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CLINICAL TRIALS

Cluster-randomized Trial of Infant Nutrition Training for Caries Prevention

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Abstract: *The objective of this study was to estimate the caries impact of providing training in infant feeding guidelines to workers at Brazilian public primary care clinics. In a cluster-randomized controlled trial (n = 20 clinics), health care workers either were trained in guidelines for infant nutrition, stressing healthful complementary feeding, or were assigned to a 'usual practices' control, which allowed for maternal counseling at practitioner discretion. Training occurred once; the amount of counseling provided to mothers was not assessed. Eligible pregnant women were enrolled to follow health outcomes in their children. Early childhood caries (ECC) was measured at age three years (n = 458 children). The overall reductions in ECC (relative risk, 0.92; 95%CI, 0.75, 1.12) and severe ECC (RR, 0.87; 95%CI, 0.64, 1.19) were not statistically significant. There was a protective effect among mothers who remained exclusively at the same health center (S-ECC RR, 0.68; 95%CI, 0.47, 0.99) and among those naming the health center as their principal source of feeding advice (S-ECC RR, 0.53; 95%CI, 0.29, 0.97). Health care worker training did not yield a statistically significant reduction in caries overall, although caries was reduced among children of mothers more connected to their health centers (ClinicalTrials.gov NCT00635453).*

Key Words: feeding behavior, preschool child, continuing education, oral health, complementary feeding, community health centers.

Introduction

Early childhood caries is a frequent, often untreated disease (Selwitz *et al.*, 2007) with quality-of-life implications (Abanto *et al.*, 2011; Leal *et al.*, 2012). Diet-based interventions from medical providers might offer novel solutions, since infant feeding influences caries development (Selwitz *et al.*, 2007; Mobley *et al.*, 2009; Nunn *et al.*, 2009; Thitasomakul *et al.*, 2009; Feldens *et al.*, 2010a), and physicians can be key partners (Keels *et al.*, 2008; Kressin *et al.*, 2009; Pahel *et al.*, 2011). Although feeding guidelines rarely contain specific oral health messages, recommendations to limit added sugars and serve well-spaced meals have likely dental benefits. The World Health Organization (WHO) has prioritized this common risk-factor approach to disease prevention (WHO, 2009).

Previously, in São Leopoldo, Brazil, new mothers were randomized to an in-home dietary counseling intervention (Vítolo *et al.*, 2005). Guidance was from the "Ten Steps of a Healthy Diet for Brazilian Children Under Two" (Brazilian Ministry of Health, 2002; Coitinho *et al.*, 2002), a collection of complementary feeding recommendations based on WHO guidelines. In addition to general health benefits (Vítolo *et al.*, 2005), ECC occurrence was significantly reduced (Feldens *et al.*, 2007, 2010b).

Unknown is whether a less intensive, more affordable approach *via* medical facilities would have similar impact. This trial, in neighboring Porto Alegre, intervened at public health care centers, expecting that trained providers would incorporate Ten Steps guidelines when counseling mothers. The trial originally aimed to improve feeding practices and nutritional status of children born to clinic attendees. After observation of a significant positive effect on exclusive breastfeeding (Bernardi *et al.*, 2011), this study expanded the suite of outcomes to include dental status. We hypothesized that fewer children from intervention group health centers would experience caries by age 3 years.

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A supplemental appendix to this article is published electronically only at http://jdr.sagepub.com/supplemental.

Methods

Ethics Review

Ethics committees at the Federal University of Health Sciences of Porto Alegre (UFCSPA) and the University of California Berkeley approved this study. Children with caries or suspected anemia, under-nutrition, or overweight status were referred to local health centers.

Setting and Design

Porto Alegre has 1.4 million residents and fluoridated water at 0.7 ppm (Municipality of Porto Alegre). Of 52 municipal health centers, 31 met eligibility criteria for this cluster-randomized controlled trial (Fig. 1). Exclusion criteria were: ≤ 100 infant patient visits in 2006, staff-sharing among clinics, or participation in a contemporaneous community-based dietary program. Of the 31 eligible health centers, 16 were initially selected *via* a witnessed drawing, by the principal investigator, of labeled markers from an opaque container, such that 2 health centers would be included from each of the city's 8 geo-administrative districts. Following a stratified randomization scheme, health centers were block-randomized by district, with one health center *per* district allocated to the intervention and another to the control. To increase statistical power, 4 additional health centers from the original 31, regardless of district, were randomly drawn. Health center size differed, and thus, to maintain a balanced number of births by group, these additional 4 health centers were block-randomized at a 1:3 ratio. This yielded 9 intervention and 11 control group health centers. These 20 health centers were invited to participate without disclosure of allocation status, and all consented.

Patient Participants

Following staff training at intervention sites, all pregnant women with scheduled clinic visits from April to December 2008 were invited to enroll for outcome tracking by fieldworkers not involved in health center recruitment or the training session and masked to allocation status. Births occurred from May 2008 to February 2009. Women reporting a positive HIV test were excluded because of concerns of HIV transmission through breastfeeding. Of 736 eligible women, 715 (97.1%) enrolled. Informed consent was obtained from mothers on behalf of their children at each stage of data collection.

Intervention

In early 2008, an experienced nutritionist delivered a standardized, one-hour training session for physicians, nurses, and administrative staff, outlining the Ten Steps recommendations and strategies for incorporation into maternal consultations. Intervention clinics were given posters to display and pamphlets to distribute to pregnant and lactating women. Control group health centers continued usual practices, in which health care workers provided any complementary feeding guidance they deemed advisable. The intervention was designed to mimic a low-cost program for large-scale implementation. Training was delivered once, and the number of times mothers were provided dietary counseling was not monitored.

Briefly, the Ten Steps recommendations are: (1) exclusive breastfeeding to 6 mos of age; (2) continued breastfeeding to 2 yrs of age, with gradual introduction of complementary foods; (3) at 6 mos, start complementary feeding (grains, meat, fruits) 3 times daily while continuing breastfeeding; (4) mealtimes at regular intervals, adjusted to the child's internal hunger cues; (5) new foods should gradually get thicker until the child is able to eat a family meal, but foods should never be liquefied; (6) provision of a variety of healthy foods every day; (7) daily intake of different fruits and vegetables; (8) avoidance of sugar, sweets, soft drinks, salty snacks, and processed and fried foods; (9) implementation of good hygiene practices in food preparation and handling; and (10) adequate, responsive feeding during illness.

Statistical Power

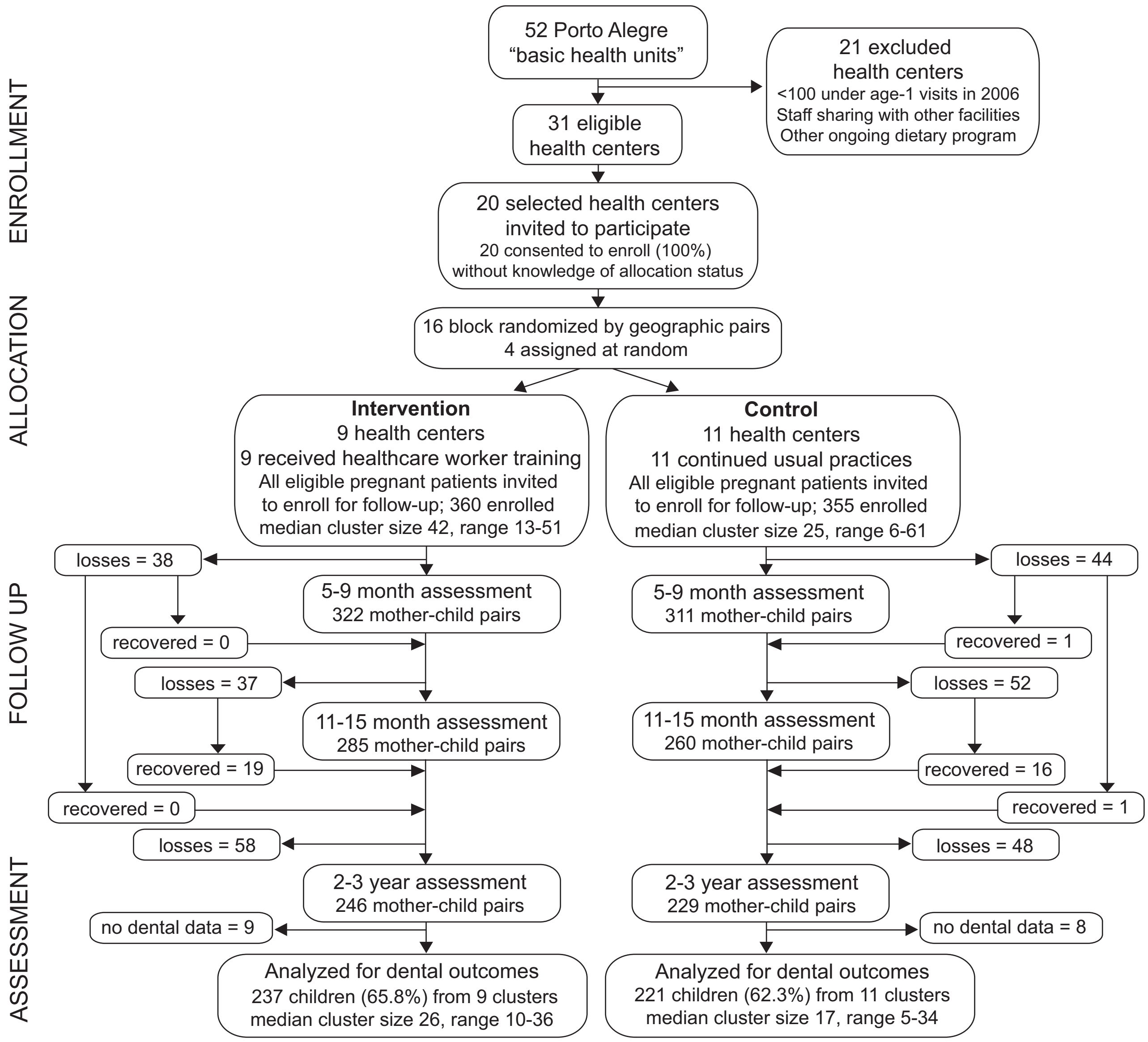
The sample size initially recruited for the trial was based on the goal of detecting a difference in the prevalence of exclusive breastfeeding at 4 mos (Bernardi *et al.*, 2011). These 715 mother-child pairs were enrolled at baseline, prior to the decision that dental outcomes would be assessed. For this study, we aimed to detect a 25% relative reduction in the prevalence of caries at 2 to 3 yrs, while expecting 55% prevalence in the control group and 30% loss to follow-up, based on interpolation from the São Leopoldo study (Feldens *et al.,* 2010b), which measured caries at different ages. At an alpha of 5% (two-sided) and a design effect of 1.5, this available sample would have 71% power for the outcome ECC.

Measurement

Trained field workers, masked to allocation status, contacted participants at baseline and approximately 6, 12, and 36 mos after birth. Socio-demographic information (*e.g.*, maternal age, education, family income) was collected *via* a structured baseline questionnaire. When the children were 5 to 9 mos and 11 to 15 mos old, mothers in both groups were asked about their potential experiences with the intervention: whether they were still attending the same health center from which they were enrolled, and whether they had viewed Ten Steps posters or received a Ten Steps pamphlet. When children were 2 to 3 yrs old, mothers were asked whether their child had ever visited a dentist.

Visual dental assessments were completed when children were 2 to 3 yrs old, following WHO protocol (WHO, 1997), with the additional recording of non-cavitated (white-spot) lesions. Assessments took place in participants' homes with the use of a lighted intra-oral mirror. Teeth were brushed before being dried with gauze. Tooth surfaces were recorded as sound, decayed non-cavitated (white-spot), cavitated (frank lesion), missing due to caries, or restored. Following National Institutes of Health case definitions (Drury *et al.*, 1999), ECC was classified as any decayed, missing, or filled tooth surface (dmfs ≥ 1). Severe early childhood caries (S-ECC) was defined by the presence of ≥ 1 affected maxillary anterior tooth, a total dmfs ≥ 4, or, for children < 36 mos of age, ≥ 1 affected smooth surface.

Figure 1.
Flow diagram of the health center clusters and individual participants from enrollment to assessment.



One dentist-examiner completed 94.7% (434/458) of the assessments, with the remainder performed by a second calibrated dentist following an identical protocol. To estimate reliability, each examiner independently evaluated 24 children aged 3 to 5 yrs on each of 2 occasions, one wk apart. Inter-rater reliability was based on the identification of sound, cavitated, missing, or filled teeth (unweighted kappa = 0.75), as was intra-rater reliability (unweighted kappa = 0.83 for both examiners).

Analysis

Primary analysis was by intention-to-treat, with proportions (ECC, S-ECC) and means (dmfs) compared for children of mothers recruited from intervention or control group health centers, regardless of whether clinic attendance continued. To estimate p values and 95% confidence intervals while accounting for non-independence within clusters, we used log-linear (binary outcomes) or linear (continuous outcomes) regression, with allocation status as the lone independent variable and robust variance estimates from the clustered sandwich estimator (command: vce) in Stata 12.0 (StataCorp, College Station, TX, USA). Statistical tests were two-sided (alpha = 0.05) and based on cluster-adjusted variance estimates. The same approach was taken to compare baseline characteristics of the analytic sample and those lost to follow-up. In secondary analyses, the intervention effect was estimated across nine *a priori*-determined demographic and behavioral subgroups.

Inverse probability censoring weighting (IPCW) was used to assess the robustness of findings under losses to follow-up. In the first step, the probability of having a dental assessment, given allocation status and baseline covariates, was predicted by logistic regression. Next, observations were weighted by the inverse probability of having dental data. Greater weight went to children more similar to those lost to follow-up, effectively "standing-in" for missing observations. Missing baseline information (1% of data) was estimated by multiple imputation. Point estimates were averaged over 50 imputations; 95% confidence intervals were estimated from 10,000 bootstrap re-samples.

Results

Dental assessments occurred from August 2011 to June 2012 (age range, 31-46 mos). Previous dentist contact was uncommon (117/440, 26.6%) and did not differ significantly by allocation status, as was true for baseline characteristics (Table 1). Dental outcomes were available for 64.1% (458/715) of the initial sample (Fig. 1). Losses were principally due to withdrawal from the study or inability to locate and did not differ significantly by allocation status (Fig. 1). Children available for analysis differed statistically significantly from those lacking dental information for 3 variables: mean maternal age (26.4 yrs intervention *vs.* 25.2 yrs control), proportion having fathers with ≤ 8 yrs of education (49.9% *vs.* 43.3%), and proportion low social class (78.3% *vs.* 82.4%). The initial and analytic samples were otherwise similar, with no other statistically significant differences, including for maternal education and self-identified race.

Overall, 78.2% (495/633) and 70.7% (383/542) of mothers were exclusively attending the same health center from which they were recruited at the 5- to 9-month and the 11- to 15-month assessments, respectively (Appendix Fig.). Only among intervention group mothers did a substantial number report seeing Ten Steps posters or receiving the pamphlets distributed to intervention group health centers (Appendix Fig.).

There was no statistically significant reduction in ECC (52.3% intervention *vs.* 57.0% control), cavitated decay (37.1% *vs.* 42.1%), or S-ECC (32.1% *vs.* 36.7%) (Table 2). The mean number of affected tooth surfaces was lower in the intervention group, but not statistically significant.

Subgroup analyses (Fig. 2) indicated no difference in the impact of the intervention on S-ECC by family or demographic characteristics. However, there was a statistically significant reduction in S-ECC among the children of mothers who continued exclusively attending the same health center from which they were recruited (RR, 0.68; 95%CI, 0.47, 0.99), and among the children of those who listed the health center as their principal source of infant feeding guidance (RR, 0.53; 95%CI, 0.29, 0.97) (Fig. 2). Among these subgroups, reductions were also observed for ECC (RR, 0.78; 95%CI, 0.60, 1.03 in those attending the same health center, and RR, 0.74; 95%CI, 0.54, 1.00 for those with the health center the main source of guidance) and for cavitated decay (RR, 0.73; 95%CI, 0.53, 0.99 for those attending same health center, and RR, 0.55; 95%CI, 0.32, 0.93 for those with the health center the main source of guidance), although the former was not statistically significant.

The overall and subgroup findings did not differ in the IPCW analysis. For example, the estimated overall effect of the intervention on S-ECC was RR 0.86 (95%CI, 0.64, 1.12).

Discussion

To our knowledge, this study is the first to evaluate oral health following medical care provider training in complementary feeding guidelines. Partnering with non-dental health professionals has been proposed to combat hypoplasia-associated S-ECC, for which pre-birth interventions may be vital (Caufield *et al.,* 2012). Here, health care worker training reduced caries slightly among children whose mothers attended intervention group clinics, although the difference was not statistically significant.

Stronger effects were observed in São Leopoldo, where counseling in the same guidelines was provided directly to mothers (Feldens *et al.*, 2010b). The impact on exclusive breastfeeding in Porto Alegre (Bernardi *et al.,* 2011) was also weaker than that observed in São Leopoldo (Vítolo *et al.*, 2005). The Porto Alegre intervention might have lacked the intensity needed for sustainable behavior change among physicians. Messages were relayed to mothers with unknown consistency and accuracy, but ≥ 40% of intervention group mothers reported receiving no written information. Additionally, many participants sought care at different facilities. Others did not list health professionals as a valued source of feeding advice. These factors likely contributed to our inability to observe a statistically significant effect in the overall population. Future interventions could incorporate multi-level and/or multi-stage elements into health care worker training to reinforce knowledge and behavior change, as well as assessments of knowledge transfer from trainer to health care workers to mothers.

In subgroup findings, among children of mothers who remained at the same health center and those who named the health center a primary source of guidance, there were significant protective effects. The former might reflect mothers with more continuous access to dietary counseling, leading to better feeding practices. Had the intervention been available at more health care sites, its impact might have been greater. Those valuing health center advice could be more receptive or compliant regarding any counseling received. Perhaps mothers who more highly valued feeding advice from family members or other sources were less likely to benefit. These findings could inform future interventions, but should be interpreted cautiously, however, since the upper limits of the confidence intervals approached one.

Rarely has caries been measured following infant feeding interventions lacking specific oral health components. Caries reduction was not found following peer-led "social support" for recommended feeding practices in London (Scheiwe *et al.,* 2010). In a large hospital-based cluster-randomized trial of

Table 1.
Descriptive Characteristics at Baseline of Individual Participants with Dental Data

Characteristic	Intervention (n = 237)	Control (n = 221)
Maternal age at delivery, mean (SD) [range], yrs	27.1 (6.7) [15.5-43.9]	25.7 (6.6) [12.3-44.3]
Child age at dental examination, mean (SD) [range], yrs	3.2 (0.2) [2.6-3.8]	3.2 (0.2) [2.8-3.8]
Male child, No. (%)	119 (50.2)	114 (51.6)
Household members, mean (SD) [range]	4.1 (1.9) [1-11]	4.3 (2.3) [1-16]
Mother has previous children, No. (%)	140 (59.1)	119 (53.9)
Mother is literate, No. (%)	235 (99.2)	219 (99.1)
Mother has ≤ 8 yrs of formal education, No. (%)	111 (46.8)	103 (46.6)
Father has ≤ 8 yrs of formal education, No. (%) (n = 439)[a]	112 (49.8)	107 (50.0)
Household monthly income, mean (SD) [range], BRL (n = 444)[a]	1109 (707) [0-4100]	1061 (681) [0-3800]
Household income ≤ 3 times minimum monthly salary,[b] No. (%) (n = 444)[a]	181 (79.4)	178 (82.4)
Social class by ABIPEME index,[c] No. (%) (n = 457)[a]		
A1	0 (0)	0 (0)
A2	0 (0)	0 (0)
B1	8 (3.4)	7 (3.2)
B2	46 (19.5)	38 (17.2)
C	137 (58.1)	135 (61.1)
D	40 (17.0)	39 (17.7)
E	5 (2.1)	2 (0.9)
Self-identified maternal race, No. (%)		
White	144 (60.8)	112 (50.7)
Black, mixed, or other	93 (39.2)	109 (49.3)
Maternal smoking status in pregnancy, No. (%)		
Never	134 (56.5)	111 (50.2)
Current	42 (17.7)	45 (20.4)
Former	61 (25.7)	65 (29.4)
Maternal BMI < 18.5 by self-reported pre-pregnancy weight, No. (%) (n = 443)[a]	15 (6.6)	15 (6.9)
Maternal BMI ≥ 25 by self-reported pre-pregnancy weight, No. (%) (n = 443)[a]	66 (29.1)	75 (34.7)

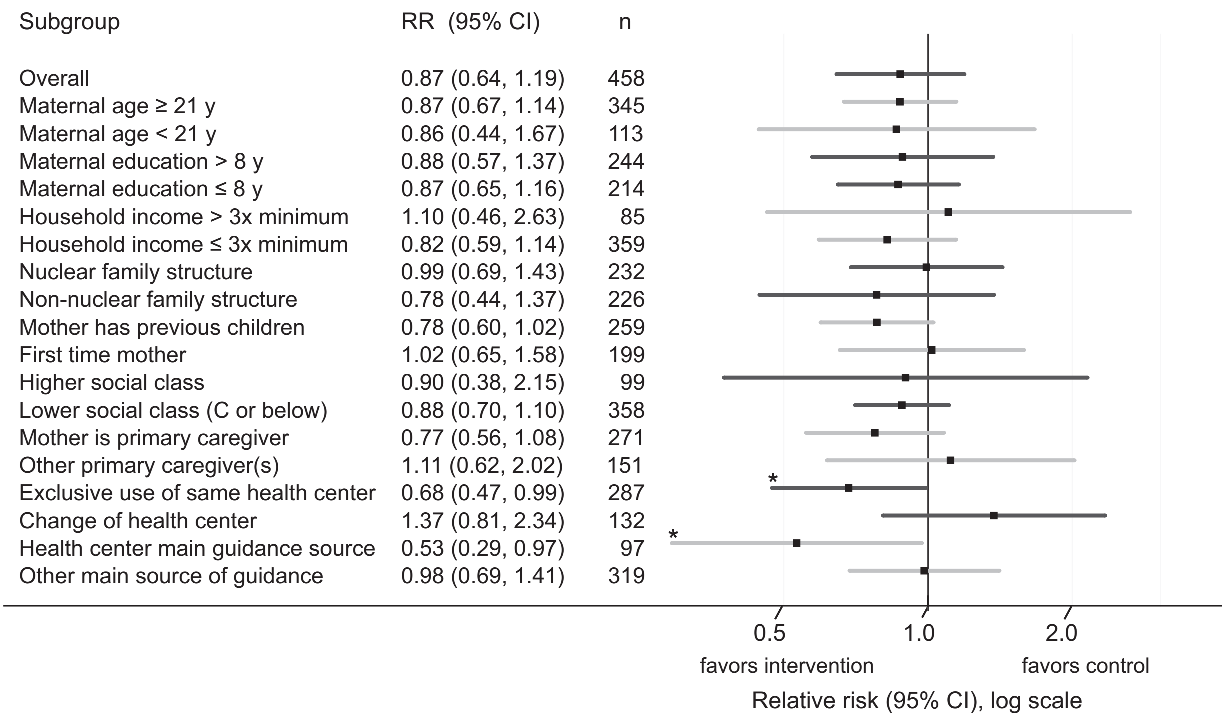
Abbreviations: ABIPEME, Brazilian Association of Economic Research Institutes; BMI, body mass index; BRL, Brazilian real.
[a]Sample size < 458 for some variables due to missing data at baseline.
[b]Equivalent to approximately 900 US dollars in 2008 currency.
[c]Socio-economic classification scale based on material possessions and education, with A = highest status and E = lowest status.

Table 2.
Dental Outcomes by Allocation Status

Dental Caries Outcomes (binary)	Intervention	Control	ICC	Relative Risk (95% CI)	Risk Difference (95% CI)	*p* value[a]
Early childhood caries	124/237	126/221	0.014	0.92 (0.75, 1.12)	-5% (-16%, 6%)	.40
Cavitated decay	88/237	93/221	0.020	0.88 (0.66, 1.17)	-5% (-16%, 7%)	.39
Severe early childhood caries	76/237	81/221	0.015	0.87 (0.64, 1.19)	-5% (-15%, 6%)	.39
Dental caries outcomes (count)					**Mean difference (95% CI)**	
dmfs, mean (SD), any decay	2.8 (5.4)	3.6 (6.9)	0.010		-0.8 (-2.2, 0.6)	.25
dmfs, mean (SD), cavitated decay only	2.1 (5.0)	3.0 (6.8)	0.010		-0.9 (-2.2, 0.4)	.18

Abbreviations: CI, confidence interval; dmfs, decayed, missing, filled surfaces index; ICC, inter-cluster correlation coefficient; SD, standard deviation.
[a] Wald test.

Figure 2.
Impact of the intervention on severe early childhood caries by subgroups. Relative risk estimates for S-ECC across demographic and behavioral subgroups are shown. Squares represent point estimates; widths of bars show 95% confidence intervals; shading denotes pairs of related strata. Some pairs total less than 458 due to missing data. * $p < .05$. Abbreviations: RR, relative risk; CI, confidence interval.



breastfeeding promotion, no caries effect was reported at age 6 yrs (Kramer *et al.*, 2007).

Study strengths included randomization and the ability to compare results with the São Leopoldo intervention, which differed by implementation scheme. Subgroups were defined *a priori*, although not adjusted for multiple hypothesis tests. As a limitation, statistical power was estimated expecting a stronger intervention effect than observed. Losses to follow-up reduced the analytic sample for differentiating smaller, yet potentially meaningful, intervention effects. This is of heightened importance in cluster-randomized trials, in which intra-cluster similarities restrain statistical power. The extent of losses to follow-up was typical of long-term trials in low-resource settings. While this affected power, the results of IPCW analysis did not differ from those based on complete cases, suggesting that losses did not systematically bias the point estimates.

Despite a modest impact, this study demonstrates the feasibility of adding oral health assessments to the evaluation spectrum of dietary interventions. This would both help characterize oral health benefits owing to improved feeding behaviors, and help foster cross-disciplinary collaboration in a common risk-factor approach to disease prevention.

Conclusions

Previous research has indicated that one-on-one maternal dietary counseling can reduce ECC in a low-income Brazilian population. Here, a more easily implemented training program for medical providers featuring the same feeding guidelines did not reduce caries to a statistically significant extent in the full sample, but S-ECC was reduced by one-third to one-half in subgroup analyses based on health center attendance and attitudes regarding health professionals' advice, respectively. This suggests that the medical care system could aid in caries prevention for populations with low dental service access and utilization. However, interventions of greater intensity should be tested.

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