Preventive Medicine 47 (2008) 384–388

Contents lists available at ScienceDirect

Preventive Medicine

journal homepage: www.elsevier.com/locate/ypmed

Effectiveness of a nutrition program in reducing symptoms of respiratory morbidity in children: A randomized field trial ☆

Márcia Regina Vitolo [a,*], Gisele Ane Bortolini [b], Paula Dal Bó Campagnolo [c], Carlos Alberto Feldens [d]

[a] Department of Public Health, Federal University of Health Sciences of Porto Alegre (UFCSPA), Porto Alegre, Brazil
[b] Post-graduation Program in Medical Sciences, Federal University of Health Sciences of Porto Alegre (UFCSPA), Porto Alegre, Brazil
[c] Department of Public Health, Federal University of Health Sciences of Porto Alegre (UFCSPA), Porto Alegre, Brazil
[d] Department of Paediatric Dentistry, Lutheran University of Brazil. Canoas, Brazil

ARTICLE INFO

Article history:
Available online 16 July 2008

Keywords:
Infants
Infant care
Signs and symptoms
Respiratory
Primary health care

ABSTRACT

Objectives. To assess the effectiveness of home visits advising mothers about breast feeding and weaning in reducing symptoms of respiratory morbidity at the age of 12 months.

Methods. A randomized field trial was conducted with mothers who gave birth within the public health system in the Brazilian city of Sao Leopoldo (2001/2002). The intervention group received dietary advice during the first year based on a Brazilian national health policy for primary care, which is based on WHO guidelines. Morbidity data was assessed in 397 children at 12 months.

Results. A total of 23.3% of the children in the intervention group and 39.7% of the controls had one or more of the following symptoms during the month preceding assessment: cough, stuffy nose, runny nose, or breathlessness. The risk of respiratory morbidity symptoms was 41% lower for the intervention group (RR: 0.59; 95% CI: 0.43–0.81). The number of families needed to be visited to avoid one children presenting symptoms of respiratory morbidity (Number Needed to Treat) was 6.1. The intervention-group status was also associated with a longer duration of exclusive (RR:1.59; 95% CI: 1.21–2.07; $p=0.001$) and total breastfeeding (RR: 1.25; 95% CI:1.02–1.55; $p=0.032$) later introduction of solid foods (RR:1.11; 95% CI: 1.02–1.21; $p=0.023$), and a lower proportion of current medication use (RR:0.56; 95% CI:0.34–0.91;$p=0.016$).

Conclusion. A nutrition education program during the first year of life has a positive impact on reducing respiratory symptoms in infants.

Introduction

Respiratory tract diseases are common, and young children represent an important subgroup of patients with respiratory illness. There is theoretical evidence that early childhood respiratory tract infections play a role in the development of atopy and asthma in school-age children, as well as asthma and chronic bronchitis in adults (Ramsey et al., 2007; Latzin et al., 2007). Global malnutrition is associated with a higher frequency of respiratory morbidity symptoms, as demonstrated by the Government of Niger and the United Nations Children's Fund (UNICEF) in collaboration with the Centers of Diseases and Control (CDC) in an emergency survey that assessed the magnitude of malnutrition and recent illness among young children in Niger (Centers for Disease Control and Prevention, 2006).

Nutritional programs during the first year of life seem to be a successful strategy for improving childhood health, as has been shown by cohort and interventional studies (Wilson et al., 1998; Sripaipan et al., 2002). Malnutrition, growth faltering, micronutrient deficiencies, and morbidities are highly prevalent during the first 2 years of life and have long-term consequences. Therefore, it is essential to adopt policies and programs that target this vulnerable age group. Most studies have focused on the benefits of breastfeeding, including protection against infectious diseases, pneumonia, hospitalization and diarrhea (Chandra, 1979; Popkin et al., 1990; Duncan et al., 1993; Victora et al., 1994; César et al., 1999; Quigley et al., 2007). Others have evaluated the impact of providing food supplementation or nutrition education on linear growth (Bhandari et al., 2001; Bhandari et al., 2004; Guldan et al., 2000) and the role of specific micronutrient supplementation on mortality and morbidities (Sazawal et al., 2006, Long et al., 2006). However, there have been few well-designed intervention trials aimed at evaluating the effectiveness of various approaches toward health and the nutritional conditions of children during early life (Dewey et al., 2002).

This randomized field trial was part of a much larger study (Vitolo et al., 2005) that was conducted to assess the impact of home visits advising mothers about good feeding practices during the first year of their children's life. Implementation of the "Ten Steps for Healthy

☆ Funding: funded by the CNPq (National Funding for Research).
* Corresponding author. Department of Public Health, Rua: Sarmento Leite 245, Porto Alegre – RS 90050-170, Brazil.
E-mail address: vitolo@fffcmpa.edu.br (M.R. Vitolo).

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doi:10.1016/j.ypmed.2008.07.008

Feeding" (Brazil, 2002), based on home visits for nutritional advice during the first year of life, reduced the proportion of children with diarrhea and early childhood caries (ECC) in 12- to 16-month-old children. However, the intervention had no effect on the occurrence of anemia and stunting (Vitolo et al., 2005; Feldens et al., 2007).

The principal aim of this study was to examine the effectiveness of home visits advising mothers about breast feeding and weaning in reducing symptoms of respiratory morbidity at 12 to 16 months.

Methods

This randomized trial investigated the effectiveness of nutritional advice about breastfeeding and healthy weaning based on WHO recommendations in the city of São Leopoldo (Rio Grande do Sul/Brazil), which has a population of about 200,000.

The sample size was previously calculated considering the main objective of the major project – improvement of the duration of exclusive breastfeeding duration – but not the primary outcome of this article. A sample of 363 children (intervention = 145; control = 218) was required to detect an increase of 65% in the frequency of exclusive breastfeeding in the intervention group (RR ≥ 1.65) considering a study power of 80%, a statistical significance of 5%, an unexposed/exposed ratio of 3:2, and a 21.5% frequency of exclusive breastfeeding up to 4 months in the control group (Brazil, Ministry of Health, 2001). Allowing for losses of 25% of the children during the follow-up, 500 mother–child pairs were recruited. All mothers who gave birth to an apparently normal, single, full term (≥37 weeks) and normal birthweight (≥2500 g) baby were invited to participate in the trial. Exclusion criteria were: HIV-positive mothers, congenital malformation and infants referred to the intensive care unit.

The mother–child pairs were recruited in the maternity wards of the city's only publicly funded hospital, which mainly serves the low-income population. From October 2001 to June 2002, the nurse responsible for the ward informed the fieldworkers of which mother–child pairs were eligible for the study. All eligible mothers were informed by the fieldworkers about the overall aims of the study (advice on feeding of infants and its effects on the child's health) as well as all research procedures, including use of a questionnaire, anthropometric and blood hemoglobin measurement, dental examination, and differences between the intervention and control groups. Mothers were then invited to participate in the trial until a total of 500 participants was attained (89.5% of the 559 invited mothers). Fig. 1 presents the trial profile. To guarantee allocation concealment, a researcher not involved in the eligibility and entry of mothers in the trial conducted the randomization and assignments of two fifths of the mothers to the intervention group (n=200) and the others to the control group (n=300). Blocked randomization was used to avoid imbalance at any point of the randomization process. The mothers who had agreed to participate were included in a sequential list based on time of delivery, and then grouped in blocks of five. Two mothers from each block were randomly assigned to the intervention group. A larger control group was chosen to increase the study power with a reasonably small increase in study costs. Given that randomization was used to allocate the individuals to the two study groups, an imbalance in the composition of the groups was not expected.

Both groups received routine assistance from their respective pediatricians in the health service. Research assessment was conducted usually within 1 month following the child's 6- and 12-month birthdays. The intervention group received home visits to advise the mother about healthy breast feeding and weaning within 10 days of the child's birth, monthly up to 6 months, and at 8, 10, and 12 months. Dietary advice was given by 12 trained fieldworkers who counselled the mothers about breast feeding and healthy weaning based on the WHO recommendations known as the 'Ten Steps for Healthy Feeding for children from birth to two years' (Brazil. Ministry of Health, 2002).

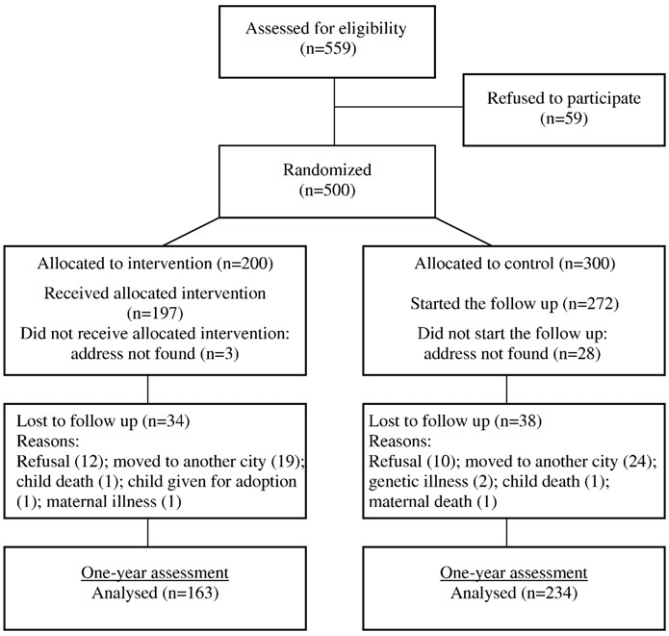

Fig. 1. Trial profile (São Leopoldo, Rio Grande do Sul, Brazil, 2001/2002). A nutrition education program during the first year of life has positive impact on reducing some respiratory symptoms in 397 infants.

The dietary advice was aimed at promoting exclusive breastfeeding up to 6 months. After 6 months, mothers of breastfeeding babies were encouraged to continue breastfeeding and introduce a three-times-a-day solid diet including a variety of fruits, cooked vegetables, meat, and cereals in order to coincide with family meals by the age of 1 year. Mothers of breastfed babies who were older than 6 months were encouraged to continue breastfeeding. Mothers of bottle-fed babies were counselled to gradually replace some bottles with a five-times-a-day solid diet rich in nutrients, maintaining reasonable intervals between meals. All mothers were advised not to use the bottle as a pacifier and were encouraged to gradually restrict bottle during the night. The mothers were also advised against the addition of sugars (cane sugar, honey) to fruits, porridge, juices, milk, or other liquids and against the provision of soft drinks, sweets, and savory snacks; they were encouraged to avoid fried food and to use salt in moderation. Advice on hygiene practices in food preparation and handling was also provided.

A leaflet was used as guidance for the advice, and was given to the mothers as a reminder. The mothers also received verbal and written information about the preparation of complementary foods and recipes for foods traditionally used by families in this region that are healthy for the child's age. The fieldworkers who carried out the dietary advice were previously trained in the 10 steps for healthy feeding of infants and in counselling skills. They received 8 h of theoretical training and 8 h of practical training based on detailed guidelines prepared for the study, and were calibrated against the advice provided by a pediatric nutritionist. They were systematically supervised by this nutritionist during the fieldwork on a weekly basis. The nutritional advice was expected to have a positive effect on the child's overall health, including decreased symptoms of respiratory morbidity.

Research assessment questionnaires

At six and 12 months, 16 fieldworkers carried out structured face-to-face interviews with the mothers. At six months, demographic, socioeconomic, and environmental variables were investigated: child's sex, mother's education (number of years of schooling), family income, mother's occupational status, and family structure. Family

Table 1
Comparability between the intervention and control groups for baseline characteristics (São Leopoldo, Rio Grande do Sul, Brazil, 2001/2002)

Variables	Group status	
	Intervention *n* (%)	Control *n* (%)
Family income (BMW[a])[b]		
≤3	122 (74.8)	160 (69.6)
>3	41 (25.2)	70 (30.4)
Total	163 (100)	230 (100)
Maternal schooling		
<8 years	99 (60.7)	131 (56.0)
≥8 years	64 (39.3)	103 (44.0)
Total	163 (100)	234 (100)
Maternal age		
<20 years	29 (17.8)	48 (20.5)
20–29 years	86 (52.8)	122(52.1)
≥30 years	48 (29.4)	64 (27.4)
Total	163 (100)	234 (100)
Family structure		
Nuclear	48 (29.4)	66 (28.2)
Non-nuclear	115 (70.6)	168 (71.8)
Total	163 (100)	234 (100)
Maternal smoking		
Yes	28 (17.2)	45 (19.2)
No	135 (82.8)	189 (80.8)
Total	163 (100)	234 (100)

[a] BMW=Brazilian Minimum Wage.
[b] The total was smaller for this variable than the effective sample (n=397) due to missing information (family income: n=393).

structure was considered nuclear (child living with mother and father) or non-nuclear (child not living with both). Monthly family income was assessed in terms of the current Brazilian Minimum Wage (BMW: about US$ 100.00). Mothers were asked about cigarette smoking status and breastfeeding status. Exclusive breastfeeding was defined if the child received non-solids, non-breast milk, water, or other liquids (World Health Organization, 2003). At six months, mothers were also asked about the introduction of solid foods. Although the last interview was scheduled for 12 months, it was not possible for all children. For this reason, the age was extended to 16 months. In the last interview, the mothers were asked about the use of medications (excluding vitamin and mineral supplements) during the previous month. Data on cow milk intake was obtained by 24 h dietary recall.

Symptoms of respiratory morbidity

At 12 to 16 months, home visit mothers were asked about the occurrence of cough, runny nose, stuffy nose, and breathlessness during the previous month. The primary outcome of this trial – symptoms of respiratory morbidity – was defined if children had manifested one or more of the symptoms listed above.

Ethical aspects

This study was approved by the Ethics Committee of the Federal University of Rio Grande do Sul. Written informed consent for the various research procedures was obtained from a parent and dietary advice was provided by a fieldworker after the 12-month research assessment. Children with anemia or who were overweight, wasting, stunting, or exhibiting developmental problems were referred to their primary care pediatrician for further assessment and treatment.

Statistical analysis

The impact of the intervention on reducing respiratory morbidity symptoms was expressed by Relative Risks (RR) and 95% Confidence Intervals (CI 95%), which was not adjusted for baseline variables because the groups were alike regarding these variables. The number needed to treat (NNT: 100 divided by the absolute risk difference) is also presented to provide an estimate of the number of families who need to be counselled in order to avoid one child presenting the outcome (Laupacis et al., 1988). Further support for the impact of home-visit dietary intervention on feeding practices and current medication use was presented using RR (95%CI) and the two-tailed chi-square test for differences between the intervention and control groups.

Results

Of the 500 children initially recruited, 397 received the one-year research assessment, and the reasons for losses to follow-up are presented in Fig. 1. Baseline variables hypothesized as strong predictors of respiratory morbidity symptoms in the intervention and control groups are presented on Table 1. Both groups were alike regarding family income, maternal schooling and age, family structure at the time of the child's birth, and maternal smoking. All families exhibited low income and social conditions. The number of children assessed at 12–16 months was 163 and 234 for the intervention and control group, respectively. It was not possible to obtain income data for four families and there was a lack of information on solid food introduction for two children.

The prevalence of respiratory morbidity symptoms during the previous month was 33.2%. Individual prevalence of symptoms related to all children of the study were: cough: 20.4%; runny nose: 26.2%; stuffy nose: 16.6%; breathlessness: 9.6%.

Differences in respiratory morbidity symptoms between the intervention and control groups were observed (Table 2). The proportion of children with such symptoms was 23.3% (38/163) in the intervention group and 39.7% (93/234) for the controls. The risk of these symptoms was 41% lower for the intervention group compared with the controls (RR: 0.59; 95% CI: 0.43–0.81). The number of families requiring visitation in order for one child to avoid symptoms of respiratory morbidity (NNT) was 6.1.

During the first month of life, 33.3% of the children in the intervention group and 48% in the control group were not exclusively breastfed. The prevalence of exclusive breastfeeding (EB) at 4 months of age was 44.8% in the intervention group and 28.2% in the control group, and the difference was statistically significant (EB≥4 months: RR 1.59; 95% CI: 1.21–2.07). The proportion of children who were breastfed at 12 months was higher for the intervention group (total breastfeeding≥12 months: RR 1.25; 95% CI: 1.02–1.55). Intervention-group status was also associated with later introduction of solid foods (solid foods introduction≥4 months: RR 1.11; 95% CI 1.02–1.21) and a lower proportion of current medication use (RR 0.56; 95% CI: 0.34–0.91). For two children, it was not possible to obtain the correct period of introduction of solid foods. Mean consumption of cow milk was 616 ml/day (SD±340), and the association between group status and cow milk consumption was not statistically significant (RR: 0.90; 95% CI: 0.74–1.10) (Table 3). The frequency of respiratory morbidity symptoms was not different according to the birth season,

Table 2
Number of children assessed for symptoms of respiratory morbidity and relative risk (RR) by group allocation at the age of one year (São Leopoldo, Rio Grande do Sul, Brazil, 2001/2002)

Group status	Symptoms of respiratory morbidity					
	N	*n*	(%)	RR	(CI 95%)	NNT
Intervention	163	38	(23.3)	0.59	(0.43–0.81)	6.1
Control	234	93	(39.7)	1.00		

NNT— Number needed to treat.

Table 3
Comparability between intervention and control groups for feeding practices and medication use targeted by the dietary intervention (São Leopoldo, Rio Grande do Sul, Brazil, 2001/2002)

Variables	Group status		RR (95% CI)	*P* value
	Intervention *n* (%)	Control *n* (%)		
Duration of exclusive breastfeeding			1.59 (1.21–2.07)	0.001
<4 months	90 (55.2)	168 (71.8)		
≥4 months	73 (44.8)	66 (28.2)		
Total	163 (100)	234 (100)		
Duration of total breastfeeding			1.25 (1.02–1.55)	0.032
<12 months	77 (47.2)	136 (58.1)		
≥12 months	86 (52.8)	98 (41.9)		
Total	163 (100)	234 (100)		
Current medication use			0.56 (0.34–0.91)	0.016
Yes	19 (11.7)	49 (20.9)		
No	144 (88.3)	185 (79.1)		
Total	163 (100)	234 (100)		
Cow milk consumption			0.90 (0.74–1.10)	0.291
>400 ml	79 (48.5)	126 (53.8)		
≤400 ml	84 (51.5)	108 (46.2)		
Total	163 (100)	234 (100)		
Introduction of solid foods			1.11 (1.02–1.21)	0.023
<4 months	20 (12.5)	49 (22.3)		
≥4 months	140 (87.5)	183 (77.7)		
Total	163 (100)	232 (100)		

considering the months of winter and summer in the south of Brazil. (RR 0.84; 95% CI: 0.59–1.19).

Discussion

The results of this randomized trial demonstrated that a nutrition program based on counselling of mothers during the first year of their child's life was effective in reducing symptoms of respiratory morbidity among children aged 12 to 16 months. It is essential to identify factors that protect against respiratory morbidity during the first year of life, given that it can lead to more serious conditions including severe respiratory tract infections, which increase the risk of respiratory morbidity in adulthood (Boezen et al., 2002). The use of cough and cold medications that contain nasal decongestants, antihistamines, cough suppressants, and expectorants in an attempt to relieve symptoms of upper respiratory tract infection in children <2 years of age is also associated with adverse events, including death (Centers for Disease Control and Prevention, 2007). Lower current use of medication was observed in the intervention group of this study, which probably reflected improved nutrition.

The present investigation was characterized by an education program, the goal of which was to implement the Ten Steps, a national policy designed to: a) increase the duration of exclusive and total breastfeeding; and b) stimulate an introduction of "basic" complementary foods such as cereals, roots, regional vegetables, and fruits. These practices may be adopted by low-income families despite their limited resources. Our findings showed a higher proportion of children who were exclusively breastfed and who received breast milk for a longer time in the intervention group. It is likely that children who were not fully breastfed for at least 4 months were exposed to pathogens through contaminated weaning foods at an earlier age (Eckhardt et al., 2001). Early childhood viral exposure, observed during the first year of life, has been associated with respiratory symptoms and asthma at ages of 1 and 2 years (Lee et al., 2006). It has also been demonstrated that the probability of respiratory illness occurring at any time during childhood is significantly reduced if the child is exclusively breastfed for at least 15 weeks, and no solid foods are introduced during this period (Wilson et al., 1998). A WHO Collaborative Trial used meta-analyses to assess the impact of breastfeeding on mortality, and found that the risk of neonatal mortality was 2.5–7 times greater for non-breastfed babies compared to breastfed. This trial also concluded that acute respiratory infection is one of the most important causes of late mortality (World Health Organization, 2000).

Our nutrition program was effective in delaying the introduction of solid foods during the first year of life, which probably contributed to the better respiratory health observed in the intervention group. A cohort study in Dundee (Scotland) demonstrated that the incidence of respiratory illness (runny nose, wheeze, and persistent cough) was increased by early introduction of complementary food, even after adjustment for parental smoking and poor social conditions (Forsyth et al., 1993). These results can be attributed to lower immunological protection resulting from reduced breast milk intake and the high risk of contamination during the preparation of supplementary foods, resulting in harm to children's health during the first months of life. This hypothesis was raised by a study in which nutritional intervention consisted of the distribution of a milk-based cereal that was prepared by the mothers and offered to the babies as supplementary food (Bhandari et al., 2001). The results showed a shorter period of breastfeeding and increased occurrence of diarrhea in the supplemented group. There is no doubt that a nutritional education program based on current local dietary practices, as proposed by our national policy, is the best strategy for obtaining a positive health outcome in children, as demonstrated in our study. The nutritional program was basically focussed on increasing the period of exclusive breastfeeding and the introduction of good quality supplementary food, as well as better care and hygiene in the preparation of children's food. Other outcomes, such as improvement of growth velocity and lower malnutrition, morbidity and mortality, have been observed in other studies that improved feeding behavior during the first year of life (Penny et al., 2005; Santos et al., 2001; Leite et al., 2005; López-Alarcón et al., 1997; Bhandari et al., 2003; Salehi et al., 2004).

Some limitations of this study need to be pointed out. Block sizes remained fixed throughout the trial. This is a potential source of selection bias in trials that are not double-blinded since a sequence can be discerned from the pattern of past assignments (Meinert, 1986). As collection of the dietary variables took place six months after allocation to the groups and outcome was assessed after twelve months, this is unlikely to have allowed the child's group to be identified. Similar to other dietary intervention studies, mothers may have been aware of the group to which they belonged as they received dietary advice and were visited regularly. This represents a possible source of aferition bias of dietary practices since it is possible that these mothers were more likely than the controls to report that they followed the dietary advice when they did not carry out such behaviors in order to please the research staff. To minimize this problem, the research assessments were carried out by fieldworkers who had not applied the intervention, although it is possible that the origin of the group could have been discovered during the interview. It is impossible to blind patients in studies in which the intervention involves dietary orientation (Fletcher et al., 1996).

In studies that investigate dietary practices, the possibility of recall bias has to be considered since the investigators have to rely on participants' memories (Persson and Carlgren, 1984). In our study, the dietary practices and data collection were never longer than six months, thus limiting bias. The respiratory morbidity symptoms reported by the mothers were not a limitation of the study since they were investigated only for the last month. Another point is that home visiting per se could be responsible for improved feeding practices and care of children. In general, children in families who were enrolled in home visiting programs fared better than control group children (Sweet and Appelbaum, 1994). For this reason, it was not possible to ascertain whether the positive results were exclusively related to improved feeding practices. The intervention protocol established at the beginning of the study was not fully realized as some of the

children in the intervention group did not receive the ten planned visits because some mothers were not home during some visits.

Cost-benefit analyses may help to more clearly outline the practical benefit of interventions delivered through home visits in relation to other service delivery strategies. This program was also effective in preventing diarrhea and dental caries (Vitolo et al., 2005; Feldens et al., 2007). However, this program must be implemented in public health services and should become a routine to provide wider coverage assistance, especially for the most disadvantaged groups. Dewey (2005) has pointed out that there is clear evidence that appropriately designed interventions can work.

The results of this study suggest that a nutrition education program during the first year of life has a positive impact on some symptoms of respiratory morbidity in infants of 12 to 16 months, and that this strategy should be implemented in a systematic way. Further studies should examine longer-term effects of the program.

Conflict of interest statement

We declare that we have no conflict of interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ypmed.2008.07.008.

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