visits where professional fluoride treatments were given (a total of 4 times / year). The rationale behind this was firstly the fact that professional fluoride gel applications gain effectiveness while increasing the frequency of applications (Marinho et al., 2002) and secondly to exclude the
possibility that extra visits by itself (disregarding the content of that visit) may have a positive effect on caries preventive effectiveness.

**Questionnaires**

Dental knowledge and perceived resistance to perform dental hygiene measures were scored using a dental knowledge questionnaire and a perceived dental hygiene burden questionnaire, respectively. Scores on the dental knowledge questionnaire varied from 0 to 5 with a higher score indicating higher dental knowledge. Scores on dental hygiene burden varied from 0 to 5 with higher scores indicating a higher perceived burden. A detailed description of these questionnaires is given elsewhere (Vermaire et al., 2012).

**Caries scores**

Clinical examinations were carried out by one experienced and trained dentist, blinded to the treatment groups. At baseline and after three years, 11% and 10%, respectively, of the children were re-examined by a second experienced and trained dentist. Inter-examiner agreement scores for dmfs/DMFS and plaque scores were $\kappa = 0.89$ and $\kappa = 0.74$ for the baseline measurements, and $\kappa = 0.91$ and $\kappa = 0.80$ after three years, respectively. Neither of these dentists participated in the dental healthcare programme for the children. Due to medical-ethical objections, no radiographs were taken for the purpose of this study; therefore, the incidence of caries was exclusively clinically assessed. The children’s oral health condition was assessed clinically during a visit at the dental clinic using mirror, light, a blunt probe and compressed air. Oral hygiene was assessed using the simplified oral hygiene index (OHI-s) (Greene & Vermillion, 1964) and caries were assessed using the dmfs-/DMFS-index, with caries scored at the dentine-threshold (d3/D3) (WHO, 1979).

**Statistical analysis**

All statistical analyses were performed using IBM SPSS Statistics 20.0. The sample was characterized using descriptive statistics. Mean dmfs / DMFS scores were compared using independent samples t-tests. The significance level was set at alpha = 0.05.

The study was approved by the Medical Ethical Committee of the VU University Amsterdam, the Netherlands. Protocol number NL13709.029.06.
Results

After three years, complete data for a total of 179 children was available for analysis. A flowchart of the attrition of participants in this study is presented in Figure 1. Some of the reasons for withdrawal were the following: inconvenience for the child (20 parents), burden of travelling to the clinic (20 parents), inconvenience for the parent (10 parents), and serious illness (1 child). In the IPFA group, 60% of the withdrawals were because of the perceived inconvenience by the child (especially gagging because of the use of fluoride gel filled trays), while in the NOCTP group, 46% of the withdrawals discontinued participation in the study because of the burden of travelling. Almost 25% of the withdrawals in the NOCTP group did so because these parents felt that they were preventing their child from receiving the regular care that they were used to.

Sample characteristics and non-clinical outcomes at 6 and 9 years of age are presented in Table 1. It was found that after three years, knowledge on dental topics was greatest in the NOCTP group. The NOCTP group also had the lowest scores on oral hygiene burden questions; however, this was also the case at the age of 6 and is therefore not to be attributed to the intervention.

Table 2 shows the outcomes of the clinical measurements at baseline and after three years for each experimental group. After three years, children in the NOCTP group had developed 0.15 (± 0.50) DMFS, while the children in the IPFA group and the control group developed 0.34 (± 0.87) and 0.47 (± 1.04) DMFS, respectively. Independent sample t-test showed that this mean difference between the NOCTP and control group was statistically significant (t = 2.13; p = 0.02).

Table 3 shows the percentages of caries-free children in both primary and permanent dentition for each experimental group. In the NOCTP group, 5.4% of the children who were caries-free at the age of 6 developed caries into dentin in their primary dentition in a period of three years. In the IPFA and control groups, this was 14.6% and 21.8%, respectively. For the permanent dentition, the percentages were the following: 9.4%, 24.6% and 25.5%, respectively. Children in the NOCTP group who developed caries did so less frequently than children in the other groups. However, these differences were not statistically significant (t = -1.77, p = 0.09, compared to control and t = -1.67, p = 0.11, compared to IPFA).
After three years, the total duration of the visits was comparable for the NOCTP group and control group. In the first year of the study, the average contact time with the dentist for the NOCTP group, IPTA group, and control group were 14.40 minutes (± 5.18), 13.61 minutes (± 4.57) and 8.70 minutes (± 2.87), respectively. In the third year of the study, no statistically significant difference was found (8.85 minutes (± 2.83) in the NOCTP group vs. 9.00 minutes (± 3.41) in the control group). The total cumulative difference in contact time between the NOCTP group and the control group after three years was approximately 7 minutes. After three years, the mean number of visits for NOCTP group, the IPFA group, and the control group were the following: 7.45 (± 1.44), 11.26 (± 1.33) and 6.28 (± 1.02), respectively. The higher values in the IPFA group may be attributed to the fact that the protocol in that group prescribed at least 4 sessions per year during which professional fluoride treatments were provided.

Table 4 presents an overview of all actions taken at every visit in the NOCTP group. The number of visits per year decreased during the three years of the experiment. The number of actions taken per visit also decreased over time. Furthermore, in this group, restoration placements were highest in the 3rd year, yet still lower than that in the IPFA and control groups.

Discussion

This study aimed to compare the caries-preventive effect of a non-operative caries treatment and prevention strategy (NOCTP) that is based on increased parental home care and includes an individually assessed recall interval, with two strategies that are based on different professional topical fluoride application frequencies (4/year (IPFA) and 2/year (control) in addition to routine twice-a-year dental check-ups and sealing all erupting permanent molars. The NOCTP program turned out to be an effective program for caries-prevention in this regular dental practice in the Netherlands. Children in this program had better oral hygiene, a lower mean DMFS and the biggest chance to be – clinically – caries-free at the age of 9 compared to children in the other two programs.

A mean difference of 0.32 ΔDMFS between children in the control group and NOCTP group after three years was found. Taking into account the low caries prevalence in the study group, the results can be regarded as clinically significant; only approximately 3 children had to follow the NOCTP program to prevent one extra DMFS. Following the IPFA regime, children had a statistically non-significant reduction of 0.13 DMFS compared to the control group, which would mean a number needed to treat of about 8 children to prevent 1 DMFS.
A larger number of children in the NOCTP group discontinued participation in the study compared to the other two groups. This was mainly because of travel-related reasons and this happened mostly in the first year of the trial. Apparently, the parents found that the investment that they had to make to follow the program did not outweigh the possible benefits for their child. Other parents indicated that they felt uncomfortable ‘withholding’ their children regular care, especially when the children had older brothers or sisters who had followed the standard approach in the past.

Most children in the IPFA group who discontinued participation in the study did so because of inconvenience; undergoing the professional fluoride application was regularly accompanied with gagging because of the fluoride gel-filled tray. This, together with the uncertain effectiveness, limits the usefulness of this caries prevention strategy: if a strategy works but compliance is limited, no long-lasting effects should be expected. This may be considered an established fact for all strategies.

Limiting the indication for placement of occlusal sealants in the NOCTP strategy resulted in a considerable decrease in the number of placed sealants (Table 2). Whether this decrease is a lasting result or only a postponement is still unknown. But, as is shown in Table 4, after an increase in the number of placements of sealants in the second year of the trial (2 sealants in the first year vs. 11 in the second year), the number of placements of sealants in the NOCTP group seems to have levelled off in the third year (4 sealants). Whether this trend is the same for the placement of restorations is highly relevant as well because, as Table 4 also shows, the number of restorations doubled in the third year of the trial (8 restorations), compared to the other two years (4 in the first year, 5 in the second year). Whether this will also level off or increase further in the fourth year and beyond will become evident when longer-term results become available 6 years after the start of the trial, at the age of 12.

The NOCTP program in the current study is copied from the original study in Nexø, Denmark, where the program ran from the age of 8 months until the age of 18 (Ekstrand & Christiansen, 2005). In 18-year-olds, the mean number of DMFS was 1.23 (± 2.26), while in the comparison groups in other parts of Denmark, DMFS varied between 2.73 (± 3.94) and 3.93 (± 3.77). It should be noted that the comparison groups were among of the best performing health-service clinics in Denmark, with very low caries rates. The percentage of caries-free children was 55% in Nexø compared to 24-39% in the comparison groups. In spite of obvious differences in the age groups between the current study and the Nexø study, the same trend in caries development can be seen: children following a non-operative caries treatment and prevention
strategy had lower DMFS scores and more children in this group have no caries experience. This was also the case in a study where the NOCTP strategy was applied in Moscow, Russia (Ekstrand & Christiansen, 2005). Although the opposite has also been reported (Arrow, 2000), most other studies using individually delivered caries prevention strategies have reported outcomes that are comparable to those of the current study (Warren et al., 2010; Hausen et al., 2007; Pienihäkkinen & Jokela, 2002). Considering all of the studies mentioned above, it is clear that individualizing caries prevention results in a net-positive gain in effect. It can be argued that the NOCTP approach used in the current study in the Netherlands is a feasible approach and an effective way to prevent caries in this sample of children.

A relevant issue that needs to be addressed is that of the costs involved in applying the followed strategies. The original study in Nexø reported that the mean costs of applying the NOCTP regime was approximately € 130 / year (converted from the original amount of 1172 DKK / year), which was among the lowest in Denmark (Ekstrand & Christiansen, 2005). The reported costs in that study were only included to monitor the effect of implementation of the NOCTP regime on the cost per child per year. In Nexø, these costs were significantly lower than before NOCTP had been implemented. It was emphasized that because the way healthcare (including dental health) is organized and financed is different throughout countries and therefore the reported statistics are inadequate for economic comparisons with preventive programmes that are tested outside Denmark. From an earlier study we know that in the population of the current study, the mean stated parental willingness to pay to keep their children’s teeth healthy until the age of 18 years is € 32 / month (Vermaire et al., 2012). However, money is not the only investment needed in caries prevention: the investment in the number of preventive visits needed, the extra time parents have to invest travelling to the clinic and accompanying their children, and brushing their children’s teeth themselves may even be of greater importance. Hence, economic evaluations are necessary to compare both strategies with the control group and to identify the necessary resources used to achieve the extra gain in caries prevention.

In light of the results of this study, we can conclude that a non-operative caries treatment and prevention strategy (NOCTP) like the one that was used in Nexø, Denmark can be regarded as clinically effective in a general dental clinic in the Netherlands. In the future, it may be useful to expand the implementation of this strategy, both in more dental clinics in more regions, as well as in more age groups, and to perform a health economic evaluation of the strategy to assess its cost-effectiveness.
Table 1: Non-clinical outcomes
Percentages of total divided by research groups n = 179

<table>
<thead>
<tr>
<th></th>
<th>NOCTP (n = 54)</th>
<th>IPFA (n = 62)</th>
<th>CONTROL (n = 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SEX</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>27 (50.0%)</td>
<td>29 (46.7%)</td>
<td>31 (49.2%)</td>
</tr>
<tr>
<td>female</td>
<td>27 (50.0%)</td>
<td>33 (53.2%)</td>
<td>32 (50.8%)</td>
</tr>
<tr>
<td><strong>SES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>low</td>
<td>14 (25.9%)</td>
<td>21 (33.9%)</td>
<td>20 (31.8%)</td>
</tr>
<tr>
<td>medium</td>
<td>17 (31.5%)</td>
<td>23 (37.1%)</td>
<td>23 (36.4%)</td>
</tr>
<tr>
<td>high</td>
<td>23 (42.6%)</td>
<td>18 (29.0%)</td>
<td>20 (31.8%)</td>
</tr>
<tr>
<td><strong>Oral hygiene habits</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>only child brushes</td>
<td>17 (31.5%)</td>
<td>35 (64.8%)</td>
<td>15 (24.2%)</td>
</tr>
<tr>
<td>only parent brushes</td>
<td>16 (29.6%)</td>
<td>4 (7.4%)</td>
<td>7 (11.3%)</td>
</tr>
<tr>
<td>both child &amp; parent</td>
<td>21 (38.9%)</td>
<td>15 (27.8%)</td>
<td>40 (64.5%)</td>
</tr>
<tr>
<td><strong>Fluoride in toothpaste?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>consciously no</td>
<td>3 (5.6%)</td>
<td>1 (1.8%)</td>
<td>2 (3.2%)</td>
</tr>
<tr>
<td>yes, age specific toothpaste*</td>
<td>41 (75.9%)</td>
<td>41 (75.9%)</td>
<td>49 (79.0%)</td>
</tr>
<tr>
<td>yes, adult’s toothpaste*</td>
<td>4 (7.4%)</td>
<td>9 (16.7%)</td>
<td>6 (9.7%)</td>
</tr>
<tr>
<td>I don’t know</td>
<td>6 (11.1%)</td>
<td>3 (5.6%)</td>
<td>5 (8.1%)</td>
</tr>
<tr>
<td><strong>Dietary habits – regular meals</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>breakfast</td>
<td>48 (90.5%)</td>
<td>47 (88.7%)</td>
<td>54 (88.9%)</td>
</tr>
<tr>
<td>lunch</td>
<td>51 (96.2%)</td>
<td>48 (90.6%)</td>
<td>56 (93.3%)</td>
</tr>
<tr>
<td>dinner</td>
<td>51 (96.2%)</td>
<td>52 (98.1%)</td>
<td>58 (96.7%)</td>
</tr>
<tr>
<td><strong>Dietary habits – between meal snacks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>not every day</td>
<td>2 (3.7%)</td>
<td>2 (3.7%)</td>
<td>2 (3.2%)</td>
</tr>
<tr>
<td>1-5 / day</td>
<td>41 (75.9%)</td>
<td>45 (83.3%)</td>
<td>48 (77.4%)</td>
</tr>
<tr>
<td>&gt; 5 / d day</td>
<td>11 (20.4%)</td>
<td>7 (13.0%)</td>
<td>12 (19.4%)</td>
</tr>
<tr>
<td><strong>Dental knowledge score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5</td>
<td>4 (7.4%)</td>
<td>2 (3.7%)</td>
<td>4 (6.5%)</td>
</tr>
<tr>
<td>5-7</td>
<td>19 (35.2%)</td>
<td>23 (41.9%)</td>
<td>12 (19.4%)</td>
</tr>
<tr>
<td>&gt; 7</td>
<td>31 (57.4%)</td>
<td>39 (72.2%)</td>
<td>35 (55.3%)</td>
</tr>
<tr>
<td><strong>Dental hygiene burden score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 2</td>
<td>21 (38.9%)</td>
<td>14 (27.7%)</td>
<td>17 (27.4%)</td>
</tr>
<tr>
<td>2-4</td>
<td>21 (38.9%)</td>
<td>30 (55.6%)</td>
<td>19 (30.6%)</td>
</tr>
<tr>
<td>&gt; 4</td>
<td>12 (22.2%)</td>
<td>9 (16.7%)</td>
<td>26 (42.0%)</td>
</tr>
</tbody>
</table>

NOCTP: Non-Operative Caries Treatment and Prevention;
IPFA: Increased Professional Fluoride Application.
Fl- in toothpastes: < 5 y: 500ppm, < 5y 1000-1500ppm
Table 2: Mean scores of clinical variables divided by experimental group

<table>
<thead>
<tr>
<th>Clinical data at baseline (6-years-old) n = 179</th>
<th>NOCTP (n = 54)</th>
<th>controls (n = 63)</th>
<th>t</th>
<th>p</th>
<th>IPFA (n = 62)</th>
<th>controls (n = 63)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>OHI-s (0-3)</td>
<td>0.85 (± 0.65)</td>
<td>0.90 (± 0.62)</td>
<td>-0.42</td>
<td>0.68</td>
<td>0.82 (± 0.68)</td>
<td>0.90 (± 0.62)</td>
<td>-0.63</td>
<td>.53</td>
</tr>
<tr>
<td>Sealants</td>
<td>0.19 (± 0.81)</td>
<td>0.19 (± 0.85)</td>
<td>0.01</td>
<td>.31</td>
<td>0.48 (± 1.23)</td>
<td>0.19 (± 0.85)</td>
<td>1.58</td>
<td>.12</td>
</tr>
<tr>
<td>dmfs</td>
<td>4.55 (± 6.20)</td>
<td>6.88 (± 8.99)</td>
<td>-1.59</td>
<td>.11</td>
<td>5.00 (± 8.23)</td>
<td>6.88 (± 8.99)</td>
<td>-1.03</td>
<td>.31</td>
</tr>
<tr>
<td>DMFS</td>
<td>0.06 (± 0.31)</td>
<td>0.02 (± 0.13)</td>
<td>0.98</td>
<td>.33</td>
<td>0.05 (± 0.29)</td>
<td>0.02 (± 0.13)</td>
<td>0.84</td>
<td>.40</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical data after 3 years (9-year-old) n = 179</th>
<th>NOCTP (n = 54)</th>
<th>controls (n = 63)</th>
<th>t</th>
<th>p</th>
<th>IPFA (n = 62)</th>
<th>controls (n = 63)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>OHI-s (0-3)</td>
<td>0.80 (± 0.51)</td>
<td>1.01 (± 0.56)</td>
<td>-2.15</td>
<td>.03</td>
<td>0.99 (± 0.59)</td>
<td>1.01 (± 0.56)</td>
<td>-0.21</td>
<td>.83</td>
</tr>
<tr>
<td>Sealants</td>
<td>1.45 (± 1.76)</td>
<td>3.89 (± 1.40)</td>
<td>-8.16</td>
<td>.00</td>
<td>3.45 (± 1.10)</td>
<td>3.89 (± 1.40)</td>
<td>-1.95</td>
<td>.05</td>
</tr>
<tr>
<td>dmfs</td>
<td>5.04 (± 6.19)</td>
<td>7.31 (± 7.10)</td>
<td>-1.85</td>
<td>.07</td>
<td>5.77 (± 6.44)</td>
<td>7.31 (± 7.10)</td>
<td>-1.28</td>
<td>.20</td>
</tr>
<tr>
<td>DMFS</td>
<td>0.21 (± 0.60)</td>
<td>0.48 (± 1.04)</td>
<td>-1.80</td>
<td>.08</td>
<td>0.39 (± 0.93)</td>
<td>0.48 (± 1.04)</td>
<td>-0.55</td>
<td>.58</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Differences after 3 years n = 179</th>
<th>NOCTP (n = 54)</th>
<th>controls (n = 63)</th>
<th>t</th>
<th>p</th>
<th>IPFA (n = 62)</th>
<th>controls (n = 63)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Δ OHI-s</td>
<td>-0.05 (± 0.64)</td>
<td>0.14 (± 0.77)</td>
<td>-1.40</td>
<td>.16</td>
<td>0.17 (± 0.70)</td>
<td>0.14 (± 0.77)</td>
<td>0.19</td>
<td>.85</td>
</tr>
<tr>
<td>Δ Sealants</td>
<td>1.26 (± 1.71)</td>
<td>3.70 (± 1.55)</td>
<td>-8.01</td>
<td>.00</td>
<td>2.97 (± 1.58)</td>
<td>3.70 (± 1.55)</td>
<td>-2.64</td>
<td>.01</td>
</tr>
<tr>
<td>Δ dmfs</td>
<td>0.49 (± 4.65)</td>
<td>0.44 (± 6.79)</td>
<td>0.05</td>
<td>.96</td>
<td>0.77 (± 6.18)</td>
<td>0.44 (± 6.79)</td>
<td>0.29</td>
<td>.77</td>
</tr>
<tr>
<td>Δ DMFS</td>
<td>0.15 (± 0.50)</td>
<td>0.47 (± 1.04)</td>
<td>-2.17</td>
<td>.03</td>
<td>0.34 (± 0.87)</td>
<td>0.47 (± 1.04)</td>
<td>-0.67</td>
<td>.45</td>
</tr>
</tbody>
</table>

NOCTP: Non-Operative Caries Treatment and Prevention;
IPFA: Increased Professional Fluoride Application;
OHI-s: Simplified Oral Hygiene Index
Table 3: Percentages of caries-free children and mean caries scores in primary (dmfs) and permanent (DMFS) dentition (only in those who did develop new caries).

<table>
<thead>
<tr>
<th></th>
<th>dmfs = 0</th>
<th>Δ dmfs &gt; 0</th>
<th>DMFS = 0</th>
<th>ΔDMFS &gt; 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 y</td>
<td>9 y</td>
<td>N</td>
<td>mean Δdmfs (sd)</td>
</tr>
<tr>
<td>NOCTP</td>
<td>39.6%</td>
<td>34.0%</td>
<td>25</td>
<td>3.52 (3.39)</td>
</tr>
<tr>
<td>IPFA</td>
<td>51.6%</td>
<td>40.3%</td>
<td>26</td>
<td>5.31 (4.58)</td>
</tr>
<tr>
<td>Controls</td>
<td>43.8%</td>
<td>25.0%</td>
<td>30</td>
<td>5.17 (3.82)</td>
</tr>
<tr>
<td>Total</td>
<td>45.3%</td>
<td>33.0%</td>
<td>81</td>
<td>4.70 (3.99)</td>
</tr>
</tbody>
</table>

NOCTP: Non-Operative Caries Treatment and Prevention;
IPFA: Increased Professional Fluoride Application
Table 4: visit-specific content of recall sessions in NOCTP group (n = 54)

<table>
<thead>
<tr>
<th>Visit</th>
<th>Children</th>
<th>Reason for extra visit*</th>
<th>Intervention $</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>oral hygiene</td>
<td>diet</td>
<td>eruption M1</td>
</tr>
<tr>
<td>1st year</td>
<td>1 54</td>
<td>30</td>
<td>13</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>2 49</td>
<td>27</td>
<td>5</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>3 38</td>
<td>16</td>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>4 37</td>
<td>14</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>5 19→ 5th visit was 1st visit of 2nd year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd year</td>
<td>1 54</td>
<td>24</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>2 35</td>
<td>16</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3 20</td>
<td>14</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>4 18→ 4th visit was 1st visit of 3rd year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd year</td>
<td>1 54</td>
<td>17</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2 21</td>
<td>6</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>3 13</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>4 6→ 4th visit was 1st visit of 4th year</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* double-counting possible when multiple reasons per child were recorded; $ multiple interventions in same visit are possible
230 6-year-old children randomized

79 following intensified, monitored self care
withdrawal during 3 years n = 25
6 because of inconvenience child
12 because of traveling
6 because of inconvenience parent
1 because of illness
54 completed 3-year follow-up

77 following increased fluoride application
withdrawal during 3 years n = 15
9 because of inconvenience child
5 because of traveling
1 because of inconvenience parent
62 completed 3-year follow-up

74 controls withdrawal during 3 years n=11
4 because of inconvenience child
4 because of traveling
3 because of inconvenience parent
63 completed 3-year follow-up