

Application of the Nexø method in a general dental practice in the Netherlands: 6-year results of a RCT

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Abstract

Objectives: The aim of this study was to establish the effect of a non-operative caries treatment programme (the Nexø method) in a general dental practice on dental caries, oral hygiene and self-reported motivational factors for a 6-year period.

Methods: A randomized clinical controlled trial study on caries-preventive measures in 6- to 12-year-old children was performed among 3 groups of children: (i) care as usual (dental check-ups twice a year, accompanied by a professional fluoride application and the placement of occlusal sealants on a routine basis) (CONTROL); (ii) care as usual plus 2 extra professional fluoride applications (IPFA); or (iii) a non-operative caries treatment programme based on the Nexø method in which recall interval and caries-preventive measures were individualized based on caries activity, eruption stage and motivation of the parent (NOCTP).

Results: A total of 106 12-year-old children of the initial 230 6-year-olds completed the full-length study. Children in the NOCTP group developed 0.67 decayed, missing or filled surfaces (DMFS). This value was 0.86 in the IPFA group and 1.02 in control group. The level of oral hygiene was most favourable in the NOCTP group (OHI-s score 0.61 vs 0.87 [IPFA] and 0.70 [control]). Differences were not statistically significant.

Conclusion: Children who followed the NOCTP programme in this general dental practice did not develop significantly fewer new caries lesions compared with children in the IPFA group or the control group after 6 years. However, the differences identified after the first 3 years of the trial remained apparent.

KEYWORDS

caries, clinical trial, DMF-S/T, Nexø studies

1 | INTRODUCTION

In the light of changing viewpoints towards the development and management of dental caries, which consider the condition to be a manageable disease, the application of non-operative caries treatment and prevention (NOCTP) has gained popularity. NOCTP (also named “Nexø method”) is an individualized caries prevention programme in which preventive measures and the recall interval are

individually assessed based on risk criteria. Those criteria are caries progression, patient's or parents' compliance/motivation and eruption stage of permanent molars. Based on the assessed criteria, points are rewarded to each criterion: (i) point if a low-risk situation occurs (for example no caries activity, compliant parents/caregivers and fully erupted molars) and (ii) points for high-risk situations. Based on the total number of points, a recall period is suggested varying from 12 months (in case of 4 points) to 1 month (in the case of 8 points).

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After the publication of the long-term outcomes of the first study applying this approach, showing that the programme is effective in the reduction in caries in children and adolescents between 0 and 18 years,¹ 3 studies have successfully applied the programme in different settings. In Russia, the method was applied in one district of Moscow,² in Greenland, NOCTP was part of a national caries strategy change,³ and in the Netherlands, the strategy was applied in one large dental clinic for children up to 18 years.⁴ A study that was performed in Australia concluded that the tested programme did not differ from care as usual.⁵ However, parents' involvement was no focus in this programme.

Follow-up studies are important to gain knowledge on the long-term effects of implementing the method in general oral health clinics. The initial study¹ reported 18-year results of adolescents who followed the programme from the eruption of the first deciduous tooth. Long-term outcomes of the implementation of the programme in Moscow revealed increased knowledge on caries control factors and a lower mean DMFT/S in the test group,⁶ suggesting long-term positive effects when the Nexø method is implemented in early childhood.

This study describes both clinical and self-reported results from 3 different groups of children. One group followed a non-operative caries prevention programme (NOCTP), a second group received an increased professional fluoride application (IPFA)-approach, and a third group (control) received standard care only. For a description of the separate groups, please refer to the methods-section. The results of the first 3 years of the study were published earlier.⁴ After 3 years, per-protocol analyses revealed a mean DMFS increment of 0.15 in children following the NOCTP regime, 0.34 in children in the IPFA group and 0.47 for the control group. Supplementary baseline data on DS, MS and FS level are presented in Table 2.

The aim of this study was to test the hypothesis that a different caries-preventive effect can be found between children who followed an NOCTP regimen or an IPFA regimen compared with regular care (routine twice-yearly dental check-ups with professional topical fluoride application and sealing the occlusal surfaces of newly erupting first permanent molars on a routine basis) after 6 years. In this study, the outcomes after 6 years (when the children were 12 years old) are compared with the results at baseline and after 3 years.

2 | MATERIALS AND METHODS

This study was approved by the Medical Ethical Committee of the Free University Amsterdam, the Netherlands (protocol number NL13709.029.06), as a part of the complete research protocol lasting 6 years after inclusion.

At baseline, parents of all 271 6-year-old patients (± 3 months) of a large dental clinic in 's-Hertogenbosch, the Netherlands, which focus on dental care for children up to 18 years old, were asked for consent to let their child participate in a randomized controlled clinical trial on caries-preventive strategies. The design of the study is published earlier,⁴ but for completeness, please refer to this summary:

The inclusion period was 2 years (September 2006-September 2008). The children were allocated to the research group by the

dental assistant -who was not familiar with the research protocols before the initial dental health assessment. An allocation list that was generated by randomization programme "Research-randomizer"⁷ was used. A total of 230 children were included and assigned to one of the following groups:

1. Control group. Children in this group received "care as usual" consisting of routine twice-yearly dental check-ups including professionally applied fluoride gel (1.23% F⁻) and preventive pit and fissure sealants in all first permanent molars on a routine basis.
2. IPFA group (Increased Professional Fluoride Applications). In addition to standard care, children in this group received two extra professionally applied fluoride applications.
3. NOCTP group (Nexø). Children in this group received no routine-based check-up or routinely applied professional caries-preventive measures. The protocol was based on the understanding of 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 al⁸: the cooperation of the parents, the activity of caries lesions within the dentition, the eruption stage of permanent first molars (and 6 years later of the second permanent molar) and caries activity in the occlusal surfaces of the present permanent molars. Each of these criteria was assigned either one (when favourable) or two (when unfavourable) points. The recall interval was set between 1 and 9 months, based on the number of points. 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 development was recorded despite repeated counselling sessions. Placement of pit and fissure sealants was restricted to those situations where intensified brushing with fluoride toothpaste and additional professional fluoride applications were not able to inhibit caries progression. These actions were tailored for individual, child-specific situations based on risk criteria (caries activity, cooperation of the parent and stage of eruption of the first permanent molar). Dental staff completed a checklist each visit so accurate records of all preventive and restorative actions in each participant could be filed.

After 3 years (inclusion period September 2009-September 2011), a total of 179 children of the initial sample were still in the trial (22% dropout rate). The results on caries progression, restorative treatment and oral hygiene levels after these 3 years were published earlier⁴ as well. However, to enhance comparability, baseline results are included in the results section (Tables 1 and 2) as well.

2.1 | Clinical assessment

After 6 years, all remaining 179 children (now 12 years old) were invited to attend another final oral health assessment in a dental clinic in 's-Hertogenbosch (NL) and to complete a final questionnaire. Their parents were also asked to fill out a short questionnaire on

TABLE 1 Descriptive statistics and non-clinical outcomes of research population in different groups at ages 6, 9 and 12

	NOCTP			IPFA			CONTROL		
	Age 6	Age 9	Age 12	Age 6	Age 9	Age 12	Age 6	Age 9	Age 12
Number of participants	79	54	34	77	62	36	74	63	36
Mean age (SD)	5.8 (0.30)	8.9 (0.38)	11.5 (0.51)	5.8 (0.32)	8.8 (0.34)	11.6 (0.50)	5.9 (0.33)	8.9 (0.31)	11.6 (0.54)
Socio-economic status									
Low	18 (22.8%)	14 (25.9%)	8 (23.5%)	25 (32.5%)	21 (33.9%)	10 (27.8%)	24 (32.4%)	20 (31.8%)	9 (25.7%)
Medium	32 (40.5%)	17 (31.5%)	16 (47.1%)	30 (38.9%)	23 (37.1%)	17 (47.2%)	25 (33.8%)	23 (36.4%)	14 (40.0%)
High	29 (36.7%)	23 (42.6%)	10 (29.4%)	22 (28.6%)	18 (29.0%)	9 (25.0%)	25 (33.8%)	20 (31.8%)	13 (34.3%)
Sex									
Male	41	27	16	35	29	16	37	31	14
Female	38	27	18	42	33	20	37	32	22
Maximum willingness to pay-child									
Money (€/mo) (SD)	–	–	19.6 (24.9)	–	–	16.9 (16.1)	–	–	16.1 (16.7)
Time/effort (minutes brushing/d) [SD]	–	–	12.4 (24.8)	–	–	7.0 (14.3)	–	–	9.0 (19.5)
Maximum willingness to pay-parent									
Money (€/mo) (SD)	–	20.17 (23.3)	16.14	–	21.23 (25.0)	14.96	–	18.86 (22.4)	18.21
Time/effort (preventive dental visits/y) (SD)	–	3.22 (1.5)	2.10 (0.7)	–	3.13 (1.5)	2.17 (0.5)	–	2.75 (1.6)	2.09 (0.5)
Time/effort (minutes of brushing/d) (SD)	–	4.35 (1.3)	–	–	4.03 (1.8)	–	–	3.61 (1.8)	–

self-reported motivational factors. The children were examined by one experienced dentist (the same as the dentist who performed the measurements from September 2009-September 2011). A total of 15 (14%) children were also examined by an experienced calibrated second dentist. Interexaminer agreement was considered "good" for both oral hygiene ($\kappa = 0.82$) and caries scores ($\kappa = 0.90$). Both examiners were blinded to the regimen followed by the children, and none of the two examiners was involved in the regular dental care of the participants or affiliated otherwise with the dental clinic.

Oral hygiene was measured using the simplified oral hygiene index (OHI-s), as described by Greene and Vermillion.⁹

Caries was measured using WHO criteria (DMFS index with caries scored at the dentine threshold (D_2)).¹⁰ Both caries scores and caries increment (Δ DMFS) in the last 3 years of the study (9-12 years) and after 6 years (6-12 years) were considered main outcome variables.

2.2 | Statistical analyses

The sample was characterized using descriptive statistics. Clinical data were analysed per protocol using two-sided independent

samples *t* tests for differences in levels of oral hygiene and caries experience. ANOVA was used to compare OHI-s and caries increment between the 3 research groups both after the last 3 years of the trial and after completion of the full length. Nonparametric data were analysed using Mann-Whitney *U* and Kruskal-Wallis tests. Significance level was set at $\alpha = .05$. All statistical analyses were performed using IBM SPSS Statistics 22.0.

3 | RESULTS

Reasons for withdrawal are presented in Figure 1. A total of 73 children dropped out of the study due to lack of interest or time or moving to another city of residence or dental practice, resulting in a total of 106 children with data available for per-protocol analysis after 6 years. This means a 40% dropout rate for the sample of 179 9-year-old children and a 54% dropout rate for the initial sample of 230 6-year-olds. Dropouts were spread evenly between groups. Reasons for withdrawal were provided by the participants themselves rather than by their parents and

TABLE 2 Mean scores and (SD) in different groups at ages 6, 9, and 12

	NOCTP (n = 33)			IPFA (n = 35)			CONTROL (n = 36)		
	Age 6	Age 9	Age 12	Age 6	Age 9	Age 12	Age 6	Age 9	Age 12
Number of participants	79	54	34	77	62	36	74	63	36
Oral hygiene (OHI-s)	0.90	0.82 (0.47)	0.61 (0.47)	0.84	1.01 (0.65)	0.87 (0.37)	0.89	1.08 (0.53)	0.69 (0.50)
DS	0.06 (0.31)	0.01 (0.0)	0.09 (0.29)	0.05 (0.29)	0.0 (0.0)	0.22 (0.48)	0.02 (0.13)	0.08 (0.37)	0.28 (0.51)
FS	0.0	0.15 (0.62)	0.56 (0.93)	0.0	0.31 (0.93)	0.61 (1.38)	0.0	0.36 (0.96)	0.75 (1.61)
DMFS	0.06 (0.31)	0.21 (0.62)	0.67 (0.96)	0.05 (0.29)	0.39 (0.93)	0.86 (1.44)	0.02 (0.13)	0.48 (1.13)	1.03 (1.89)
ΔDMFS (6-9)		0.15 (0.50)*			0.34 (0.87)			0.46 (1.04)	
ΔDMFS (9-12)			0.52 (0.79)			0.55 (1.17)			0.59 (1.51)
Number of sealants	0.19 (0.81)	1.12 (1.75)**	1.12 (1.74)**	0.48 (1.23)	2.77 (1.66)	3.00 (2.06)	0.19 (0.85)	2.86 (2.50)	2.89 (2.48)
% DMFS = 0	96.2	86.8	66.7 *	96.9	82.2	57.7	98.4	76.6	57.1

DMFS, total of decayed, missing and filled surfaces; DS, decayed surfaces; FS, filled surfaces; IPFA, increased professional fluoride application; MS, missing/extracted surfaces; NOCTP, non-operative caries treatment programme; OHI-s, Simplified Oral Hygiene Index.

*P < .05; **P < .01.

therefore may be categorized differently compared with the first 3 years.

In Table 1, sample characteristics of the 12-year-old children and non-clinical outcomes of the children and their parents are presented together with the outcomes of the parents 3 years earlier. At the age of 9 years, the children were not asked to complete a questionnaire themselves.

Table 2 presents clinical outcomes of the children at 9 and 12 years of age. The mean OHI-s of children in the NOCTP group was significantly reduced compared with the other two groups ($F = 3.23, P = .05$). The number of pit and fissure sealants was reduced in the NOCTP group compared with the other two groups ($F = 8.13, P = .01$). Caries increment was not statistically significantly different between groups between age 9 and 12.

Table 3 shows self-reported outcomes at the age of 12 years concerning their dietary habits, perception of their own (oral) health and how onerous they find it is to brush their teeth. No differences were found to be statistically significantly different (all P values > .07).

4 | DISCUSSION

The aim of this study was to test the hypothesis that a different caries-preventive effect can be found between children who followed an NOCTP regimen or an IPFA regimen compared with regular care (routine twice-yearly dental check-ups with professional topical fluoride application and sealing the occlusal surfaces of newly erupting first permanent molars on a routine basis) after 6 years. In this study, the outcomes after 6 years (when the children were 12 years old) are compared with the results at baseline and after 3 years.

In the first 3 years of the trial, it was found that differences among the NOCTP, IPFA and control groups were considerable given the low caries prevalence in this age group in the Netherlands.⁴ In the 3 following years of the trial (the current study), these differences were not further reduced. Therefore, the hypothesis was rejected.

In this study, information on oral hygiene and dietary behaviour, willingness to pay, dental hygiene burden and attitude towards oral health was obtained separately from the parents and the children, using a questionnaire. Children completed the questionnaires prior to or directly after the clinical assessment, depending on the time of arrival at the appointment. In some cases, completion of the questionnaire was interrupted by the clinical assessment. There is no reason to assume that results have been influenced by this variation because no questions were asked about the specific appointment. Some parents completed their questionnaire at the oral health assessment appointment when they accompanied their child; all others were asked to complete the questionnaire by mail or email.

Some limitations of this study should be addressed. First, the combination of a relatively small sample size and the high number of dropouts (40%) represents a considerable problem for external validity. This dropout rate resulted in a loss of statistical power. No information could be gathered from these dropouts; therefore,

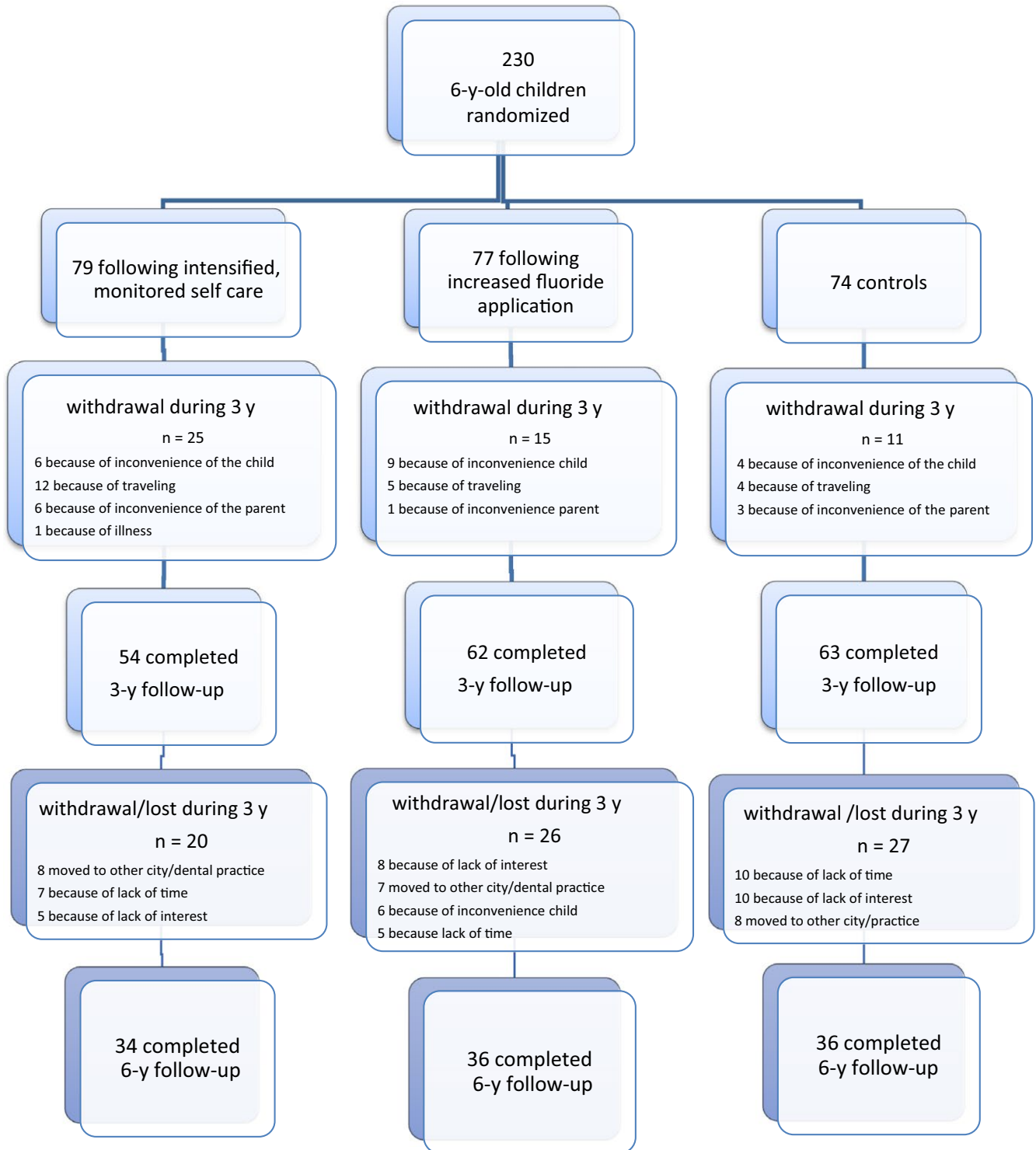


FIGURE 1 Flow chart of participation in the study

no possible differences between the remaining participants and the dropouts could be identified. However, given that the dropout rates between groups were not significantly different, it was assumed that there was no reason to suppose that the differences between groups would be different due to this high dropout rate. Dropout rates of 20%-50% have been suggested as acceptable for

epidemiological cohorts, whereas rates of 15%-25% are acceptable for RCTs. However, these recommendations have not been tested to date.^{11,12} Second, the fact that this trial was exclusively performed in one large dental clinic for children in 's-Hertogenbosch implies that the results are representative for this type of practice alone. The organized care and cure processes of this institution may differ

TABLE 3 Self-reported outcomes of 12-y-olds concerning dietary habits, (oral) health perception and dental hygiene burden

	NOCTP (n = 33)	IPFA (n = 35)	CONTROL (n = 36)
What meals do you eat on a regular basis?			
Breakfast	93.7%	90.5%	89.0%
Lunch	97.5%	93.7%	90.4%
Dinner	96.2%	96.8%	97.3%
How many between-meal snacks do you eat on a regular basis?			
≤3	11.4%	6.8%	6.8%
4-5	73.4%	72.63%	76.1%
≥5	15.2%	20.6%	17.1%
How healthy are you on 1-10 scale 1: not healthy at all, 10: very healthy	8.4 (SD: ±0.91)	7.9 (SD: ±1.34)	8.0 (SD: ±1.17)
How healthy are your teeth on a 1-10 scale 1: not healthy at all, 10: very healthy	7.4 (SD: ±1.01)	7.6 (SD: ±1.17)	7.8 (SD: ±1.70)
How hard is it on a 1 to 5 scale to (1 not hard at all, 5: very hard)			
Brush your teeth in the morning on a daily basis	1.64 (SD: ±0.90)	1.51 (SD: ±0.56)	1.55 (SD: ±0.77)
Brush your teeth in the evening on a daily basis	1.40 (SD: ±0.55)	1.65 (SD: ±0.84)	1.47 (SD: ±0.75)
Visit the dentist for dental check-ups	6.8 (SD: ±0.77)	8.6 (SD: ±0.94)	9.1 (SD: ±1.02)
How much fun is it on a 1-10 scale to go to the dental practice? 1: no fun at all, 10: a lot of fun	7.6 (SD: ±1.99)	3.57 (SD: ±2.22)	6.6 (SD: ±1.78)

IPFA, increased professional fluoride application; NOCTP, non-operative caries treatment programme.

from other situations (smaller clinics, a specific patient population). Nevertheless, this study is the first to provide long-term information on the implementation of an NOCTP regimen in a general dental practice.

When we compare the current results to earlier mentioned studies reporting the long-term effects of the implementation of NOCTP, the most important difference is the absence of statistical significance in the current study. This finding can be attributed to the previously described loss of power due to the significant dropout rate. On the other hand, other factors may have contributed to this finding. Caries prevalence in the Netherlands can be regarded as relatively low (in 2005 this was 1.1 DMFS ± 2.5) in the region of 's-Hertogenbosch¹³ compared with 2.24 (±2.10) in 9-year-olds in Moscow and 1.7 (±3.5) in 9-year-olds in Greenland. At the start of the Nexø study, the DMFS in Danish 12-year-olds was 2.6 (95% CI: 2.1-3.1). Another possible relevant difference is the age at which children in the current study started the NOCTP intervention was 6 years of age (±3 months). An intervention that relies on self-care by patients and parents may gain effectiveness when beneficial behaviour is taught immediately from the start.

The groups had a comparable caries risk at the start of this trial (at the age of 6). However, after the first 3 years of this study, significant differences between groups were noted. This notion may have caused selection bias in the second 3 years of this study.

Despite the earlier mentioned limitations, the results of this study still can be considered favourable for the NOCTP strategy.

A trend of reduced DS, FS, DMFS and OHI-s and an increased percentage of DMFS = 0 and willingness to pay was noted in children who followed the NOCTP strategy for 6 years compared with peers who followed the IPFA strategy or the care as usual. Although caries increment in the last 3 years of the study was not statistically significantly different between the 3 groups, the lower levels of caries development in the NOCTP group were maintained in the last 3 years; no catching-up phenomenon did occur. A remarkable finding was the reduced number of placed pit and fissure sealants in the NOCTP group, where the indication was exclusively limited to the first signs of demineralization of the enamel rather than as a routine measure as noted in the other two groups. Given that most of these sealants are placed soon after eruption, this treatment is typically executed between the ages of 6 and 7. The fact that the number of sealants did not increase in the NOCTP group between 9 and 12 years may be an indication that the results after the first 3 years were not simply a delay but can be considered a solid finding.

In conclusion, children who followed the NOCTP programme in this general dental practice did develop fewer new caries lesions compared with children who received care as usual (control group) or standard care plus 2 extra professionally applied fluoride applications (IPFA) after 6 years but these differences were not statistically significant. However, the differences that were found in the first 3 years of the trial remained apparent. The replication of this study in more dental practices with larger numbers of participants and starting from the eruption of the first tooth is highly encouraged.

5 | CLINICAL RELEVANCE

5.1 | Scientific rationale

Viewpoints towards the development and management of dental caries, which consider this condition a manageable disease, are changing and leading to an increase in the popularity of non-invasive strategies. The application of prevention-based caries management, such as NOCTP, is pre-eminently a tool that will be used more frequently in the future by dentists and dental hygienists. In particular, given that the core business of the latter is the prevention of dental diseases.

5.2 | Principle findings

Children who followed the NOCTP programme in this general dental practice did not develop significantly fewer new caries lesions compared with children in the IPFA group or the control group after 6 years. However, the differences that were identified after the first 3 years of the trial remained apparent.

5.3 | Practical implications

Individually addressed caries prevention measures based on caries progression, eruption stage and parental motivation such as NOCTP can be considered less invasive and at least as effective as "care as usual", which consists of routine check-ups twice a year, fluoride applications and the placement of preventive fissure sealants on a routine basis.

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