Prevention of early childhood caries (ECC) through parental toothbrushing training and fluoride varnish application: A 24-month randomized controlled trial

Short title: Parental toothbrushing training and fluoride varnish in ECC prevention

Emily Ming JIANG, Research Assistant

Edward Chin Man LO, Professor

Chun Hung CHU, Associate Professor

May Chun Mei WONG, Associate Professor

Faculty of Dentistry, University of Hong Kong, Hong Kong, China

Key words*: child, dental caries, toothbrushing, fluoride, randomized controlled trial*

Corresponding to : Lo, Edward Chin Man
Faculty of Dentistry
3/F Prince Philip Dental Hospital
34 Hospital Road, Hong Kong

Tel: 852-2859 0292
Fax: 852-2858 7874
E-mail: edward-lo@hku.hk

Abstract

***Objectives**: To investigate the effectiveness of hands-on training in parental toothbrushing, with or without semi-annual applications of 5% sodium fluoride varnish in preventing ECC.*

***Methods**: Study was conducted in Hong Kong where water is optimally fluoridated. Children aged 8-23 months were recruited and randomly allocated to one of three groups: Gp 1 - control, one-off oral health education talk to parents; Gp 2 - oral health education talk and parental toothbrushing training, reinforced every six months; Gp 3 – semi-annual application of fluoride varnish onto child's teeth in addition to the intervention provided to Gp 2. Clinical examinations of the children and interviews were conducted at baseline and after 24 months to assess the children's dental caries status and toothbrushing behavior.*

***Results**: Out of the 450 child-parent dyads recruited at baseline, 415 (92%) remained after 24 months. At baseline, 2% of the children had noncavitated enamel caries lesions and the mean dmft score was 0.03±0.24. Most of the children did not have daily parental toothbrushing (65-73%) and self toothbrushing (86-90%). At 24-month follow-up, including both noncavitated and cavitated carious lesions, the incidences of ECC in Gp 1 to Gp 3 were 11.9%, 11.8%, and 17.5%, respectively ($p>0.05$) and; the mean new dmft scores in Gp 1 to Gp 3 were 0.3, 0.2, and 0.3, respectively ($p>0.05$). Proportions of parents who practiced parental toothbrushing twice daily were 62.7%, 60.4%, and 65.7% in Gp 1 to Gp 3, respectively ($p > 0.05$).*

***Conclusions**: In a water fluoridated area, hands-on training in parental toothbrushing, with or without semi-annual application of 5% sodium fluoride varnish may not have additional effect on preventing ECC in young children with low risk of dental caries compared to provision of oral health education to parents.*

***Clinical Significance**: In a water fluoridated area, provision of individual oral health education to parents may be sufficient for preventing ECC in young children below age three. Supplemental training in parental toothbrushing and semi-annual applications of fluoride varnish may not have additional caries prevention effect in young children with low risk of dental caries.*

Introduction

Early childhood caries (ECC), defined as "presence of one or more decayed (noncavitated or cavitated lesions), missing (due to caries) or filled tooth surfaces in any primary tooth in a child 71 months of age or younger",[1] is one of the most prevalent chronic diseases among children worldwide.[2] It was reported that 52% of the 5-year-old children in Hong Kong had dental caries.[3] Among the 3-year-old children in Hong Kong, the prevalence of ECC was reported to be 31% and the mean dmft score was 1.2.[4] The vast majority of the decayed teeth were left untreated.[5] The dental status of preschool children in Hong Kong is far from satisfactory and needs to be improved.

Dental caries is a disease caused by dental plaque bacteria. Early colonization of cariogenic bacteria is a key risk factor for the initiation and development of ECC in the early stage of life.[6] It was reported that children with high prevalence of ECC had more dental plaque deposition.[7] Proper toothbrushing is an effective mechanical method to remove dental plaque. In a systematic review it was found that brushing with manual toothbrushes could reduce plaque by 30% to 50%.[8] Preschool children are often too young to perform effective toothbrushing and therefore, parental toothbrushing is recommended.[9] It is suggested that parents should start to clean their child's teeth twice a day, as soon as the eruption of the first primary tooth.[10] However, the oral hygiene practice of preschool children in Hong Kong is not good. It was reported that less than 40% of the preschool children started brushing their teeth before 18 months old. [3] Only 18% of the parents assisted their child's toothbrushing until three years old.[11]

Nowadays, the effectiveness of fluoride in preventing dental caries has been confirmed[12] and regular use of fluoride toothpaste is considered to be one of the most cost-effective dental caries prevention methods. The effectiveness of fluoride toothpaste has been shown to be positively related to the concentration of fluoride ion.[13] The common concentrations of fluoride ion in toothpaste are between 1000 and 1500 ppm.[14] For young children, due to the immature swallowing reflex, some authorities recommend the use of low-

fluoride toothpaste with a concentration of around 500 ppm to reduce fluoride ingestion from toothpaste.[15] However, evidence for the effectiveness of child toothpaste with low fluoride concentration in preventing dental caries is inconclusive.[16] Some researchers found that low concentration fluoride toothpaste was not effective in preventing dental caries in primary teeth.[17]

Fluoride varnish was introduced for topical application to prolong the contact of fluoride with tooth surface and its effectiveness in preventing dental caries is supported by robust scientific evidence from clinical trials. However, most of the studies were conducted in school children or in adolescence and very few studies investigated the effect of fluoride varnish in young children aged below three years. [18] The evidence for applying fluoride varnish to prevent dental caries in young children aged below three years is still inconclusive and more longitudinal, high quality clinical studies need to be conducted.

Due to the poor oral hygiene and dental status among the young children in Hong Kong, this study aimed to investigate the effectiveness of hands-on training in parental toothbrushing, with or without semi-annual applications of a 5% sodium fluoride varnish in preventing dental caries in young children. In this study, specific instructions in the use of child fluoride toothpaste were not given to the parents and they could decide on whether to use fluoride toothpaste or not for their child's toothbrushing.

Methods

This study was implemented in 2010 in Hong Kong where the drinking water is fluoridated at an optimal concentration of 0.5 ppm. [19] Ethical approval from the IRB of the University of Hong Kong (HKClinicalTrials.com, registration #HKCTR-831) was obtained prior to the implementation of the study.

Subject recruitment

Subject recruitment and allocation were performed by a dental assistant who was not involved in the provision of intervention. The target population of this randomized controlled trial was preschool children aged 8-23 months. The inclusion criteria were being in good general health and not on long-term medication. Recruitment was carried out in parenting education centers and child day care centers. Children meeting the inclusion criteria and with parental consent were recruited into the study. Children with major systemic disease or on long-term medication, and those who were not cooperative and refused examination were excluded.

Allocation

The recruited subjects were randomly allocated into three groups through stratified block randomization by a statistician who was not involved in this study. A name list with the information on age and gender of all children who met the inclusion criteria and agreed to participate in this study was obtained prior to the allocation. Children were divided into 2 subgroups according to their gender and were sequenced according to their age in each subgroup. A block randomization list was produced for each subgroup separately and the block size was six, generating 90 different combinations. Children were allocated according to the randomly chosen combinations generated by computer software. According to the result of the group assignment, interventions for the study children and parents were delivered by a dental hygienist at baseline.

Intervention

There were three groups in this study. Gp 1 was the positive control group and parents of the children in this group were provided with a one-off oral health education talk and printed materials at baseline. The content of these printed materials included information on children's tooth eruption, suggested method for cleaning baby's mouth, parental toothbrushing methods, healthy oral health-related dietary practice, need for regular dental visits, and a brief introduction to early childhood caries. There was no reinforcement of the oral health education messages by the investigators during the study period. Gp 2 and Gp 3 were test groups. In

addition to an oral health education talk and printed materials, parents of children in Gp 2 received hands-on training on brushing their child's teeth from a trained dental hygienist. Demonstration on proper brushing was performed by the dental hygienist on a model and the parents were asked to brush their child's teeth in front of the dental hygienist to ensure that they could master the toothbrushing technique. They also got the same oral health education materials distributed to the parents in Gp 1. Follow-up visits were made every 6 months by a dentist who was not involved in the outcome assessment so as to reinforce the dental health messages and to monitor the practice of parental toothbrushing. A new toothbrush for each study child was given to the parents at baseline and in each of the follow-up visits. Toothpaste without fluoride was applied onto the child's teeth with a microbrush as placebo in the follow-up visits, to blind parents from knowing whether their child received fluoride varnish or not. Parents of the children in Gp 3 were provided with the same dental health intervention program as that provided to the parents in Gp 2. However, instead of the placebo, a 5% sodium fluoride varnish (Clinpro White Varnish, 3M ESPE Dental Products, St. Paul, U.S.A.) was applied onto all of the child's erupted teeth during the semi-annual follow-up. Same as in Gp 2, a new child size toothbrush was provided in each follow-up visit.

Data collection

At baseline and 24-month follow-up, the study children were clinically examined by a trained dentist who did not know the group assignment of the children. Calibration exercise on the clinical diagnosis of dental caries with an experienced epidemiologist was carried out prior to the start of this study. Children were examined in a face-to-face or a knee-to-knee position. Tooth status was assessed by careful visual inspection using a disposable mouth-mirror attached to an intraoral LED light. A microbrush was used to remove plaque and food debris that obstructed inspection, if any. A CPI probe with a 0.5-mm ball tip was used to confirm the presence of a carious cavity when necessary. Diagnostic criteria for dental caries were based on the International Caries Detection and Assessment System (ICDAS) criteria. [20] Drying of teeth by air blow was not carried out in this study and thus code 1 of the ICDAS was not used. Dental caries was assessed at two levels. At Level 1, the diagnosis of caries included both

noncavitated and cavitated lesions (ICDAS codes 2-6), and at Level 2, it involved cavitated lesions only (ICDAS codes 5 and 6). A random sample of 10% of the children were re-examined in the baseline and follow-up examinations to monitor intra-examiner reproducibility.

All parents were asked to complete a structured questionnaire at baseline and also at 24-month follow-up to collect information on the child's socio-demographic background and child's oral health-related behaviors. Child's socio-demographic background included the child's age and gender, monthly household income, and parent's education level. Child's oral health-related behaviors included parental toothbrushing, child's self toothbrushing, and use of toothpaste. In each questionnaire, one question selected randomly was repeated to assess the reproducibility of the parent's answers. Information on the frequency of practice of parental and child self toothbrushing, as well as the use of toothpaste was collected from the parents every 6 months in a face-to-face interview in Gp 2 and Gp 3 or at the 12-month follow-up by an interview over the telephone in Gp 1. The questions which were asked during the follow-ups were standardized for all three groups and were the same as those in the structured questionnaire used at baseline.

Sample size calculation

The primary outcome of this study was the development of new dental caries in the children over the 24-month study period. It was reported that the mean dmft score of Hong Kong children at the age of 3 years was 1.2, the standard deviation of the dmft score was around 1.0.[4] It was anticipated that there was a 30% reduction in new dental caries development between the group with highest mean dmft score and the group with the lowest score, i.e. a difference of 0.4 in mean dmft score. Results of the sample size calculation, based on a 5% statistical significance level and an 80% power, showed that a minimum of 120 children in each group were required. To allow for loss of power due to drop-out over 24 months, the initial sample size should be around 25% larger, i.e. 150 children were needed in each group at the beginning of the study. Thus, the total initial sample size was 450 children (150 x 3 groups).

Data analysis

The collected data were entered into a computer and analyzed by using the statistical software SPSS for Windows 19.0. The primary outcome of this study was the development of new dental caries in the children over the 24-month study period, and the secondary outcome was the practice of parental and child self toothbrushing. Chi-square test was used to assess the difference in caries incidence, the practice of parental and child self toothbrushing, and the use of fluoride toothpaste between the three study groups. Since the results of the normality test showed that the distribution of dental caries among the study children was not normal, the differences in the severity of new dental caries (measured by the dmft score) among the three study groups were assessed by Independent-Samples Kruskal-Wallis test. The level of statistical significance for all tests was set at 0.05.

Results

A total of 450 children, 201 boys (45%) and 249 girls (55%) with a mean age of 16 months (SD = 3.9) were recruited from one parenting education center and thirteen child care centers at the baseline. The flow of subjects from baseline to the 24-month final evaluation is shown in Figure 1. At the 24-month evaluation, 415 children were examined and all examined children's parents completed the questionnaire. Overall, the retention rate was 92% and no significant differences were found in the retention rates among the three groups (Chi-square test, $p>0.05$). Overall, the children who dropped out were not significantly different from those who remained in the study in terms of their age and gender. However, compared to those who remained in the study, parents of the children who dropped out from the study had lower education levels (Chi-square test, $p=0.001$) and lower income levels (Chi-square test, $p<0.001$). No adverse effects were reported by the parents over the 24-month study period.

There were no statistically significant differences between the 3 groups in terms of the children's age, gender, family income, parents' education level, parental toothbrushing and child self toothbrushing at baseline (Table 1). Around two thirds (59-68%) of the children came

from high income families. More than half (52-60%) of the mothers and the fathers received at least 14 years of education. Most of the children had no regular daily parental toothbrushing (65-73%) or self toothbrushing (86-90%).

The percentage of agreement of the answers to the repeated parental questions at baseline was 82%. For the repeated questions at the 24-month follow-up, the percentage of agreement of the answers was 86%. The kappa value for the intra-examiner reproducibility in dental caries diagnosis were 0.97 and 0.98, at baseline and 24-month follow-up, respectively.

At the 24-month evaluation, the mean number of erupted teeth among the study children was 19.7 (SD = 0.9) and there were no significant differences among the three groups (One-way ANOVA, $p>0.05$). At baseline, a total of 14 noncavitated enamel caries lesions were detected in 10 (2%) children and no dentine caries lesion was found. There were no significant differences in dmft scores between three groups at baseline (Independent-Samples Kruskal-Wallis Test, $p>0.05$) and the overall mean dmft score was 0.03±0.24. The overall incidences of ECC for the children in the 24-month study period were 13.7% (57/415) and 8.4% (35/415) at Level 1 and Level 2, respectively (Table 2). There were no statistically significant differences in the incidences of ECC among the three groups, at both levels of caries diagnosis ($p>0.05$). No statistically significant differences in the 24-month dental caries increment among the three groups were found (Table 3, $p>0.05$). Overall, the mean new dmft scores were 0.3 and 0.2 at Level 1 and Level 2, respectively.

Among the children with new caries, their dmft scores ranged from 1 to 9 and from 1 to 7, at Levels 1 and 2, respectively (Fig. 2). The distribution of dental caries among these children was highly skewed. At Level 1, only 16% of these children had a dmft score of 3 or higher, but they contributed 43% of the teeth with caries experience. At Level 2, 23% of these children had a dmft score of 3 or higher, but they contributed 54% of the teeth with caries experience.

As shown in Table 4, there were no statistically significant differences in parental toothbrushing among the three groups at the 24-month follow-up ($p>0.05$). Overall, most of the study parents brushed their child's teeth every day; 62.9% of the parents brushed their child's teeth at least twice a day and more than one quarter of the parents performed parental toothbrushing once daily. However, the child's self toothbrushing behaviors were significantly different between the study groups. The proportion of children who did not carry out self toothbrushing was significantly higher in the control group than those in the two test groups ($p=0.018$).

There were no statistically significant differences in the use of fluoride toothpaste between the three study groups at the 24-month follow-up (Table 5, $p>0.05$). In all three study groups, more than 70% of children used fluoride toothpaste.

Discussion

In this study, only 8% of the parents and their children dropped out over two years and the retention rate was very high. The high retention rate may be due to the parents' high socio-economic status (SES) which was found to be associated with patient's compliance in clinical trial. [21] Parents' education level was also found to be positively related to children's compliance. [22] In this study, most of parents had middle to high SES and education level, which suggests that they would have good compliance with the interventions and follow-ups.

Most of the previous studies on toothbrushing supervision and training was school-based or community-based and took a class or a community as a unit for intervention. [23-25] In the present study, an individualized face-to-face approach was adopted in the delivery of toothbrushing training so to establish a closer relationship between the parents and dental hygienist. This individualized training approach probably had made a deep impression on the parents and enhance the learning outcome.

In the present study, no significant differences in the development of new dental caries in the young children were found between the groups. This may be related to the low caries experience of the children in the study. Compared to the 3-4-year-old children in Hong Kong, dental status of the children in both the control and test groups in this study was much better. In recent epidemiological surveys conducted in Hong Kong, the prevalence of ECC among the preschool children was reported to be 30% to 35% and the mean dmft score was reported to be 1.2 to 1.5.[5, 26] The low dental caries experience among the control group children in this study may be partially due to the Hawthorne effect, which refers to the behavioral change that is caused by the observation itself. [27] Hawthorne effect has been found to be common in longitudinal clinical trials. [28, 29] In this study, parents in the control group knew that they were involved in a dental caries prevention clinical trial and they might pay more attention to their child's oral health. Another possible reason is that most of the children in this study came from families in the middle to high socio-economic classes and their parents received good education. Children's SES and their parents' education level have been reported to be risk factors in the development of ECC. [30] High SES and education level are associated with good health behaviors and low dental caries experience. [31]

In recent oral health surveys conducted in Hong Kong, it was found that the distribution of dental caries among Chinese preschool children was highly skewed.[3,4] The result of the present study is consistent with these findings. The pattern of dental caries among the study children showed a polarized distribution. Around half of the decay teeth were contributed by a small proportion of the children with a dmft score of 3 or higher. For better use of resources, dental caries prevention program should focus more on the children who are in high caries risk.

Not involving specific instructions in the use of child fluoride toothpaste is one of the limitations in this study, which might have an influence on the children's caries experience. However, the proportion of children who used fluoride toothpaste was over 70% in all three groups and there were no significant differences between groups at 24-month follow-up. The popular use of fluoride toothpaste probably partially contributed to the children's low caries

incidence in this study. However, from the information provided by parents on the brand name of the toothpaste, it was found that the fluoride toothpastes used by the children in this study were mainly child toothpaste with a low fluoride concentration of around 500 ppm. Although fluoride toothpaste has been found to be effective in caries prevention, its effectiveness is dose-dependent[32] and the effectiveness of low fluoride concentration toothpaste is still controversial[33]. More health education for the parents regarding the use of fluoride toothpaste is needed and supervised or parental toothbrushing is recommended.

In the present study, no significant difference in the children's dental caries experience was found between the fluoride varnish group and the other two groups. A recent study reported that among the 6-15-month-old children from low income families with high risk of dental caries, fluoride varnish was effective in preventing dental caries at the cavitated level, but not for prevention of dental caries at the precavitated level. [34] However, in the present study, most of the children came from middle and high SES families and they would have a low risk of dental caries. The outcomes from this study suggest that semi-annual applications of fluoride varnish for young children aged below three years who are at low risk of dental caries is not necessary.

One of the shortcomings of this clinical trial is that a rather large proportion of the study children came from families with high parental education and income. In future studies, parental toothbrushing promotion program should focus more on children in deprived communities or whose parents have poor education and low income. Children in high caries risk may benefit more from oral health promotion program in ECC prevention. In addition, long-term follow-up should be carried out to assess the long-term effect of parental toothbrushing training in preventing dental caries in children.

Conclusion

Based on the findings of this study and within limitations, it is concluded that the effectiveness of providing oral health education and hands-on training in parental

toothbrushing to parents in preventing dental caries in young children with low risk of dental caries may not be different from that of providing oral health education alone. In an optimally water fluoridated area, semi-annual application of 5% sodium fluoride varnish may not be effective in preventing dental caries in young children aged below three years with low risk of dental caries.

Acknowledgement

This study was funded by Hong Kong Research Grant Council with Grant # HKU771709M.

References

1. American Academy of Pediatric Dentistry. Definition of early childhood caries (ECC). (accessed February 2014) http://www.aapd.org/assets/1/7/D_ECC.pdf.
2. Kagihara LE, Niederhauser VP, Stark M. Assessment, management, and prevention of early childhood caries. *Journal of the American Academy of Nurse Practitioners* 2009; **21**: 1-10.
3. Chu CH, Ho PL, Lo ECM. Oral health status and behaviours of preschool children in Hong Kong. *BMC Public Health* 2012; 12:767. (doi:10.1186/1471-2458-12-767)
4. Lo EC, Loo EK, Lee CK. Dental health status of Hong Kong preschool children. *Hong Kong Dental Journal* 2009; **6**: 6-12.
5. Wong HM, McGrath CP, King NM, Lo EC. Oral health-related quality of life in Hong Kong preschool children. *Caries Research* 2011; **45**: 370-6.
6. Poureslami HR, Van Amerongen WE. Early Childhood Caries (ECC): An infectious transmissible oral disease. *Indian Journal of Pediatrics* 2009; **76**: 191-94.
7. Al-Jobair AM, Al-Sadhan SA, Al-Faifi AA, Andijani RI. Medical and dental health status of orphan children in central Saudi Arabia. *Saudi Medical Journal* 2013; **34**: 531-6.
8. Slot D, Wiggelinkhuizen L, Rosema N, Van der Weijden G. The efficacy of manual toothbrushes following a brushing exercise: a systematic review. *International Journal of Dental Hygiene* 2012; **10:** 187-97.
9. Rayner J, Holt R, Blinkhorn F, Duncan K, British Society of Paediatric Dentistry. British Society of Paediatric Dentistry: a policy document on oral health care in preschool children. *International Journal of Paediatric Dentistry* 2003; **13**: 279-85.
10. American Academy of Pediatric Dentistry. Guideline on infant oral health care. 2012 (accessed February 2014) http://www.aapd.org/media/Policies_Guidelines/G_InfantOralHealthCare.pdf.
11. Chan SC, Tsai JS, King NM. Feeding and oral hygiene habits of preschool children in Hong Kong and their caregivers' dental knowledge and attitudes. *International Journal of Paediatric Dentistry* 2002; **12**: 322-31.

12. Marinho VCC. Cochrane reviews of randomized trials of fluoride therapies for preventing dental caries. *European Archives of Paediatric Dentistry* 2009; 10: 183-91.
13. Wong MCM, Clarkson J, Glenny AM, et al. Cochrane reviews on the benefits/risks of fluoride toothpastes. *Journal of Dental Research* 2011; 90: 573-9.
14. Preston AJ. A review of dentifrices. *Dental Update* 1998; 25: 247-50, 252-3.
15. Holt RD, Nunn JH, Rock WP, Page J. British Society of Paediatric Dentistry: A policy document on fluoride dietary supplements and fluoride toothpaste for children. *International Journal of Paediatric Dentistry* 1996; 6: 139-42.
16. Twetman S, Axelsson S, Dahlgren H, et al. Caries-prevention effect of fluoride toothpaste: a systematic review. *Acta Odontologica Scandinavica* 2003; 61: 347-55.
17. dos Santos APP, Nadanovsky P, de Oliveira BH. A systematic review and meta-analysis of the effects of fluoride toothpaste on the prevention of dental caries in the primary dentition of preschool children. *Community Dentistry and Oral Epidemiology* 2013; 41: 1-12.
18. Marinho VCC, Worthington HV, Walsh T, Clarkson JE. Fluoride varnishes for preventing dental caries in children and adolescents. *Cochrane Database of Systematic Reviews* 2013; **7**: CD002279
19. Wong HM, McGrath C, Lo EC, King NM. Association between developmental defects of enamel and different concentrations of fluoride in the public water supply. *Caries Research* 2006; **40**: 481-6.
20. Ismail AI, Sohn W, Tellez M, Willem JM, Betz J, Lepkowski J. Risk indicators for dental caries using the International Caries Detection and Assessment System (ICDAS). *Community Dentistry and Oral Epidemiology* 2008; **36**: 55-68.
21. Smith LK, Thompson JR, Woodruff G, Hiscox F. Factors affecting treatment compliance in amblyopia. *Journal of Pediatric Ophthalmology and Strabismus* 1995; **32**: 98-101.

22. Loudon SE, Fronius M, Looman CW, et al. Predictors and a remedy for noncompliance with amblyopia therapy in children measured with the occlusion dose monitor. *Investigative Ophthalmology and Visual Science* 2006; **47**: 4393-400.
23. Jackson RJ, Newman HN, Smart GJ, et al. The effects of a supervised toothbrushing programme on the caries increment of primary school children, initially aged 5-6 years. *Caries Research* 2005; **39**: 108-15.
24. Pine CM, Curnow MM, Burnside G, Nicholson JA, Roberts AJ. Caries prevalence four years after the end of a randomised controlled trial. *Caries Research* 2007; **41**: 431-6.
25. Rosema NAM, van Palenstein Helderman WH, van der Weijden GA. Gingivitis and plaque scores of 8- to 11-year-old Burmese children following participation in a 2-year school-based toothbrushing programme. *International Journal of Dental Hygiene* 2012; **10:** 163-8.
26. Wong MC, Lu HX, Lo EC. Caries increment over 2 years in preschool children: a life course approach. *International Journal of Paediatric Dentistry* 2012; **22**: 77-84.
27. Leonard K, Masatu MC. Outpatient process quality evaluation and the Hawthorne Effect. *Social Science & Medicine* 2006; **63**: 2330-40.
28. Leung WC, Lam HS, Lam KW, To M, Lee CP. Unexpected reduction in the incidence of birth trauma and birth asphyxia related to instrumental deliveries during the study period: was this the Hawthorne effect? *BJOG: An International Journal of Obstetrics and Gynaecology* 2003; **110**: 319-22.
29. McCarney R, Warner J, Iliffe S, van Haselen R, Griffin M, Fisher P. The Hawthorne effect: a randomised, controlled trial. *BMC Medical Research Methodology* 2007; **7**: 30.
30. Harris R, Nicoll AD, Adair PM, Pine CM. Risk factors for dental caries in young children: a systematic review of the literature. *Community Dental Health* 2004; **21**: 71-85.

31. Kim Seow W. Environmental, maternal, and child factors which contribute to early childhood caries: a unifying conceptual model. *International Journal of Paediatric Dentistry* 2012; **22**: 157-68.

32. Hellwig E, Lussi A. What is the optimum fluoride concentration needed for the remineralization process? *Caries Research* 2001; 35(Suppl 1): 57-9.

33. Ammari AB, Bloch-Zupan A, Ashley PF. Systematic review of studies comparing the anti-caries efficacy of children's toothpaste containing 600 ppm of fluoride or less with high fluoride toothpaste of 1000 ppm or above. *Caries Research* 2003; 37: 85-92.

34. Minah G, Lin C, Coors S, Rambob I, Tinanoff N, Grossman LK. Evaluation of an early childhood caries prevention program at an urban pediatric clinic. *Pediatric Dentistry* 2008; **30**: 499-504.

Table 1 Socio-demographic background and oral health-related behaviors at baseline of the children who completed the study

	Group			p-value*
	Gp 1 (n=134)	Gp 2 (n=144)	Gp 3 (n=137)	
Age at baseline(month)				
mean (SD)	15.5 (3.9)	15.6 (3.8)	15.3 (3.8)	0.764
Gender				
Boys	58 (43%)	62 (43%)	62 (45%)	0.921
Girls	76 (57%)	82 (57%)	75 (55%)	
Monthly household income (HKD)				
<15,000	20 (15%)	24 (17%)	21 (15%)	
15,000-25,000	23 (17%)	35 (24%)	30 (22%)	0.603
>25,000	91 (68%)	85 (59%)	86 (63%)	
Father's education level (years of education)				
=< 9	12 (9%)	19 (14%)	16 (12%)	
10 – 13	49 (37%)	39 (27%)	38 (28%)	0.384
>= 14	72 (54%)	85 (59%)	82 (60%)	
Mother's education level (years of education)				
=< 9	6 (5%)	12 (9%)	15 (11%)	
10 – 13	50 (37%)	45 (31%)	50 (37%)	0.260
>= 14	78 (58%)	87 (60%)	72 (52%)	
Parental toothbrushing				
<1/day	98 (73%)	93 (65%)	88 (65%)	
1/day	24 (18%)	32 (22%)	28 (20%)	0.414
>=2/day	12 (9%)	19 (13%)	21 (15%)	
Child self toothbrushing				
No	106 (79%)	116 (80%)	117 (85%)	
<1/day	10 (7%)	11 (8%)	7 (5%)	0.741
1/day	17 (13%)	14 (10%)	11 (8%)	
>=2/day	1 (1%)	3 (2%)	2 (2%)	

* One-way ANOVA/Chi-square test

Table 2 Incidence of ECC among the children in the three study groups according to the two levels of caries diagnosis

Group	n	Incidence (Level 1^{+})	p-value*	Incidence (Level 2^{+})	p-value*
Gp 1	134	16 (11.9%)		11 (8.2%)	
Gp 2	144	17 (11.8%)	0.291	10 (6.9%)	0.610
Gp 3	137	24 (17.5%)		14 (10.2%)	
Total	415	57 (13.7%)		35 (8.4%)	

* Chi-square test; $^{+}$ Level 1 included non-cavitated and cavitated lesions, Level 2 included cavitated lesions only.

Table 3 Mean dmft increment of the children in the three study groups at 24-month follow-up

Group	n	Level 1+			Level 2+		
		Mean	SD	p-value*	Mean	SD	p-value*
Gp 1	134	0.3	1.2		0.2	1.0	
Gp 2	144	0.2	0.6	0.323	0.1	0.5	0.630
Gp 3	137	0.3	1.0		0.2	0.9	
Total	415	0.3	0.9		0.2	0.8	

* Independent-Samples Kruskal-Wallis Test; + Level 1 included non-cavitated and cavitated lesions, Level 2 included cavitated lesions only.

Table 4 Parental and child self toothbrushing at the 24-month follow-up

	Group			p-value*
	Gp 1 (n = 134)	Gp 2 (n = 144)	Gp 3 (n = 137)	
Parental toothbrushing				
<1/day	14 (10.4%)	11 (7.6%)	11 (8.0%)	
1/day	36 (26.9%)	46 (32.0%)	36 (26.3%)	0.735
>= 2/day	84 (62.7%)	87 (60.4%)	90 (65.7%)	
Self toothbrushing				
No	26 (19.4%)	18 (12.5%)	7 (5.1%)	
<1/day	12 (9.0%)	22 (15.3%)	23 (16.8%)	0.018
1/day	37 (27.6%)	41 (28.5%)	39 (28.5%)	
>= 2/day	59 (44.0%)	63 (43.7%)	68 (49.6%)	

* Chi-square test

Table 5 Toothpaste usage among the three study groups at the 24-month follow-up

Group	n	Use of toothpaste			p-value*
		No use	No F- paste	F- paste	
Gp 1	134	18 (13.4%)	22 (16.4%)	94 (70.2%)	
Gp 2	144	20 (13.9%)	12 (8.3%)	112 (77.8%)	0.113
Gp 3	137	12 (8.8%)	24 (17.5%)	101 (73.7%)	
Total	415	50 (12.0%)	58 (14.0%)	307 (74.0%)	

* Chi-square test

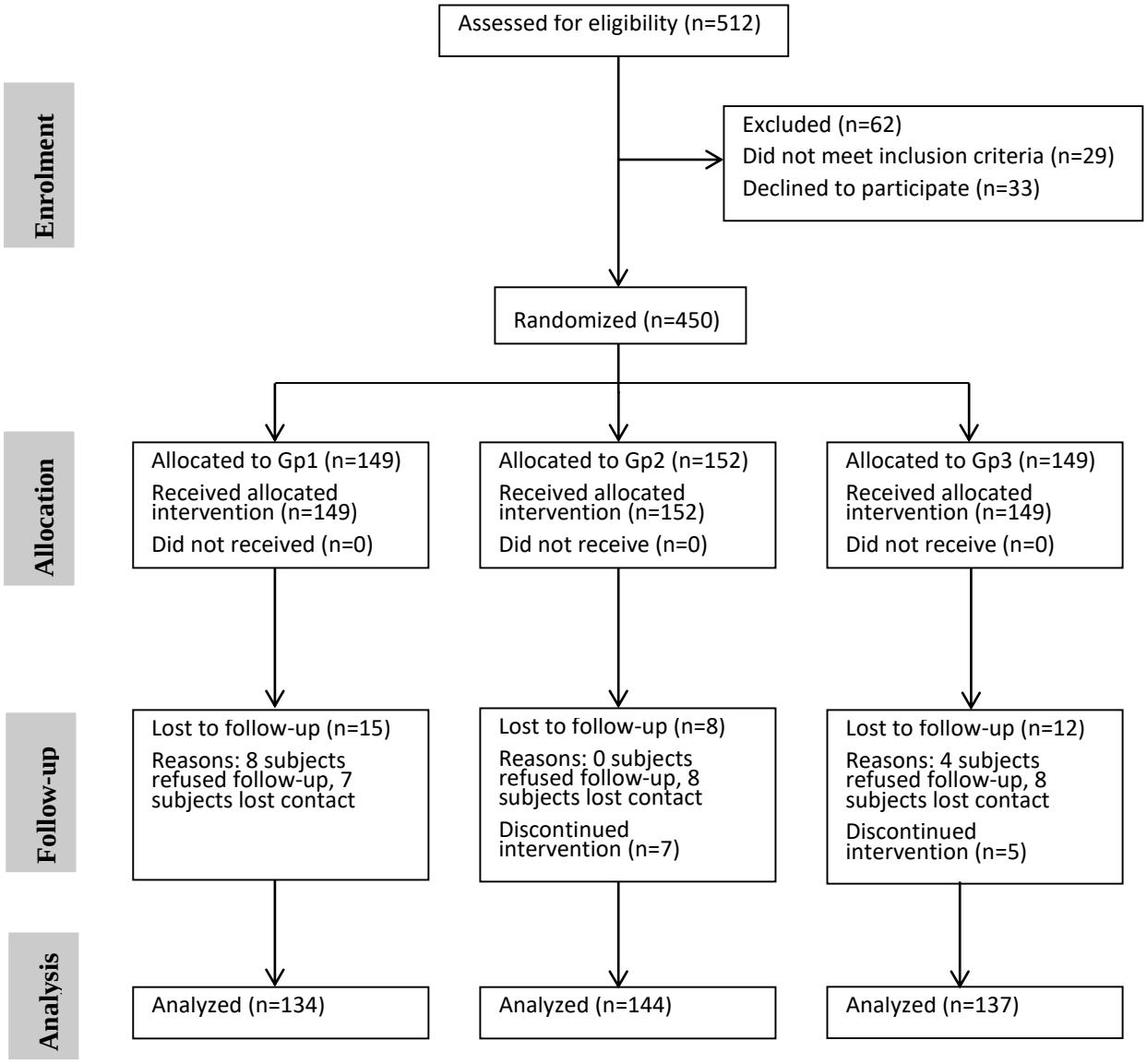

Figure 1 Flow diagram of this study, from baseline to 24-months follow-up

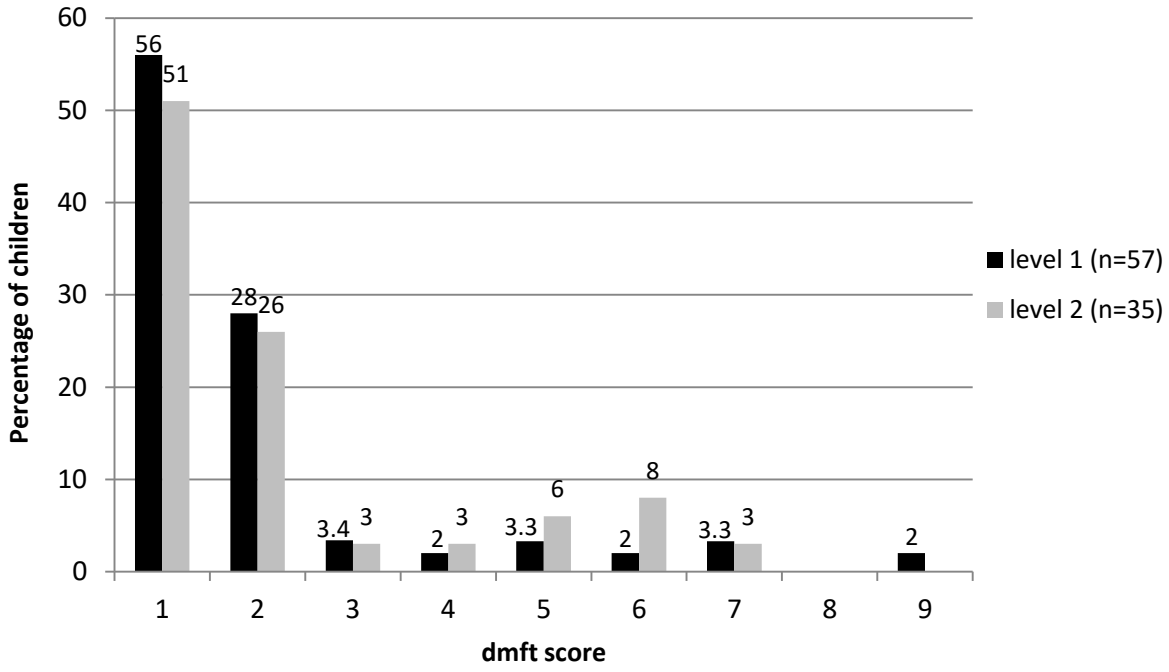

Figure 2 Percentage distribution of the children according to dmft score (1-9) among those with dmft increment>0 at 24-month evaluation (Level 1 included non-cavitated and cavitated lesions, Level 2 included cavitated lesions only)