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A comparison of dentist-led, teacher-led, peer-led and self-learning strategies for educating school children aged 10-13 years about prevention of oral diseases including tooth decay, gum disease and oral cancer

Submission date
19/01/2012

Recruitment status
No longer recruiting

Registration date
03/02/2012

Overall study status
Completed

Last Edited
05/01/2016

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Oral health education in schools for the prevention of diseases such as tooth decay, gingivitis (gum inflammation) and oral cancer has largely been imparted by dentists. As this expert-led approach is expensive, strategies relying on teachers, peer-leaders and learners themselves have also been used. However, the evidence for the effectiveness of these strategies is lacking. The aim of this study is to compare the effectiveness of dentist-led, teacher-led, peer-led and self-learning strategies of oral health education at increasing knowledge about oral health and bringing about a positive change in oral health behavior and oral health status.

Who can participate?
Children in class six, aged 10-11.

What does the study involve?
Participating schools are randomly allocated into five groups. Three of the groups receive oral health education from dentists, teachers or peer group leaders, respectively, and are evaluated four times over two years. The fourth group is a self-learning group while the fifth group (control group) does not receive any form of oral health education, and these groups are surveyed at the start and end of the two years. Knowledge about oral health, preventive behavior, oral hygiene, and tooth decay are assessed through a questionnaire, a structured interview and an oral examination.

What are the possible benefits and risks of participating?
The children received information about the prevention of the most common oral diseases and were provided with a colorful booklet related to these topics. Even the children in the self-learning and control groups received the full benefits of the study after the study was over. In addition all the children received a thorough examination of their teeth at least twice during the

course of the study. A detailed report about the findings of the oral examination was sent to the parents of all participating children.

Where is the study run from?
Forty public and private middle and secondary schools in two selected towns of the cosmopolitan city of Karachi, Pakistan.

When is the study starting and how long is it expected to run for?
January 2004 to February 2006.

Who is funding the study?
The World Health Organization/Government of Pakistan Collaborative Program.

Who is the main contact?
Dr Abdul Haleem

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A cluster randomized controlled clinical trial of school-based oral health education strategies for adolescents aged 10-13 years

Study objectives
1. The dentist-led, teacher-led, peer-led and self-learning strategies of oral health education are not significantly different from one another as well as from the control group in increasing knowledge about oral health; and in bringing about a positive change in oral health behavior and oral health status of school children aged 10-13 years.
2. The repetition of oral health education messages has no statistically significant effect on the oral heath knowledge, behavior and oral health status of the study participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Shaikh Zayed Medical Complex, Lahore, 15/11/2003, ref: SZH/IRB /017-03

Study design
Double-blind cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Oral health education for preventing dental caries, gingivitis and oral cancer

Interventions
Dentist-led group
Teacher-led group
Peer-led group
Self-learning group
Control group

Ten boys and ten girls schools each were randomly selected from the respective lists of public and private schools fulfilling the eligibility criteria. It was followed by a random allocation of two boys and two girls public as well as private schools to each of the five study groups. Afterwards in each school a section of class six was randomly chosen for the study.

The intervention in the three educator-led groups i.e. dentist-led, teacher-led and peer-led involved a single oral health education (OHE) input after baseline data collection in January 2004, no education for six months, monthly reinforcement of OHE messages from September 2004 to February 2005 and no further education till February 2006. The three groups were evaluated in February 2004 (evaluation I), August 2004 (evaluation II), August 2005 (evaluation III) and February 2006 (evaluation IV).

The pupils in the self-learning group were asked to learn from an OHE booklet provided to them in the beginning of the trial while the control group did not receive any form of OHE over the period of the trial. These two groups were surveyed at baseline and evaluation IV with the other study groups. The total duration of follow-up for all study groups was two years.

The data for outcome measures of the trial at baseline and all evaluations were collected through a self-administered questionnaire, a structured interview and a clinical oral examination of the study participants. The questionnaire comprised of eighteen close-ended questions: two about attitudes of children towards maintenance of oral hygiene, twelve about oral health knowledge and two about oral health behavior. The structured interview consisted of eight questions, all related to oral health behavior with right-wrong and yes-no type of responses. Therefore, a total of twenty six questions were asked: two about oral health attitudes, twelve

about knowledge and twelve about behavior. Since every question had only one right answer, therefore, the responses to all questions were dichotomized as either correct or incorrect. The correct response was given a score of 1 and incorrect 0.

The clinical oral examination involved recording of teeth with caries experience, sextants of mouth with plaque, bleeding on probing and calculus, and cases of oral submucous fibrosis.

The data produced in the study were organized to develop five composite indices: oral health knowledge, oral health behavior, oral hygiene status (computed as the number of sextants of the oral cavity free of dental plaque, bleeding on probing and calculus), caries experience (computed by combining the number of decayed, missing and filled teeth due to dental caries) and the number of the positive cases of oral submucous fibrosis.

The data were analyzed using the SPSS 16 program. During analysis, schools were used as clusters. The study groups were compared using Generalized Estimating Equations (GEEs) for outcome measures of the study. The mean scores of composite indices were adjusted for sex and type of schools using the two as independent variables in the model along with the OHE strategy. The different evaluation scores were also adjusted to baseline values by using the latter as covariate in the model. Pearsons Chi-square test was used to find out differences among the study groups according to the number of subjects in different groups, sex and type of school. The t-test was used to calculate the unadjusted means of the clinical indicators. The intra-group comparisons at baseline and different evaluations were made by applying paired t-test. The minimum level of statistical significance for comparing the study groups was set at $p<0.05$.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Assessed through an oral examination of the study subjects included:
1. Incidence and severity of dental caries measured through Decayed, Missing and Filled Teeth index (DMFT) which indicated the number of teeth affected by dental caries in an individuals mouth
2. Change in the prevalence and incidence of oral submucous fibrosis (OSMF)
3. Improvement of oral hygiene status (OHS) measured through a decrease in the number of sextants of oral cavity having dental plaque, bleeding on probing and calculus. The total OHS score for an individual ranged from 0 to 12.
Measures were repeated five times (including baseline in January 2004) for the dentist-led, teacher-led, peer-led groups in February 2004 (evaluation I), August 2004 (evaluation II), August 2005 (evaluation III) and February 2006 (evaluation IV). The self learning and control groups were measured at baseline and at evaluation IV with the other study groups

Key secondary outcome(s))
1. Knowledge about oral health (OHK) measured on a scale with scores ranging from 0 to 12
2. Preventive oral health behavior (OHB) about gingivitis and OSMF/ oral cancer measured on a scale having scores ranging from 0 to 12
Measures were repeated five times (including baseline in January 2004) for the dentist-led, teacher-led, peer-led groups in February 2004 (evaluation I), August 2004 (evaluation II), August

2005 (evaluation III) and February 2006 (evaluation IV). The self learning and control groups were measured at baseline and at evaluation IV with the other study groups

Completion date
28/02/2006

Eligibility

Key inclusion criteria
Schools (clusters):
Public and private schools including both boys and girls schools in the two selected towns of Karachi, Pakistan

Study subjects:
Students of randomly chosen sections (one per school) of class six in the selected schools with a positive parental consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Schools:
1. The schools having only one section of class six
2. Schools having less than thirty five students per section

Study subjects:
1. Students with a negative parental consent
2. Students not willing to participate

Date of first enrolment
01/01/2004

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
Pakistan

Study participating centre
Shaikh Zayed Medical Complex
Lahore
Pakistan
54600

Sponsor information

Organisation
Shaikh Zayed Medical Complex (Pakistan)

ROR
https://ror.org/002tz8e96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The World Health Organization/ Government of Pakistan Collaborative Program- Oral Health Component through Shaikh Zayed Medical Complex (Pakistan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/12/2012		Yes	No
Results article	results	04/01/2016		Yes	No