Author's response to reviews

Title: Signs and symptoms associated with primary tooth eruption. A clinical study of nonpharmacological remedies

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Author's response to reviews: see over
Replies to the reviewers’ comments

Reviewer's report

Title: Signs and symptoms associated with primary tooth eruption. A clinical study of nonpharmacological remedies

Version: 1
Date: 23 February 2015
Reviewer: Elizabeth Oziegbe

Reviewer's report:
Thank you for asking me to review the article. My comments and suggestions are below.

1. Is the question posed by the authors well defined?
The research question is original, easily identifiable and well understood.

2. Are the methods appropriate and well described?
There some incomplete sentences in the first paragraph of the methods
Paragraph 1 line 2 – Dentistry ……..
Paragraph 1 line 4 – the name of the city was not included.
Answer: In the blinded version of the manuscript the name of the school of dentistry and city were omitted. This information has now been added.

The authors did not explain if the dentist who examined the children was standardized on the examination of newly erupted and measuring of tympanic temperature.
Answer: Yes. The dentist was given instructions by a senior author. (Lines 111-114).

Did the authors rely on oral information given by the mothers or there was a written birth document/record presented to the authors by the mothers with respect to the birth weight of the children?
Answer: Yes. For all neonates a health status evaluation form is issued at birth. This form must be completed by the doctor or midwife attending the delivery, and parents are instructed to keep the form. Therefore access to the data was possible. The parents brought these forms with them when they came to the public health clinics to receive health care, and the data was recorded in the child’s medical record.
What information were the authors interested in under the dental history?
Answer: Oral or dental anomalies or disabilities, type of erupted tooth.

What is the basis for making use of 27 items on local and systemic teething disturbances attributable to eruption?
Answer: Systemic and local signs and symptoms ascribed to primary tooth eruption. The 27 questions were designed on the basis of a comprehensive literature review [9-11,22].

The pilot test of the questionnaire on the mothers should be moved to the section under data recording.
Answer: Moved as requested.

The authors should explain how they ensured that good level of internal consistency was obtained during the pilot test of the questionnaire on the mothers.
Answer: We pretested the questionnaire in a group of 25 mothers to ensure the items were clear for participants. We have deleted the mention of internal consistency. The pretest is now reported in the revised manuscript (lines 114-115).

The authors did not state when the mothers commenced the nonpharmacological therapy.
Answer: Added as requested (lines 133-136). The mothers were asked to come to the health clinic as soon as they observed the initial signs of tooth eruption. Then they were interviewed to record the occurrence of symptoms during the previous 24 hours and the daily data record sheet was completed, including nonpharmacological treatments used as teething remedies.

Oral examination
Paragraph 1 line 4 – what is this initial sign of tooth eruption?
Answer: There are several signs as mentioned in the Introduction. The mothers were informed about the teething signs and symptoms at the beginning of the study (before tooth eruption). They were asked them to come to the health clinic as soon as they observed the first signs of teething.
Did the mothers bring the children to the clinic for consecutive 8 days?

Answer: Yes.

Paragraph 1 lines 5-6 – this is not clear. What about the signs and symptoms that could have occurred on the first two days of the 8 days. How did you obtain this information?

Answer: The mothers were asked to come to the health clinic as soon as they observed the initial signs of tooth eruption. The mothers were interviewed to record the occurrence of signs and symptoms during the previous 24 hours (the first day of tooth eruption), and the daily data record sheet was completed. However, a potential limitation of our study is that some mothers may have reported signs and symptoms inaccurately. Their reporting may be influenced by their beliefs regarding popular knowledge about teething, as exemplified by their reports of fever when their child's temperature was only very slightly increased. This limitation of the study is now mentioned in the Discussion (lines 314-316).

Paragraph 1 line 7 – What did the dentistry try to palpate on the alveolar ridge with the index finger.

Answer: Added as requested. The dentist tried to palpate the incisal edge or tip of the tooth cusp (lines 138-139).

Paragraph 1 line 10 – I suggest that the sentence “Body temperature was ………..at every appointment” be moved to the section under Teething signs and symptoms.

Answer: We described the data recorded at each appointment in the subsection headed “Oral examination”, and therefore prefer to note that we recorded body temperature in this subsection.

Experimental groups

Paragraph 1 line 1 – “……..54 children were initially enrolled each group”. Was there another grouping after this?

Answer: No. However, during follow-up, 16 children were excluded from the study.
Food for chewing – Here the authors explained that children in this group were those who had started eating solid food. I quite agree with this but comparing this group with those who have not started taking solid food may not be appropriate.

Answer: In the present study we compared different methods used as teething remedies. Chewing food is one of the methods has been mentioned in the literature and can be used in children who have started to eat solid food. The other methods may be not suitable in these children. We only considered the effectiveness of each remedy before and after use, and for anterior teeth and molars.

Paragraph 7 line 1 – “The next appointment was scheduled for each child”. What was this appointment for?
Answer: Added as requested. The next appointment was scheduled for each child after initial signs of tooth eruption were observed by the mothers and the dentist. Appointments were scheduled between 9:00 and 12:00.

Result:
Paragraph 2 line 2 – the authors should state the most frequent disturbances observed.
Answer: Added as requested (lines 205-206).

Paragraph 5 lines 1 – 7 – “We defined …………………..analysis of recovery” should be moved to the methods section this is not result
Answer: Moved as recommended (lines 167-173).

9. Abstract:
Methods –
Line 1 – “270” should be written in words.
Answer: Corrected as requested.

Lines 3 -5 – “The five methods ------- food for chewing”. This sentence is not clear.
Answer: This sentence has been checked.
Results
Line 1 – I suggest this should be written as “two hundred and fifty four children with mean age 16 + 7.2 months completed the study”.
Answer: Revised as recommended.

Line 5-6 – I suggest that this should be changed to “There was a significant difference in body temperature the day before and after eruption (p<0.001)
Answer: Body temperature on the day of eruption differed significantly from body temperature on the days before and after eruption.

10. Is the writing acceptable?
The article should be reviewed by a native English speaker.
Answer: The manuscript was edited by a native English speaker with many years of professional experience in health care research writing, editing and publishing.

A major revision of the article should be done

Reviewer's report
Title: Signs and symptoms associated with primary tooth eruption. A clinical study of nonpharmacological remedies
Version: 1 Date: 30 January 2015
Reviewer: Nicola Innes

Reviewer's report:
Thank you for the invitation to review this interesting observational study. Generally, the methodology seems appropriate although it seems unclear why the authors have not reported this as a randomised control trial. Some additional detail in some areas would help clarification (I have detailed these below). I believe that this study will be of wide interest to paediatric dentists, general dentists and possibly medical practitioners, not to mention parents!
Answer: It was not possible to randomly allocate cases into the five groups. 1) Mothers who knew each other could share their recommended methods and thus compromise the allocation. 2) Only children who had already started chewing solid food could be allocated to the fifth group
(food for chewing). Therefore, this study was a nonrandomized trial. This is now stated in the Abstract and the Methods section (line 30, lines 92-95).

Major Compulsory Revisions:

• The manuscript doesn’t comply with the standard of reporting and it should be re-written to comply with the CONSORT guidelines. These can be found at: http://www.equator-network.org/

  Answer: Corrected as requested.

• There needs to be a table with baseline characteristics to show the groupings of participants following randomisation.

  Answer: Table 1 added as request. The mothers’ level of education was classified in three categories, and p values were calculated according to the new classification in Table 1.

• Line 130 – 139 Please explain exactly the sequence of events including what the initial signs of tooth eruption were. There should be clear information on how parents were able to collect data 4 days before tooth eruption – I can’t figure out how they would know that the tooth was going to erupt in 4 days time?

  Answer: The mothers described the signs of the tooth eruption with the help of a questionnaire at the beginning of the study. The dentist explained the teething signs and symptoms and asked mothers to come to the clinic when they observed the first signs of teething. At the first appointment the child’s mother was asked about new erupting teeth if signs of tooth eruption had appeared. All the children had at least one erupted primary tooth, so the mothers were familiar with teething symptoms. Because teething signs and symptoms varied among the children, we could not identify or record only one particular sign in each participant. During the 8 days of tooth eruption the mothers were interviewed to record the occurrence of symptoms during the previous 24 hours, and the daily data record sheet was completed. However, body temperature was measured by the researcher with a tympanic thermometer at every appointment.

Other areas for clarification and additional recommendations/ comments:

• Change the title to fit in with Consort guidelines
Answer: Corrected as requested.

• Primary and secondary outcomes should be clearly stated.
Answer: Added as requested (lines 179-181). As mentioned in the revised manuscript, we report the primary outcomes in Tables 2-4. The mothers’ satisfaction was considered as a secondary outcome, and is now reported in Table 5.

• A power calculation needs to be discussed and how the number of children entered were chosen.
Answer: Although we did not calculate sample size before starting the study, post-power analysis was conducted on the results for recovery rates between the groups. Post-power analysis with NCSS-PASS 2004 showed that the power of the chi-square test for between-group comparison was at least 86%, which indicated that the sample sizes in the groups were sufficient. However, this analysis was not done for cases with signs that were not clinically significant, such as gum irritation, finger sucking and crying. Earlier studies cited in our paper used similar sample sizes [4, 28].

• Line 158 - what was the order of selection and randomisation regarding the children who had started to eat solid foods? Did having to place children with this characteristic (and possibly with an age bias) affect randomisation?
Answer: The children included in this trial were between 8 and 36 months of age. All had at least one erupted primary tooth, and the parents were familiar with teething symptoms. The children also had at least one primary tooth in the process of eruption. It was not possible to randomly allocate cases into the five groups. 1) Mothers who knew each other could share their recommended methods and thus compromise the allocation. 2) Only children who had already started chewing solid food could be allocated to the fifth group (food for chewing). Therefore, this study was a nonrandomized trial. This is now stated in the Abstract and the Methods section. In addition in the present study we compared different methods as teething remedies. Chewing food is one of the methods has been mentioned in the literature, and can be use in children who have started to eat solid foods. The other methods may be not suitable in these children. We
considered the effectiveness of the remedies before and after use, and for anterior teeth and molars.

• Separate out how the children were selected and the randomisation process
Answer: The children were between 8 and 36 months of age. All had at least one erupted primary tooth (no natal or neonatal teeth), and the parents were familiar with teething symptoms. The children also had at least one primary tooth in the process of eruption [22]. The inclusion criteria are now specified in lines 96-99. For group 5; food for chewing: The children in this group were selected among those who had started to eat solid foods.

• Line 93 – why is there no name of city?
Answer: In the blinded version the name of the city was omitted. Shiraz (name of the city) has been added as requested.

• Line 91 – the Ethics approval isn’t clear – why is it blank?
Answer: This is now stated in the first paragraph of the Methods section. It had been omitted from the blinded version of the manuscript to avoid revealing the name (and hence location) of the institution.

• A CONSORT flow chart will help clarify process and order of events
Answer: Added as requested.

• Line 184 and 189 – what was the range of ages?
Answer: 8.4 to 32.2 months

• Line 193 – “Most” – how many?
Answer: Added as requested.

• Tables 1, 3 and 4. I suggest separate columns for the % values to make the table easier to read – the % sign can then go in the heading.
Answer: Corrected as requested.
• Figure 1 would benefit from more information. How about the max and min values and s.d. Can these be added to the graph? Or something to show the variance?

Answer: Because the SD values were very similar in the three steps (all SD=0.4), we preferred to not report SD in the graph.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

'I declare that I have no competing interests'