Effectiveness of an Early Intervention on Infant Feeding Practices and “Tummy Time”

A Randomized Controlled Trial

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Objective: To assess the effectiveness of a home-based early intervention on infant feeding practices and “tummy time” for infants in the first year of life.

Design: Randomized controlled trial with follow-up measures scheduled at 6 and 12 months.

Setting: Socially and economically disadvantaged areas of Sydney, Australia.

Participants: We recruited 667 first-time mothers and their infants in 2007 and 2008.

Interventions: The intervention consisted of 5 or 6 home visits from a specially trained research nurse delivering a staged home-based intervention in the antenatal period and at 1, 3, 5, 9, and 12 months.

Main Outcome Measure: Changes in infant feeding practices and “tummy time.”

Results: The intervention group had a significantly higher median duration of breastfeeding at 12 months than the control group (17 weeks [95% confidence interval, 13.9-20.4 weeks] vs 13 weeks [95% confidence interval, 10.1-15.0 weeks]; P = .03). Compared with the control group, the hazard ratio for stopping breastfeeding in the intervention group was 0.82 (95% confidence interval, 0.68-0.99). The intervention also resulted in a significantly later introduction of solid foods (P < .001 for trend), reducing the proportion of mothers who introduced solids before 6 months by 12% (95% confidence interval, 4%-20%) from 74% to 62%. The intervention also decreased the age at which infants started tummy time (P = .03 for trend) and increased the daily practice of tummy time by 7% from 76% to 83% (P = .05).

Conclusion: The home-based early intervention delivered by trained community nurses significantly improved some infant feeding practices and resulted in earlier daily practice of tummy time.

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Childhood obesity affects both developed and developing countries. In Australia, 21% of boys and 18% of girls aged 2 to 3 years are overweight or obese. These data emphasize the importance of early intervention in the first few years to prevent the onset of obesity. The American Academy of Pediatrics recommends that families be educated and empowered through anticipatory guidance to recognize the effect they have on their children’s development of lifelong habits of physical activity and nutritious eating. Infant feeding practices are among the most identifiable factors contributing to early onset of childhood obesity. Two systematic reviews on this topic conclude that breastfeeding is protective against childhood obesity, with some studies showing a dose response. There is also a growing body of evidence linking the early introduction of solid foods and risk of obesity.

Another important aspect of infant development is regular “tummy time” for infants. This is a colloquial term used to encourage parents to ensure that their infants spend time in the prone position. This leads to strengthening of the infant’s neck and back muscle motor movement, which are crucial for more complicated movements, such as sitting, rolling over, crawling, and pulling bodies to a standing position, as well as enhanced motor development.

To date, there is limited evidence of the effectiveness of early interventions on early-life risk factors for obesity in children. In 2007, some of us commenced the Healthy Beginnings Trial to address this...
evidence gap. To our knowledge, internationally, the Healthy Beginnings Trial is the first randomized controlled trial to test the effectiveness of an early childhood obesity intervention in the first 2 years. It is a home-based early intervention designed to improve family and behavioral risk factors for childhood obesity. The Healthy Beginnings Trial has been performed in some of the most socially and economically disadvantaged areas of Sydney, where the risk of obesity is greater than in areas of higher socioeconomic status.15

This article reports the 12-month results of the trial. Duration of breastfeeding and timing of introduction of solids are planned primary outcomes of the trial in the first year.14

METHODS

STUDY DESIGN

This randomized controlled trial (Figure 1) was conducted in southwest Sydney, Australia, from January 1, 2007, through December 31, 2010, and approved by the Ethics Review Committee of Sydney South West Area Health Service (Royal Prince Alfred Hospital Zone). The details of the Healthy Beginnings Trial research protocol have been reported elsewhere.14

PARTICIPANTS AND RECRUITMENT

From July 1, 2007, to June 30, 2008, pregnant women who attended antenatal clinics of Liverpool and Campbelltown Hospitals, located in southwestern Sydney, Australia, were approached by research nurses with a letter of invitation and information about the study. Women were eligible for the trial if they were aged 16 years or older, were expecting their first child, were between weeks 24 and 34 of pregnancy, were able to communicate in English, and lived in the local area. Women were excluded from the study if they had a severe medical condition as evaluated by their physicians. Approximately 2700 mothers were approached; 780 of these were eligible, but 113 declined. A total of 667 first-time mothers were recruited for the study.

Once eligibility was established and consent obtained, women were asked to fill in a registration form with their contact information to allow the nurses to make arrangements for baseline data collection. The baseline assessments were conducted at their homes by 1 of 4 research nurses before the random allocation. The face-to-face interview took 20 to 30 minutes and included a range of standardized questions about general health, physical activity, and nutrition, as well as demographic information. Four hundred nine women were interviewed before giving birth and 258 after giving birth.

RANDOMIZATION

Random allocation was concealed by sequentially numbered, sealed, opaque envelopes containing the group allocation, which was determined by a computer-generated random number. Randomization was stratified by hospital, with a block size of 50. A research assistant who had no direct contact with participating mothers was responsible for generating the random numbers and preparing the envelopes. Immediately after the baseline data collection, the nurse opened the sealed envelope and informed the mother of the outcome of randomization.

MASKING

The outcome data were collected at 6 months of age by telephone and at 12 months of age by face-to-face interview in the home. The data collectors and the research staff who dealt with data entry and analysis were masked to treatment allocation.

INTERVENTION GROUP

Four community nurses were recruited and then trained by health promotion practitioners to deliver the staged intervention, which in the first year comprised 1 home visit at 30 to 36 weeks’ gestation and 5 home visits at 1, 3, 5, 9, and 12 months after birth. Those mothers who received the baseline assessment after giving birth received only 5 home visits. The timing of the visits corresponds to milestones in early childhood development, particularly with regard to healthy feeding practice, nutrition, and physical activity, as well as parent-child interactions.

At each visit, the research nurse spent 1 to 2 hours with the mother and infant. The nurse addressed 4 key areas: infant feeding practices, infant nutrition and active play, family physical activity and nutrition, as well as social support. The intervention was developed through a pilot study and was delivered by trained research nurses sequentially in accordance with a protocol (http://www.healthybeginnings.net.au/).

Each visit involved standard information with key discussion points for each key area and appropriate resources to reinforce the information. A checklist for each visit was developed to ensure all information was covered. The intervention resources promoting breastfeeding, appropriate timing of introduction of solids, tummy time and active play, as well as family nutrition and physical activity were developed on the basis of the Infant Feeding Guidelines for Health Workers,16 the Australian National Health and Medical Research Council Dietary Guidelines,17 the Australian Guide to Healthy Eating,18 and the...
National Physical Activity Guidelines. The key intervention messages included “breast is best”; “no solids for me until 6 months”; “I eat a variety of fruits and vegetables every day”; “only water in my cup”; and “I am part of an active family”.

CONTROL GROUP
Families in the control group received the usual childhood nursing service, comprising 1 home visit within a month of birth if needed. Additional visits at baseline and 12 months were conducted by a research assistant for the purpose of data collection only.

OUTCOME MEASURES
The primary outcome measures were duration of breastfeeding and timing of introduction of solids, as described in the published research protocol. When an infant was 6 months of age, we conducted a structured short telephone interview to collect information about the duration of breastfeeding and introduction of solids. For example, mothers were asked, “Is [child’s name] currently being breastfed?” If they answered no, they were further asked, “Including time of weaning, what is the time ‘child’ was breastfed?” Mothers were also asked, “At what age was ‘child’ first given solid foods regularly?” The questions on breastfeeding and timing of solids’ introduction have been described in detail elsewhere. These questions were also asked at 12 months of age.

In this study, the term breastfeeding refers to a child receiving breast milk regardless of whether other solid foods or liquids are also being received. Exclusive breastfeeding refers to a child receiving only breast milk and no other liquids or solid foods, with the exception of drops, ie, syrups consisting of vitamins, mineral supplements, or medicines.

For tummy time, a secondary outcome, mothers were asked at the 6 months’ survey, “How often does ‘child’ spend time on his/her tummy when he/she is awake?” and “At what age did ‘child’ start spending time on his/her tummy when he/she was awake?”

Other secondary outcomes including cup usage, bottle at bedtime, and food for reward were collected by face-to-face interview at 12 months. These questions were selected from the New South Wales Child Health Survey15 and the Childhood Asthma Prevention Study.22

SOCIODEMOGRAPHIC CHARACTERISTICS
At baseline, we collected sociodemographic data including age, employment status, educational level, marital status, language spoken at home, and country of birth of mothers, using the standard New South Wales Health Survey questions.23

ANALYSIS
All statistical analyses were by intention to treat and were performed using SPSS, version 18. Proportions were compared between intervention and control groups using Pearson χ² tests or Mantel-Haenszel χ² tests for trend when appropriate.

Survival analysis was used to compare breastfeeding duration for the intervention and control groups. Kaplan-Meier curves were used to estimate median breastfeeding time and were compared between the groups using the log-rank test. The survival curves were plotted using the computer package Stata, version 10 (StataCorp, College Station, Texas). The estimated hazard ratio for stopping breastfeeding in the intervention group compared with the control group was calculated using Cox proportional hazards regression. To test whether the effect of the intervention differed between subgroups, we added an interaction between treatment group and subgroup to this Cox model.

Of the 667 participating mothers, 337 were randomized to the intervention and 330 to the control group (Figure 1). The mean (SD) age of mothers was 26.0 (5.5) years (range, 16–47 years). Most of the mothers (87.3%) were either married or living with their de facto partner. Twenty-four percent had completed tertiary education, 10.8% spoke a language other than English at home, 20.7% were unemployed, and 31.2% had a household income before tax of less than A$40,000 per year (equivalent to US$). The characteristics of participating mothers are shown in Table 1.

A total of 106 participating mothers were lost to follow-up at 6 months and an additional 34 at 12 months. Of the 140 lost to follow-up, 69 were from the intervention group and 71 from the control (Figure 1). Those lost to follow-up were significantly younger and less educated and were more likely to be unemployed or have low income (Table 1). The main reasons for loss to follow-up were as follows: could not be contacted (67.8%), moved out of the area (14.2%), no longer interested (8.9%), too busy (4.0%), and illness or death (5.0%). This was similar across both groups.

We were unable to complete the baseline assessment and randomization before birth, as planned, for 190 women (93 in the intervention group and 97 in the control group). There was no significant difference between these 190 and the 337 who were assessed and randomized before birth (175 in the intervention group and 162 in the control group) for any of the characteristics shown in Table 1. Of the 268 participating mothers remaining in the intervention group at 12 months, 34.7% received 5 home visits after giving birth and 33.3% received 6 home visits, including an antenatal visit.

PRIMARY OUTCOMES
Breastfeeding rates were significantly higher in the intervention group than in the control group at both 6 and 12 months (42.2% vs 32.1% and 21.0% vs 14.9%, respectively) (Figure 2). At 12 months, the median breastfeeding duration was 17 weeks (95% confidence interval [CI], 13.9–20.4 weeks) in the intervention group compared with 13 weeks (95% CI, 10.1–15.6 weeks) in the control group (P = .03, log-rank test). Compared with the control group, the hazard ratio for stopping breastfeeding in the intervention group was 0.82 (95% CI, 0.68–0.99).

We performed a post hoc subgroup analysis to examine whether the effect of the intervention differed between those who received it antenatally and those who first received it after giving birth; the test for interaction gave P = .09 (likelihood ratio test). Figure 3 and Figure 4 show the survival curves for breastfeeding for the intervention and control groups stratified by whether the mothers were randomized before or after giving birth. For mothers who had an antenatal intervention, the intervention effect on breastfeeding was significant (P = .009)
and appeared early, at around 2 weeks, with a 25% reduced risk of stopping breastfeeding in the intervention group (hazard ratio, 0.75 [95% CI, 0.60-0.93]). For mothers without the antenatal intervention, the intervention effect appeared later, at approximately 12 weeks, and was not significant during the entire year (hazard ratio, 0.96 [95% CI, 0.74-1.24]; \( P = .74 \)).

The intervention also resulted in a significantly later introduction of solids (\( P < .001 \) for trend), reducing the proportion of mothers who introduced solids before 6 months by 12% (95% CI, 4%-20%), from 74% to 62%.

SECONDARY OUTCOMES

The intervention also decreased the proportion of mothers using food for reward by 7% from 25% to 18% (\( P = .04 \)) and increased the proportion of children drinking from a cup by 7% from 85% to 92% (\( P = .01 \)), as well as reduced the proportion of children needing a bottle to go to bed by 9% from 44% to 33% (\( P = .04 \)) (Table 2).

The intervention also decreased the age at which infants started tummy time (\( P = .03 \) for trend) and increased daily practice of tummy time by 7% from 76% to 83% (\( P = .05 \)) (Table 2).

COMMENT

In this study we found significant improvements in duration of breastfeeding, appropriate timing of introduction of solids, and practice of tummy time among those receiving the home-based intervention. The intervention also significantly decreased the proportion of mothers using food for reward, significantly increased the proportion of children drinking from a cup, and decreased the proportion of children needing a bottle to go to bed.
Whether these positive differences in feeding practices will lead to prevention of early onset of childhood obesity remains to be tested at 2 years.

The intervention effect on duration of breastfeeding is consistent with the findings from a systematic review that concluded that additional professional support was effective in prolonging breastfeeding, but its effects on exclusive breastfeeding were less clear.23 Our study further suggests the intervention needs to start during the antenatal period to have an early and maximal intervention effect. The timing of delivery of support for breastfeeding is important and should be considered when planning interventions. This fact might explain why a recent United Kingdom trial that recruited infants at approximately 10 weeks of age found that a social support intervention did not have any effect on duration of breastfeeding.25 Our study further suggests the intervention needs to start during the antenatal period to have an early and maximal intervention effect. The timing of delivery of support for breastfeeding is important and should be considered when planning interventions. This fact might explain why a recent United Kingdom trial that recruited infants at approximately 10 weeks of age found that a social support intervention did not have any effect on duration of breastfeeding.25 A combination of antenatal and postnatal breastfeeding interventions is recommended in increasing the rates of both intermediate and long-term breastfeeding.26 However, our current intervention did not show an effect of the intervention on exclusive breastfeeding at 6 months. Very few mothers (3.8%) followed the recommended duration of exclusive breastfeeding to 6 months. Maternal lack of understanding of recommended duration and misinterpretation of infant cues and behaviors may partially explain this.28

An important aspect of the intervention design was to ensure consistency of health information on breastfeeding and introduction of solids using updated recommendations. The feedback from the research nurses who delivered the intervention suggested mothers were exposed to many inconsistent messages, particularly in relation to timing of introduction of solids. As a result, most mothers (67.7%) introduced solids to their infants at 4 to 5 months instead of 6 months. Our finding that the intervention resulted in significant improvement in appropriate timing of introduction of solids has important implications for improving infant feeding practices because, to our knowledge, no previous intervention studies have been conducted specifically on this issue.

It should be noted that the optimal timing of introduction of solids is still in discussion. A recent study suggests that late introduction of solid foods may increase the risk of allergic sensitization.29 However, a 2009 review that took into account all aspects of health confirmed the recommended duration of exclusive breastfeeding and age of introduction of solids to be 6 months but not later.30

Current national infant feeding guidelines state that infants from 6 months of age should be introduced to drinking from a cup and that use of a bottle should be actively discouraged after the age of 1 year.16 However, we found a substantial proportion (39.1%) of children at 12 months were taking a bottle to bed. This supports a call to encourage the use of a cup at an earlier age and to discourage the use of a feeder bottle.31 The intervention effect on using a bottle was consistent with a previous study.28

Despite the benefits of tummy time,11,12 we found that approximately a quarter of mothers in our study did not practice tummy time daily with their child. The intervention decreased the age at which infants started tummy time and modestly increased the daily practice of tummy time. To our knowledge, this is the first time that an intervention effect of this kind has been reported.

To our knowledge, this is the first randomized controlled trial to test the effectiveness of an early-childhood obesity intervention in the first 2 years using a home-based early intervention designed to improve infant feeding practices and family and behavioral risk factors for childhood obesity. The intervention was conducted in some of the most socially and economically disadvantaged areas of Sydney. It was built on evidence supporting the use of sustained home visiting programs to improve several child and parent outcomes associated with health and behavior problems.32-34 The trial had a relatively large sample size and moderate to high follow-up rates at 6 and 12 months for both groups. The main outcome measures were assessed using well-developed and widely used population survey tools.

However, the study has a number of limitations. First, effects of the intervention on traditional service delivery models and comparisons of cost-effectiveness vs health benefits of a large-scale intervention are unknown and worthy of further investigation. Second, we were not able to fully address the many social, cultural, economic, and environmental factors that may influence early infant feeding practice. Third, the effect of this intervention on infant weight gain remains unanswered. Fourth, generaliz-
ability may be limited because of the locality of the study area and the significantly greater loss to follow-up of younger, poorer, and less educated mothers. In addition, measurements of breastfeeding at 6 and 12 months are subject to recall bias, because some mothers discontinued breastfeeding before either data collection time point.

In conclusion, the early onset of childhood overweight and obesity requires health promotion intervention programs to commence as early as possible and to be family-focused. A home-based intervention through multiple home visits in addressing the risk factors for childhood obesity could be effective in improving infant feeding practices, including longer duration of breastfeeding, delayed introduction of solids, and increased usage of a cup, and in improving practice of tummy time. To be effective, the breastfeeding intervention should start before birth. Whether this intervention has any lasting effects will need to be further tested.

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Table 2. Comparison of Infant Feeding Practices and Tummy Time Between the Intervention and Control Groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Total</th>
<th>Intervention</th>
<th>Control</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At the 6-mo survey&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exclusively breastfed&lt;sup&gt;b&lt;/sup&gt;</td>
<td>543</td>
<td>266 (95.7)</td>
<td>277 (97.9)</td>
<td>.14</td>
</tr>
<tr>
<td>Yes</td>
<td>514</td>
<td>253 (98.6)</td>
<td>261 (97.4)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>13 (4.3)</td>
<td>6 (2.1)</td>
<td></td>
</tr>
<tr>
<td>Introduction of solid food regularly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤4 mo</td>
<td>123</td>
<td>49 (17.7)</td>
<td>74 (26.1)</td>
<td>&lt;.001&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>5 mo</td>
<td>256</td>
<td>121 (43.7)</td>
<td>135 (47.8)</td>
<td></td>
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<tr>
<td>6 mo</td>
<td>181</td>
<td>107 (38.6)</td>
<td>74 (26.1)</td>
<td></td>
</tr>
<tr>
<td>Age of starting tummy time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;4 wk</td>
<td>301</td>
<td>162 (58.3)</td>
<td>139 (49.1)</td>
<td></td>
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<tr>
<td>4-8 wk</td>
<td>155</td>
<td>62 (22.3)</td>
<td>73 (25.8)</td>
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<tr>
<td>&gt;8 wk</td>
<td>125</td>
<td>54 (19.4)</td>
<td>71 (25.1)</td>
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<tr>
<td>Frequency of tummy time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not daily</td>
<td>115</td>
<td>48 (17.3)</td>
<td>67 (23.9)</td>
<td>.05</td>
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<tr>
<td>Daily</td>
<td>442</td>
<td>229 (82.7)</td>
<td>213 (76.1)</td>
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<tr>
<td>At the 12-mo survey&lt;sup&gt;d&lt;/sup&gt;</td>
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<td></td>
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<td>Food for reward</td>
<td>405</td>
<td>216 (64.1)</td>
<td>189 (75.0)</td>
<td>.04</td>
</tr>
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<td>No</td>
<td>109</td>
<td>46 (17.6)</td>
<td>63 (25.0)</td>
<td></td>
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<tr>
<td>Drinking from a cup</td>
<td>62</td>
<td>22 (8.2)</td>
<td>40 (15.4)</td>
<td>.01</td>
</tr>
<tr>
<td>No</td>
<td>465</td>
<td>246 (69.8)</td>
<td>219 (84.6)</td>
<td></td>
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<tr>
<td>Yes</td>
<td>118</td>
<td>56 (15.9)</td>
<td>62 (19.4)</td>
<td></td>
</tr>
<tr>
<td>Having a bottle to go to bed</td>
<td>321</td>
<td>175 (54.3)</td>
<td>146 (56.4)</td>
<td>.04</td>
</tr>
<tr>
<td>No</td>
<td>206</td>
<td>93 (28.7)</td>
<td>113 (43.6)</td>
<td></td>
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<tr>
<td>Yes</td>
<td>115</td>
<td>56 (17.1)</td>
<td>59 (20.9)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>n=561.
<sup>b</sup>Only breastmilk and no other liquids or solid foods with the exception of drops, ie, syrups consisting of vitamins, mineral supplements, or medicines.
<sup>c</sup>P value for trend.
<sup>d</sup>n=527.

REFERENCES
