# A Cluster Randomized Controlled Trial of a Dental Health Education Program for 10-year-old Children

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**Abstract**

***Objective:*** *Using a cluster randomized trial, this study tested the effectiveness of a dental health education program designed to improve the oral hygiene and dental knowledge of 10-year-old children.* ***Methods:*** *Thirty-two primary schools in the northwest of England participated. After a baseline assessment of plaque and the completion of a dental knowledge questionnaire by the children, the schools were allocated randomly to active or control groups. Children in schools allocated to the active group received the dental health program, which consisted of four one-hour lessons. After four months the children were examined clinically and scored for plaque, and a second questionnaire was administered. The schools in the control group were then allocated randomly to receive the program or not over the following three months, the program being withdrawn from the schools who initially received it. A further assessment of plaque was made and a questionnaire administered seven months after the baseline of the study.* ***Results:*** *The active groups had 20 percent and 17 percent lower mean plaque scores than the control group at four and seven months (P<.001). The children's knowledge of which type of toothbrush should be used and the role of disclosing tablets improved in the initial test group when compared with the control group and this was retained over the second part of the study.* ***Conclusion:*** *The children receiving the program had significantly lower mean plaque scores and greater knowledge about toothbrushes and disclosing tablets than the control children who had not received the program. [J Public Health Dent 2001;61(1):22-27]*

*Key Words: dental health education, RCT, cluster randomized controlled trial, schoolchildren.*

Dental health education programs for schoolchildren have as their major theme the improvement and maintenance of oral health through giving information and invoking changes in behavior. It is a minor budgetary item in most dental health care systems throughout the world; nonetheless, by its very public profile it often attracts critical scrutiny (1). The development of health education as a scientific discipline within dentistry has been slow (2); all too often action takes precedence over evaluation. For example, two recent reviews (3,4) have suggested that dental health education programs should be scientifically robust and fully evaluated. Kay and Locker (3) argued that most studies investigating the value of dental health education programs did not use a randomized controlled trial (RCT) design. The failure to use an RCT study design means the groups at baseline may be seriously imbalanced in unknown but important factors that could influence the outcome measures (5).

Evaluation of any health education intervention can be problematic, given the wide range of factors influencing lifestyle and there has been some debate on whether it is possible to design studies as RCTs in a community setting (6). This study aimed to test the effectiveness of a school-based dental health education program for 10-year-old children using a cluster randomized trial.

The intervention evaluated was entitled the "Good Teeth Program—My Mouth Matters." The educational approach was designed specifically to allow pupils to investigate dental health issues and draw their own conclusions with the aid of a professional facilitator. The children worked in groups because this approach harnesses peer group pressure. This process is also termed "active participation" and has been used successfully in a factory setting by Schou (7), but has not been fully investigated in young children. Dental caries is still a major problem in the northwest of England; hence, there is a need to develop and evaluate programs that raise dental awareness and improve health.

## Methods

The study took place in Chorley, Lancashire, from August 1997 to September 1998 following three pilot initiatives in another location. The program was designed to fit with Key Stage 2 of the national curriculum, which centers on group work and discussions to learn new knowledge. All 45 primary schools in the Chorley District were invited to take part in the program.

**Study Design.** The local Health Trust for Chorley is interested in research and development and agreed to support the project. However, the Trust demanded that all the children be given the opportunity to benefit from participation in the program. To facilitate this request, the study was designed as shown in Figure 1. The study was designed as a cluster RCT because it was thought there would be

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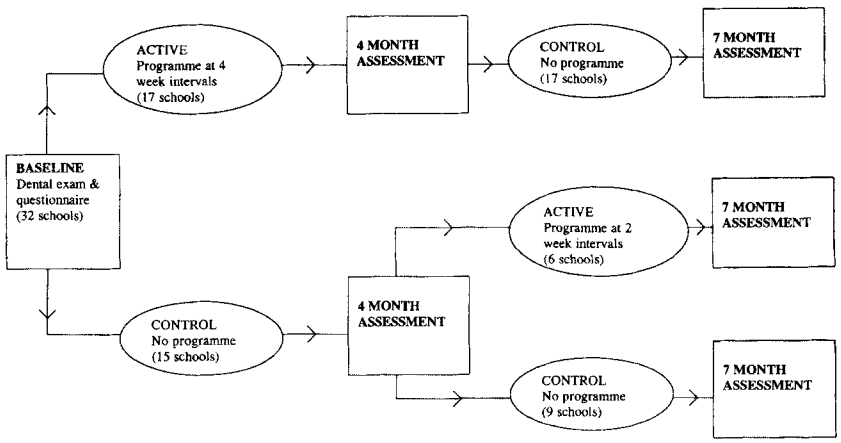
FIGURE 1
**Design of Cluster RCT for Evaluating Dental Health Education Program**




"contamination" of the program within schools due to the children talking to each other. After the baseline assessment, the schools were randomly allocated to active and control groups. During the following four months, the active group received four lessons at four weekly intervals, while the control group received no program. An evaluation of the plaque levels and knowledge of the children was made at four months. The control group was then split into a new active group and a residual control group and a further evaluation was undertaken at seven months. The new active program was given to the children every two weeks and the program was withdrawn from the original active group. This design had three advantages: (1) more children were exposed to the program, (2) it was possible to monitor how well the knowledge was retained by the initial active group, and (3) it was possible to assess whether exposing the children to the program more frequently led to better reductions in plaque and greater improvements in knowledge.

**Evaluation.** Ten children were selected randomly from each school to have plaque levels assessed clinically by one trained examiner who was not aware which were active and which were control schools. Plaque was measured on the mesiobuccal, midbuccal, and distobuccal sites of the upper and lower incisors and first permanent molars according to the method described by Löe and Silness (8).

At baseline and after four and seven months, all children completed a tested questionnaire designed to measure oral health knowledge and reported behavior about aspects of oral hygiene, sugar in the diet, and dental attendance, which had been covered in the program. The questionnaire was completed in school under the supervision of the class teacher and consisted of 31 questions covering the topics included in the program. The majority of the questions (24) were closed and offered a range of options for the children to consider. The open-answer questions allowed the children to comment on the following aspects of the program:

- the reasons for brushing teeth,
- foods that can be eaten between meals that will not cause dental caries, and
- how to remove dental plaque effectively.

Three specific knowledge-based, open-answer questions also were included to determine whether the children had retained specific dental information. These questions recorded knowledge about the anatomy and function of teeth.

In addition, at the baseline and four-month evaluations, six focus groups were convened in three active and three control schools to discuss oral health. The teachers in the participating schools were asked to comment on the dental health education program by completing an assessment form recording their opinions on lessons being of appropriate educational ability level, the standard of the workbook, the concept of group work, whether the program motivated the children, any noticeable changes in snacking habits, whether follow-up projects were undertaken, and whether the facilitator was useful.

**Teaching Program.** Teaching was performed by one dental facilitator in each school using a program entitled "My Mouth Matters," which consisted of four one-hour lessons based on interactive group activity. The facilitator was a qualified dental nurse who received one day of training on how to use the program and the importance of group work. Lesson 1 centered on tooth function and appearance and used case studies of people of different ages and their dental problems. Lesson 2 focused on diet and its effect on teeth, Lesson 3 concentrated on toothbrushing and the use of disclosing tablets, and Lesson 4 reviewed dietary topics and toothbrushing. Home extension work involving parents, caregivers, and grandparents was an integral part of the program. Three projects following the same themes as the schoolwork formed the home-based part of the program and each project took approximately one hour to complete. The whole program including the facilitator handbook is available free of charge from the University of Manchester.

Five to seven children worked in a group and every attempt was made by the facilitators to ensure that all children actively participated in all of the given tasks.

**Analysis.** The children were clustered within the unit of randomization, the school. A true randomization of individuals within school is impossible in a dental health education program for obvious logistical reasons. It is important that cluster RCTs are analyzed correctly, taking into account the clustering of children within schools (9,10). The mean plaque score was calculated for each child; generalized estimating equations with identity link and an exchangeable correlation coefficient were then used to make the comparison between groups. These are an extension of linear regression, which allows for the clustering of participants within schools.

For all the questionnaire data, the analysis was carried out using a binary outcome for each question, which was coded as either correct or not. Generalized estimating equations were used with logit link and an exchangeable correlation matrix to make the comparison between the study groups. These are an extension of logistic re-

gression, which allows for the clustering of participants within schools.

After the four-month assessment, two schools from the initial control group who were allocated randomly to receive the program refused to have it, preferring to remain in the control group. The data were analyzed by combining the data from these schools with those for the other schools who never received the program.

## Results

Forty-five schools were approached and 32 agreed to participate. Of the 13 schools that did not take part, six were closing or merging. The remaining seven were in the middle of a government-sponsored inspection scheme and felt that participation would be too difficult. All children in grades 5 and 6 (898) took part in the program; only those children who returned a positive consent could be sampled for the clinical examination. Completion of the questionnaire was considered part of the educational activity. Sixty-eight percent ($n$=611) of the children returned positive consents for the clinical examination. Ten children from each school were selected at random to participate in the clinical assessment. There were no significant differences between the schools for permission to carry out the clinical examinations.

The baseline questionnaire was completed by 794 children (88%), with a mean age of 10.1 years (range=9–11 years). After the baseline examination, 17 schools were randomly allocated to receive the program for the next four months, while the remaining 15 schools were allocated randomly to the control group over this period (Figure 1). Eight of the 15 schools who did not receive the program during this initial four-month period were then randomly allocated to receive the program during the next three months. Two of these schools refused to participate in the program, so that six schools received the program between the four- and seven-month examinations.

**Plaque scores.** Ten children from each school were selected randomly from those who returned a positive consent form at each of the participating schools, giving a total of 320. Of these, 310 (97%) were examined at baseline, 281 (88%) at four months, and 288 (90%) at seven months by a single trained dental examiner. At baseline the groups were well balanced for plaque, with mean plaque scores of 1.22 for the active group and 1.18 for the control (Table 1). At the four-month examination, the active group had a mean plaque score of 1.09 compared to 1.36 in the control group, a difference of 20 percent ($P$<.001).

The groups were reconfigured after the four-month examination, with the original control group being subdivided into new active and control groups (Figure 1). At the seven-month examination, both the initial active group (17 schools) and the new active group (six schools) had mean plaque scores of 1.22, which were lower than the mean plaque score for the control group (nine schools) of 1.47, each showing a 17 percent reduction ($P$<.001).

All the analyses were conducted using the generalized estimating equation approach described in the methods section. The interclass correlation coefficients for the plaque scores at baseline, four months, and seven months were 0.099, 0.023, and 0.052, respectively, indicating that there was

**TABLE 1**
**Mean Plaque Scores of the Study Groups at Baseline, 4 Months, and 7 Months**

| Group | $n$ | | Mean Plaque Score (SD) | $P$-value* |
|---|---|---|---|---|
| | Schools | Children | | |
| Baseline | | | | |
| Active | 17 | 166 | 1.22 (0.39) | .46 |
| Control | 15 | 144 | 1.18 (0.38) | |
| 4-month examination | | | | |
| Active | 17 | 146 | 1.09 (0.39) | <.001 |
| Control | 15 | 135 | 1.36 (0.45) | |
| 7-month examination | | | | |
| Active | 17 | 151 | 1.22 (0.34) | <.001 |
| New active | 6 | 57 | 1.22 (0.35) | .001 |
| Control | 9 | 80 | 1.47 (0.40) | |

*$P$-values comparing active with control groups, calculated taking into account the clustering of participants within schools.

**TABLE 2**
**Within-school Correlation Coefficients from the Statistical Models used to make Comparisons between Study Groups**

| | Baseline | 4-month Exam | 7-month Exam |
|---|---|---|---|
| Mean plaque scores | 0.099 | 0.023 | 0.052 |
| Appropriate toothbrush for cleaning teeth | 0.030 | 0.037 | 0.041 |
| Define what disclosing tablets are used for | 0.253 | 0.083 | 0.013 |
| Knew about sugary foods being harmful to teeth | 0.055 | 0.005 | 0.007 |
| Understood the need to eat sweets over short period of time | 0.109 | 0.123 | 0.057 |
| Identification of sugary foods | 0.005 | –0.007 | 0.012 |
| Brushing frequency | 0.125 | 0.036 | 0.019 |
| Reported dental visiting | 0.013 | 0.028 | 0.001 |
| Consumption of sugary snacks when arrived home from school | –0.001 | 0.039 | 0.016 |
| Snack consumption before bedtime | 0.007 | –0.003 | –0.001 |

a school effect (Table 2).

**Questionnaire.** All subjects were asked to complete a questionnaire, regardless of whether they had completed a consent form, because the schools considered it to be an integral part of the children's education and because oral health is part of the UK government's core curriculum. The response rates ranged from 88 to 95 percent (Table 3).

**Knowledge on Aspects of Oral Hygiene.** At baseline the majority of the participants in the active (60%) and control (68%) groups gave the correct response about the type of toothbrush to use (Table 4). The knowledge in both groups improved at the four-month evaluation, but the active group (94%) was better than the control group (83%) ($P<.001$). At seven months the original active group had maintained the knowledge level (96%), the new active group had improved (93%), and the control remained similar to the four-month level (81%). Similar trends were noted when the children were asked about the role of disclosing tablets. Although the knowledge in all groups had improved from baseline, the improvement was significantly greater in the active groups ($P<.001$).

**TABLE 3**
**Number and Percent of Children Who Completed the Questionnaire at Baseline, 4 Months, and 7 Months**

| Evaluation | No. Eligible to Answer | Response Rate No. (%) |
|---|---|---|
| Baseline | 898 | 794 (88) |
| 4 months | 794 | 741 (93) |
| 7 months | 741 | 707 (95) |

**Frequency of Sugar Consumption.** At baseline the majority of children (65% active; 71% control) knew that eating sugary foods between meals could be harmful to teeth. The percentages giving the correct response at four months increased to 92 percent for the active group and 93 percent for the control. Similar percentages were evident at seven months.

The children also were asked about the best way to eat a bag of sugary sweets. The correct answer was to eat them all at once rather than to eat them slowly over a long period of time. At baseline 34 percent of children in the active group gave the correct answer, compared to 57 percent in the control group ($P=.004$) (Table 5). At four months more children in the active group (78%) than in the control group (61%) knew the correct answer ($P<.001$). Although more children in both active groups knew the correct answer at seven months than at baseline, the percentage of children answering correctly did not differ significantly from the control group.

**Identification of Sugary Foods.** Few children had problems identifying a selection of foods containing sugar. Over 90 percent of both groups at baseline gave the correct answers. This pattern continued at both subsequent evaluations.

**Reported Behavior.** Prior to the intervention, 99 percent of the children reported that they brushed their teeth twice a day. This high level of reported brushing continued in all groups throughout the study period.

The reported dental visiting behavior was similar to that of the brushing responses, with 97 percent of children at baseline claiming to have a dentist whom they visited approximately twice a year. There was no change over the course of the program.

At baseline, 15 percent of active and 19 percent of control groups reported that they routinely consumed sugary snacks when they arrived home from school. These percentages did not change markedly over the course of the evaluations. Snack consumption before bedtime was reported by approximately one-third of participants at baseline (active, 30%; control, 37%). The reported consumption declined in all groups to between 20 and 25 percent at the four- and seven-month assessments; however, the differences were not statistically significant.

The within-school correlation coefficients for the baseline questionnaire data ranged from –0.001 to 0.253 (Table 2). The value of –0.001 was found for children reporting that they routinely consumed sugary snacks when returning home from school, indicating no within-school correlation, compared to the high value of 0.253 for

**TABLE 4**
**Number and Percent of Children in the Active and Control Groups Who Knew an Appropriate Toothbrush for Cleaning Teeth and Were Able to Identify Use of Disclosing Tablets**

| | | Identified Appropriate Toothbrush | | | Identified Use of Disclosing Tablet | | |
|---|---|---|---|---|---|---|---|
| Group | Number | *n* | (%) | *P*-value | *n* | (%) | *P*-value |
| Baseline | | | | | | | |
| Active | 481 | 289 | (60) | .08 | 174 | (36) | .12 |
| Control | 313 | 213 | (68) | | 164 | (52) | |
| 4-month assessment | | | | | | | |
| Active | 435 | 407 | (94) | <.001 | 413 | (95) | <.001 |
| Control | 306 | 253 | (83) | | 203 | (66) | |
| 7-month assessment | | | | | | | |
| Active | 412 | 394 | (96) | <.001 | 384 | (92) | <001 |
| New active | 124 | 115 | (93) | <.001 | 121 | (98) | <.001 |
| Control | 171 | 138 | (81) | | 125 | (73) | |

*P-values comparing active with control groups, calculated taking into account the clustering of participants within schools.

TABLE 5
**Number and Percent of Children Who Understood the Need to Eat Sweets Over a Short Period of Time, by Group Assignment and Period of Assessment**

| Group | N | Eat Sweets Quickly | | |
|---|---|---|---|---|
| | | n | (%) | P-value |
| Baseline | | | | |
| Active | 481 | 165 | (34) | .004 |
| Control | 313 | 179 | (57) | |
| 4-month assessment | | | | |
| Active | 435 | 341 | (78) | .003 |
| Control | 306 | 186 | (61) | |
| 7-month assessment | | | | |
| Active | 412 | 316 | (77) | .70 |
| New active | 124 | 100 | (81) | .38 |
| Control | 171 | 125 | (73) | |

*P-values comparing active with control groups, calculated taking into account the clustering of participants within schools.

TABLE 6
**Teachers' Qualitative Comments on the Dental Health Education Program (N=24)**

| Comments | Yes | | No | | No Comment | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Appropriate ability level | 16 | (67) | 7 | (29) | 1 | (4) |
| Workbooks suitable | 21 | (88) | 2 | (8) | 1 | (4) |
| Group concept worked | 21 | (88) | 2 | (8) | 1 | (4) |
| Pupils motivated | 15 | (63) | 8 | (33) | 1 | (4) |
| Snacking habits changed | 2 | (8) | 15 | (63) | 1 | (4) |
| Follow-up projects undertaken | 13 | (54) | 10 | (42) | 1 | (4) |
| Thought facilitator useful | 21 | (88) | 3 | (12) | — | — |

knowledge about what disclosing tablets do. The within-school correlation coefficients from the statistical models comparing the study groups at the four- and seven-month examinations ranged from –0.007 for identification of sugary foods to 0.123 for understanding the need to eat sweets over a short period of time.

**Focus Groups.** The focus group discussions were held just after the baseline and four-month questionnaires were issued. At baseline most of the children reported that they did not brush their teeth more than once per day, did not eat sugary snacks when they got home from school, and were unsure of the timing of their dental visits. Compared to the control groups, after four months the children in the active group claimed to eat less sugary foods, had discussed fluoride toothpaste with their parents, brushed at least twice per day, had asked their mothers to buy fruit, and had asked their parents to arrange a dental check-up.

**Teacher's Questionnaire.** Evaluation forms were completed by the teachers after four and seven months for the 24 active groups. On the whole, the program was well received (Table 6). However, the teachers reported little change in the children's snacking behavior.

## Discussion

This study tested the effectiveness of a dental health program and found that the children receiving the program had significantly lower mean plaque scores and greater knowledge about toothbrushes and disclosing tablets than children in the control groups. The study also demonstrated the feasibility of using an RCT to measure the effectiveness of a dental health dental education program (3). In particular, it demonstrated the use of cluster analysis in the frequently encountered situation in which a program is delivered to groups of participants rather than to individuals.

The study was designed and analyzed as a cluster randomized trial to overcome the "contamination" of subjects within the same school. The analysis showed that the within-school correlation coefficient for plaque at baseline ranged from 0.023 to 0.099. This illustrates that there is a substantial school effect, which must be taken into account in analyzing studies of this type. The within school correlation coefficients for the questionnaire data at baseline ranged from –0.007 to 0.253. The value of –0.007 was found for children identifying sugary foods, indicating no within-school correlation, probably due to over 90 percent of the children giving the correct answers. The high baseline within-school correlation coefficient of 0.253 for knowledge about disclosing tablets indicates that the children in some of the schools probably had received some dental health education prior to the study.

These findings suggest that the design and analysis were highly appropriate for studies of this type, and that data analyses ignoring the clustering of children within schools would have been incorrect (9,10). Knowledge of the within-schools correlation coefficients is useful for calculating the number of clusters and the number of children per cluster in the design of future cluster RCTs (11).

The clinical significance of the reductions in dental plaque is difficult to determine because the small changes found in this study may have little impact on gingival health. Nevertheless, more frequent brushing with fluoride toothpaste could reduce dental caries. This study has shown a small effect; however, the program must be built on through other interventions if it is to be of any lasting value.

One surprising feature of the investigation was the knowledge gained by the control group. Some of the control schools were visited by the dental health educators from the local Community Dental Service, who gave advice on diet and dental decay to younger children in the school. One

can only postulate on the effect of the spread of information from the younger children, but it reinforces the difficulties of carrying out research in real-life settings.

It is gratifying to note that the first active group retained useful knowledge at the seven-month assessment, despite cessation of their dental health program three months earlier. How long the benefit will be retained is an important question in all health education programs.

Clearly, the results of this study show it is possible to undertake a randomized controlled trial of a dental health education program. Nutbeam (12) has argued that it is important to combine different research methodologies when assessing health promotion. This study accepted that advice, and conducted focus group interviews (13) and a survey of teachers, in addition to the quantitative survey and clinical examination of the schoolchildren. However, the key point is that it was possible to evaluate the program in a rigorous scientific manner.

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