Chapter 8

Summary and general discussion
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This chapter first provides a summary of the findings of this thesis. Then, these findings are discussed. The chapter ends with recommendations in light of the findings of this thesis.

Summary

This thesis had three main aims. First to describe a randomized controlled clinical trial (RCT) on caries prevention strategies in 6- to 9-year-old children; this trial compared the clinical performance of two different caries-prevention strategies to that of a regular/standard approach; second to perform an economic evaluation of these strategies to determine their ‘value for money’ and third to explore parents’ willingness to invest in the oral health of their child, the parents’ prevailing attitudes towards prevention, and the relation between the attitudes and the reported behaviour to ensure oral health for their children.

Chapter 2 of this thesis described the RCT. A total of 179 6-year-old children were randomly assigned to one of two experimental groups or the control group. The control group received routine bi-annual check-up appointments additionally comprising professionally applied fluoride gel treatments and resin-based sealants in the occlusal surfaces of the first permanent molars upon eruption. One experimental group followed an Intensified Professional Fluoride Application (IPFA) program, which consisted of the regime of the control group plus two additional visits for professional fluoride treatment; thus, the children in the IPFA group received a total of four fluoride applications per year. The other experimental group followed a Non-Operative Caries Treatment and Prevention program (NOCTP) that was copied from an earlier study in Nexø, Denmark (Ekstrand & Christiansen, 2005). This strategy comprised an individually assessed recall interval for check-up appointments, based on risk factors including the cooperation of the parent, caries experience / development, the eruption stage of the first permanent molar, and caries experience / development and progression specifically in the occlusal surface of the first permanent molars. Besides this individually assessed recall interval, professional fluoride applications and placements of pit and fissure sealants were provided strictly on individual indication. The main outcome measure was the caries increment in permanent dentition. After three years of the trial, the caries increment in the control group, the IPFA group, and the NOCTP group were 0.47 (±
1.04), 0.34 (± 0.87) and 0.15 (± 0.50) DMFS, respectively. Based on the results of this study, it was concluded that following a NOCTP regime in this population resulted in three times less caries development than in the control condition.

Chapter 3 dealt with the effect of non-participation on the external validity of the outcomes of the randomized clinical trial described in chapter 2. Although many RCTs encounter the phenomenon of non-participation, studies reporting clinical and non-clinical parameters of participants and non-participants of trials are scarce. In the available studies, non-participants often showed less favorable outcomes than participants on both socioeconomic parameters as well as on caries experience. In this study, as part of baseline data collection, all children eligible to participate in the RCT, 346 parents of children of 6.0 years (± 3 months) of age were approached to let their child participate. Sixty parents refused, but 56 of them were willing to fill out the same set of questionnaires and allowed their child to be clinically examined once. The results showed that parents from participating children had higher socioeconomic status, were more often of autochthonous origin and scored better on knowledge questions than parents of non-participating children. Furthermore, parents of participating children reported a higher willingness to invest, both parents and children were more likely to have regular meals on a daily basis and their child had lower levels of plaque. Surprisingly, the participating children had higher dmfs scores than the non-participating children. Non-participating children had however a higher number of untreated carious lesions into dentin and therefore their care index (fs/ds + fs) was lower than that of participating children. Based on the findings of this study, the often-declared presumption that non-participating children will show less favorable clinical outcomes cannot be supported. Thus the external validity of a randomized controlled trial on caries-prevention strategies is not necessarily negatively affected by non-participation bias.

Chapter 4 described the results of an economic evaluation of the two experimental caries prevention strategies compared with the regular care strategy (control group). Information on resource use (like treatment time, travel time and distance and mode of transport) during the 3-year period of the trial was collected and documented by the dental nurses at every patient visit. Caries increment scores (at the D3MFS-level; caries into dentin) were used to assess effectiveness of the caries prevention programs. Cost calculations were performed using bottom-up micro costing; including all cost components that are believed to have a significant impact on the total costs. Incremental cost-effectiveness ratios (ICERs) were expressed as additional costs per prevented DMFS.
The ICERs compared with regular dental care from a health care perspective and societal perspective were € 733 and € 977 per prevented DMFS in the IPFA programme, and € 108 and € 111 in the NOCTP programme. The costs for the NOCTP group were highest in the first year of the study. Costs of the programme decreased in the second year of the study and equalled the costs of the control group in the third year. Given the findings of this study, the NOCTP programme may be considered preferred in the prevention of caries from both a medical and an economic point of view.

In Chapter 5, the willingness of the parents to invest in the oral health of their child was investigated. This willingness to invest was assessed in terms of money and time, and this was related to oral-health-related knowledge and reported behaviour of the parents. 290 parents of the 6-year-old children initially participating in this RCT on caries prevention strategies in the Netherlands were asked to provide information on education, oral health habits, dietary habits, knowledge on dental topics, willingness to pay in time and money and stated resistance to invest in preventive actions for the oral health of their children. Despite the fact that overall, parents highly valued their child’s oral health, almost 12% of the parents were unwilling to spend any money or invest any time in brushing their child’s teeth to maintain good oral health for their child. Additionally, these parents indicated that they were unwilling to visit the dentist for preventive measures more than once a year. Hence, the children of these parents may be considered at higher risk of developing oral diseases because worse oral hygiene habits and dietary habits were also found in this group. These results suggest that it may be necessary to differentiate caries-prevention programs to target parents in the most effective way, or even target these programs directly at the involved children (e.g., via school).

Chapter 6 described an effort to identify prevailing attitudes of parents regarding the oral health of their children. Parental attitudes are likely to play a role in achieving and maintaining a desired level of oral health in children. Q-methodology was used for this purpose. This method has been proven to be successful in identifying attitudes in a wide range of disciplines but in dentistry these Q-studies are scarce. In this study, 39 parents ranked 37 statements regarding dental health behaviour that parents may apply to their children. The parents later explained their rankings in a short interview. In Q-methodology, rather than reporting one average composed attitude and opinion, various (combinations of) opinions and attitudes are identified using by-person factor analysis of the ranking of the statements. Based on parents’ beliefs, attitudes and cognitions, five profiles were identified: (1) conscious and responsible, (2) trivializing
and fatalistic, (3) appearance-driven and open-minded, (4) knowledgeable but defensive and (5) conscious and concerned. Q-methodology appeared to be a useful way to structure the complexity of parents’ opinions and attitudes towards their children’s dental health. Q-methodology also appeared to provide comprehensive clusters of individual attitudes, based on various levels of responses to a wide range of questions. The five identified profiles may be useful in developing tailor-made prevention strategies in caries prevention.

The first steps in that direction were made in Chapter 7. On the basis of the results of the study reported in chapter 6, five vignettes with textual descriptions of the profiles, described in that chapter, were made, using distinguishing and identifying statements. Parents were asked to indicate the extent to which they felt the vignettes applied to them. These results were compared with data on oral hygiene, preventive and dietary behaviour, willingness to invest and caries activity. Univariate and multivariate regression analyses revealed that SES, dietary behaviour, dental knowledge and the perceived importance of oral health and general health remained associated with different profiles. Parents belonging to profile 2 (Trivializing and fatalistic) were more likely than the other parents to indicate less desirable (oral health) behavior: i.e. eating less regular meals on a daily basis, being less prepared to invest in their child’s oral health, valuing less their oral health and general health, scoring lower on dental knowledge and perceiving preventive measures as more burdensome than other parents. Moreover, differentiation in clinical outcomes was shown as well; children of parents with profiles 2 and 4 appeared to have less favourable outcomes in levels of oral hygiene and dmfs/DMFS. Beyond the vignette-tool’s usefulness as an additional risk-assessment tool, it may also provide information that is useful in planning more targeted caries-prevention strategies. It may also be used in counseling sessions (e.g., using motivational interviewing) to, tailor-made, emphasize important issues for parents belonging to specific behavioural groups.

General discussion

Before addressing the implications of the findings of this thesis, some limitations of this study will be discussed.

Although the calculated, necessary number of 181 participants was almost reached, 179 participants may be considered a relatively small research sample. As in any clinical study, many factors influenced the successful inclusion and continuation of respondents
in this study; e.g., parents as well as their children should be willing to invest additional time in the programs, etc. The anticipated dropout percentage of 20% was slightly exceeded (22%). The highest dropout rates were found in the NOCTP group (31%). This may result in a selection bias because of the possibility that more children with less involved parents dropped out of the NOCTP programme.

The duration of the trial is another issue that needs noting. It was assumed beforehand that a 3-year follow up period would be sufficiently long to identify possible differences concerning the development of carious lesions. However, the longer the period during which results can be evaluated, the more evidence regarding long-term costs and effects can be gathered. On the one hand, the caries preventive effect of the NOCTP strategy may turn out to be even larger in the longer run, if the positive effects endure over time while the intensity of the programme decreases. On the other hand, the effectiveness may also diminish over time, for instance, if following a restrictive indication policy only would appear to have resulted in a postponement of dental problems, rather than avoiding them completely. However, no examples for these situations have been encountered during the length of this trial. A longer-term follow-up measurement is currently performed, but the results of that study are not available yet and fall outside the scope of this thesis.

The fact that the whole experiment took place in one single large dental clinic may reduce external validity. The city of ‘s-Hertogenbosch was chosen because it is demographically representative of the Netherlands (Schuller et al., 2009). What the effectiveness of the studied strategies will be in, for instance, more privileged or deprived parts of the country (with different socio economic status) but also on the basis of attitudes or travel distance (e.g., more in rural areas) cannot be concluded from the current study. More research on this matter is required and encouraged.

Despite these limitations, the results of this study have some important implications for dental care in the Netherlands. In order to address these, results of the separate studies in this thesis will be merged and discussed in a clinical perspective, a health economics perspective, a patient’s perspective and a dental professional’s perspective.

Chapters 2 and 4 investigated respectively effectiveness and cost-effectiveness of two different caries-prevention strategies compared to regular care. In the IPFA strategy, professional preventive interventions were intensified, while in the NOCTP strategy the efforts in improving parental homecare were strengthened. When a treatment strategy
gains more health benefits at lower costs, that strategy is considered to ‘dominate’ the alternative. In chapter 4 it was found that in the current RCT, IPFA was dominated by NOCTP. Therefore, the discussion will be further focussed on the NOCTP strategy.

Let us assume that the NOCTP programme was to be implemented nationwide. Given our findings and using caries prevalence numbers, the number of extra-prevented carious lesions in The Netherlands could be calculated. Unfortunately, no exact data on caries prevalence in the permanent dentition of 9-year-olds in the Netherlands is available. However, we do know that in 2005 the caries prevalence of 11-year-old children in the Netherlands was 1.7 (± 2.8) (Poorterman & Schuller, 2006). With approximately 204,000 11-year-old children living in the Netherlands (website Statistics Netherlands, 2013), 346,800 decayed, missing or filled surfaces because of caries in permanent dentition could be expected. If all of these children were to follow the NOCTP regime for three years and the same extra caries reduction would be achieved as found in our RCT, approximately 110,000 extra carious surfaces would be prevented in this age group after a three-year program. As described in Chapter 4, following this NOCTP regime does not only yield better oral health outcomes, but also entails additional costs. Using an economic evaluation, it was assessed that the incremental cost effectiveness ratios (ICERs) for the NOCTP program relative to standard care would be € 108 per prevented DMFS for the three year program from a health care perspective and € 111 per prevented DMFS for the three year program from a societal perspective. Whether this can be considered value for money depends on the societal value placed on preventing caries. If this is more than € 111 per prevented DMFS, than implementing NOCTP is welfare improving.

One should be aware of the fact that the calculated ICERs in Chapter 4 only pertain to the observed three-year period. To establish long-term cost-effectiveness, longer follow-up periods can be used (as currently done), but commonly decision analytic modelling is applied to cover very long time horizons (e.g., 30 year or life time). In such modelling exercises, assumptions have to be made on aspects like long term effectiveness of the NOCTP program, transition probabilities (e.g., the possibility that a carious lesion will progress or not progress, that a tooth will be restored, that a restoration will be replaced, that an endodontic treatment will be performed, or that the tooth will be extracted, etc.) and the costs in every stage of dental decay. Doing so can result in a more favourable or less favourable outcomes than reported here. In the United States, lifetime costs for having a carious tooth have been estimated at $1811 (Anderson, 2001). In the current composition and execution of the NOCTP approach
€111 (societal perspective) for a prevented carious surface seems reasonably cost effective but further research, applying decision analytic modelling for caries prevention, is highly encouraged.

In the original Nexø study (Ekstrand & Christiansen, 2005), as well as in another non-invasive caries control study (Hausen et al., 2007), dental auxiliaries were actively involved in running the program. In the Netherlands, the process of task delegation and task reallocation in dentistry can be regarded as quite advanced. Dental hygienists and dental prevention nurses have become quite common. Since prevention is a core business for both types of professionals (the former partially self-employed and the latter under the responsibility of a dentist), the application of a NOCTP regime may be effectively applied by both. The ICER of the NOCTP strategy that was reported in Chapter 4 may be positively influenced by the deployment of these dental auxiliaries, provided this deployment has the same effectiveness. Further research seems necessary to identify the most optimal design of the NOCTP strategy.

In addition to being a health care professional, the general dental practitioner in the Netherlands is an entrepreneur. Considering the current reimbursement system in the Netherlands, implementing NOCTP – while perhaps cost-effective – may not be financially attractive for dentists. Currently, the dental professional in the Netherlands is paid for every procedure or activity that is performed. When tangible interventions – like restorations and routinely applying professionally fluoride or placing occlusal resin-based sealants – are more financially attractive than promoting self-care-based prevention activities, a ‘paradigm-shift’ towards more self-care-based, preventive strategies and thus a potential wider acceptance of the NOCTP strategy is hampered. Only very recently, a tariff has been introduced for every 5 minutes of time that dentists use for prevention visits. What the effect of this change will have on the dental professional’s behaviour is still unknown but considering the given tariff (€12.10 / 5 minutes), this possible financial obstacle to implement NOCTP in daily practice seems to have met. If one would aim at stimulating the broader implementation of NOCTP-like strategies, it is therefore important to equal profits for various treatments and preventive actions and, doing so, incentivise dentists in such a way that this paradigm shift is indeed feasible. In that context it is worth noting that ‘outcome-based financing’ or ‘pay-for-performance’ (P4P) are concepts that have not been introduced in dentistry yet but certainly may be considered to be suitable for oral care, as well (Jha, 2013; Tinanoff, 2012). Health insurers and policy makers also may be interested in supporting to implement the NOCTP programme on a larger scale. In the original Nexø-study, the
costs of running the dental service clinic with the NOCTP strategy was significantly lower than the costs before the NOCTP strategy had been implemented (Ekstrand & Christiansen, 2005). This cost calculation was not based on an economic evaluation and therefore cannot be compared one-on one to the results of the current study. However, also in this current study, it was also found that, in the short run, more resources were used, but that already after 3 years the costs of the NOCTP programme equalled the regular costs.

Another issue that may hamper the dental professional’s willingness to adopt to the NOCTP approach is the fact that it may be perceived as a strategy of ‘doing nothing’ or ‘supervised neglect’, given its non-invasive, restraint and preventive nature. However, the way that the profession looks at caries and caries prevention nowadays appears to be changing (Fisher, 2012; Fejerskov, 2004), while evidence on the effectiveness of non-invasive caries treatment and prevention approaches accumulate (Thylstrup et al., 1997; Ekstrand et al., 2000; Ekstrand & Christiansen, 2005). Nevertheless, this does not alter the fact that a thorough monitoring of the development of the caries process can be regarded desirable.

A monitoring system that records caries activity at the dental visits is desirable for several reasons. It may give the dental professional an indication of whether he or she is on the right track with the chosen prevention strategy. It may also be helpful in communicating with other dental health professionals (task delegation). Furthermore it can justify presented invoices for health insurers (reimbursement) and finally it may be used for the communication with patients (and their parents). An index, comparable to the Dutch Periodontal Screenings Index (DPSI) that is used in the Netherlands (van der Velden, 2009), may be developed for this purpose.

Implementation of the NOCTP strategy may require adaptation of the organisational structure of the dental practice and the skills of dental professionals. Hence, successful implementation of NOCTP may require investments, perhaps not in terms of technologies, but in training, education, informing clients and reorganising practices. Perhaps, if NOCTP would play a more prominent role in dental education, implementation of the strategy will progress more easily. Dental professionals could be trained in delivering tailor-made caries preventive care, based on the individual’s needs and their attitude towards a healthy mouth. This may require a shift in thinking, organizing and acting, which may well be part of their education.
Concerning the parents, it was found that a significant proportion was hesitant to consenting to participate or in continuing participation. The percentage of discontinuation was largest in the NOCTP group (Chapter 2 and Chapter 4). The most prevalent reason for non-consent or discontinuation was the parents’ feeling of their child ‘withholding care’. However, as described in Chapter 2, children in the NOCTP group developed 70% less carious surfaces than in the regular care group. It is therefore important and potentially possible to relieve the worry of these parents, for instance through better information on the favourable outcomes. Another argument for the parents of the NOCTP group to discontinue participation in the study had to do with the fact that extra efforts were required in terms of travel time and extra visits to the dental clinic. This can be nuanced as well based on results that are described in Chapter 4. It is true that initially extra investments had to be made by the parents, but over the three years of the trial this difference disappeared later. Moreover, in a NOCTP programme, parents themselves are, to a large extent, in control of the number of extra visits they have to make by adhering to the dental professional’s instructions and advice.

Concerning successful implementation of the NOCTP strategy, it is essential to realize that parental involvement and investments are pivotal for success. Hence, when a caries prevention strategy is ‘home-care based’ and, therefore, largely dependent on the parental willingness to invest, it is important to know what can be expected in this respect from parents. In Chapter 6, five types of parental attitudes were distinguished based on a Q-methodological study. Moreover, in Chapter 7 we found that these different parental attitudes were associated with different self-reported dietary behaviour, oral hygiene behaviour and even differences in clinical outcomes like oral hygiene and caries prevalence. One should bear in mind that following the NOCTP strategy requires a clear investment by the parent in their child’s oral health. Hence, it may not be the most effective or cost-effective strategy for children of the 11.5% of parents who indicated that they were not willing to invest any money or time (brushing their children themselves) and not willing to visit a dental clinic more than once a year for prevention visits. If these parents would nonetheless be confronted with a NOCTP regime, their compliance may be insufficient to make the programme effective. In fact, the programme may then be less effective than a currently conventional programme. Techniques like Motivational Interviewing may change the behaviour in the desired direction of some of these parents, but for those cases where success isn’t forthcoming as yet, children of these parents may benefit more from a professionally directed approach, which, in some cases, may circumvent the active participation of parents. In such cases, directly targeting children, for instance through school dental services, may
be more effective and cost-effective. Future research should be aimed at further investigating the exact conditions under which NOCTP is an effective and cost-effective strategy and which alternatives could be offered best in cases where NOCTP is not the best option (e.g., because of low involvement of parents). Another approach is to attempt to motivate parents to participate actively. In that sense, the potential benefits of the NOCTP program and the fact that the additional efforts are limited in time (to especially the first year) and that parents themselves strongly influence the required efforts, may need emphasis in contact especially with more reluctant parents. This may be tailored by using information on parental attitudes.

**Recommendations**

On the basis of this dissertation, it can be concluded that a broader implementation of a Non-Operative Caries Treatment and Prevention strategy on a broader scale should be encouraged. Stepwise implementation is preferred because the following aspects of such an implementation process then could be monitored closely.

The design of the NOCTP strategy itself may be fine-tuned to gain effectiveness. It is suggested to evaluate the prescribed recall-interval, to upscale the indication of the program to a broader population (e.g., 0-18 years), to explore how to involve a larger part of the patient-population and how to best target dropouts.

The instruments for monitoring and registering the caries process should be further developed. Also, the application of attitude-dependent caries prevention (e.g., using vignettes) is an issue that requires further research. The incorporation of the NOCTP strategy in dental practices should be monitored closely. It is suggested that all possible barriers to implementation of the strategy are mapped in various populations and practise settings in order to make NOCTP a feasible strategy. Linked up closely to this, it is important to consider optimal reimbursement systems to facilitate the uptake of caries preventive measures and incentivise dental practices to do so. This may require a shift from ‘fee for service’ to outcome based financing or ‘pay for performance’ (P4P).

Furthermore, it is suggested to perform longer follow-up studies of the effectiveness and cost-effectiveness of NOCTP, as well as exploring its cost-effectiveness in decision analytic modelling. To that end, transition probabilities for various stages of caries progression and treatment need to be determined.
In addition, it is recommended – next to training manual skills – to continuously secure sufficient emphasis on the prevention of caries in dental education.

**Concluding remark**

This thesis has investigated several aspects of preventive measures in oral health. It hopes to have contributed to the understanding of effectiveness and cost-effectiveness of alternative approaches to maintain and restore oral health, as well as of attitudes of parents regarding their children’s oral health. Ultimately, I hope this thesis will contribute to optimizing oral health – a worthwhile goal!