Pediatrician-led Motivational Interviewing to Treat Overweight Children: An RCT

WHAT’S KNOWN ON THIS SUBJECT: Obesity and overweight can seriously affect health outcomes. Many obesity prevention interventions have been proposed, but few have been effective. Motivational interviewing in primary care seems promising, but results in BMI control are controversial and require further investigation.

WHAT THIS STUDY ADDS: This is the first study to demonstrate the effectiveness of pediatrician-led motivational interviewing for BMI control in overweight children aged 4 to 7 years. Nevertheless, no effect was observed in boys or when the mother’s education level was low.

abstract

OBJECTIVE: The aim of this study was to evaluate the effect of family pediatrician–led motivational interviews (MIs) on BMI of overweight (85th ≥BMI percentile ≥95th) children aged 4 to 7 years.

METHODS: All the family pediatricians working in Reggio Emilia Province (Italy) were invited to participate in the study; 95% accepted. Specific training was provided. Parents were asked to participate in the trial if they recognized their child as overweight. Children were individually randomly assigned to MIs or usual care. All children were invited for a baseline and a 12-month visit to assess BMI and lifestyle behaviors. The usual care group received an information leaflet, and the intervention group received 5 MI family meetings. The primary outcome was the individual variation of BMI, assessed by pediatricians unblinded to treatment groups.

RESULTS: Of 419 eligible families, 372 (89%) participated; 187 children were randomized to MIs and 185 to the usual care group. Ninety-five percent of the children attended the 12-month visit. The average BMI increased by 0.49 and 0.79 during the intervention in the MI and control groups, respectively (difference: −0.30; P = .007). MI had no effect in boys or in children whose mothers had a low educational level. Positive changes in parent-reported lifestyle behaviors occurred more frequently in the MI group than in the control group.

CONCLUSIONS: The pediatrician-led MI was overall effective in controlling BMI in these overweight children aged 4 to 7 years, even though no effect was observed in male children or when the mother’s education level was low. Pediatrics 2013;132:e1236–e1246

AUTHORS: Anna Maria Davoli, MD,a Serena Broccoli, PhD,b Laura Bonvicini, MSc,b Alessandra Fabbri, MD,ε Elena Ferrari, MD,ε Stefania D’Angelo, MSc,ε Annarita Di Buono, MD,ε Gino Montagna, MD,ε Costantino Panza, MD,ε Mirco Pinotti, MD,ε Gabriele Romani, MD,ε Simone Storani, PhD,ε Marco Tamelli, PhD,ε Silvia Candela, MD,b and Paolo Giorgi Rossi, PhDb

4Primary Care Pediatrician, 6Epidemiology Unit, 7Public Health Nutrition Unit, and 8Primary Health Care, Local Health Authority, Reggio Emilia, Italy; 9MRC Lifecourse Epidemiology Unit, University of Southampton, Southampton General Hospital, Southampton, United Kingdom; and 10Promotion Health Researchers, League Against Cancer, Reggio Emilia, Italy

KEY WORDS
BMI, motivational interview, overweight children, pediatrician, randomized controlled trial

ABBREVIATIONS
ΔBMI—BMI score variation
CI—confidence interval
MI—motivational interview
PA—physical activity
RE—Reggio Emilia

(Continued on last page)
Obesity is 1 of the leading causes of morbidity and mortality in the industrialized world, with being overweight and obese during childhood having well-documented short- and long-term physical and psychosocial health implications. Obesity in children is recognized as a complex, multifactorial problem. Weiss et al discussed a "toxic obesity-inducing environment" that should be counteracted through family-, school-, and community-based interventions. There is general agreement that the damage and the cost of remedies increase with age, and that efforts should concentrate on early childhood obesity prevention. Furthermore, interventions should target the widest possible range of population groups because the lowest socioeconomic groups are the most likely to suffer from the problem but are also the most difficult to reach. Primary care providers and family pediatricians, in particular, may be an effective point of contact for early prevention, but their involvement is not so obvious. In fact, screening and tracking BMI percentile according to age and encouraging healthy nutrition and physical activity (PA) are recommended but are not universally delivered in pediatric care. Although most pediatricians want to prevent obesity, few believe there are any effective treatments once a child is overweight. Practitioners often rely on their professional judgment or on adult diagnostic criteria to identify pediatric obesity because they are unaware of, or lack access to, the appropriate diagnostic tools and guidelines. There is evidence, however, that pediatricians who attended continuing medical education courses on obesity were more likely to use BMI-percentiles and had higher self-efficacy in practices related to childhood and adolescent overweight and obesity.

Systematic reviews have found strong evidence that childhood obesity prevention programs can reduce BMI, particularly those programs targeting children aged 6 to 12 years compared with those targeting teenagers. They have also shown that a behavioral approach to changing lifestyle in children or multisetting strategies can produce significant and clinically meaningful weight reduction in children compared with standard care or self-help. Some studies also highlight the need to pay attention to parental influence, especially for younger children, as parents are sometimes unconcerned about their child's weight status and they may not believe that excess weight gain can negatively affect their child's health. Expert Committee recommendations suggest the use of patient-centered counseling techniques such as motivational interviewing, which helps families identify their own motivation for making changes. The US Preventive Services Task Force recommends screening children aged ≥6 years for obesity and referring to behavioral interventions. The task force found that effective comprehensive weight-management programs incorporated counseling and other interventions that targeted diet and PA. Despite the strength of the recommendations in guidelines, many studies found small or no impact of motivational interviews (MIs) on BMI or obese children. Therefore, it is still necessary to test the effectiveness of the interventions in any context, when possible by using randomized controlled trials. Based on the available literature, we developed a family pediatrician-led MI targeting diet and PA behaviors to control BMI in overweight children aged 4 to 7 years. Obese children were referred to specialized care. The objective of the current paper was to present the results of an individually randomized trial designed to evaluate the effect of the MI intervention on BMI.

**METHODS**

**Study Design and Study Setting**

We conducted an individually randomized controlled, parallel-group trial in the province of Reggio Emilia (RE), Italy, from June 2011 to June 2012. The RE Province had a resident population of 530,543 on January 1, 2011; 15.2% were children 0 to 14 years old, assisted by 82 public health service family pediatricians. Routine visits are scheduled yearly up to age 6 years and then every 2 years until age 14 years for all children. In 2010, the estimated prevalence of overweight children was 22%. 

**Participants**

During 2010, all pediatricians of the RE Province opportunistically screened children aged 3 to 14 years for BMI and identified 7,396 overweight and obese children (13% of the resident population; 22% of the children scheduled for a visit in that target age group according to guidelines (yearly visits up to age 6 years and then a visit every 2 years)). In June 2011, a maximum of 12 overweight children (based on the 2010 survey results) for each pediatrician who agreed to participate in the study were randomly selected for eligibility assessment by the Epidemiology Unit. Pediatricians scheduled baseline visits for children aged 3 to 14 years for BMI and assisted by that pediatrician for at least 12 months. Exclusion criteria were metabolic pathologic conditions and all pathologic conditions related to obesity and overweight. Moreover, those families who did not consider childhood overweight a problem and were not interested in the negative consequences or in advice on how to lose weight (families in the “precontemplation stage”) were also excluded. Propensity was assessed through a standardized grid investigating 4 topics: health behaviors, general dietary...
hhabits, specific dietary habits, and PA. Only those who demonstrated no interest in changing with regard to any of these topics were excluded. The study protocol was approved by the local ethics committee, and the parents provided written informed consent for participation.

**Randomization**

Eligible children whose parents signed the informed consent form were centrally allocated to intervention or control groups according to a randomization list created by the Epidemiology Unit by using the package RALLOC (Stata version 11.0; Stata Corp, College Station, TX).

Due to the practical constraints of a maximum of 3 treated children per pediatrician, different allocation rules were used according to the number of eligible children. To balance allocation within strata, observations were opportunely weighted (Appendix). Each pediatrician was informed of the group allocation by means of a corporate Intranet Web form customized for the trial (Supplemental Tutorial).

**Interventions**

Before enrollment began, all pediatricians attended a 4-hour training course on how to accurately measure weight and height and how to calculate BMI percentile, as well as a 20-hour training course on MI conducted by specialized psychologists from “Luoghi di Prevenzione,” the regional reference center for training in health promotion. Participating pediatricians attended all of the training hours.

During the baseline visit, a pre-intervention questionnaire on dietary habits and PA was individually administered to all children and their parents (Supplemental Instrument Q1). Weight, height, BMI and BMI percentile, and additional variables relating to sociodemographic characteristics of children and parents were also collected. The same information was collected at a final visit 12 months after the intervention.

For masking purposes, children who were randomly assigned to the control group received a booklet with the main information on obesity prevention. During the year of intervention, they received the usual care currently offered by pediatricians to overweight children (ie, opportunistic advice if the pediatrician is seeing the child for other reasons).

A family pediatrician–led MI was offered to children assigned to the intervention group consisting of 5 individual meetings based on the transtheoretical model of addiction and behavior change (Table 1). The child and parents always had to leave the meeting having agreed on 2 objectives (1 concerning food and 1 concerning PA improvements) that were clearly defined and achievable. During each subsequent interview, the degree of achievement of the objectives set at the previous meeting was assessed; the objectives were then reinforced or redefined and recorded accordingly (tools used in MIs in Supplemental Instruments A–E).

**Outcomes**

The primary outcome was the individual BMI score variation ($\Delta$BMI), as suggested by Cole et al. BMI score was calculated as the weight (kilograms) divided by the square of height (meters). The $\Delta$BMI was calculated as the within-child difference between BMI score at 12 months and at baseline. BMI $z$ scores and changes from overweight status to normal weight or obesity were also reported to allow comparability with previous studies.

Secondary outcomes were the percentage of positive changes in parent-reported dietary behaviors and in PA. These factors were measured by using the questionnaire. Both primary and secondary outcomes were assessed by the pediatricians without any blinding.

**Sample Size**

To detect a between-group difference in $\Delta$BMI of at least 0.5 with a 5% significance level and a power of 90%, assuming an SD of $\Delta$BMI of 1, a sample size of 85 children per group was necessary. Considering a 30% dropout rate, recruitment of at least 110 children per arm was planned.

**Statistical Methods**

To perform an intention-to-treat analysis for the primary objective, missing values for $\Delta$BMI were replaced with the mean variation of BMI calculated in the control group. All inferential analyses were performed by using weights to balance allocation within strata (Appendix). Mean BMI and BMI $z$ scores with relative 95% confidence intervals (95% CIs) are presented. Differences in the $\Delta$BMI between the intervention and control groups were analyzed by using the nonparametric Wilcoxon-Mann-Whitney test because outcome was not normally distributed.

The difference between the control and intervention groups in the final distribution of healthy weight (5th $\leq$BMI percentile $\leq$84th), overweight (85th $\leq$BMI percentile $\leq$94th), and obese (BMI percentile $\geq$95th) was tested with $\chi^2$ for linear trend.

Multilevel linear models were performed to test the influence of pediatricians on intervention effectiveness. Two multilevel models (children, pediatricians) were specified: random intercept and random intercept and slopes. The intraclass correlation coefficients are reported with the likelihood ratio tests to compare the models.

Post hoc subgroup analyses according to children’s age, gender, and maternal education level are also reported. We report the significance of the F statistic obtained comparing the regression models with and without interaction. Differences between intervention and control groups in changes in parent-
reported PA and parent-reported dietary habits were tested by using the Wilcoxon rank sum test. The statistician was not blinded to group assignments. The statistical significance level was set at 5%, and all analyses were performed by using Stata 11.0.46

### RESULTS

Of the 82 pediatricians working in the RE Province in 2010, only 4 declined to participate in the trial; the remaining all completed training for BMI measurement and MI (Fig 1). Children were recruited from June to August 2011. Of the 795 children sampled among those who proved to be overweight according to the 2010 survey, 69 (8.7%) did not attend the eligibility assessment visit. Out of the 726 children who were contacted 307 (42.3%) were not eligible, primarily because either they were no longer overweight (n = 262 [36%]) or because the family was in a pre-contemplative stage (n = 81 [11%]). Of the 419 eligible children, 372 (88.8%) agreed to participate; 187 were randomly allocated to the intervention group and 185 to the control group. A median of 6 children (3 per treatment group) per pediatrician were included.

Of the 372 enrolled children, 95% completed the 2 visits for the control group and 5 visits for the intervention group. The median time between the baseline visit and the 12-month visit was 385 (25th–75th percentile: 355.5–396) days in the intervention group and 384 (25th–75th percentile: 358–396.5) days in the control group. Baseline characteristics of children and pediatricians are presented overall and according to study group (Table 2, Supplemental Table 7). The baseline characteristics of the children who did not complete the study did not differ from those who did complete the study.

### TABLE 1 Description of the MI and Control Procedures Adopted During the Trial

<table>
<thead>
<tr>
<th>Time</th>
<th>Meeting</th>
<th>Objective</th>
<th>Duration</th>
<th>Instrumentsa</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>Baseline</td>
<td>To negotiate 2 objectives: changes in diet and PA, respectively</td>
<td>15 min</td>
<td>Q</td>
</tr>
<tr>
<td>2nd</td>
<td>MI</td>
<td>To assess the degree of achievement of the negotiated objectives</td>
<td>45/60 min</td>
<td>A–B–C</td>
</tr>
<tr>
<td>3rd</td>
<td>After 1 mo</td>
<td>To reinforce or redo negotiated objectives</td>
<td>30 min</td>
<td>D–E</td>
</tr>
<tr>
<td>4th</td>
<td>After 3 mo</td>
<td>To reinforce or redo negotiated objectives</td>
<td>45/60 min</td>
<td>D–E</td>
</tr>
<tr>
<td>5th</td>
<td>1 y After Baseline</td>
<td>To reinforce or redo negotiated objectives</td>
<td>45 min</td>
<td>D–E</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Final strength of objectives</td>
<td></td>
<td>B</td>
</tr>
</tbody>
</table>

*Supplemental Instruments: Q, parent-reported diet and PA habits questionnaire named “Eating Habits of Children Ages 4 to 7”; A, table for the assessment of family readiness to change their lifestyle (Motivational Diagnosis); B, readiness-to-change graph; C, decisional balance; D, risk factors and protective factors of negotiated changes; E, “Food and Emotions.”
Primary Outcome

There was a significant difference in $\Delta$BMI between the intervention and control groups ($P = .007$) (Table 3). According to standardized growth charts, the expected variation of BMI score in 12 months for overweight (90th BMI percentile) 6-year-olds is 0.60 for male subjects and 0.70 for female subjects; these data are similar to the control group results (0.79 [95% CI: 0.61–0.97]). The proportion of the pediatrician-level variance on the overall variation in $\Delta$BMI (intraclass correlation coefficient) was 7.73%. The mean $\Delta$BMI in the control group was significantly different across pediatricians (likelihood ratio test – random-intercept versus linear-regression model: $\chi^2[2] = 8.63$, $P = .013$). The effectiveness of MI did not vary significantly across pediatricians (likelihood ratio test – random-intercept and slopes versus random-intercept model: $\chi^2[2] = 0.86$, $P = .645$).

The MI effect on $\Delta$BMI was stronger in girls (interaction test $P = .072$), whereas there was almost no effect in
boys. The interaction was even stronger for mother’s education level (interaction test \( P = .008 \)); for children whose mother’s education level was low, we observed a slightly non-significant, negative effect. The effect was homogeneous in children aged <6 years and \( \geq 6 \) years (Table 5).

### Secondary Outcomes

Compared with controls, children in the intervention group strongly increased nonorganized parent-reported PA and slightly decreased parent-reported time spent watching television (Table 6, Supplemental Fig 2).

Concerning parent-reported dietary habits (Table 6, Supplemental Fig 3), many more positive changes were observed in the intervention group than in the control group with regard to salty snacks, desserts, sweet snacks or candies, and sweetened drinks, and, to a lesser extent, for consumption of vegetables, vegetable soups, and fried food.

### DISCUSSION

Children who received MI had a significantly lower increase in BMI than did the control group; BMI increased on average by 0.49 in the intervention group and by 0.79 in the control group. MI was more effective among girls and was not effective among those children.
whose mothers had a low level of education. As shown by the BMI z scores, an increase in BMI does not imply a negative result because from ages 6 to 7 years, BMI curves increase.34,41

To our knowledge, only a few studies have evaluated the efficacy of MI conducted in the primary care setting in preventing obesity.27,28 and none has found a positive effect on BMI outcome. The main limits declared by authors include short program duration (<12 months),21,26 high drop-out rates,21,22,25 nonrandomized or clustered randomized designs,21,22,25 and the absence of a “standard care only” group.26 Our study overcomes these limits; the program lasted 12 months, there was excellent compliance (95.4%), and it was a population-based, individually randomized trial. Patrick et al23 found limited effects of a primary care and home-based MI intervention among a group of generally healthy (not only overweight) adolescents. Conversely, a subsequent study suggested that a primary care–based MI was effective in preventing obesity in children aged 2 to 6 years; Taveras et al22 found a small (not significant) effect on BMI in the whole population (−0.21; P = .15), with a significant effect among girls (−0.38; P = .03). Unlike the current study results, they found that the intervention was more effective in low-educated and low-income families. The low mean age of the enrolled children (4.9 years), the fact that counseling was conducted by pediatric nurses, and that 3 of the 7 interviews were conducted via telephone are the main differences compared with our study.

Other types of interventions conducted in the primary care setting have been demonstrated to be feasible but not effective, at least not regarding the BMI outcome.42 Only Keller et al43 found that a low threshold intervention in children aged 4 to 7 years at risk for obesity conducted at home by pediatricians stabilized the BMI of treated children. The BMI of children randomized in the intervention group who were not interested in participating and the BMI of children in the control group increased over the 1-year observation period. Programs that include individual MI not conducted by health care workers have not been effective in reducing BMI in female teenagers.31,44

Analyzing the secondary outcomes, we can argue that the effect of MI on BMI control is due to the impact of the treatment on the children’s lifestyle. In fact, the parent-reported eating habits and parent-reported PA of treated children also improved, confirming the hypothesized causal chain.

Nevertheless, the variations in BMI score did not correspond to a significant increase in the percentage of healthy-weight children. The clinical relevance of such a reduced increase in BMI should be assessed; we know that there is a dose-response relation between BMI in childhood and the risk of obesity and diabetes in adulthood,45,46 and we can assume that any difference in BMI implies a difference in health outcomes. However, the clinical relevance of a reduction in 1-year BMI increase of 0.30 is not obvious. A Cochrane Review44 considered the estimated BMI reduction of 0.15, calculated in predominantly non-overweight children aged 6 to 12 years, a “small but clinically important shift in population BMI.”

Our study had several strengths as well as some limitations. Compliance to the 1-year intervention was high, even for a population-based study involving almost all the pediatricians in the RE Province and a relevant sample of their overweight patients. Therefore, this is a pragmatic trial, in which efficacy matched effectiveness: we measured exactly what should be done when the intervention is implemented as a regular practice; we know that the intervention is sustainable as a regular practice in primary care; and we know that time and costs are compatible with the daily activities of the pediatrician.

All pediatricians received standardized, complete training. Other studies highlighted situations in which pediatricians reported low confidence in their ability to counsel.21,47 In our study, positive feedback came from the health
TABLE 5  ΔBMI According to Children's Age, Gender, Mother's Education Level, and Study Group

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>ΔBMI Intervention</th>
<th>ΔBMI Usual Care</th>
<th>Between-Group Difference in ΔBMI</th>
<th>Interaction Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>95% CI</td>
<td>Mean</td>
<td>95% CI</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>0.77</td>
<td>0.46 to 1.07</td>
<td>0.77</td>
<td>0.44 to 1.10</td>
</tr>
<tr>
<td>Female</td>
<td>0.29</td>
<td>0.05 to 0.54</td>
<td>0.80</td>
<td>0.59 to 1.02</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 y</td>
<td>0.46</td>
<td>0.13 to 0.78</td>
<td>0.77</td>
<td>0.43 to 1.11</td>
</tr>
<tr>
<td>≥6 y</td>
<td>0.50</td>
<td>0.26 to 0.74</td>
<td>0.80</td>
<td>0.59 to 1.01</td>
</tr>
<tr>
<td>Mother's educational level</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;13 y of school</td>
<td>0.86</td>
<td>0.49 to 1.23</td>
<td>0.85</td>
<td>0.33 to 0.97</td>
</tr>
<tr>
<td>13 y of school</td>
<td>0.34</td>
<td>0.13 to 0.56</td>
<td>0.96</td>
<td>0.61 to 1.11</td>
</tr>
<tr>
<td>&gt;13 y of school</td>
<td>-0.20</td>
<td>-0.71 to 0.30</td>
<td>0.84</td>
<td>0.31 to 1.36</td>
</tr>
</tbody>
</table>

TABLE 6  Number (%) of Changes (None, Positive, or Negative) in Parent-Reported PA and Dietary Habits According to Study Group

<table>
<thead>
<tr>
<th>Habit</th>
<th>Pre/Post Intervention Changes</th>
<th>Pre/Post Usual Care Changes</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative</td>
<td>None</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>No. %</td>
<td>No. %</td>
<td>No. %</td>
</tr>
<tr>
<td>PA habits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organized PAc</td>
<td>15</td>
<td>8.6</td>
<td>120</td>
</tr>
<tr>
<td>Nonorganized PAc</td>
<td>22</td>
<td>12.6</td>
<td>91</td>
</tr>
<tr>
<td>Screen timec</td>
<td>14</td>
<td>8.0</td>
<td>126</td>
</tr>
<tr>
<td>Dietary habits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having breakfastc</td>
<td>14</td>
<td>8.1</td>
<td>130</td>
</tr>
<tr>
<td>Fruitc</td>
<td>30</td>
<td>17.2</td>
<td>83</td>
</tr>
<tr>
<td>Vegetablesc</td>
<td>32</td>
<td>18.4</td>
<td>76</td>
</tr>
<tr>
<td>Vegetable soupc</td>
<td>13</td>
<td>7.5</td>
<td>130</td>
</tr>
<tr>
<td>Dessertsc</td>
<td>22</td>
<td>12.6</td>
<td>89</td>
</tr>
<tr>
<td>Fried foodc</td>
<td>17</td>
<td>9.8</td>
<td>117</td>
</tr>
<tr>
<td>Salty snacks/candiesc</td>
<td>18</td>
<td>10.3</td>
<td>110</td>
</tr>
<tr>
<td>Sweetened drinksd</td>
<td>14</td>
<td>8.0</td>
<td>80</td>
</tr>
</tbody>
</table>

* P values represent the probability that the direction of changes is not different in the 2 groups. It has been computed through a Wilcoxon rank sum test comparing the rank of changes in the 2 groups according to the categories (0, 1, 3, 4, 5, 7, 9), daily, more answers in the questionnaire.

a Increases in time spent or consumption are considered positive changes.

b Decreases in time spent or consumption are considered positive changes.

CONCLUSIONS

A family pediatrician–led MI was effective in BMI control for overweight children aged 4 to 7 years. According to the population-based design, the intervention is feasible and affordable. However, further efforts are needed to understand why it is not effective for male subjects and for children whose mothers have less education. Our results, considered in light of the heterogeneity of previous studies, further stress the need to conduct pragmatic trials to test the effectiveness of similar interventions in any social and cultural contexts.

ACKNOWLEDGMENTS

We are grateful to all pediatricians working in the RE Province for their participation in this project. Their work and attention to details contributed to the success of the study. We thank Paola Albertini (Local Health Authority RE) for her support and assistance in providing the corporate Intranet Web form customized for the trial. We are also grateful for the highly constructive comments of the reviewers and the editor.
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Dr Davoli designed the study, coordinated and supervised the pediatricians, and drafted the introduction and discussion of the manuscript; Dr Broccoli contributed to designing the study, coordinated and supervised the first months of data collection, conducted the analyses, and drafted the methods and results of the manuscript; Dr Bonvicini contributed to designing the study, coordinated and supervised the final months of data collection, conducted the analyses, and reviewed and revised the manuscript; Dr Fabbrì contributed to designing the study, supervised the data collection, analyzed the results, and reviewed and revised the manuscript; Dr Ferrari contributed to designing the study, coordinated and supervised the recruitment phase, and collaborated in the pediatricians’ training and study conduct; Dr D’Angelo supervised the final months of data collection and reviewed the manuscript; Dr Di Buono contributed to designing the study, and coordinated and supervised the recruitment phase; Dr Montagna contributed to designing the study, coordinated and supervised the recruitment phase, collaborated in study conduct, and directed the pediatricians’ involvement (pediatricians’ component); Dr Panza contributed to study conception and design, and conducted the preliminary systematic review of the interventions for obesity prevention in children; Dr Pinotti contributed to study conception and directed the pediatricians’ involvement (local health unit component); Dr Romani coordinated the implementation of the intervention and conducted the recruitment phase with pediatricians; Drs Storani and Tamelli contributed to designing the intervention and trained the pediatricians; Dr Candela conceived the study, contributed to designing the study, and reviewed and revised the manuscript; and Dr Giorgi Rossi planned the data analysis, drafted the outline of the manuscript, and critically reviewed and revised the manuscript. All authors approved the final manuscript as submitted.

This trial has been registered at www.clinicaltrials.gov (identifier NCT01822626).

www.pediatrics.org/cgi/doi/10.1542/peds.2013-1738
doi:10.1542/peds.2013-1738
Accepted for publication Aug 23, 2013

Address correspondence to Serena Broccoli, PhD, Epidemiology Unit, Local Health Authority of Reggio Emilia, via Amendola 2, Reggio Emilia, Italy. E-mail: serena.broccoli@ausl.re.it

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).
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FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.
### APPENDIX Allocation Rules, Probability Weights, and Block Size According to Number of Eligible Children

<table>
<thead>
<tr>
<th>Eligible Children</th>
<th>Allocation Rule (Intervention:Control)</th>
<th>Intervention Weight</th>
<th>Control Weight</th>
<th>Block Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1:0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1:1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>2:1</td>
<td>0.75</td>
<td>1.5</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>1:1</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>3:2</td>
<td>0.83</td>
<td>1.25</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>1:1</td>
<td>1</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>3:4</td>
<td>1.17</td>
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<td>1:2</td>
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/content/132/5/e1236.full.html