Infant Feeding Practices and the Effect in Reducing Functional Constipation 6 Years Later: A Randomized Field Trial

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ABSTRACT

Objective: The aim of this study is to assess the impact of health worker training on infant feeding practices on the prevalence of functional constipation (FC) among children at 6 years of age.

Methods: Cluster randomized field trial conducted in Porto Alegre, Brazil. Health centers were randomly allocated into intervention (n = 9) or control (n = 11) groups. In intervention sites, health workers joined training sessions on the "Ten Steps for Healthy Feeding for Children from Birth to Two Years of Age." Pregnant women in the last trimester of both groups were identified, invited to participate and enrolled in the study as the potential mothers to receive the dietary counseling provided by the health workers. At 6 years of age, the prevalence of FC was evaluated based on Rome III, defined by 2 or more of the following: infrequent defecation, fecal incontinence, history of retentive posturing, or/and history of painful defecation.

Results: Among 387 mother-child pairs (206 intervention, 181 control) evaluated at 6 years of age, the prevalence of FC was lower in the intervention group compared with the control group (15.0% vs 23.9%, respectively). The probability of being constipated was 38% lower in the intervention group (PR = 0.62; 95% CI 0.44–0.87; P < 0.01).

Conclusion: The health workers training to promote the “Ten Steps” was an effective way to reduce the prevalence of constipation among children at 6 years of age.

Key Words: community health centers, dietary interventions, primary care

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Functional constipation (FC) in childhood represents a public health issue (1–3), with a worldwide prevalence ranging from 0.7% to 29% (4). Nowadays, the disease poses a healthcare burden on the budgets of many countries regarding to patient care, expenditure for investigations, and prescriptions (5). In addition, FC is related to low quality of life (6–9) and poor school performance (5,10), and may persist through young adulthood (6–8).

The most widely accepted diagnostic criteria for FC is Rome III (11). Also, the National Institute for Health and Clinical Excellence guideline (12) has recommended a detailed exploration of common signs that suggest organic causes of constipation ("red flags"). Currently, studies focus on treatment that includes educating the child and family, improving diet quality, and organizing toilet habits, by administering laxatives for the regulation of bowel movements (13). Despite the etiology remains unclear (14), studies have been suggested that FC begins early in life, many even in the first year (15–18). Thus, early dietary factors (15,19,20) may play a role in the pathophysiology of the disorder and that is the reason to believe that adequate feeding practices early in life may be a protection against constipation.

We conducted a cluster randomized field trial with health care centers’ staff to promote the “Ten Steps for Healthy Feeding for Children from Birth to Two Years of Age.” Previous studies showed that the intervention was effective to improve breastfeeding rates and complementary feeding practices (21,22). Therefore, the question of this present study was to verify the impact of the early intervention on the FC later in childhood, when the children were 6 years of age.
METHODS

Study Design and Participants

This study was a cluster randomized field trial conducted in Porto Alegre, Brazil. The trial included health centers that provide primary care services predominantly to low-income families. Of 52 municipal health centers, 31 met eligibility criteria for the trial (Fig. 1). Exclusion criteria were: <100 infant patient visits per year, staff-sharing between clinics, or participation in other community-based dietary programs.

The initial sample size for the trial aimed to detect the impact of the intervention on exclusive breast-feeding duration. Six hundred mother-child pairs would be needed to detect a 40% exclusive frequency of exclusive breast-feeding up to 4 months of age in the

56 city-wide “basic health units”

25 excluded health centers: < 100 under age-1 visits in 2006 staff sharing with other facilities other ongoing dietary program

31 eligible health centers

20 health centers sampled for study (100% enrolled)

INTERVENTION

9 health centers
Eligible pregnant: 373

Refusal (n=13)

2008 Pregnant woman enrolled at baseline: 360

Losses (n=38)
Refusal: 16
Moved to another city: 4
Death/maternal incapacity: 5
Inability to locate: 13

2008/2009
6 months assessment:
322 mother-child pairs

Analysis

2014/2015
6 years assessment:
206 mother-child pairs

Constipation data (n=174)
Children analyzed for outcomes (n=167)
Congenital disease excluded (n=2)
Criteria for Irritable Bowel Syndrome (n=4)
Autism spectrum disorder (n=1)

CONTROL

11 health centers
Eligible pregnant: 363

Refusal (n=8)

2008 Pregnant woman enrolled at baseline: 355

Losses (n=44)
Refusal: 13
Moved to another city: 7
Death/maternal incapacity: 3
Inability to locate: 21

2008/2009
6 months assessment:
311 mother-child pairs

Losses (n=110)
Refusal: 23
Moved to another city: 74
Death/maternal incapacity: 2
Inability to locate: 31

Analysis

2014/2015
6 years assessment:
181 mother-child pairs

Constipation data (n=147)
Children analyzed for outcomes (n=142)
Congenital disease excluded (n=3)
Criteria for Irritable Bowel Syndrome (n=2)

FIGURE 1. Flow diagram of the health center clusters and individual participants from enrollment to 6 years of age.
intervention group (23) and a 25% frequency in the control group (90% power and α of 0.5) and a design effect of 1.5. Seven hundred and twenty pregnant women were enrolled to obtain required study power, accounting for an anticipated loss of 20%.

Following staff training at the intervention sites, interviewers visited both groups’ health centers (intervention and control), from April to December 2008, to identify and enroll pregnant women who were in the last trimester of pregnancy. The study was explained to them and who agreed to participate answered a questionnaire about their socioeconomic status and expected due date. Addresses and telephone numbers were obtained in order to schedule subsequent home visits. Births occurred from May 2008 to February 2009. Women reporting a positive HIV test were excluded because of concerns on virus transmission through breast-feeding.

Ethics

The study was approved by the Ethics Committee of the Universidade Federal de Ciências da Saúde de Porto Alegre, and was registered on the ClinicalTrials.gov website under the identification number NCT00635453. Mothers provided informed consent on behalf of their children.

Randomization and Masking

The randomization process took place in the university research office. Of the 31 eligible health centers, 16 were initially selected via a witnessed drawing, by the main investigator, of labeled markers from an opaque container, so that 2 health centers from each of the city’s 8 geo-administrative districts would be included. Following a stratified randomization scheme, health centers were block-randomized by district, with 1 health center per district allocated to the intervention and another to the control group. In order to increase statistical power, 4 additional centers were randomly drawn. Health center size differed to maintain a balanced number of births by intervention group, the additional 4 centers were block-randomized by district, with 1 health center from each of the city’s 8 geo-administrative districts would be included. Following a stratified randomization scheme, health centers were block-randomized by district, with 1 health center per district allocated to the intervention and another to the control group. In order to increase statistical power, 4 additional centers were randomly drawn. Health center size differed to maintain a balanced number of births by intervention group, the additional 4 health centers were block-randomized at a 1:3 ratio. This yielded 9 intervention and 11 control group centers. The 20 health centers were invited to participate without disclosure of allocation status, and all consented.

Intervention

Physicians, nurses, and administrative staff in the treatment group health centers participated in a training, in January 2008, based on the “Ten Steps for Healthy Feeding for Children from Birth to Two Years of age” guideline (24). In summary, the recommendations provide: exclusive breast-feeding until 6 months of age; continue breast-feeding until 2 years of age with the gradual introduction of complementary food; start complementary feeding at 6 months of age while continuing breast-feeding; provide meals at regular intervals, adjusted to the child’s internal hunger cues; new food should be gradually made thicker until the child is able to eat a normal family meal; offer of a variety of healthy food every day; present daily intake of different fruits and vegetables; avoid sugar, sweets, soft drinks, salty snacks, and processed/fried food; use good hygiene practices for food preparation; and afford appropriate, responsive feeding when the child is ill.

A standardized training session, conducted by an experienced nutritionist, for the health care team to outline the “Ten Steps” recommendations and strategies and to incorporate these into follow-up consultations. Health staff members received a pocket guide for use during the appointments and waiting room sessions. The research team did not involve in the consultations at any time in the study.

The health workers received 2 printed materials, developed by the principal researcher, which would be delivered to mothers during the follow-up consultations. Both flyers included illustrative pictures to facilitate explanation by the health workers. The first one mentioned the “Steps,” suggesting to mothers that she should get more information about it with the health workers. The second one included detailed messages about the guideline. In addition, we provided 2 colorful posters for display in the waiting rooms of health care centers with information about introducing complementary food, the number of meals, and food scheme; and colorful pictures of foods that should not be offered to children under 2 years of age. The 2 posters remained in the clinics after the intervention.

Control Group

Healthcare centers randomized to nonintervention groups continued their routine of assistance without the research team interference. No material was provided to them.

Data Collection

Trained field workers, who were not involved in the intervention and who were unaware of group allocation, conducted maternal interviews in pregnancy and later for follow-up home-visits at 6 months and 6 years of child age. At 6 months, data on sex, date of birth, weight and length at birth were collected from the maternity records during home visits. The field workers received theoretical and practical 8-h training and were supervised by the main investigator. At 6 years of age (2014), the interviews were conducted at the University, in an appropriate location. A single interviewer, unaware of group allocation, performed the questionnaire based on Rome III (11), related to the functioning of the gastrointestinal. After the data collection, the information was confirmed through telephone calls made to 5% of the mothers surveyed, who were randomly selected.

Definition of Constipation

The FC diagnosis was defined based on Rome III, considering positive by 2 or more of the following: 2 or less bowel movements in the toilet per week—positive answer; 1 or more episodes of fecal incontinence per week—positive answer equivalent to “yes, at least once a week”; history of retentive posturing or excessive volitional stool retention—positive answer equivalent to “yes, at least once a week” or “frequently holds the stools until lose the necessity to evacuate”; history of painful or hard bowel movements—positive answer equivalent to “intense pain” or “very intense pain”; (5) history of large diameter stools that may obstruct the toilet—positive answer equivalent to yes. All the answers were considered positive when the period was confirmed—at least 2 months. The presence of a large fecal mass in the rectum was not examined.

Statistical Analyses

The database was built using Statistical Package for the Social Science, version 16.0 (SPSS Inc.), and all statistical analyses were performed using the same software. The Kolmogorov-Smirnov test was used to assess distribution normality. Characteristics of children and their household were compared between groups using the χ² test and Student t-test, or the Mann-Whitney U test, as deemed appropriate. Statistical significance was set at P < 0.05.
The analysis was conducted on the basis of an intention-to-treat approach. The intervention effect on the prevalence of constipation and each characteristic of the disorder was evaluated by using the Generalized Estimation Equation (GEE) model adjusted for clustering. Data were expressed using percentage, risk ratio (RR), and 95% confidence interval (95% CI).

RESULTS
Among the 715 mothers initially registered, 633 mother-child pairs (322 intervention; 311 control) were indeed in the study at 6 months of age and 387 children (206 intervention; 181 control) remained in the follow-up at 6 years of age (Fig. 1). For the purpose of this study, children with genetic diseases (n = 5), autism spectrum disorder (n = 1), irritable bowel syndrome (n = 6), and incomplete data (n = 66) were excluded from the analyses. Thus, 309 children (167 intervention; 142 control) underwent FC assessment at 6 years of age. No adverse events were reported during the intervention.

No differences were found between children who were lost to follow-up and those who remained at age 6 in terms of race, sex (P = 0.73), weight at birth (P = 0.74), length at birth (P = 0.87), maternal age at child’s birth (P = 0.58), maternal education level (P = 0.26), and family per capita income (P = 0.52). Characteristics of children and their household were similar for both groups (Table 1). Overall, 20.4% (n = 79) of the mothers were under age 20 at the child’s birth, 29.2% (n = 113) had 8 years of schooling or less, 99.2% (n = 614) were able to read and write, and 66.7% (n = 258) did not have paid employment. Family per capita income was low for most families (P = 0.66). The prevalence of FC was lower in the intervention group compared with the control group (15% [n = 25] vs 23.9% [n = 34], respectively). Furthermore, the number of children who presented infrequent defecation (2 or less bowel movements in the toilet per week) and history of retentive posturing differed between the intervention and control groups (PR = 0.64; 95% CI 0.44–0.87; P < 0.01).

DISCUSSION
To our knowledge, this is the first randomized field trial to investigate the effects of a primary care intervention aimed at improving infant feeding practices on the prevalence of FC later in life. The lower prevalence of constipation in the intervention group may be explained by the improvement in breast-feeding and complementary feeding practices observed among these children during the first year of life. First, we found that the prevalence of exclusive breast-feeding in the intervention group was higher than in the control group in the first (72.3% vs 59.4%; RR = 1.21; 95% CI 1.08–1.38), second (62.6% vs 48.2%; RR = 1.29; 95% CI 1.10–1.53), and third months of life (44.0% vs 34.6%; RR = 1.27; 95% CI 1.04–1.56) (18). Exclusive breast-feeding is known to be a protective factor for FC because it promotes more frequent bowel movements when compared with formula-fed infants (25,26). The high digestibility of human milk and the presence of oligosaccharides can affect stool consistency and frequency (27). Other studies have found that exclusive breast-feeding for 3 or 4 months results in a normal evacuation pattern and softer consistency of stools compared with other feeding practices (28,29). We also found that the intervention was effective during the first years of life in increasing meat consumption (36.8% vs 22.6%; RR = 1.62; 95% CI 1.32–2.03) and reducing the consumption of nonrecommended foods, such as soft drinks (34.9% vs 52.5%; RR = 0.66; 95% CI 0.54–0.80) (21). Although there is no evidence that healthier complementary feeding is associated with FC, we suppose that a better dietary pattern was tracked by the children in the intervention group and that, as a consequence, higher fiber intake was achieved by this group in the subsequent years. Nevertheless, fiber intake plays a role in FC among school-aged children (20). Some evidence was

### TABLE 1. Characteristics of children and their household according to the group at age 6 months

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention</th>
<th>Control</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>619</td>
<td>168</td>
<td>52.8</td>
</tr>
<tr>
<td>Households at baseline</td>
<td>608</td>
<td>309</td>
<td>24.4 ± 4.6</td>
</tr>
<tr>
<td>Maternal pre-pregnant BMI</td>
<td>607</td>
<td>311</td>
<td>11.14 ± 6.1</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>561</td>
<td>285</td>
<td>39.17 ± 1.6</td>
</tr>
<tr>
<td>Delivery by caesarean section</td>
<td>616</td>
<td>103</td>
<td>32.4</td>
</tr>
<tr>
<td>Maternal age at child’s birth &lt;20 years</td>
<td>619</td>
<td>62</td>
<td>19.5</td>
</tr>
<tr>
<td>Marital status (living with partner)</td>
<td>619</td>
<td>254</td>
<td>79.9</td>
</tr>
<tr>
<td>Mother’s education ≤8 years</td>
<td>619</td>
<td>151</td>
<td>47.5</td>
</tr>
<tr>
<td>Father’s education ≤8 years</td>
<td>590</td>
<td>142</td>
<td>47.0</td>
</tr>
<tr>
<td>Mother’s unemployment</td>
<td>619</td>
<td>207</td>
<td>65.1</td>
</tr>
<tr>
<td>Father’s unemployment</td>
<td>596</td>
<td>29</td>
<td>9.5</td>
</tr>
<tr>
<td>Annual household income &lt;US$ 3000</td>
<td>601</td>
<td>261</td>
<td>85.0</td>
</tr>
<tr>
<td>Monthly income per capita &lt;US$ 188.6</td>
<td>601</td>
<td>231</td>
<td>75.2</td>
</tr>
</tbody>
</table>

*a Numbers and percentages; mean values and standard deviations.

*n indicates the number of responses recorded for each characteristic.

Student t-test or χ² test was used (depending on categorical or continuous variables).

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found linking junk food consumption (30) and lower meat consumption with a higher prevalence of constipation among children ages 2 to 7 (20). These dietary differences found between groups can explain our results, as there is evidence that constipation starts in the first year of life for 17% to 40% of children (15–18,31).

The strategy implemented at the health centers was effective in reducing the prevalence of constipation in children at age 6 by 38%. This result underscores the impact of the gastrointestinal disorder treatment, as children with constipation require high medical attention, at a cost of $3.9 billion per year (2). FC treatment is complex and has a poor prognosis, as only 50% of children will recover and not require laxatives after 6 to 12 months of age (32). The present study was not designed specifically to prevent FC.

However, this outcome was evaluated at age 6 years because of the evidence that exists impacts of dietary practices in first years of life on health later in life (33–35). A recent review confirmed the importance of the first 1000 days of life as a critical period for nutritional interventions to reduce potential future health risks (36).

In our results, the prevalence of infrequent defecation and retentive posturing was lower in the intervention group than in the control group. Although the prevalence of painful defecation did not differ between the groups, the high prevalence of retentive posturing among constipated children may reflect a vicious circle. A child may hold in a stool because he/she is afraid to feel pain while defecating. This condition, in turn, leads to greater water reabsorption through the rectal mucosa and a hardening of the stool, thus making the next bowel movement more painful (37,38).

Some potential limitations should be discussed. First, the number of participants lost to follow-up from birth to 6 years of age. Our losses are similar to those of other studies involving the follow-up of people living in low-income urban areas (39). In addition, selection bias is unlikely to be a major problem, considering the similarity in characteristics between those who were lost and those who were not. Second, we included only children from low-income families. In response, we note that this target population is of particular interest for the introduction and evaluation of large-scale dietary interventions to improve population health in regional or national health programs. Third, the self-report questionnaire could be biased in diagnosing FC because of possible answer subjectivity. However, Roma III was repeatedly tested and validated for the FC diagnosis (1,11). Another limitation was the impossibility to know the health workers’ accomplishment to the dietary counseling and who were the mothers receiving such counseling. The study was designed to implement an action in the primary care that would apply to all families assisted in the health services and not only to the children enrolled in the study. Our hypothesis is that the training led the health workers to bring this matter during the care, promoting healthier dietary practices to the children. Furthermore, we did not assess FC in earlier ages, preventing us from knowing when this dysfunction started.

FC is an emerging public health problem with serious implications for the lives of children and their families (5) and our results highlight that training health workers who promote the “Ten Steps” is an effective way to reduce the prevalence of FC among children at 6 years of age.

Acknowledgments: We thank the health care centers, health workers, and families who participated in the study.

REFERENCES

TABLE 2. The prevalence of functional constipation and each symptoms of the disorder among children at 6 years of age (n = 309)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Intervention % (n)</th>
<th>Control % (n)</th>
<th>PR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrequent defecation</td>
<td>9.6 (16)</td>
<td>17.6 (25)</td>
<td>0.54 (0.30–0.97)*</td>
</tr>
<tr>
<td>Fecal incontinence</td>
<td>10.2 (17)</td>
<td>10.6 (15)</td>
<td>0.96 (0.50–1.83)</td>
</tr>
<tr>
<td>Retentive posturing</td>
<td>6.6 (11)</td>
<td>19 (27)</td>
<td>0.34 (0.22–0.54)**</td>
</tr>
<tr>
<td>Painful defecation</td>
<td>28.7 (48)</td>
<td>30.3 (43)</td>
<td>0.94 (0.71–1.26)</td>
</tr>
<tr>
<td>Large diameter stools</td>
<td>9.9 (14)</td>
<td>10.2 (17)</td>
<td>1.03 (0.58–1.82)</td>
</tr>
<tr>
<td>Two or more of the symptoms</td>
<td>15.0 (25)</td>
<td>23.9 (34)</td>
<td>0.62 (0.44–0.87)**</td>
</tr>
</tbody>
</table>

*P < 0.05.  **P < 0.01.