A Cluster Randomized Controlled Trial Testing the Effectiveness of a School-based Dental Health Education Program for Adolescents

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Abstract

Objectives: *This trial investigated the value of a school-based dental health education program in terms of changes in knowledge, reported behavior, and plaque scores.* ***Methods:*** *A total of 2,678 pupils with a mean age of 12.1 years attending 28 schools participated in a school-based dental health education program. The study used a cluster randomized controlled study design. The health service administrators stipulated that all participants receive the intervention; to meet this requirement, a rolling program of two six-month periods was utilized. During the first six months, half the adolescents received the intervention program, the other half acting as controls. Throughout a further six-month period, all participants received the intervention program. This research design allowed comparisons between participants receiving the program for six and 12 months. At baseline, six, and 12 months, a random subsample of 40 children in each participating school had their plaque scores recorded and a questionnaire was used to record their knowledge of dental health and reported dental behavior.* ***Results:*** *The analysis used the subjects clustered within the schools, which were the units of randomization. The intervention program produced statistically significant improvements (P<.001) in knowledge about periodontal disease and the frequency of sugar intake and dental caries in both assessment time periods. The reported frequency of brushing did not change, but the group who had received 12 months of the intervention were more likely (P<.05) to brush for over a minute. At six months the early intervention group had a statistically significant, 13 percent reduction in the mean proportion of sites with plaque compared with the late intervention group (P=.043). This difference was sustained at 12 months (P=.037).* ***Conclusion:*** *This cluster randomized control trial demonstrated that the intervention program resulted in an improvement in knowledge of dental disease and an increase in the reported duration of brushing. These improvements were accompanied by a significant improvement in oral hygiene and a reported reduction in gingival bleeding. [J Public Health Dent 1999;59(1):12-17]*

Key Words: oral health promotion, adolescents, evaluation, RCT.

Recent reviews (1,2) have highlighted the need for oral health promotion studies to be based on a theoretical framework, be scientifically robust, and be fully evaluated. In their most recent systematic review commissioned by the English Health Education Authority, Kay and Locker (1) emphasized that most studies investigating the potential value of dental health education programs did not use a randomized controlled design. The randomized controlled trial (RCT) is regarded widely as the gold standard for evaluation research, as its use minimizes threats to validity caused by bias introduced by confounding factors.

Some debate has occurred over whether it is possible to apply an RCT design to the evaluation of dental health education programs. The research described in this paper addresses this debate by demonstrating the use of the RCT methodology in a community health education setting.

Adolescents are a group in particular need of preventive programs. They have high levels of plaque (3), which leads to problems in later life (4,5). Although dental caries in this age group is declining in many areas of the United Kingdom, caries levels are still high in many places, particularly in the northwest of England (6).

Although adolescents have a basic knowledge of dental health and in particular the importance of brushing teeth twice a day (7,8), many fail to brush their teeth effectively (9-11). It has been suggested that when adolescents care for their teeth, they do so for the short-term rewards relevant to them—in particular, to improve appearance and social attractiveness (7,12-14). These seemingly conflicting findings suggest that ways of motivating adolescents to maintain or improve their oral health are fertile ground for evaluative research.

This paper describes a study in which the value of a school-based dental health education program was investigated in terms of changes in knowledge, reported behavior, and plaque scores. The key element in our intervention model was to persuade adolescents that the appropriate oral health behavior would contribute greatly to social acceptability and attractiveness. An RCT study design was used and the randomization was undertaken centrally by individuals not directly involved in the implemen-

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tation of the program.

Methods

The program took place over a period of one year from April 1996 to April 1997. The investigation was funded by a grant from the Department of Health to Salford and Trafford Health Authorities, two districts of Greater Manchester, UK. At the outset, the Health Authorities stipulated that schools whose pupils were known to have low dental needs be excluded. Accordingly, all secondary schools in these two districts—with the exception of four schools where dental need was low as measured by the 1994–95 British Association for the Study of Community Dentistry (BASCD) Survey (6)—were invited to participate. Of these 30 schools, all except two agreed to participate in the project. Consequently, 3,881 first-year pupils attending 28 secondary schools were invited to join the program.

Study Design. Both the two commissioning Health Authorities, Salford and Trafford, stipulated that all pupils of the appropriate age attending participating schools be given the opportunity to receive the program, which potentially conflicted with the demands of a randomized controlled study. To overcome this problem, the study was designed as a rolling program in two time periods of six months each.

Each school was allocated randomly either to the early or the late intervention group. During the first six months, the early intervention group received the intervention program and the late intervention group, who did not, served as the control. This design gave a true randomized control trial during the first six-month period (Figure 1). During the second six-month period, both groups received the intervention. This research design allowed comparison between participants receiving the program for six and 12 months.

Evaluation. To comply with a request from schools to cause minimum disruption, 40 children were selected randomly from each school. Levels of oral health knowledge and reported dental behavior were recorded at baseline, six, and 12 months using a pretested questionnaire (Figure 2). Clinical plaque levels were evaluated at the same time.

Following the baseline evaluation, the schools were allocated randomly either to the early or the late intervention group. Two trained and calibrated examiners undertook the clinical examinations in the schools. At each examination they examined pupils in the same schools and were not aware of which ones were early or late intervention schools. Throughout the study the participants were not informed of the dates on which they would be examined; these were always conducted at least one month after the last intervention.

Plaque was measured on the mesio-buccal, mid-buccal, and disto-buccal sites of the upper and lower central incisors and first permanent molars using the method described by Silness and Löe (15). The teeth were dried with air and the plaque scores were dichotomized: scores 0 and 1 were recorded as plaque absent and scores 2 and 3 were recorded as plaque present. Pupils with a fixed orthodontic brace were excluded from the clinical examination.

Teaching Program. Teaching was undertaken by dental facilitators employed specifically for the project using a methodology designed to encourage behavior change. Pupils were given three lessons in each six-month period. Lessons were given to small groups of pupils, with a maximum of 10 per group, each lesson lasting approximately 20 minutes. The project emphasized that good oral health contributes to appearance and social acceptability, topics deemed highly relevant to adolescents. The teaching sessions were interactive, with facilitators encouraging pupils to discuss their ideas of how to change their behavior and to appreciate that decayed teeth and bad breath affected their day-to-day lives. Support and reinforcement for new behaviors were provided by

FIGURE 1
Overview of Study Design

		Assessment		
	Intervention	Baseline	6 Months	12 Months
Group	Early	Evaluation	Intervention Evaluation	Intervention Evaluation
	Late (control)	Evaluation	Evaluation	Intervention Evaluation

FIGURE 2
Questions and Correct Answers for Knowledge Questions

	Question	Correct Answer
Qi	You can tell when you have gum disease because—	Bleeding and/or redness
Qii	You can stop gum disease by—	Brushing
Qiii	When you clean your teeth you are removing—	Plaque
Qiv	When is it least damaging to your teeth to have a sugary snack?	Meals
Qv	If you have a bag of sweets is it better for your teeth to —	Eat them all in one go
Qvi	Did you brush your teeth this morning?	
Qvii	Did you brush your teeth last night?	
Qviii	Did your gums bleed last time you brushed your teeth?	No
Qix	Do you brush your teeth every day?	
Qx	How long does it take you to brush your teeth?	>1 minute

other group members. Lessons included toothbrushing instruction to enable pupils to improve their oral hygiene. Toothbrushes, toothpaste, and disclosing tablets were provided for home use. A letter was sent home to parents following each lesson to encourage parental support.

The relationship between good oral health and social acceptability was further reinforced by three take-home leaflets designed for this program with the help of pupil focus groups. The leaflets related the "continuing story of young love" and good oral health using language appropriate to the age group. The pupils who received the intervention for 12 months received the same teaching during both the first and the second six-month periods.

Analysis. The subjects were clustered within the unit of randomization, the school. 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 (Figure 2). Generalized estimating equations were used with logit link and an exchangeable correlation matrix to make the comparison between the study groups. These techniques are an extension of logistic regression, and allow for the clustering of subjects within schools. To improve the fit of the model for plaque three covariates—baseline plaque, sex, and dental attendance—were included.

The proportion of sites with plaque was calculated for each subject; then generalized estimating equations with identity link and exchangeable correlation coefficient were used to make the comparison between groups.

To detect a 25 percent reduction in the mean proportion of sites with plaque, with alpha=0.05, power=80 percent, assuming a control group mean=0.60 (standard deviation=0.30) and an intraclass correlation coefficient=0.15, 12 schools with 40 pupils examined in each were required.

Results

Twenty-eight of the 30 schools targeted participated. The two that withdrew thought that the project would be too disruptive. All pupils in the first year of secondary school (3,881 pupils) were eligible for inclusion; 2,678 (69%) returned positive consents and were included in the teaching program. They had a mean age of 12.1 years (SD=0.3; min=11.3, max=13.3). The percentage of pupils participating in each school varied from a maximum of 86 percent to a minimum of 54 percent.

Study Population. Forty pupils were selected randomly from each school to participate in the evaluation component of the study, giving a sample of 1,116 (one small school only had 36 eligible pupils), 46 percent of whom were male. A total of 1,063 (95% of the sample) pupils were available at baseline, 570 from 15 schools in the early intervention group and 493 from 13 schools in the late intervention group. All children were examined for plaque; however, three were excluded from the baseline analysis because they did not answer any questions in the questionnaire. Unanswered questions could have been coded as either missing or incorrectly answered. Because more than 99 percent answered the simpler questions and only 87 percent answered the more difficult ones, a decision was made that children who did not answer specific questions were coded as not giving correct answers. The way in which the answers were coded did not affect the results. The parents of three children withdrew consent and the remainder were absent from school on the evaluation days.

A total of 915 (82%) of pupils were examined at six months and 856 (77%) after 12 months. The questionnaire was completed by 942 pupils at six months and 904 after 12 months.

Knowledge. *Knowledge of Periodontal Disease (Qi, Qii, Qiii).* At baseline only a few of the participants had knowledge of the signs and symptoms of periodontal disease; 110 (19%) in the early intervention group and 103 (21%) in the late intervention group knew that bleeding and/or redness are symptomatic of gum disease (Ta-

TABLE 1
Comparisons Between Study Groups of the Number and Percent of Pupils Who Gave Correct Answers to Questions, by Assessment Period

	Intervention Group					
	Baseline		6 Months		12 Months	
	Early (*n*=567)	Late (*n*=493)	Early (*n*=510)	Late (*n*=432)	Early (*n*=481)	Late (*n*=423)
Qi	110 (19)	103 (21)	398 (78)*	171 (40)	419 (87)	343 (81)
Qii	370 (65)	301 (61)	464 (91)*	340 (79)	461 (96)	392 (93)
Qiii	443 (78)	368 (75)	478 (94)*	343 (79)	459 (95)†	385 (91)
Qiv	50 (9)	45 (9)	321 (63)†	54 (13)	324 (67)†	231 (55)
Qv	90 (16)	75 (15)	268 (52)†	75 (17)	320 (66)	266 (63)
Qvi	477 (84)	432 (88)	433 (85)	383 (89)	422 (88)	380 (90)
Qvii	414 (73)	357 (72)	408 (80)†	312 (72)	367 (76)	310 (73)
Qviii	358 (63)	308 (62)	396 (78)†	304 (71)	402 (83)	342 (81)
Qix	503 (89)	444 (90)	472 (92)	395 (92)	454 (94)	392 (93)
Qx	415 (73)	349 (71)	447 (87)†	318 (73)	429 (89)†	349 (83)

Numbers in parentheses are percentages.
*P<.001, calculated taking the clustering of the subjects within schools into account.
†P<.05.

TABLE 2
Between-group *P*-values for Each Time Period and Intragroup *P*-values Between Different Time Periods

	Comparing Groups			Intervention Group					
				Comparing Baseline w/6 Months (*n*=939)		Comparing Baseline w/12 Months (*n*=900)		Comparing 6 with 12 Months (*n*=825)	
	Baseline	6 Months	12 Months	Early (*n*=509)	Late (*n*=430)	Early (*n*=479)	Late (*n*=421)	Early (*n*=442)	Late (*n*=379)
Qi	0.69	<0.001	0.09	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Qii	0.30	<0.001	0.06	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Qiii	0.33	<0.001	0.02	<0.001	0.02	<0.001	<0.001	0.12	<0.001
Qiv	0.97	<0.001	0.06	<0.001	0.08	<0.001	<0.001	0.14	<0.001
Qv	0.90	<0.001	0.77	<0.001	0.10	<0.001	<0.001	<0.001	<0.001
Qvi	0.15	0.12	0.32	0.69	0.79	0.16	0.36	0.03	0.30
Qvii	0.85	0.01	0.46	0.004	0.79	0.21	0.61	0.15	0.92
Qviii	0.85	0.02	0.44	<0.001	0.02	<0.001	<0.001	<0.001	<0.001
Qix	0.60	0.70	0.44	0.052	0.64	0.007	0.36	0.09	0.56
Qx	0.52	<0.001	0.01	<0.001	0.56	<0.001	<0.001	0.10	<0.001

TABLE 3
Comparisons Between Mean Proportion of Sites with Plaque for Pupils in Early and Late Intervention Groups at Baseline, Six, and 12 Months, and Changes from Baseline

	Early Intervention Group (*n*=570)		Late Intervention Group (*n*=493)		
	n	Mean Proportion of Sites with Plaque (SD)	*n*	Mean Proportion of Sites with Plaque (SD)	*P*-value
Baseline	570	0.59 (0.26)	493	0.58 (0.26)	.77*
6 months	500	0.47 (0.28)	415	0.54 (0.26)	.14* [.043]†
12 months	453	0.41 (0.28)	403	0.47 (0.29)	.15* [.034]†
Difference between baseline and 6 months	500	0.12 (0.27)	415	0.03 (0.28)	.075‡
Difference between baseline and 12 months	453	0.18 (0.26)	403	0.11 (0.28)	.038‡

*Calculated taking the clustering of subjects within schools into account.
†From model taking clustering into account and including covariates; baseline plaque, sex, and dental attendance.
‡From paired *t*-test.

ble 1). A total of 671 (63%) stated that it was important to brush their teeth to stop gum disease and the majority, 811 (76%), knew that they were removing plaque when they brushed. None of the differences between the groups at baseline were statistically significant (*P*>.05) (Table 2).

At the six-month examination 398 (78%) pupils in the early intervention group knew that bleeding and redness was symptomatic of gum disease, compared with 171 (40%) in the late intervention group (Table 1). Although this knowledge had improved significantly in both groups from baseline (*P*<.001), the difference between the two groups was statistically significant (*P*<.001) (Table 3). In both groups the proportion of pupils who knew that brushing removed plaque and prevented gum disease had increased (*P*<.05); however, the level of knowledge in the early intervention group was significantly better than that of the late intervention group (*P*<.001).

After a further six months, during which all pupils received the intervention program (Figure 1), the level of knowledge increased in both groups (Tables 1 and 2), but particularly from the six- to 12-month examination in the late intervention group.

Frequency of Sugar and Caries (Qiv, Qv). At baseline only a small proportion of pupils (9%) knew when it was least damaging to eat sugary snacks or sweets (Table 3). However, after the first and second six-month periods of intervention, a much higher proportion of pupils in the early and late intervention groups, respectively, knew about the role of dietary factors in oral disease. At the six-month examination those in the early intervention group had a significantly greater level of knowledge than those in the late intervention group (*P*<.001) (Table 2).

Reported Behavior (Qvi to Qx). Prior to the intervention most pupils reported that they brushed their teeth in the morning and "usually" at least

every day (Tables 1 and 2). The intervention did not have an effect on these high baseline levels. The effect of the program on pupils reporting that they brushed their teeth at night was unclear. Despite the high percentage reporting nighttime toothbrushing, we found some increase in the early intervention group after six months; however, this increase was not sustained during the second period. No change in nighttime toothbrushing was evident in the late intervention group after their active involvement in the teaching sessions. An increase was observed in the percentage of pupils in the early intervention group who did not report bleeding gums after the first six months and a similar reduction in the late intervention group at 12 months. At the 12-month examination the early intervention group was more likely ($P=.01$) to report that they brushed for over one minute.

Clinical Examination. At baseline the mean proportion of sites with plaque was 0.59 in the early intervention group and 0.58 in the late intervention group (Table 3) ($P=.77$). The mean proportion of sites with plaque was significantly reduced in both groups at six months, with a 20 percent reduction in the early intervention group and a 7 percent reduction in the late intervention group. Comparisons between the means for the groups at six months showed a 13 percent reduction in favor of the early intervention group ($P=.14$), which was statistically significant when baseline plaque, reported attendance at the dentist within the last six months, and sex were included in the model ($P=.043$). The early intervention group continued to improve and there was a 13 percent significant difference between the mean proportion of sites with plaque for the groups at 12 months when the same covariables were included in the model ($P=.034$). The intraclass correlation coefficient for the mean proportion of sites with plaque at the six-month examination was 0.16.

Dental Visiting. At baseline 76 percent of pupils in the early and 73 percent in the late intervention groups reported they had visited a dentist in the last six months. These estimates did not change in either group during the study.

Sex. In a further analysis of the data, more girls than boys ($P<.05$) reported at baseline that they brushed their teeth in the morning, at night, and "usually" every day and could list at least one sign of gum disease. After one year a significant increase occurred in the number of boys who reported that they usually brushed their teeth every day ($P<.05$).

At baseline girls had 54 percent of sites with plaque as compared to 64 percent in boys. However, after participating in the program for one year, boys in the early intervention group had levels of plaque similar to the girls, whereas boys in the late intervention group still had significantly ($P<.001$) higher plaque levels than girls.

Discussion

A true randomized control trial design is considered to be the best method of demonstrating a clear cause-and-effect relationship between an intervention and subsequent observation (16). Recent reviews of oral health promotion programs (1,17) have highlighted the fact that few studies have employed an RCT design; consequently, the evidence underpinning oral health promotion is weak. In the present study the schools were allocated randomly to the two study groups. Such a cluster design overcomes the problem of contamination of subjects within the same school and—accompanied by the correct analysis—is highly appropriate for studies of this nature. The study also was designed in a novel way to satisfy the health authority requirement that all subjects potentially benefit from the intervention. Such a design, where only one group received the intervention during the first six months, enabled a simple assessment to be made in the gain in knowledge, reported behavior, and oral hygiene during this period. During the second six months all subjects received the intervention, enabling a comparison to be made of the effects of six-months' intervention with that of 12 months. This design meant that it was not possible to assess the absolute benefit of receiving the intervention for 12 months, only the relative benefit at 12 compared with six months.

Kay and Locker (1) noted in their review that dental health education programs can improve knowledge and reported behavior, but that this improvement might not necessarily be accompanied by a health gain. The present study observed an improvement in knowledge of dental disease, but only limited improvements in reported behavior. This finding was due partly to the fact that at baseline most participants reported brushing at least once a day. However, those who received the intervention program reported brushing for longer. While reported behavior is not a robust measure, the accompanying reduction in the proportion of sites with plaque and the self-reported reduction in gingival bleeding suggest a clinical benefit. However, the public health significance of these improvements is debatable. It has been suggested that a population strategy is most likely to benefit the periodontal health of the majority of people because a small overall reduction in plaque, if sustained, will reduce the general level of periodontal disease (18). A longer follow-up period would be needed to establish whether this is the case.

The design and analysis of this cluster randomized study address many of the methodologic criticisms raised by Kay and Locker (1). However, it is questionable whether the health gain observed justified the financial and personnel resources involved.

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