



Impact of Health Centre Nurses on the Reduction of Early Childhood Caries in Lima, Peru

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Authors' contributions

This work was carried out in collaboration between all authors. Collaborating in the designing and writing the protocol of the study. All authors read and approved the final manuscript.

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Study Protocols

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ABSTRACT

Background: The prevalence of early childhood caries (ECC) among 36-47 months-old children in Lima, Peru, is 65.5%. Dentists have no easy access to see infants but nurses do. If nurses will be trained on oral health behaviours and early recognition of signs of ECC in infants, they could assist parents in keeping infant teeth healthy, during their regular well-child visits, using an oral health advisory and control cards and by referring infants to the health centre dentist earlier.

Aims: The primary aim of the study is to reduce the prevalence of ECC. Nurses will be trained in educating mothers on oral health behaviour and in detecting signs of ECC in infants. They will assist parents in keeping infant teeth healthy with assistance of an oral health advisory card during regular well-child controls and referring infants with ECC risk to the health centre dentist.

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Study Design: The study is a three-arm randomized clinical trial. (A) Active intervention group: nurses will receive training in oral health education and in detecting carious lesions, supported by validated oral health advisory and control cards. (B) Passive intervention group: nurses will receive the oral health advisory and control cards together with written instructions, while nurses in the (C) control group will be lectured once on good oral health behaviours. In the three groups, knowledge of nurses will be evaluated, using a validated questionnaire, pre- and post-training. The pattern of referrals and treatments will be obtained from records available in the office of the health centre dentist. The ECC status among three year olds will be assessed at baseline and after three years, as will the quality of life of the infants.

Place and Duration of the Study: The study will be carried out in three districts in Lima, Peru between September 2014 and September 2017.

Keywords: Early childhood caries; nurses; health promotion; primary prevention.

1. INTRODUCTION

Early childhood caries (ECC) is the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth in a child 71 months (5 years) of age or younger [1]. It is considered the most chronic disease in infancy. Untreated, ECC can lead to serious adverse conditions in the child's psychological [2], social [3] and physical development [4]. The Global Burden of Disease 2010 study ranked untreated caries lesions in primary teeth 10th on the list of 291 diseases and injuries [5].

Although ECC is preventable, its progressive nature can quickly change the general health and quality of life of the child [3]. If treatment for ECC is delayed, the condition worsens and the disease becomes more difficult to treat [6]. Occasionally children require hospitalization and treatment under general anaesthesia, which significantly increases treatment costs and chance for mortality [7]. The number of professionals trained to manage the infant behaviourally and to perform the more complicated procedures is usually few per country.

In Peru, preventive health care for infants is embedded in the national healthcare system. The prevalence of ECC among 0-11- and 36-47-months-old children from deprived areas of Lima (capital of Peru) was 10.5% and 65.5%, respectively [8]. It appears that this high ECC prevalence cannot be managed by the dental profession alone and, therefore, needs a multi-disciplinary approach. Collaboration with primary health care providers (PHCPs), such as nurses, is considered the way forward. Nurses see mothers during pregnancy and after birth when their infants require immunization and well-child

visits. Adding oral health related educational and behavioural activities to the duties of nurses offers huge potential in maintaining healthy dentition of infants. If nurses are also trained in detecting signs of carious lesions in enamel and dentine early, and refer the infant to the health centre dentist for verification and professional care, they will then perform an important function as the first gatekeeper in controlling ECC. This approach might reduce the current burden of ECC in infants of Peru.

2. METHODOLOGY

2.1 Aim of the Study

The primary objective of the present study is to reduce the prevalence of ECC in 3-year-old children. Secondary study and operational objectives are: to investigate the ECC prevalence and quality of life of 3-year-olds that have attended mother-and-child clinics at baseline; to investigate potential barriers amongst nurses against participation in this oral health program; to develop and validate oral health advisory and control cards; to establish a training program for nurses in the use of those cards, inspection of the mouths and detection of signs of carious lesions, and in providing oral health advises; to assess the oral health knowledge of nurses, and their recognition and detection of carious lesions pre- and post-training; to determine the number of referrals of infants by nurses to the health centre dentists; to train the health centre dentists in using appropriate preventive measures and care procedures for treating infants, such as the Atraumatic Restorative Treatment (ART) approach and; to compare the prevalence of dental caries and the quality of life among the different study groups after 3 years of implementation [9].

2.2 Study Design

The design of the study is a randomized controlled trial (RCT) with three arms: (A) an active intervention group (training of nurses + their usage of the oral health advisory and control cards); (B) a passive intervention group (nurses receive only printed materials on oral health and the oral health cards) and; (C) a control group (nurses receive a lecture on oral health education) (See Fig. 1).

2.3 Randomization

The study will be carried out in 3 districts of the city of Lima-Peru, which are considered to belong to the category "low socio-economic status" [10]. Extensive geographic distance was considered an adequate stratification factor for avoiding group contamination. Staff members, workloads, infrastructure of health centres and cultural distribution of the population in the districts will have comparable characteristics. The districts that met these characteristics were: San Juan de Lurigancho (SJL), Chorrillos (CHO) and Puente Piedra (PPI). They were randomly assigned to one of the study arms, using a randomization software programme (EASYRA1 Easy Randomizer® Version 4.1, State University of Michigan), resulting in PPI being the active intervention group, CHO the passive intervention and SJL the control group. Each of the three districts has a main health centre, which will serve as the place of study implementation.

Mothers with infants attending mother-and-child clinics in the three districts between September and October 2014 will be invited to participate in the study. They will be requested to sign a consent form after having been informed about the content of the investigation.

2.4 Masking

Using this study design, mothers will be masked as they will be unaware about the three different study arms. Investigators cannot be masked. Examiners performing the epidemiological studies will be independent, as will the statistician, by concealing the different arms until the first report has been published using the one year data.

2.5 Sample Size Calculation

The null-hypothesis tested is that there will be no difference in the prevalence of ECC between the

three groups after three years. A reduction of at least 26% in the prevalence of ECC (from 66% at 3 years [8] to 40%) in the active intervention group after three years is expected. Using an alpha of 5% and a power of 0.8, the sample size is 54 infants per group. Counting for a dropout of 10% per year, the final sample size per study group is 70 infants at baseline.

2.6 Barriers to the Implementation

The main objective of the present study demands nurses to perform oral health activities and mouth inspections. For such duties to become effective, possible barriers against adopting and implementing these oral healthcare activities need to be addressed first.

A validated questionnaire for assessing barriers against performing oral health tasks amongst nurses in primary healthcare settings does not exist. Therefore, such a questionnaire must be developed and validated. Its design and validation will start with interviewing nurses about factors that might hinder these activities during performance of their normal duties. The responses will be used for construction of an open-ended questionnaire that will be discussed with nurses in a focus group. The outcomes will determine the close-ended questionnaire to be presented to a group of nurses for pilot testing. The final questionnaire will be presented to a representative sample of nurses within the city of Lima.

2.7 Development of Oral Health Advisory Card

In 2010 the Ministry of Health (MINSA) of Peru launched a health card known as the *Integral Attention Card for Children* (IACC). To act as a checklist for delivery of oral health advice and activities by nurses, a separate oral health card and related illustrations needs to be designed and validated. The design will follow the Peruvian Association of Dentistry for Infants (ASPOB) guidelines to prevent and managing children with ECC [11]. The RAND modified e-Delphi method will be used to validate the card [12]. Panel members will be drawn among specialists in child and infant dentistry, and healthcare from Spanish-speaking Latin-American countries, using a website resource. After validation by the experts, the card and related illustrations will be pilot tested among 30 mothers from a district outside the study area, which is similar in characteristics to the study area. The pilot study

will be done, using validated indexes, and the illustrations, after which it will be printed and outcomes will be used to alter the card and copied for use in the study.

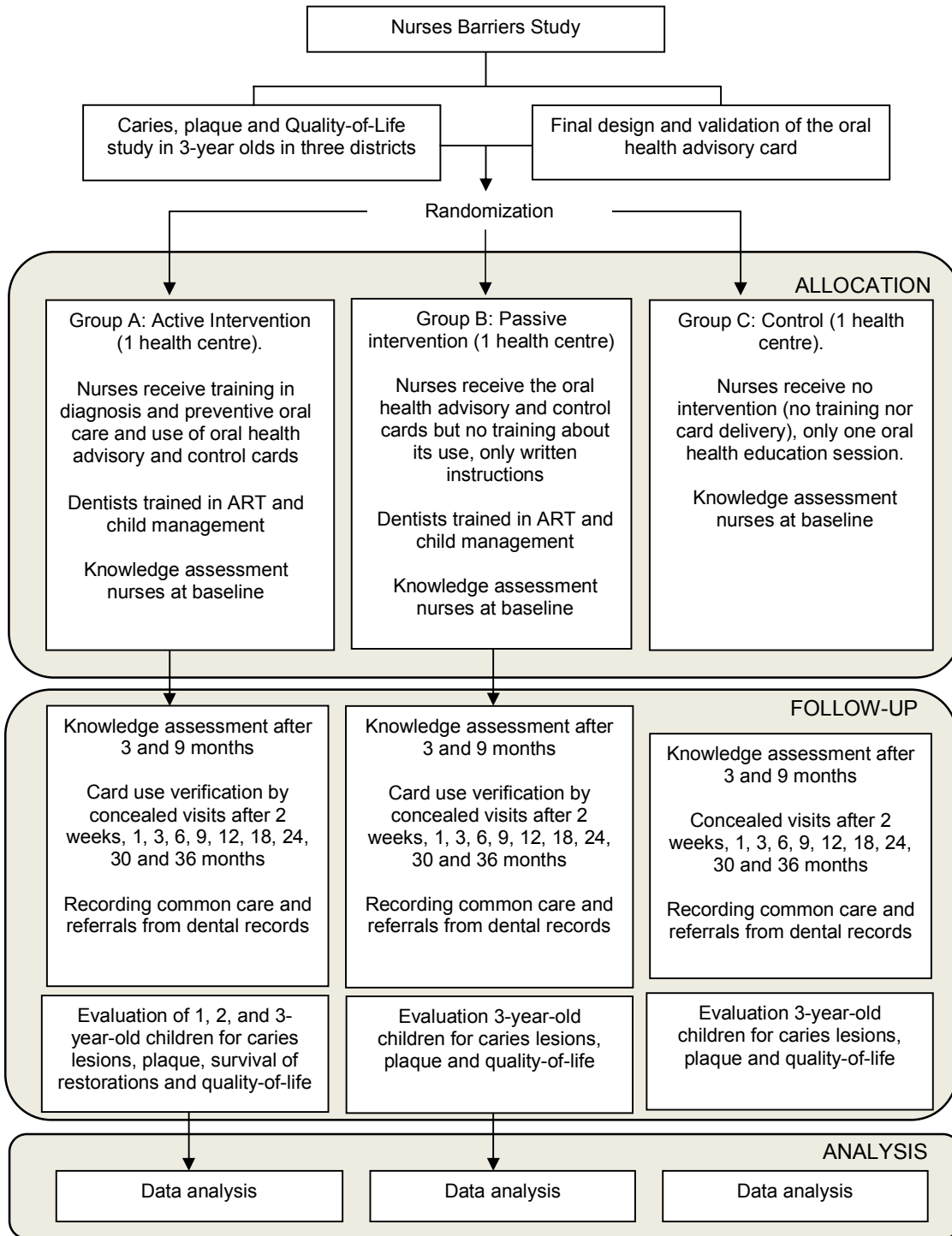


Fig. 1. Design, timeframe and flow of the participants through all stages of the study, according to CONSORT 2010 Flow Diagram [13]

2.8 Protocol Implementation

2.8.1 Active intervention group (A)

Nurses from the main health centre in the area will be enrolled in a training program of "Diagnosis and management of ECC". Its content will be based on the 'Document of International Agreements' of the ASPOB meeting of 2010. Nurses will be educated and instructed on how to handle the oral health advisory and control cards and how to make referrals to the dentist. The training will comprise lectures, communication and physical skills development, discussions and explanation of printed and visual materials and the use of a website resource to support the theoretical training. Skills for performing a simple oral examination (OE) will be demonstrated and practiced. Each participant will receive a folder with printed information regarding the content of each teaching module and regarding that of the oral health advice cards. Each module will be presented using a power point presentation. The topics of the four modules include: 1) Determinants of health and oral anatomy, 2) Dental caries diagnosis, 3) Prevention of dental caries and periodontal disease, and 4) Implementation of the preventive strategy.

Following the domains presented in the modules, a pre-test questionnaire will be designed and validated for face and content, using focus group discussions and feedback meetings with experts. The questionnaire will be tested in a pilot study among nurses not included in the study. Previously, immediately after the training and during the follow-up visits at 3 and 9 months, post-test questionnaires will be used to assess the effectiveness of the training course. Supportive supervision visits will be held 2 weeks and 1 month post-training. In addition, feedback will be gathered through use of the cards from nurses and mothers. Furthermore, mothers who have attended the mother-and-child clinic will be interviewed in a concealed manner at the health centre after 2 weeks and 1, 3, 6, 12, 18, 24, 30 and 36 months by an independent person, not connected to the research team, to verify the use of the card by nurses.

Dentists in the health centre will be trained in child management, fluoride varnish application and in the ART approach in infants. The treatment logbook will be checked semi-annually.

A pilot investigation will be held, one month before the start of the training program for nurses, in a health centre situated in a district not

involved in the present study. The research tools, registration strategies and flow of research activities will be tested and modified if necessary.

2.8.2 Passive intervention group (B)

In the second study arm, nurses will receive printed information on oral health advice regarding infants, as well as the oral health card plus written instructions on how to use it, without any further explanation or training.

Nurses will be interviewed regarding their oral health knowledge at baseline and after 3 and 9 months, using the same pre-test and post-test questionnaire used in the active intervention group. They will receive no reminder visits. Mothers will also be interviewed by the same independent person, employed in the active intervention group after 2 weeks and 1, 3, 6, 12, 18, 24, 30 and 36 months in a concealed way, to verify the use of the card by the nurses. The dentists will be trained in child management, fluoride varnish application and in the ART approach in infants. The treatment logbook will be checked semi-annually.

2.8.3 Control group (C)

Nurses in the third arm will be educated on oral health using a PowerPoint presentation. No printed material will be distributed. The independent person employed in the two other arms will deliver the same interview to the mothers, to assess whether nurses have given advice, have inspected the mouth of the infants and have referred infants with carious lesions to the health centre dentist. These assessments will be held 2 weeks and 1, 3, 6, 12, 18, 24, 30 and 36 months after the start of the study and will be performed in a concealed way.

Nurses will be interviewed regarding their oral health knowledge at baseline and after 3 and 9 months, using the same pre-test and post-test questionnaire as used in the active intervention group. The dentists will receive semi-annual visits for checking the logbook on treatments provided.

3. MATERIALS

At baseline, the presence of caries lesions will be assessed using the Caries Assessment Spectrum and Treatment (CAST) instrument [14] and the Visible Plaque Index [15] will be used in assessing the presence of dental plaque among

3-year-olds who had attended the mother-and-child clinics since birth. Their mothers will be asked to respond to the S-ECOHIS questionnaire that assesses the quality-of-life of young children [16].

Examiners will be trained and calibrated in the use of CAST criteria. Intra- and inter-examiner consistency tests will be performed.

3.1 Data Collection

Data collection related to the three study arms comprises: identifying barriers perceived by nurses to participate in the oral health program; an epidemiological oral health survey and assessment of the quality-of-life among 3-year-old children at baseline and after 3 years; determining pre- and post-training knowledge of nurses on oral health matters and the dental caries process, and their ability to detect signs of carious lesions; usage of card by nurses in the first and second study arm; actual treatment data (e.g. frequency and types of treatment provided by the dentists in the three health centres).

Data collected in the active intervention group further comprise: referral of cases by nurses to the health centre dentist using a record sheet; a follow-up record sheet of referrals and one for mothers (and other family members) seeking care as part of the oral health program in the dental clinic; number and type of ART restorations and an epidemiological survey after 1 and 2 years in infants.

3.2 Statistical Analysis

The primary outcome measures the effect of the training program plus the usage of the validated oral health advisory and control cards on the level of ECC prevalence reduction in 3-year olds over a period of 3 years. To determine its effect, clinical records of the post-intervention register will be assessed. The baseline caries and plaque data of 3-year olds in the active intervention group will be compared with data on these conditions after the implementation, and with records of these conditions in 3-year olds in the passive intervention and negative control groups. The secondary outcomes concern barriers of nurses to participation in the training program, referrals by nurses to the dental office, knowledge acquired by nurses about oral health diagnostic and preventive measures, and the quality of life of 3-year olds at baseline and at the end of the study. Survival of ART restorations will be part of the data analysis.

The SAS Version 9.2 statistical program (SAS Institute, Cary, NC, USA) and the Statistical Package for Social Sciences - SPSS™ Version 21 will be used for the data analyses.

3.3 Main Outcome Benefits

The intervention approach is intended to increase the knowledge of nurses about oral health and preventive measures and to increase the awareness about the importance of oral health in mothers who use the vaccination and well-child visits. It will encourage nurses to look inside the mouths of babies and infants and, when necessary, refer them to the dentist and consider this normal practice within well-child programmes at health centres. As a result, the number of referrals to the dentist might increase and the dental care knowledge of nurses might increase. Moreover, ECC prevalence levels might drop as a consequence of two factors: the oral health preventive advice, check-ups and referrals by nurses; early visits to the dentist, for managing the risk factors in infants, and perhaps mothers / carers, and providing preventive treatments. Finally, the expected results would improve the quality-of-life of young children and their mothers and might reduce the expenditure earmarked for treating oral health problems in infants.

3.4 Patient Safety

Patient confidentiality will be respected throughout the study. Information collected will be for research purposes only.

3.5 Voluntariness

The nurses will receive an informative visit including a clear written and verbal introduction of the purpose and content of the study in plain Spanish. Informed consent will be obtained from all participating staff members who will be registered in electronic databases with their basic information and will receive a card with the contact details of the main researcher.

4. DISCUSSION

Dental caries in young children is a public health issue worldwide, especially among disadvantaged communities. A multi-disciplinary approach might be an opportunity to reach these populations at early ages. Some long-term studies, promoting education and preventive care

during the first years of life, have shown to be effective in reducing the prevalence of ECC [17-19].

The proposed training program and development of an educative tool (oral health advisory and control cards) might alert policymakers to consider integrating oral health care promotion into PHCPs settings for all patients, as suggested by the World Dental Federation [20]. After a positive effect of the implementation has been proven, the training and materials used in the present project might be integrated into the existing government health programme as an extension to the well-child visits. It may enable the provision of oral healthcare to the needy at the appropriate moment with minimal intervention. Moreover, early detection and treatment of children with initial signs of ECC might significantly reduce the total costs of restorative dental care. Preventive and early intervention strategies against ECC might reduce sleep and eating disorders, school absenteeism, and stimulate growth and development of the child that will lead to a better quality of life [2].

The continuity of the study carries some risks that include the level of drop-out rates over time. These can be controlled through collecting the cell phone numbers of the family members of the included infants for easy contact, and through increased levels of participation of nurses over time, who are currently not obliged to perform oral examinations and referrals for dentists as part of their daily duties. The research team will need to keep the nurses motivated to meet the challenge, of a reduction in the prevalence of ECC.

CONSENT

All authors declare that written informed consent will be obtained from all the nurses and mothers who will participate in the present study.

ETHICAL APPROVAL

The study was approved by the ethical committee of the San Martin de Porres University of Lima (R.D. 252-2013-D-FO-USMP) and registered at the Netherlands Trial Centre under number, NTR 4510.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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