Long-term effectiveness of a nutritional program in reducing early childhood caries: a randomized trial


Abstract – Objectives: To investigate the effectiveness of home visits advising mothers about healthy feeding practices during the first year of life on the occurrence of early childhood caries and severe early childhood caries at 4 years of age. Methods: We conducted a parallel randomized trial of mothers of single, full-term children with birthweight ≥ 2500g in São Leopoldo, Brazil. The intervention group received monthly advice up to 6 months and then at 8, 10 and 12 months by undergraduate nutrition students, based on the ‘‘Ten Steps for Healthy Feeding’’, a Brazilian national health policy for primary care based on World Health Organization guidelines. The primary outcome was the occurrence of early childhood caries at age four. Secondary outcomes included the occurrence of severe early childhood caries and the number of affected teeth: decayed (white spots and cavities), missing and filled teeth (d1+mft). Blinded observers ascertained feeding habits in the home and one blinded dentist performed dental examinations in a municipal clinic. This study is registered with ClinicalTrials.gov, number NCT00629629. Results: Of 500 mother-child pairs (200 intervention, 300 control) enrolled, 340 (141 intervention, 199 control) completed 4 year follow-up. As 138 (69.3%) controls but only 76 (53.9%) intervention children had early childhood caries, home counseling reduced incidence by 22% (RR 0.78; 95% CI 0.65-0.93). Severe early childhood caries incidence was reduced by 32% (RR 0.68; 95% CI 0.50-0.92). The mean number of affected teeth was lower for the intervention group (3.25) compared with the control group (4.15) (Mann Whitney U-test; p=0.023). No adverse effects were noted. Conclusions: Home nutritional advice during the first year of life decreases caries incidence and severity at four years of age in a low income community.

Early childhood caries (ECC) is the single most prevalent chronic childhood disease, representing a public health problem that affects infants and preschoolers worldwide (1–3). In Brazil, national data on dental caries from 2002 to 2003 showed a prevalence of 60% among 5-year-old children (4). Investigations of severe early childhood caries (S-ECC), the more severe pattern of disease, demonstrate that a high proportion of children do not benefit from any current preventive approach (5–7). Childhood caries may cause pain, chewing difficulty, speech and psychological problems and hinder the intake of important nutrients (3, 8, 9).

There is a growing consensus that prevention of ECC is most likely to accrue through early childhood interventions (10), which require testing in studies of high methodologic quality (1–3). In consonance with the World Health Organization (WHO) general strategy for combating chronic diseases (11), an approach targeting risk factors.
common to many chronic conditions, including oral ones, has been proposed to promote oral health in early childhood (12). In Brazil, our implementation of the ‘Ten Steps to Healthy Feeding’ (13, 14), based on home visits providing nutritional advice for the first year of life to families from low socioeconomic settings, reduced the incidence of diarrhea (15) and of respiratory disease symptoms (16), although not affecting the occurrence of anemia and low height-for-age. We have previously reported a decrease in caries from 18% to 10% on early assessment (12–16 months) (17). The aim of the present study, by extending the follow-up to 4 years of age, was to assess the long-term effectiveness of home-based nutritional counseling in preventing ECC and S-ECC across most of the relevant age range for the disease.

Materials and methods

Participants and study design

This randomized trial was conducted in mothers who gave birth from October 2001 to June 2002, in the public health system in São Leopoldo, Brazil, to apparently normal, single, full-term (≥37 weeks) babies with birth weight ≥2500 g. Exclusion criteria were impediment to breastfeeding (HIV/AIDS) or congenital malformation. In São Leopoldo, a municipality of about 210 000 inhabitants, almost all households are in urbanized areas and have access to public water supply with fluoride level of 0.7 ppm. Approximately, 95% of the population is literate and life expectancy at birth is 69 years. The municipality’s public health system includes 16 primary care health centers, 6 multi-specialty ambulatory centers and one hospital. However, restorative or preventive dental care was not widely available for young children. Mothers giving birth in the public health system in Southern Brazil typically come from low socioeconomic settings.

Randomization was conducted by a researcher not involved in the eligibility and entry of subjects into the study to warrant treatment allocation concealment. Mothers who had agreed to participate were sequentially included in a list based on time of delivery, grouped in blocks of five, and their names were separated and placed in opaque, sealed envelopes. Two mothers from each block were assigned to the intervention group while the other ones were allocated to the control group. This process was repeated for consecutive blocks. Field-workers, informed of this allocation, then proceeded with the study.

The intervention consisted of nutritional advice administered through home visits within 10 days of the child’s birth, on a monthly basis up to 6 months, and at 8, 10 and 12 months, based on the ‘Ten Steps to Healthy Feeding’ (13, 14), a primary health care policy of the Brazilian Ministry of Health. The dietary advice aimed at exclusive breastfeeding up to 6 months. After 6 months, mothers were encouraged to continue breastfeeding and gradually introduce foods. Complementary food should be given three times a day if the child is being breastfed; five times, if not. These foods should gradually get thicker up to the time when the child is able to eat a family meal. The mothers were advised not to use the bottle or breastfeeding as pacifiers, respecting the child’s appetite and maintaining reasonable intervals between meals. Daily intake of fruits and vegetables was stimulated. All mothers were advised against the addition of sugars (sugar cane, honey) in fruits, porridge, juices, milk or other liquids and against the provision of soft drinks, sweets and savoury snacks. Twelve university level nutrition students implemented the intervention after being extensively trained in terms of content and communication skills. At each approximately 30 min visit, these fieldworkers clarified and reinforced recommendations while respecting the mother’s level of cognition as well as cultural and economic background.

The trial’s main hypothesis with respect to caries is that these home visits furnishing dietary advice will reduce the incidence of early childhood caries. Secondary hypotheses include that the advice will promote healthy dietary behaviors, reduce the introduction of cariogenic feeding practices in the first year of life, and reduce severe early childhood caries as well as the number of affected teeth.

For follow-up at 4 years of age, we estimated a priori that 300 children (intervention=120; control=180) were required to detect a difference of 35% in the occurrence of ECC (RR ≤ 0.65), considering a study power of 80%, statistical significance of 5%, unexposed/exposed ratio of 3:2 and a caries prevalence of 48%, the frequency documented in a recent cross-sectional study (18). Figure 1 shows the diagram of the randomized trial, from recruitment of mother–child pairs to the assessment of outcomes at the age of 4.
Assessment of infant feeding practices

Nutrition students not involved in the intervention and blinded to group allocation carried out face-to-face structured home interviews with the mothers of all children at 6 and 12 months postpartum. Socioeconomic variables were recorded at 6 months; dietary behavior variables regarding the beginning, duration and frequency of feeding practices during the previous 6 months, at 6 and 12 months. At 12 months, a 24-h dietary recall obtained data about intake frequency (number of meals and snacks), and frequency of breastfeeding, of bottles for liquids other than milk and of nighttime bottle use. Mothers were also asked about the intake of foods with high density of sugar (>50% of simple carbohydrates in 100 g of food, e.g. candies, soft drinks, sugar and honey) and lipids (fat content > 30% in 100 g of food, e.g. salty snacks, filled cookies and chocolate) in the last month (19).

Clinical dental examination

Dental examinations at 4 years were performed by the same blinded examiner of the first year follow-up. Teeth were brushed and dried with gauze, and each dental surface was inspected with the help of a mouth mirror under artificial light. Following the National Institutes of Health (NIH) case definitions (20), occurrence of ECC (primary outcome) was defined as the presence of one or more decayed (d1+), missing or filled tooth surfaces in any primary tooth (d1+mfs ≥ 1). S-ECC was defined as one or more cavitated, missing, or filled smooth surfaces in primary maxillary anterior teeth, or decayed (d1+), missing or filled surface (d1+mfs) values of 5 or higher. The number of affected teeth was defined as the number of decayed (d1+), noncavitated or cavitated, missing (because of caries) and filled (f) teeth (d1,mft). Intra-examiner reproducibility was previously assessed as excellent in two dental examinations 14 days apart in 20 children aged 3–5 years (weighted kappa score = 0.90).

The trial was approved by the committee on ethics in research of the Federal University of Rio Grande do Sul. A parent gave written informed consent for the various research procedures. Both groups received routine assistance by their pediatricians. In the assessment at 4 years of age, children with dental caries were referred for pediatric dental treatment. Children with anemia; being overweight, wasted or stunted; or presenting...
developmental problems were also referred to their primary care doctors. Further details about methodology, including randomization, and effects on general and oral health detected at the assessment at 1 year of age have been previously reported (15–17).

Statistical analysis
Analyses were by intention to treat, because participants were analyzed according to their original group assignment. The effect of the intervention on the occurrence of caries and of cariogenic feeding practices was evaluated in contingency tables with chi-squared statistics, the size of associations being reported using relative risks (RR) with 95% confidence intervals (CI). The number needed to treat (NNT; 100 divided by the absolute risk difference, rounded up to the next whole number) is also presented to provide an estimate of the number of families who need to be counseled in order to avoid one child presenting the outcome (21). The Mann–Whitney test was used to compare the number of affected teeth across groups. Comparisons between children who were lost in the follow-up and those who remained in the trial regarding caries risk factors were also performed using chi-square and t tests for independent samples. A two-tailed p-value of less than 0.05 was considered statistically significant. All statistical analyses were performed by SPSS, version 13.0. This study is registered with ClinicalTrials.gov, number NCT00629629.

Results
Among the 500 initially recruited children, 340 (68%) underwent the assessment at 4 years of age. Losses comprised 122 children (intervention: n = 42/200, 21%; controls: n = 80/300, 27%) at the first year dental examination and 38 additional children (intervention: n = 17, 8.5%; controls: n = 21, 7.0%) at age 4 years. The main reason for losses up to the 1-year assessment, as shown in the Figure, was inability to locate the child’s home, usually because of the family having moved to another city. Losses between the assessment at 1 and 4 years of age were again mainly caused by family relocation (intervention n = 11; controls n = 13); other causes being inability to locate the address (intervention n = 4; controls n = 6) and refusal (intervention n = 2; controls n = 2).

Of the 340 children examined at 4 years of age, 195 (57.4%) were boys. Maternal level of education varied from 1 to 13 years of schooling (mean 6.9, SD 2.7; median 7.0). Family income was low for most families – 69.7% had a monthly income less than three times the national minimum wage (approximately US$ 240.00/month). Table 1 shows an even balance between the intervention and control groups in the distribution of the baseline characteristics: sex, weight and length at birth, maternal level of education, maternal age at child’s birth and family income. Additionally, age of children at the last assessment varied from 48 to 53 months, mean age in the intervention and control groups being 50.6 (SD 1.7) and 50.4 (SD 1.7) months, respectively.

Table 2 shows that the intervention succeeded in stimulating longer duration of exclusive breastfeeding, later introduction of sugar, lower frequency of dietary intake, and smaller probability of ingesting foods of high sugar and lipid density during the first year of life. However, no differences were found in the frequency of night-time

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention (n = 141)</th>
<th>Control (n = 199)</th>
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</thead>
<tbody>
<tr>
<td>Sex, males: n (%)</td>
<td>85 (60.3)</td>
<td>110 (55.3)</td>
</tr>
<tr>
<td>Weight at birth, g: mean (SD)</td>
<td>3374 (485)</td>
<td>3353 (460)</td>
</tr>
<tr>
<td>Length at birth, cm: mean (SD)</td>
<td>48.7 (2.0)</td>
<td>48.8 (2.1)</td>
</tr>
<tr>
<td>Maternal age at child’s birth, y: median (Q1–Q3)</td>
<td>26.0 (21.0–30.5)</td>
<td>25.0 (20.0–30.0)</td>
</tr>
<tr>
<td>Maternal level of education: n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤8 years</td>
<td>103 (73.0)</td>
<td>141 (70.9)</td>
</tr>
<tr>
<td>&gt;8 years</td>
<td>38 (27.0)</td>
<td>58 (29.1)</td>
</tr>
<tr>
<td>Family income: n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;3.0 NMWa</td>
<td>99 (72.3)</td>
<td>131 (67.9)</td>
</tr>
<tr>
<td>&gt;3.0 NMW</td>
<td>38 (27.7)</td>
<td>62 (32.1)</td>
</tr>
<tr>
<td>Age at 4 year examination, months: mean (SD)</td>
<td>50.6 (1.7)</td>
<td>50.4 (1.7)</td>
</tr>
</tbody>
</table>

SD, standard deviation; Q1–Q3, interquartile range; NMW, national minimum wage.

a1 NMW: US$ 80.00/month.
bottle use, introduction of solid foods and daily consumption of fruits and vegetables at 1 year.

The clinical examination at 4 years of age revealed that 37% (126/340) of children had no visible signs of caries and 63% (214/340) presented ECC. Mean d1+mft was 3.78 (SD 4.46) and median (Q1–Q3) was 2.0 (0–6). The ‘d1+’ component (non-cavitated or cavitated) contributed mostly to the d1+mft index (96.7%) while filled (2.3%) and missing teeth (1.0%) were uncommon. The proportion of children with ECC (main outcome) was 53.9% (76/141) across the intervention group and 69.3% (138/199) among controls (Table 3), a reduction of 22% (RR 0.78; 95% CI 0.65–0.93). S-ECC was present in 41 (29.1%) intervention group children and 85 (42.7%) controls, a reduction of 32% (RR 0.68; 95% CI 0.50–0.92). The NNT for ECC and S-ECC were 7 and 8, respectively. The mean number of affected teeth was 3.25 (SD 4.25) in the intervention group and 4.15 (SD 4.57) in the controls (Mann–Whitney difference in number of affected teeth, \( P = 0.023 \)).

The proportion of children who had consulted a dentist by 4 years of age was 31.2% (97/314) in the intervention group and 34.2% (68/199) among controls (\( P = 0.57 \)). Additionally, only 16 children had filled teeth (filled teeth \( \geq 1 \)). Of these, 8/141 (5.7%) were in the intervention group and 8/199 (4.0%) were in the control group (\( P = 0.48 \)). The mean number of teeth at assessment was 20.0 in the intervention group and 19.9 in the control group.
Only six children had missing teeth – 1/141 (0.7%) in the intervention group and 5/199 (2.5%) in the control group.

No difference was found between children who were lost in the follow-up and those who remained at 4 years of age regarding weight at birth [analyzed: 3355 g (SD 467); lost: 3365 g (SD 438); P = 0.87], length at birth [analyzed: 48.7 cm (SD 2.0); lost: 49.1 cm (SD 1.9); P = 0.12], maternal age at child’s birth [analyzed: 25.7 years (SD 6.6); lost: 25.8 years (SD 6.5); P = 0.90], maternal level of education [analyzed: 6.9 years (SD 2.7); lost: 6.6 (SD 2.9); P = 0.42] and family income [analyzed: U$ 259.4 (SD 178.4); lost: U$ 240.3 (SD 203.7); P = 0.47].

To investigate the effects of lost to follow-up on results, we performed two additional analyses, first carrying forward results from the first year clinic exam for children lost afterwards, and second, assuming that all lost children developed ECC. With these assumptions, calculated reductions in ECC were 21% (RR 0.79; 95% CI 0.66–0.95), and 15% (RR 0.85; 95% CI 0.76–0.95), respectively.

Discussion

Home dietary counseling during infancy reduced the incidence of early and severe early childhood caries by 22% and 32%, respectively; resulting, on average, in approximately one less tooth affected by caries per child at age 4. These findings demonstrate that early counseling of healthy infant feeding habits reduces caries incidence and severity across early childhood. Decreased and delayed consumption of foodstuffs with high sugar density and a lower frequency of meals and snacks at 1 year represent possible mechanisms explaining these results, as these variables are strongly associated with childhood caries (5, 22–25) and sugar consumption practices established in infancy tend to be maintained through the first years of life (26). The higher proportion of exclusive breastfeeding, by delaying introduction of foods with high sugar content, may have indirectly impacted on the outcomes.

On the other hand, despite improvement, a large proportion of children in the intervention group presented ECC and S-ECC. This fact and the fact that some targeted feeding practices did not differ across groups indicate that much needs to be learned about how best to promote healthy eating behavior. Analysis of the feeding practices showed higher compliance with the more objective ones, such as delaying the introduction of sugar, avoiding sweets and maintaining reasonable intervals between meals, perhaps more easily learned and followed by mothers and children. This program was not successful in promoting consumption of fruits and vegetables or reducing complex practices, such as night-time bottle use or use of bottle

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention (n = 141)</th>
<th>Control (n = 199)</th>
<th>P</th>
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<tbody>
<tr>
<td>Primary outcome</td>
<td></td>
<td></td>
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<tr>
<td>Children with early childhood caries&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>N (%)</td>
<td>76 (53.9)</td>
<td>138 (69.3)</td>
<td>0.004</td>
</tr>
<tr>
<td>RR (95% CI)</td>
<td>0.78 (0.65–0.93)</td>
<td>1.00</td>
<td></td>
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<tr>
<td>NNT (95% CI)</td>
<td>7 (4–20)</td>
<td></td>
<td></td>
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<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
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<tr>
<td>Children with severe early childhood caries&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (%)</td>
<td>41 (29.1)</td>
<td>85 (42.7)</td>
<td>0.010</td>
</tr>
<tr>
<td>RR (95% CI)</td>
<td>0.68 (0.50–0.92)</td>
<td>1.00</td>
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</tr>
<tr>
<td>NNT (95% CI)</td>
<td>8 (5–30)</td>
<td></td>
<td></td>
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<tr>
<td>Affected teeth (d&lt;sub&gt;1,mft&lt;/sub&gt;)&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mean (SD)</td>
<td>3.25 (4.25)</td>
<td>4.15 (4.57)</td>
<td>0.023&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Minimum–maximum</td>
<td>0–18</td>
<td>0–20</td>
<td></td>
</tr>
<tr>
<td>Median (Q1–Q3)</td>
<td>2.00 (0–5)</td>
<td>2.00 (0–7)</td>
<td></td>
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</table>

RR, relative risk; NNT, number needed to treat; SD, standard deviation; Q1–Q3, interquartile range.

<sup>a</sup>Early childhood caries defined as d<sub>1,mft</sub> ≥ 1.

<sup>b</sup>Severe early childhood caries defined as one or more cavitated, missing, or filled smooth surfaces in primary maxillary anterior teeth, or d<sub>1,mfs</sub> ≥ 5.

<sup>c</sup>Affected teeth (d<sub>1,mft</sub>): number of decayed (cavitated or not), missing or filled teeth.

<sup>d</sup>Mann–Whitney test.
for juices and soft drinks, which are embedded in psychological aspects of a mother-and-child relationship.

In general, behavioral changes strategies have been shown successful in altering intermediate outcomes such as parent’s cognition, hygiene and feeding practices or presence of plaque, but not in reducing the incidence of dental caries (27–29). An example is the Promotion of Breastfeeding Intervention Trial (29), in which 13 889 mother-child pairs were randomized and accompanied for 6 years in Belarus. Although this large randomized trial led to a clinically important increase in exclusive and total breastfeeding duration, no significant effects on dental caries were observed. In the other hand, Weinstein et al. (30) did find a lower incidence of early childhood caries among children whose parents had been given advice, from 6 to 18 months, on feeding and hygiene practices and counseled to seek professional help for fluoride use. Plutzer & Spencer (31) reported a major reduction in the incidence of severe early childhood caries with a program based on anticipatory guidance about oral hygiene and nutrition during the index pregnancy and further counseling when the child reached 6 and 12 months of age. The specific impact of dietary behavioral change in the positive results obtained in both of these interventions is difficult to assess, as feeding practices were only part of the intervention packages.

The results of this study should be interpreted within the context of low and middle income countries, in which dental caries afflict an important fraction of children soon after 1 year of age and represent an important disease burden in subsequent years. It is remarkable that this intervention, implemented very early in life, reduced not only the number of children affected by initial lesions but also the number affected by a more severe form of disease. Such a broad result supports the contention that future strategies to prevent early childhood caries should focus primarily on preventing their initiation rather than on controlling their severity (32). Changing eating behavior is difficult, involving acceptance on the part of the child (26). Parental attitudes and beliefs regarding diet, which have been recently shown to be closely related with caries increment in early childhood, may also represent an important barrier (33). The essence of the current intervention, an intensive face-to-face counseling during the first year of life, was to create healthy dietary practices from the beginning, as opposed to trying to modify unhealthy ones later. This fact may have played an important role in its success.

Some potential study limitations merit discussion. Of note in this regard is our large lost to follow-up rate. It may be unfair to compare our losses to those of clinic-based trials. Our losses, largely due to the family moving to an unknown address, are similar to many other household-based studies involving follow-up of young adults living in low-income, large, urban areas of developing countries and were almost always beyond our control. In this context, the similarity in baseline characteristics between those lost and those not, between the treatment groups analyzed, including their use of dental services, and the similar proportion of overall losses in each group (30% of the intervention group, 34% of controls) suggest that selection bias is unlikely to be a major problem. The greater initial loss of controls can be seen as part of this process, being most likely attributable to the somewhat longer period between hospital discharge and their first home contact. It is reassuring that even our worst-case analysis, in which all lost were assumed to have caries, demonstrated a statistically significant reduction not too different from that of our main analysis.

The inclusion of white spot lesions in caries diagnosis is important because they are highly prevalent in the first years of life, indicate caries activity, its detection might contribute to early intervention and the precision in clinical trials of preventive agents is improved (34). Although some difficulty in distinguishing white spots from hypoplastic defects, the error in the diagnosis of caries is likely to be small and equally distributed among the intervention and control groups, because the intra-examiner reproducibility was optimal and the examiner was blinded to the child’s group status. Some information bias may exist with regard to reported dietary practices: mothers from intervention group may have reported healthier practices to please the research staff. However, it is impossible to fully blind patients in studies in which the intervention involves dietary guidance (35). To minimize this problem, the research assessments were carried out by fieldworkers who had not applied the intervention.

As this trial evaluated not just oral outcomes but also nutritional and infectious disease ones (15–17), a third potential problem is that our findings may be due to chance within the context of multiple
hypothesis testing. However, as the results for half of the main nondental outcomes were also statistically significant (15, 16), and as our primary outcome was highly statistically significant, this possibility appears remote.

The aim of the present intervention – effective dietary guidance implementation – has been regarded by the WHO and others as one of the major challenges in the task of improving of general and oral health outcomes (3, 36). The reduced incidence and severity of dental caries in this study was achieved without any specific dental intervention. As dental caries and childhood diseases share common risk factors such as poor diet, adopting a combined approach rather than one that is condition-specific makes sense. Better infant feeding practices, aside from improving oral and other infectious disease outcomes, reduce risk factors for chronic diseases such as coronary heart disease, stroke, diabetes and cancer (12). But at the same time, oral health measures supported by findings with a reasonable level of evidence should be incorporated into general health programs (3, 8, 37). Recent clinical trials demonstrate that providing fluoride toothpaste and professional use of fluoride early in childhood (38–41) reduces the incidence of early childhood caries. Incorporation of such specific measures into general programs will potentially improve health and reduce inequalities in high-risk communities (3, 8, 37, 42).

As this program was implemented in a low-income community with inadequate access to dental services, it evaluated benefit in a high risk setting, which should be considered when assessing its generalizability (3). Results appear to be generalizable to the Brazilian Family Health Program, a primary care approach rich in community health workers whose principal tasks involve health education, and one which has been associated with an accelerated reduction in infant mortality rates (37). Assuming that community health workers can be adequately trained to administer nutritional advise of similar content, this approach represents an important potential strategy to reduce not just caries but other nutritionally related diseases in Brazil and other low and middle income countries.

In conclusion, this study demonstrates the feasibility and long-term effectiveness of early home-visit nutritional counseling in reducing caries occurrence and severity at 4 years of age in a low income community. Given the limited number of trials of this subject, additional ones should be performed to document the effectiveness of similar interventions in different practice settings.

Acknowledgments

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References


