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## RESEARCH ARTICLE

# BOCA BOCA SAUDÁVEL: PROTOCOL AND BASELINE FINDINGS OF AN ORAL HEALTH PROMOTION CLUSTER RANDOMIZED CONTROLLED TRIAL INTEGRATING PRIMARY HEALTHCARE IN BRAZIL

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### ABSTRACT

**Introduction:** Dental caries remains a significant public health problem and investment in multi-level oral health promotion intervention is essential. The effects of this type of intervention are only partially known; thus, further evidence is needed.

**Objectives:** This article describes the design, protocols, and baseline characteristics of centers and participants (caregiver/child dyads) involved in a multi-level oral health promotion cluster randomized controlled intervention integrated into Primary Healthcare Centers (PHCs) in Brazil.

**Methods:** Two PHCs, and by extension 170 caregiver/child dyads, were allocated to an intervention condition, and two PHCs and 174 caregiver/child dyads were allocated to a no treatment control condition (usual care). The intervention targets intra- and interpersonal (child, family) and organizational (PHC) level factors associated with oral health outcomes. These outcomes include caregivers' and children's oral health quality of life, children's dental caries and oral health-related behaviors. Caregivers' behaviors, psychosocial factors, oral health knowledge and PHCs' oral health promotion practices will be examined as potential mediators of intervention effects. The baseline survey and dental examinations occurred in 2015. Two post-intervention follow-ups occurred, the first at 12 months, and the second at 24 months from baseline.

**Results:** No baseline differences were observed between the conditions on socioeconomic and demographic characteristics, oral health quality of life, children's dental caries and PHCs' oral health practices. Some children's behaviors, as reported by their caregivers, differed statistically between conditions at baseline. Favoring the control condition were tooth brushing twice a day (44.5% versus 28.2%), low/moderate sugar consumption (54.6% versus 41.8%) and use of dental services (33.5% versus 21.2%).

**Conclusion:** This trial seeks to broaden understanding of how to prevent dental caries in young children among low-income families with low access and use of dental services. Identification of intervention mediators will inform future efforts in this area.

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## INTRODUCTION

In Brazil, around five million children (60%) aged five years have dental caries, and 80% of the decayed teeth remain untreated, suggesting the low access and utilization of dental services by this segment of the population (Brasil 2011). Investment in prevention is essential for promoting population oral health. Brazil has been investing in the expansion of primary healthcare through the Family Health Strategy, which

emphasizes the reorganization of primary clinics to focus on families and communities, as well as integrate health care with health promotion actions. Since the implementation of the National Oral Health Policy in 2004 (Brasil 2004), it has begun to include Oral Health Teams (OHTs) within the public healthcare system. In 2015, there were roughly 266,217 community health workers, 40,162 family healthcare teams, and 24,467 OHTs reaching 130 million (63%), 123 million (61%) and 76 million (38%) people in the country, respectively. Despite oral health promotion being a national priority in Brazil, in practice, it is operationally difficult to plan and execute it, especially for children, concurrent to the accumulated demand for dental treatment for adults. Most

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health professionals' practices are still based on a biomedical and curative model, becoming a hindrance to assuming an integrated health promotion perspective (Alves and Aerts 2011). Interventions aiming to promote oral health have been conducted, suggesting that the most unsuccessful studies did not sufficiently consider important behavioral determinants of oral health (Brown 1994; Kay and Locker 1996; Lemkuhl *et al.*, 2015; Twetman 2008). Interventions developed based on behavioral and organizational change theories, targeting multiple levels of influence on the health-disease process, and that are integrated into healthcare services with a multidisciplinary practice, have a greater potential to result in population health improvement compared with efforts that do not share these characteristics (Abou El Fadl *et al.*, 2016; Glanz and Bishop 2010; Menegaz *et al.*, 2018). In short, the effects of this type of intervention are only partially known (Vichayanrat *et al.*, 2012); thus, further evidence is needed. This intervention study entitled *Boca Boca Saudável* was developed to promote oral health among children aged zero to five years who are registered at Primary Healthcare Centers (PHCs) with the Unified Health System in Brazil. It targets factors at the intrapersonal, interpersonal (children and their families) and organizational (PHCs) levels of influence, following the principles of the socioecological model for health promotion (McLeroy *et al.*, 1988; Stokols 1996). It is expected that when intervening on contextual factors (e.g. dental care access) simultaneously with individual factors (e.g. caregivers' oral health knowledge and behavioral skills), prevention of children's dental caries will be possible. This paper describes the multi-level intervention design, its protocols, and the baseline characteristics of the study centers and caregiver/child dyads.

## METHODS

### Study design and setting

This cluster randomized controlled intervention study (Brazilian Registration for Clinical Trials protocol number RBR-74jbm) compares: 1) two PHCs and 170 caregiver-child dyads in an intervention condition, and 2) two PHCs and 174 caregiver-child dyads in a no treatment control condition (Figure 1). The Research Ethics Committee of the Pelotas Federal University School of Medicine approved the research protocol (1.206.247). Written informed consent was obtained from all adult participants. No incentives were provided to any participants. The study was implemented over a two and a half year period in the city of Pelotas, an urban area in Southern Brazil (from September 2015 to May 2018). In 2015, the city's estimated population was 329,435 inhabitants (94% living in urban areas), including 22,455 children from zero to five years old (Brasil 2010). In 2015, there were 68 physicians, 67 nurses, 67 nurse auxiliaries, 16 dentists, 16 dental auxiliaries, 1 dental hygienist and 257 community health workers (CHWs) across all 24 PHCs offering the Family Health Strategy. From those, eight PHCs with OHTs were located in an urban area. Further information on how Family Health Strategy works can be found at the following publication (Macinko and Harris 2015).

### Study population, recruitment and eligibility

Only eight PHCs located in urban areas and offering the Family Health Strategy with OHTs were eligible for this study. Four PHCs were selected based on the following shared characteristics:

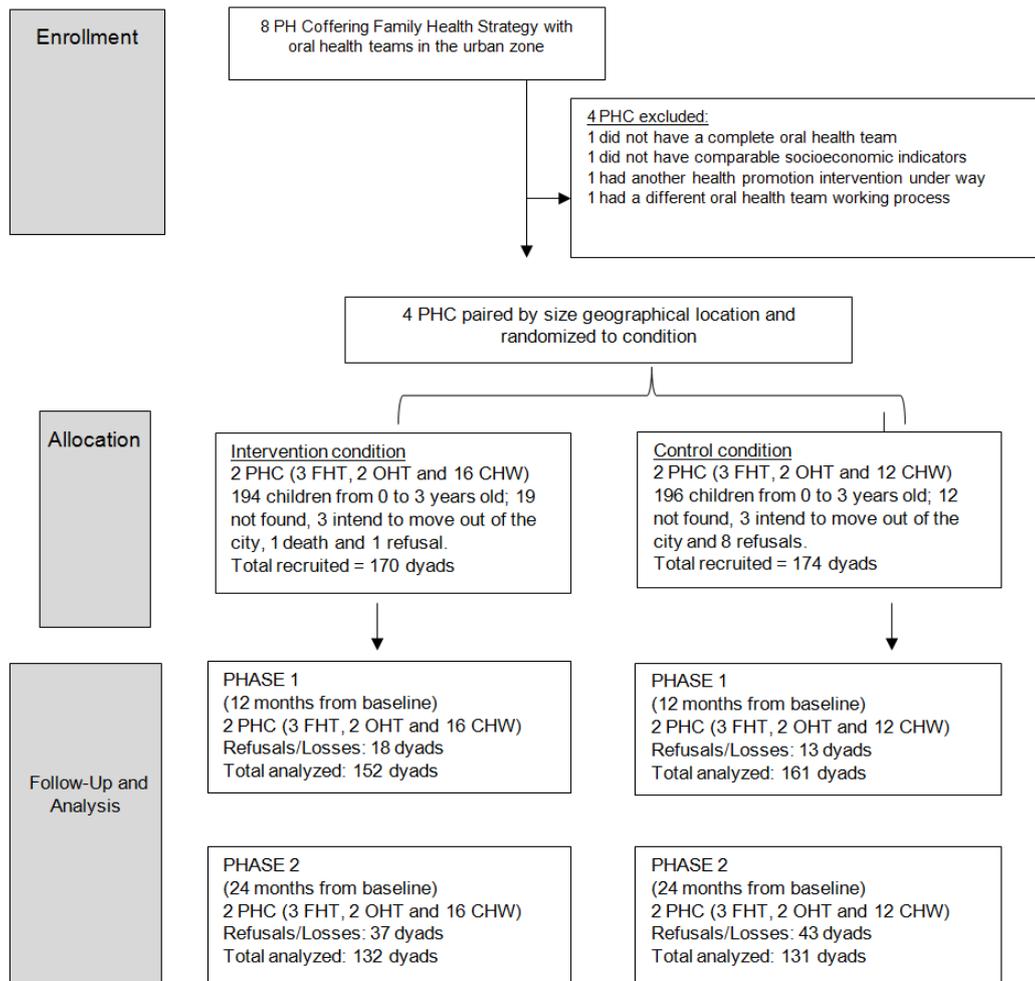
i) having a complete OHT (dentist and dental auxiliary) working together for at least one year, ii) having registered at least 200 children from zero to five years old over the past year, and iii) offering puerperal and childcare services. Four PHCs showing incomparable health or geographic indicators, having other ongoing interventions in oral health or nutrition, or presenting a different work process (e.g. OHT with dental hygienist) were excluded. The health coordinators from all four selected PHCs were invited to participate and answer a questionnaire related to FHTs' and OHTs' practices. Healthcare providers from the intervention PHCs only were invited to participate in the study. After selecting and enrolling the four PHCs, all registered children from zero to three years old were eligible for baseline recruitment. Age three was the upper age limit since the intervention was designed to occur over a two-year period, thus, covering children up to five years of age. An updated list was obtained of the registered children aged zero to three years from the last three months (301 children registered in the intervention condition and 208 in the control condition). Using these lists, a random and proportional sample according to age and number of children in every micro-area of the communities was recruited. Children with families who intended to move out of the city/neighborhood during the study follow-up period were excluded from the study. All caregivers provided written informed consent. All children identified with dental treatment needs were referred to the local PHC for care.

### Randomization and blinding

The PHCs were paired by size and geographic location and an epidemiological researcher not involved in the study, randomized them. Members of the data collection team were blinded to condition at all assessments. Blinded dental examinations were performed at baseline and final follow-up (24 months from baseline). Healthcare providers were blinded to the patients' study condition. The intervention team was not the same that conducted the evaluation.

### Intervention

The intervention protocol was implemented in the intervention PHCs only, while the control condition PHCs followed the usual care practice of Family Health Strategy. The intervention was implemented in two phases, using multiple health promotion strategies and targeting the intrapersonal, interpersonal and organizational levels of influence (McLeroy *et al.*, 1988; Stokols 1996). Both intervention phases had complementary objectives. Phase 1 prepared and engaged communities for intervention implementation. Thus, some desirable changes were expected to be observed in a short-term period. Phase 2 encompassed strategies designed to reinforce and maintain any changes achieved during Phase 1. The intervention strategies were developed based on health communication and health promotion theories (Abraham and Michie 2008; Bandura 1986; Carter and McGoldrick 2001; Kaluzny and Hernandez 1988; Michie *et al.*, 2013; Petty and Cacioppo 1986; Rosenstock 1974; Witte 1992), and resulted from two years of extensive mixed-method formative research. Quantitative (local epidemiologic survey and systematic reviews) and qualitative (in-depth interviews and focus groups) methods were used to maximize acceptability and feasibility of intervention implementation. Figure 2 describes the intervention timeline, its theoretical foundation, and the main strategies at each level of influence.



FHT = Family Health Team. OHT = Oral Health Team. CWH = Community Health Worker. Each FHT has one physician, one nurse, one auxiliary nurse. Each OHT has one dentist and one dental auxiliary.

**Figure 1 CONSORT flowchart of the Boca Boca Saudável study, Pelotas, Brazil, 2015**

Eight research assistants and one pediatric dentist comprised the intervention research team; they were responsible for delivering it. However, to maximize fit with the organization, strategies were implemented in collaboration with Family Health Teams (FHTs) members at the PHCs. For instance, during Motivational Interviewing (MI) home visits, the research assistant was accompanied by a CHW. During the first dental appointment, a pediatric dentist assisted the OHT, and discussed diagnostics, treatment needs and procedures. The research team was not part of routine counseling offered by FHT members during medical dental, nursing, and childcare appointments, and CHWs' routine home visits. Experienced professors in dental public health, pediatric dentistry, social psychology and public health nutrition were responsible for designing and implementing the trainings for healthcare providers and intervention research staff.

### Intra- and interpersonal levels

The intra- and interpersonal level interventions considered caregivers' and children's influences, delivering specific, but common strategies to them. Phase 1 began with a home visit using a 45-minute MI approach. The session was structured to develop MI behavior change strategies related to the three child target behaviors: oral hygiene, sugar consumption and dental utilization. It started with the research assistant making open-ended questions and using reflective listening to explore

caregivers' perceptions and values about their children's oral health and readiness to change. A booklet, designed for the study, was used to provide the caregivers key messages for their young children's oral health care. The information also helped the research assistant developing discrepancy between caregivers' goals or values and their children's current behavior, ultimately setting up a behavior change plan. Finally, the research assistant summarized what occurred during the counseling session, reinforcing what has been said and preparing the caregivers to move forward. At the end of the visit, the caregivers received a written booklet with the key messages for children's oral health care and were invited to attend a caregiver-child educational group session and a child dental visit at the local PHC.

The educational group session lasted 30 minutes, and was followed by a supervised child tooth brushing training. During the dental visit, children received a comprehensive dental exam and were scheduled according to treatment needs. In Phase 2, caregivers received a 45-minute MI home visit focusing on feedback and the reinforcement of behavior change plan, emphasizing a reduction in sugary food/beverage consumption. The session was structured the same as the one described above for Phase 1. During this visit, the research assistant used first follow-up data to provide feedback to caregivers on children's target behaviors (e.g. oral hygiene, sugar consumption and dental visit).

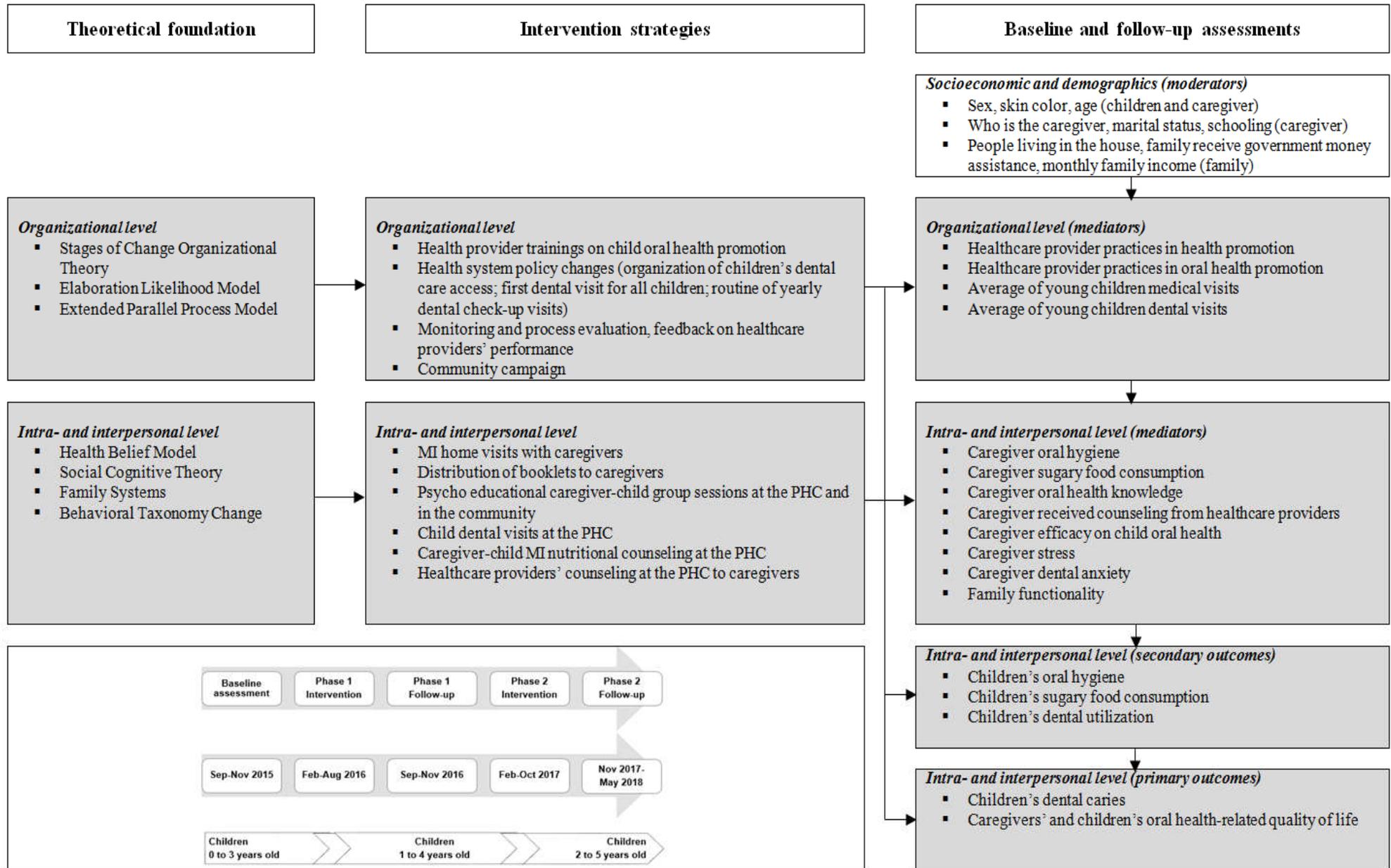


Figure 2. Timeline, theoretical foundation, intervention strategies and assessments schema in the Boca Boca Saudável study. Pelotas, Brazil, 2015

This information helped to develop discrepancy between caregivers' goals and values, and their children's current behavior, as well as setting up a behavioral change plan. At the end of the visit, all dyads were invited to participate in four weekly caregiver-child group sessions (60-minute each), that occurred at the community association hall. This strategy was delivered by the research team and it was used to support families and children with oral health behavior changes. All children were scheduled for their annual dental check-up visit at the local PHC. The children identified with a high sugary food/beverage consumption (three or more times a day) were referred to a nutritionist at the local PHC for assessment. This protocol included three visits, lasting 30 minutes each, wherein MI behavioral change strategies were used to decrease sugary food/beverage consumption.

### Organizational level

At the organizational level, a multidisciplinary 20-hour training on children's health promotion was conducted Phase 1, targeting all healthcare providers at the intervention PHCs. The trainings occurred during the regular monthly healthcare team meetings. The pedagogical approach comprised didactic lecture with PPTs on the subject matter, interspersed with case examples and discussions of situations professionals experience in daily practice. The topics included: i) introduction to the study and baseline survey results; ii) key evidence and recommendations for the promotion of healthy eating and oral health in early childhood; iii) psychosocial aspects of early childhood and the use of MI as a communication tool with caregivers; iv) organization and management of the implemented interventions; v) importance of the qualification of information records; vi) intervention monitoring and evaluation, with discussion of results, difficulties and positive aspects in professional practice. The aim of these trainings was to engage in and implement new routines, such as introduce the first dental visit for all young children and facilitate dental care access, prioritizing this age group. Also, to stimulate healthcare providers to improve oral health counseling in every contact with children and their families. Feedback on performance and management support was provided by the research team on an ongoing basis in both Phases of the study. To further change social norms and promote enactment of positive oral health behaviors, six posters with different emotional appeals and messages were displayed at intervention PHCs during the entire study period. A community campaign with educational activities for caregivers and children was implemented in Phase 1, during the poliomyelitis vaccination day at the intervention PHCs. Oral health information was provided individually to every caregiver bringing a child to be vaccinated. Demonstration on how to brush children's teeth was offered for caregivers and children, as well as games and paintings related to oral health education for children. This strategy was delivery both by the research team and the healthcare providers.

### Implementation effectiveness

Evaluating implementation effectiveness verifies the consistency and quality of intervention delivery. Measurements for this type of evaluation are described in the literature and vary according to the objectives of each intervention (Chuang *et al.*, 2015; Jorgensen *et al.*, 2016; O'Donnell 2008). In the *Boca Boca Saudável* study, these measurements were applied to understand intervention

feasibility and acceptability, determine fidelity, and propose improvements to be tested in future studies. Among these metrics included number of intervention strategies delivered to the caregiver-child dyads and healthcare providers (dose delivered); number of intervention strategies received by caregiver-child dyads and healthcare providers (dose received); intervention coverage by caregiver-child dyads and healthcare providers (reach); quality of intervention delivery and degree of fidelity (quality and degree to which components were delivered as planned) and responsiveness (participant engagement). Methods for assessing implementation effectiveness have been previously suggested. In this study, they include audio recording of MI home visits and educational group session activities; evaluating intervention checklists and staff self-evaluation on performance of MI home visits; monitoring of health providers' records for oral health counseling; and testimonials from the some participating caregivers and healthcare providers. Treatment fidelity in MI was constantly assessed by an experienced researcher based on The Motivational Interviewing Treatment Integrity (MITI 3.1.1) (Moyers *et al.*). One random interview of each research assistant was audited and feedback on their performance was provided on a weekly basis.

### Outcomes

Primary outcome include children's dental caries, measured based on the incidence of decayed, missed and filled surface index, recommended by the World Health Organization (WHO 2013) and on the visual assessment of uncavitated active and inactive dental caries lesions. Also, caregivers' and children's oral health-related quality of life. The three target health behaviors (children's oral hygiene, sugar consumption and dental service utilization), all caregiver-reported, are the secondary outcomes. Table 1 presents the detailed description of all the study variables.

### Moderators

Moderators of this intervention include demographic and socioeconomic variables, such as children and caregiver age, skin color and sex; caregiver marital status, caregiver education, family per capita income, number of individuals living in the house, government money transfer assistance, and private health insurance status for children.

### Mediators

Variables of interest include potential mediators of the outcomes. In the intra- and interpersonal level they were related to caregivers, such as oral health counseling received by healthcare providers, oral health knowledge, oral hygiene, sugary food consumption and psychosocial factors (Table 1). At the organizational level, FHTs' and OHTs' practices related to health and oral health promotion were assessed to determine whether there were improvements in the quality of health services offered to the population, specifically to young children. These practices were self-reported by the PHC health coordinator. Moreover, the average number of young child medical and dental visits at the PHC in the last month were obtained from health records. In Brazil, children are recommended to have at least one dental visit a year and at least seven medical visit consultations in the first year of life, two in the second year, and from then, once a year.

**Table 1. Variables and construct definitions in the Boca Boca Saudável study. Pelotas, Brazil, 2015**

Variables/construct definition	Response options/method
<i>Socioeconomic and demographic (moderators)</i>	
Sex, skin color, age, private health insurance (children)	Sex (male/female), Skin color (white, black, brown, yellow and indigenous), Age (in months and years), Private health insurance (Yes/No)
Sex, skin color, age, who is caregiver, marital status, schooling (caregiver)	Sex (male/female), Skin color (white, black, brown, yellow and indigenous). Age (in years), Marital status (Married or living with a partner/Single or other), Schooling (years of study)
People living in the house, family receive government money assistance, monthly income (family)	People living in the house (number and who), Government money transfer assistance (Yes/No), Per capita family income (total income/number of people in the house)
<i>Organizational level - healthcare providers (mediators)</i>	
Practices on health promotion	45-item (maximum score = 82); positive practices = total score/82 x 100
Practices on oral health promotion	22-item (maximum score = 47); positive practices = total score/47 x 100
Average of childcare medical visits	number of children with medical visit/ total children registered x 100
Average of childcare dental visits	number of children with dental visit/ total children registered x 100
<i>Intra- and interpersonal level - caregivers (mediators)</i>	
Caregiver brush teeth 2x/day	Yes/No, obtained from 1 item
Caregiver low/moderate daily consumption of sugary food	Yes/No, obtained from a 26-item food frequency questionnaire; (low/moderate = less than 3 times a day)
Caregiver oral health knowledge	24-item; True/False; maximum score = 24
Caregiver received healthcare providers' counseling on children dentist consultation, oral hygiene and healthy eating	Yes/No, obtained from 3-item, each subdivided in physicians, nurses, dentists, community health workers and others
Caregiver efficacy on child oral health	15-item; 5-point Likert-scale; maximum score = 75
Caregiver stress	Parental Stress Index Short Scale (Portuguese version) 36-item; 5-point Likert-scale; raw total scores above 90 indicates clinically significant high level of stress scores
Caregiver dental anxiety	Corah's Dental Anxiety Scale (Portuguese version) 4-item; 5-point Likert-scale; total score above 11 if the cutoff point for moderate/high dental anxiety
Family functionality	APGAR Index (Portuguese version) 5-item; 3-point Likert scale; total score under 6 is the cutoff point for family dysfunctionality
<i>Intra- and interpersonal level - children (secondary outcomes)</i>	
Children brush teeth 2x/day with fluoride toothpaste (1100ppm)	Yes/No, obtained from 3 items
Children always brush teeth before going to bed	Yes/No, obtained from 1 item
Children use an adequate quantity of toothpaste	Yes/No, obtained from 2 items
Children do not eat sugary foods between main meals	Yes/No, obtained from 1 item
Children do not consume sugary drinks between main meals	Yes/No, obtained from 1 item
Children low/moderate daily consumption of sugary food	Yes/No, obtained from a 35-item food frequency questionnaire; (low/moderate = less than 3 times a day)
Children do not intake sugary baby bottle before going to bed	Yes/No, obtained from 2 items
Children have been to the dentist	Yes/No, obtained from 1 item
Children have been to the dentist for preventive care	Yes/No, obtained from 2 items
Children have been to the local PHC dentist	Yes/No, obtained from 1 item
<i>Intra- and interpersonal level- caregivers/children (primary outcomes)</i>	
Oral health-related quality of life(caregivers/children)	Early Childhood Oral Health Impact Scale (Portuguese version) 13-item; 5-point Likert-scale; never and hardly ever items were coded 0 and occasionally, often or very often were coded 1; total % of code 0 represent the positive impact on children and family quality of life
Cavitated dental caries (children)	Index of decayed, missing and filled surfaces due to caries (mean number of surfaces per children and prevalence of children)
Uncavitated dental caries (children)	Visual assessment of active and inactive white spots lesions (mean number of surfaces per children and prevalence of children)

## Baseline and follow-up assessments

Baseline and follow-ups were conducted using the same protocol. Data were collected using a pre-tested and structured questionnaire with the caregiver during a face-to-face interview in the participants' homes. Children's dental exams were conducted by dentists in the participants' homes. The dental exam was based on a visual assessment, conducted under natural light, using the knee to knee position or on the caregiver's lap, depending on the child's age (Côrrea 2010). Gauze, a mouth mirror, a probe recommended by the World Health Organization, and a dental headlight were used during the exam. Semi-structured interviews were performed with the PHC health coordinator to assess the healthcare teams' practices in health and oral health promotion. Information on the average number of pediatric medical and dental visits at the PHC were obtained from the children's health records. The evaluation research staff was comprised of 16 interviewers and 2 dentists. Interviewers received an 8-hour theoretical and practical training.

Dentists received a 2-hour training and were calibrated using a gold-standard examiner. An excellent inter-examiner agreement (McHugh 2012) was obtained for assessments (lowest Kappa index was 0.90).

## Sample size

The sample size calculation was based on a fixed number of clusters available (N=4 PHCs), and on a fixed number of children (a mean of 75 children per PHC), with an intraclass correlation coefficient of 0.05, power of 80%, and significance level of 0.05 (Hemming *et al.*, 2011). A minimal difference to be detected varying from 10% to 16%, depending on the outcome, was considered. In order to cover possible lost-to-follow-ups and refusals throughout the study period, an extra 30% was added to the calculated sample size, resulting in 390 children for baseline recruitment (194 children in the intervention condition and 196 in the control condition). The sample size was calculated using Stata 14.0, through the command *clustersampsi*.

**Table 2. Baseline characteristics of the Boca Boca Saudável parents/caregivers, children and PHCs' providers. Pelotas, Brazil, 2015**

Characteristics	Intervention	Control	P-value
<i>Socioeconomic and demographic (moderators)</i>			
<i>Children</i>			
Female, n (%)	84 (49.4)	95 (54.6)	0.336
White skinned, n (%)	144 (84.7)	136 (78.2)	0.112
Age, in months (SD)	21.9 (11.9)	23.4 (12.1)	0.228
Have private health insurance, n (%)	66 (38.8)	58 (33.3)	0.289
<i>Caregivers/families</i>			
Mother is the main caregiver, n (%)	147 (86.5)	151 (86.8)	0.932
Caregiver is married, n (%)	149 (87.6)	150 (86.2)	0.692
Caregiver age, in years (SD)	30.7 (9.4)	29.2 (8.0)	0.115
Caregiver schooling, in years (SD)	8.8 (3.0)	8.7 (2.9)	0.906
People living in the house, mean number (SD)	4.3 (1.4)	4.2 (1.5)	0.748
Family per capita income, in Reais <sup>a</sup> (SD)	423.10 (227)	435.40 (304)	0.702
Family receives government money assistance (Bolsa Familia), n (%)	27 (16.0)	26 (15.0)	0.809
<i>Organizational level - healthcare providers (mediators)</i>			
Positive practices on health promotion, n (%)	58 (70.7)	58 (70.7)	1.000
Positive practices on oral health promotion, n (%)	30 (63.8)	30 (63.8)	1.000
Childcare medical visit at PHC in last month, n (%)	46 (11.3) <sup>b</sup>	68 (22.4) <sup>c</sup>	<0.001
Childcare dental visit at PHC in last month, n (%)	8 (2.0) <sup>b</sup>	11 (3.6) <sup>c</sup>	0.239
<i>Intra- and interpersonal level- caregivers (mediators)</i>			
Caregiver brush teeth 2x/day, n (%)	154 (90.6)	162 (93.6)	0.294
Caregiver low/moderate daily consumption of sugary foods, n (%)	118 (69.4)	123 (70.7)	0.796
Caregiver oral health knowledge (correct answers), mean score (SD)	18.69 (2.28)	18.22 (2.24)	0.052
Caregiver received counseling from any healthcare providers on children:			
Dentist consultation, n (%)	47 (27.6)	60 (34.8)	0.149
Oral hygiene, n (%)	57 (33.7)	65 (37.8)	0.434
Healthy eating, n (%)	94 (55.9)	63 (36.8)	<0.001
Caregiver efficacy on child oral health ( $\alpha=0.73$ ), mean score (SD)	36.19 (7.93)	37.99 (7.33)	0.029
Caregiver stress (high level) ( $\alpha=0.91$ ), n (%)	43 (25.3)	56 (32.2)	0.158
Family functionality (dysfunctional) ( $\alpha=0.78$ ), n (%)	37 (21.8)	31 (17.8)	0.358
<i>Intra- and interpersonal level - children (secondary outcomes)</i>			
Children brush teeth 2x/day with fluoride toothpaste (1100ppm), n (%)	37 (28.2)	65 (44.5)	0.005
Children always brush teeth before going to bed, n (%)	62 (43.1)	80 (50.3)	0.206
Children use adequate quantity of toothpaste, n (%)	87 (59.2)	88 (55.7)	0.538
Children do not eat sugary foods between main meals, n (%)	79 (46.8)	66 (38.2)	0.108
Children do not consume sugary drinks between main meals, n (%)	72 (42.6)	48 (27.6)	0.004
Children with low/moderate daily consumption of sugary foods, n (%)	71 (41.8)	95 (54.6)	0.017
Children do not intake sugary baby bottle before going to bed, n (%)	84 (49.4)	77 (44.2)	0.338
Children have been to the dentist, n (%)	36 (21.2)	58 (33.5)	0.010
Children have been to the dentist for preventive care, n (%)	22 (12.9)	46 (26.4)	0.002
Children have been to the local PHC dentist, n (%)	20 (11.8)	48 (27.8)	<0.001
<i>Intra- and interpersonal level- caregivers/children (primary outcomes)</i>			
Positive impact on caregivers' and children's oral health-related quality of life ( $\alpha=0.78$ ), n (%)	108 (63.5)	105 (60.3)	0.543
Children's cavitated dental caries surfaces, mean number per children (DP)	0.36 (1.64)	0.26 (1.46)	0.574
Children's cavitated dental caries surfaces, number of children (%)	14 (8.2)	15 (8.6)	0.898
Children's uncavitated dental caries surfaces, mean number per children (SD)	0.52 (1.37)	0.63 (1.47)	0.455
Children's uncavitated dental caries surfaces, number of children (%)	27 (15.9)	36 (20.7)	0.249

SD = Standard Deviation. PHC = Primary Healthcare Center. <sup>a</sup>1.00 US\$ = 3.86 (in Oct 2015). <sup>b</sup>Total of registered children under 5-years old = 408. <sup>c</sup>Total of registered children under 5-years old = 303.

## Statistical methods

Data collected to-date were analyzed in the statistical package Stata 14.0. The baseline data analyses compares dyads in the intervention and control conditions on all studied variables. Differences between the conditions at baseline were calculated using chi-square Pearson test (for the categorical variables) and Student's T test (for the continuous variables), with a significance level of 5%. An intent-to-treat analytical approach will be applied to assess intervention effects. Analysis of intervention effects will include estimation of the rate of change in the outcomes for each condition, on the relative risks (relative rate change), and on the absolute percentage differences, with the respective confidence intervals of 95% (Fletcher and Fletcher 2006). Mediating factors will be explored in order to understand the contribution of the different targets of the intervention to the investigated outcomes (MacKinnon and Luecken 2011) and demographic and other differences between intervention and control condition participants at baseline will be adjusted for in the analysis.

## Baseline characteristics

From 390 children randomly selected for recruitment, 344 started the study, 170 in the intervention condition and 174 in the control condition (Figure 1). The overall study response rate at first follow-up was 91%; at the second follow-up, it was 76% (Figure 1). The main reason for refusals was having good dental access at the local PHC or other private services and, consequently, perceiving their participation in the study as unnecessary. The main reason for losses was moving to another city. Table 2 compares the baseline characteristics between participants in the intervention and control conditions. There were no condition differences in socioeconomic and demographic characteristics; FHTs' and OHTs' practices on health promotion and oral health promotion; children's dental caries; and caregiver and children oral health quality of life (all variables with  $p>0.05$ ). Some behavioral outcomes differed significantly between the two conditions ( $p<0.05$ ). In favor of the control condition, 44.5% of caregivers in the control condition reported that their child was brushing his/her teeth with fluoride toothpaste at least two times a day compared with 28.2% of caregivers in the intervention condition. In addition,

54.6% of control condition caregivers reported that their children consumed low/moderate amounts of sugar beverages on a daily basis compared with 41.8% of intervention caregivers. Finally, differences were also observed on dental care utilization with a greater percent of control versus intervention condition children: i) having been to a dentist (33.5% against 21.2%), ii) having been to the dentist for preventive care (26.4% against 12.9%), and iii) having been to the local PHC dentist (27.8% against 11.8%) (Table 2). Similarly, the average number of child medical visits was twice as high among control versus intervention condition children. Favoring the intervention condition was the non-consumption of sugary drinks between meals (42.6% versus 27.6% in control condition). In relation to the caregivers, caregiver self-efficacy was 1.8 points higher in the control versus intervention condition caregivers. On the other hand, access to information on healthy feeding during early childhood was around 20 percentage points higher in the intervention versus control caregivers.

## DISCUSSION

This intervention used innovative educational strategies in oral health, such as MI, combined with changes in the local healthcare system, instead of using exclusively traditionally individualized approaches, which have been severely criticized for transferring to the patients the responsibility for their health conditions (Watt 2007). Introducing health promotion actions when the contextual factors are unfavorable can produce short-term effects only (Sallis *et al.*, 2008). For instance, in the current study, the existence of a primary care service with a Family Health Strategy was not able to ensure universal dental coverage and quality care at the first dental appointment for children. Health education strategies, directed both by the healthcare providers and the caregivers were needed in order to optimize dental utilization and focus on oral disease prevention and oral health promotion. Interventions integrated to healthcare services become relevant to health systems strengthening, as they increase the chances of sustainability (Catriona and Dominique 2008). The combination of strategies is a main point in the implementation of interventions in which the interaction of individual and contextual factors is central to obtain health behavior changes (McLeroy *et al.*, 1988). Not only is the present intervention integrated into the public health system, it also has a multidisciplinary aspect. Primary healthcare in Brazil has a high coverage (over 90%) of maternal and childcare (Victora *et al.*, 2011). However, only 33% of young children have been to a dentist (Peres *et al.*, 2012). Oral health promotion should be integrated into medical care and other health promotion strategies, rather than being vertical or isolated. Training healthcare providers, other than dentists, to deliver simple oral health messages in early childhood or refer children with a high risk for oral disorders, is a great opportunity to improve young children's oral health (Menegaz *et al.*, 2018). From 20 years of produced knowledge in multi-level health interventions, 60% of the studies (in areas such as physical activity, nutrition, smoking and sexual behavior) implemented interventions in one or two of the five levels of the socioecological model (Golden and Earp 2012). The *Boca Boca Saudável* study conducted activities in three levels (intrapersonal, interpersonal and organizational). The adaptation and implementation of this intervention at a large scale is the next step. Interventions aimed at policy changes have as their focus the process of change and not just the results, since the dissemination of these results must be

supported by previous evidence of their efficacy/effectiveness (Golden and Earp 2012). The rigorous methodological process of this study must be highlighted. A careful selection of PHCs with comparable characteristics, as well as successes in the randomization of demographic and socioeconomic characteristics maximizes the comparability across conditions. The data collection on implementation effectiveness is a rare characteristic in intervention studies for oral health promotion. Process evaluation is as important as the results, yielding valuable information to understand which intervention components were implemented as intended at each level and provide insight into interpreting its potential effectiveness in affecting the outcomes. Some limitations must also be considered. Our study did not include meaningful intervention strategies at the community level, such as childcare, due to funding constraints and difficulty identifying appropriate measurable outcomes. Moreover, we discussed the relevance of this approach considering that among low income families in Brazil, only a small percentage of children go to childcare. On the evaluation methods, although rigorous monitoring was planned, it was not possible to assess all of the strategies implemented by the healthcare providers in their daily practice. This kind of method implies a constant presence of the research team, which is economically and logistically unfeasible. The PHCs in Pelotas do not have electronic health records and information on health education and oral health promotion are usually under recorded. However, some measures of healthcare provider's implementation effectiveness were monitored and will help to understand the organizational changes among these PHCs. Still on the evaluation methods, it is important to point out the difficulty in assessing all of the relevant psychosocial factors, either due to the absence of validated instruments or to the length of certain measures that would lead to respondent fatigue.

## Conclusion

This intervention study aims to widen the comprehension of dental caries prevention among young children, mainly those who belong to low income families with low access and utilization of dental services in Brazil. This study was designed and conducted according to the principles of the Brazilian Unified Health System. This article can also inform the work of others seeking to reach young children and their families or be adapted to similar contexts.

## Author Contributions

A.M. Cascaes, contributed to conception, design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; A.M. Menegaz, L.A. Quevedo and L.C. Muniz contributed to design, data acquisition and interpretation and critically revised the manuscript; T.L. Finlayson and G.X. Ayala contributed to design, data interpretation and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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