Author's response to reviews

Title: Effectiveness of the bucco-lingual technique within a school-based supervised toothbrushing program on preventing caries: a randomized controlled trial

Authors:

Paulo Frazão (pafrazao@usp.br)

Version: 3 Date: 18 October 2010

Author's response to reviews: see over
Tim Shipley, PhD  
Executive Editor  
BMC-series Journals  

October 18th, 2010.

Dear editor:

I am writing to submit the revised version of the original article entitled *Effectiveness of the bucco-lingual technique within a school-based supervised toothbrushing program on preventing caries: a randomized controlled trial*. I also provide a point-by-point response to the reviewer’s comments.

The research was supported by The Foundation for the Support of Research of the State of São Paulo, Brazil (Grant 51300-0/2006) and the Department of Health from Sao Vicente City Hall. There was not any financial concern or other relationships that might lead to a conflict of interest.

The manuscript was reviewed, has not been published before, and is not being considered for publication elsewhere. I agree to assign exclusive copyright to EOS, if and when the manuscript is accepted for publication. The revised archive was sent with all changes made in bold type.

Yours faithfully,

Paulo Frazão

Correspondence to Professor Paulo Frazão, Faculdade de Saúde Pública da Universidade de São Paulo. Av. Dr Arnaldo 715 – São Paulo, SP, Brasil. CEP 01246-905 Tel: (55 11) 3061-7957 Fax: (55 11) 3083-3501 Email: pafrazao@usp.br
Author's response to the reviews

Title: Effectiveness of the bucco-lingual technique within a school-based supervised toothbrushing program on preventing caries: a randomized controlled trial

Author: Paulo Frazão <pafrazao@usp.br>

Version: 2

The paper was copyedited.

Date: 15 October 2010

Reviewer: Martijn Rosema

The author reports a clinical study where the effectiveness of a brushing technique is assessed and the respective effect on dental caries. This paper deals with an interesting issue, potentially relevant for preventive dental therapy and primary oral health. I recommend this paper to be published however, there are some comments.

General:
Throughout the manuscript the spelling and word order could improve for better reading. I suggest to upload your manuscript to an editing service, for instance American Journal Experts http://www.journalexperts.com/.

Background:
The study is about a special technique: "the bucco-lingual technique". It would be very useful to describe how this technique is different from other techniques. Please describe in detail how this technique is performed or add a reference to a paper which defines this brushing technique.

I would like to thank the reviewer for the comments about the work. The description of brushing technique was included in the Methods.

Methods:
- It is stated that the study is an 18 month trial. A time line incorporated into the flowchart (fig 1) would make it easier to understand.
- The preschools were randomly assigned to a test and control group but it is unclear how the schools were selected in the first place.
- Please define the primary and secondary response variables.
- The method section would read easier when the ‘topic’ statistics is extracted and put into a separate paragraph. Then a detailed description of the test procedure as well as the control procedure would improve this section. Now it is unclear in what way the two groups differ.
- The study is supposed to be blinded but the dental assistants seem to have their own group (one for the test, one for the control group). This suggests that the study is not completely blinded.

The Figure 1 was changed. The timing intervals were added. Details related to the selected preschools were added in the second paragraph of the Methods’ section.
There is only one response variable defined by incidence density rate. This description was added in the before the last paragraph of the Methods’ section. The description of the statistical procedures was separated in two paragraphs in order to attend reviewer’s comment. The review suggests that the study is not completely blinded because two dental assistants were employed and each one of them seemed to have their own group (one for the test, one for the control group). For this reason, the sentence was rewritten in the Methods.

Results:
- It seems remarkable that out of the participants, 68 have two follow-ups, and 86 have three follow-ups. Usually, more subjects would have two follow-ups than three follow-ups as the drop out rate increases by time.

It is important to keep in mind the attributes of a dynamic cohort design and the eligibility criterion to be enrolled in the study. The loss rate and participants’ input and output were controlled in each follow-up. More subjects had three follow-ups than two follow-ups because the eligibility criterion. According to Hujoel et al. (1994), “For cohort studies on disease incidence, only those participants of a population who are at risk for developing the disease of interest are eligible”.

Reviewer: Dr. Roswitha Heinrich-Weltzien

Major Compulsory Revisions
To Methods
• The chapter “Method” should be divided into subsections. The following subsections are recommended:
  a. General background
  b. Sampling and study design (including the flowchart of the study population):
     The authors should describe in more detail how the children in the control group (n=130) and test group (n=154) were recruited from the total population. Furthermore, the connection with the examinations 2 to 4 and the follow-ups is not explained. In place of the term “semester” the authors should use the term “month” to describe the follow-up time. To improve understanding of the study design the author should include the drop-out rate of the participants in each follow-up. In the present manuscript the following statements in the chapter “Results” are not understandable: -“The loss of eligible participants was noted in the first and the third follow-ups. The rates were 3.3% and 2.7% respectively.” –“Out of the participants, 130 children had one follow-up, 68 had two and 86 had three follow-ups comprising 524 measurements.”

Firstly I would like to thank the reviewer for the comments about the work. Methods were divided into following subsections: study population, interventions, oral examinations, ethical approval and parental consent and data analysis. The selection of the preschools was justified. More details were added to reinforce that the preschools belong to the same region. Six preschools were randomly assigned to the test and control groups. All five-year-old schoolchildren presenting at least one permanent molar with one or more emerged and sound surfaces were
considered eligible. At the baseline ninety schoolchildren (37 in the control units and 53 in the test units) were eligible. The connections were explained in the Results. The Figure 1 and the term ‘semester’ were also changed. The participants’ input and output were controlled in each follow-up.

c. In light of the results and conclusions of this study it is further important to know if all children of the control or test group participated in each supervised tooth-brushing or professional cross-brushing procedure.

The criterion to consider that the schoolchildren in the selected units were undergone to the interventions was added in the Methods. More details were included in the second paragraph of the Results.

d. Oral examination: (Did the children brush their teeth under supervision of the dental assistants prior to the clinical examinations?)

The following clarifications were included in the Methods. The children did not brush their teeth under supervision of the dental assistants prior to the examinations that were carried out at different period from that employed for the interventions rendered by dental assistants.

e. Ethical approval and parental consent
A specific subsection was created.

f. Statistical methods
A specific subsection was created.

To “Results”
• In Table 1 the authors presented, among other things, data on skin colour (mixed and other), but they did not explain the importance of this variable anywhere in the manuscript. Since the professional cross-brushing technique for caries prevention on the first molars was significantly more effective in boys than in girls, it is recommended to also present gender-related baseline data of age, caries prevalence and caries experience (dmft values).
• Drop-out data should be understandable from the study flowchart.
• Are there differences in the participation rate of boys and girls with respect to the professional cross-brushing technique of the first molars?

The importance of skin color variable was cleared in the Methods. Differences in the participation of boys and girls in control and test groups were not observed. Gender-related baseline dmft have already been included in the Results. Information about age mean was added. Drop-out data were included in the study flowchart.

To “Discussion”
The author should discuss the problem of children availability during the different supervised tooth-brushing procedures supervised by the dental assistants.

Children availability during the supervised toothbrushing procedures does not constitute a problem in all schools. Generally the program works well in schools.
that share a positive learning and living environment and explicitly support students’ physical, emotional and social wellbeing in addition to their academic achievement.

Reviewer: Satu Lahti

The paper aims to assess if the bucco-lingual technique can increase the effectiveness of a school-based supervised tooth-brushing program on preventing caries. This is an interesting question but the paper lacks the public health perspective which is a key element of such a study. Even more so as the author refers to cost-effectiveness and prevention strategies is a low risk population. In that context more recent work of Hausen et al. would have reserved more attention.

Firstly I would like to thank the reviewer for the comments about the work. The manuscript presents clearly the public health perspective. That is can be confirmed in the first four paragraphs of the Introduction. An oral health matter has been epidemiologically described in the first paragraph. Knowledge’s gaps have been presented in the second and third paragraphs. Limitations of the strategies for addressing the concern have been described and the relevance of the research question has been presented. I agree with the review that the study context refers to prevention strategies for low risk population. However an aspect of the same importance is the research question directed to population-based strategy programs. As the mentioned reference by the reviewer is focused on strategies related to individualized needs I could not include it in the paper.

The main shortcoming of this paper are the study design and sometimes poor language that remains a reader confused about what is actually meant. The title states the paper to be a randomized controlled trial but in the methods terms doubled blinded, dynamic cohort and analysis on individual level are used without clearly stating what was done. Besides examiners who else were blinded? How authors justify the analysis on an individual level and the selection of schools?

Expressions as ‘randomized controlled trial’, ‘doubled blinded’, ‘dynamic cohort’ and ‘analysis on individual level’ used in the Methods were justified in the manuscript. Although the cross-brushing technique has been tested on each participant of the experimental group the individual randomization was not employed reason why the expression ‘community intervention’ is more adequate to name this design on which preschools were randomized. The comments were very important and some sentences were added corresponding to the paragraphs 2, 6, 8, 10 and 12. The design can be called doubled blinded. The following sentences were included in the paragraph 7: “The participants were kept unaware if they belonged to control or test units. The examiner was kept masked to group assignment and the dental assistant in charge of the control units was kept blinded about differential characteristics of the interventions in test preschools”.

The analysis unit was the number of exposed surface-month according to reference 22 now numbered 23 (Hujoel et al. 1994). It is important to keep in mind that permanent first molars were erupting in 5-6 year-old schoolchildren. Concerning
to a dynamic cohort, new surfaces emerged in each follow-up what was controlled using the incidence density related to the number of surfaces presenting enamel/dentin lesions divided by the number of exposed surfaces-month. As the trial was not purely individual several points emerged to address in the Discussion. These aspects were presented in the paragraphs 2, 3 and 4 of the Discussion’s section.

One would have expected the flow of participants in the Figure 1 to give more light on this matter but the figure is very difficult to understand. Maybe a statistician or epidemiologist more familiar with these matters would but this should be clear to every reader. One would also expect more detailed information about the baseline characteristics: justification for their selection and how they were measured. How were surfaces-month actually calculated?

High risk group seems to have been selected for intervention but to ethical consideration is provided why part of the pupils were excluded from the program. Is this really an community intervention or high-risk approach?

According to the reviewer’s comments I added details related to study population, measured variables at baseline, and argument to reinforce why an individual-level analysis was adopted. I also changed the Figure 1. A model adjusted for age and caries-risk indicator was used to test for outcome difference between the modified and conventional program groups after 18-month follow-up. This point was also commented in the mentioned Discussion’s paragraphs.

Although several details have been presented the design was not clear for the reviewer. So the following sentences were included in the second paragraph of the Results: “The lateral columns describe the number of the examined participants and the central columns the eligible participants in each turn. At baseline 283 subjects in the control preschools and 344 in the test units were examined. Out of 37 and 53 eligible participants, 36 and 51 were reexamined after six months as showed in the central columns. Out of 73 and 84 eligible participants in the second examination all were reexamined after six months and so on”.

The number of exposed surfaces and the exposure time (in months) since the last exam were calculated in each follow-up as described in the Methods. The product of these two measurements is the surfaces-month value. The incidence density corresponds to the number of surfaces presenting enamel/dentin lesions divided by the number of exposed surfaces-month. Incidence density rate and 95% confidence intervals were obtained.

The characteristics of the study population were described in the second paragraph of Method’s section. The trial was carried out in six preschools located in a low-income fluoridated area within the city of Sao Vicente, Brazil. More details were added to reinforce that the preschools belong to the same region. Therefore the high-risk approach as defined by Geoffrey Rose (1985) was not applied. The preschools were randomly assigned to the test and control groups and five-year-old children presenting at least one permanent molar with one or more emerged and sound surfaces were considered eligible as described in the paragraph four of the Method’s section.

As the design is not clear it is very difficult to assess the results as well as discussion and conclusions based on that. Currently the results include also some parts that should be given in methods section. Numbers provided in the table are unnecessarily repeated.
in the results. Gender-specific results are also presented but no justification and reference is given to that approach in introduction or methods.

The numbers provided in the tables must be explained and I try to do this. If there are numbers unnecessarily repeated in the results they need to be pointed in order to rewrite the paragraph. A statement was included to justify the gender-specific results in the last paragraph of the Methods’ section.

In the conclusion author states that the results can be used in a broader population. Without assessing the cost-effectiveness and application in the entire community no such conclusion can be drawn.

The conclusion in the abstract was formulated in the following terms “Modified program was effective among the boys. It is licit to project a relevant effect in a larger period suggesting in a broader population substantial reduction of dental care needs”.

It is derived from the Conclusion’s section of the manuscript. The sentence is: “Useful information for evaluating and reorienting school-based supervised toothbrushing programs was produced suggesting a dental caries significant decline in a broader population which can represent substantial reduction of dental care needs through training auxiliary personnel operating in dental public services”.

All these excerpts lead to understandings that seem to be somewhat different in relation to the reviewer's comments.

The reviewer’s comment about the paper’s conclusion states that “the results can be used in a broader population. Without assessing the cost-effectiveness and application in the entire community no such conclusion can be drawn”.

I agree that economic evaluation is important and an article is being written about this issue however the purpose of the study is to assess if the bucco-lingual technique provided by a trained dental assistant can increase the effectiveness of a school-based supervised toothbrushing program on preventing caries. It is important to keep in mind that the paper assumes (see third paragraph of the Introduction and second paragraph of the Methods) that these programs are already in operation based on caries increment reduction provided by fluoride dentifrice. In this way the observed results suggest that the adoption of this practice can increase the effectiveness of such programs in those more vulnerable individuals. This point was highlighted in the conclusion.