

## Clinic and Home-Based Behavioral Intervention for Obesity in Preschoolers: A Randomized Trial

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**Objective** To test the hypotheses that an innovative skills-based behavioral family clinic and home-based intervention (LAUNCH) would reduce body mass index z score (BMIz) compared with motivational interviewing and to standard care in preschool-aged children with obesity.

**Study design** Randomized controlled trial with children between the ages of 2 and 5 years above the 95<sup>th</sup> percentile for body mass index for age and sex recruited from 27 pediatrician offices across 10 recruitment cycles between March 12, 2012 and June 8, 2015. Children were randomized to LAUNCH (an 18-session clinic and home-based behavioral intervention), motivational interviewing (delivered at the same frequency as LAUNCH), or standard care (no formal intervention). Weight and height were measured by assessors blinded to participant assignment. The primary outcome, BMIz at month 6 after adjusting for baseline BMIz, was tested separately comparing LAUNCH with motivational interviewing and LAUNCH with standard care using regression-based analysis of covariance models.

**Results** A total of 151 of the 167 children randomized met intent-to-treat criteria and 92% completed the study. Children were 76% White and 57% female, with an average age of 55 months and BMI percentile of 98.57, with no demographic differences between the groups. LAUNCH participants demonstrated a significantly greater decrease in BMIz (mean =  $-0.32$ , SD =  $\pm 0.33$ ) compared with motivational interviewing (mean =  $-0.05$ , SD =  $\pm 0.27$ ),  $P < .001$ ,  $\omega^2 = 0.74$  and compared with standard care (mean =  $-0.13$ , SD =  $\pm 0.31$ ),  $P < .004$ ,  $\omega^2 = 0.75$ .

**Conclusions** In preschool-age children, an intensive 6-month behavioral skills-based intervention is necessary to reduce obesity. (*J Pediatr* 2017;■■■■-■■■).

**Trial Registration** [Clinicaltrials.gov](http://Clinicaltrials.gov) NCT01546727.

Nearly 2 million preschool-aged children in the US meet criteria for obesity,<sup>1</sup> yet there are few published treatment studies targeting this age group.<sup>2</sup> Young children do not “outgrow” obesity. Obesity in the preschool years dramatically increases the risk of being overweight, obese, and even severely obese in later childhood and adulthood.<sup>3-5</sup> There is an association between early onset overweight and increased odds of developing diabetes<sup>6</sup> and asthma.<sup>7</sup> Efficacious treatment of obesity in the preschool years could dramatically change and even reverse this trend.

Despite the need for innovative weight management interventions for younger children, a recent review shows there are few randomized trials targeting weight reduction in preschoolers<sup>2</sup> and only one, a pilot study, targeting preschoolers who are already obese. Focusing solely on children with obesity is important because they are at higher risk for mortality compared with overweight peers.<sup>8</sup> This study examined a novel clinic and home family-based behavioral intervention (learning about activity and understanding nutrition for child health [LAUNCH]),<sup>9</sup> designed to address specific behaviors caregivers report as barriers to establishing and maintaining healthy eating patterns in preschool children,<sup>10</sup> including food neophobia and tantruming for food, through home visits designed to consolidate clinic-taught strategies into the home setting using in vivo practice of these skills. LAUNCH reduced body mass index (BMI) z score (BMIz) significantly more than 1-session counseling by a pediatrician.<sup>9</sup>

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AAP	American Academy of Pediatrics
AEs	Adverse events
BMI	Body mass index
BMIz	BMI z score
LAUNCH	Learning about Activity and Understanding Nutrition for Child Health

Since the publication of the behavioral intervention for preschoolers with obesity, 2 additional studies were published targeting preschoolers above the 85th percentile BMI in the primary care setting. A 6-month family-based behavioral intervention with 18 contacts was found to reduce overweight in this age group<sup>11</sup> compared with an education only control, while in a separate study a 12-month, 7-session motivational interviewing intervention was not found to be more effective than usual care<sup>12</sup> in reducing BMI. Motivational interviewing is one of the recommended treatment approaches by the American Academy of Pediatrics (AAP) Expert Committee on treatment of child and adolescent overweight/obesity<sup>13</sup> and is designed to address barriers of motivation and ambivalence. As parents of preschoolers often do not recognize obesity<sup>14,15</sup> and frequently feel it is unfair to implement changes to their child's diet,<sup>16</sup> motivational interviewing is a credible alternative treatment, addressing parent ambivalence about implementing diet and activity changes for their child.

The objective of this phase III randomized clinical trial ([ClinicalTrials.gov: NCT01546727](https://clinicaltrials.gov/ct2/show/study/NCT01546727)) was to test whether the skills-based behavioral family clinic and home-based intervention (LAUNCH) was superior to motivational interviewing and to standard care. It was hypothesized a priori that preschoolers receiving LAUNCH would have a greater decrease in their BMIz compared with motivational interviewing and standard care at post-treatment. Changes in parent BMI were examined secondarily.

## Methods

Across 10 recruitment periods between March 12, 2012 and June 8, 2015, children and their families were recruited from 27 pediatric practices in the Greater Cincinnati/Northern Kentucky area. The study was approved by the institutional review board at the primary medical center where the study was conducted, and written informed consent was obtained from caregivers. Inclusion criteria were (1) ages 2-5 years; (2) BMI percentile for age and sex  $\geq 95^{\text{th}}$ <sup>17</sup> but no more than 100% above the median BMI; (3) medical clearance from their pediatrician; (4) active patient with anthropometric measurements within the previous year; and (5) living within 50 miles from the medical center. Exclusion criteria included (1) developmental disability or medical conditions known to promote obesity (eg, Prader-Willi syndrome); (2) child enrolled in another weight control program; (3) taking weight-affecting medications (eg, steroids); (4) condition that would preclude full participation in the program; and (5) non-English-speaking.

Introductory letters were sent from the primary care practice with an "opt-out" postcard if families did not want to be contacted for the study. Families not returning the postcard were contacted by study staff. Seven additional practices, belonging to a unified health system whose administrative policies prevented participation in the recruitment procedures described above, were allowed to refer families to the study. Families meeting eligibility screening by phone and interest in study

participation were scheduled for 2 baseline visits, at clinic and home. Children whose families did not complete both baseline visits were not randomized into the study. Intent to treat was defined a priori as being reached for treatment assignment (standard care) and attending the first intervention session (LAUNCH and motivational interviewing).

The study protocol is described in detail elsewhere.<sup>18</sup> The randomization sequence was kept by the study statistician, concealed from study personnel, and was not assigned until all baseline measures were obtained from all children in a recruitment cycle. Child baseline BMIz was used as a stratification variable in a randomized stratification design with randomly chosen blocks of size 6 and 9, equal allocation to the 3 groups within blocks to ensure that BMIz was equivalent across the 3 arms. Beginning with cycle 8, child race/ethnicity was added to the stratification process to ensure equivalence across the 3 arms.

The overall goal of LAUNCH and motivational interviewing was to follow the Expert Committee Recommendations on Prevention, Assessment and Treatment of Child and Adolescent Overweight and Obesity<sup>13</sup> for reducing obesity in preschoolers by either stabilizing or slowing the rate of children's weight gain or to produce a gradual weight loss of 1 lb/month. Both interventions targeted (1) limiting portion size; (2) limiting consumption of energy-dense foods; (3) limiting eating out; (4) consumption of  $\geq 5$  servings of fruit and vegetables per day; (5) minimizing or eliminating sugar-sweetened beverages; (6) limiting screen time to  $\leq 2$  hours per day, and no TV in the room where child sleeps; and (7) achieving  $\geq 1$  hour of moderate to vigorous physical activity per day. All families received \$50 for completing the baseline and 6-month assessments. Beginning at recruitment cycle 7 (where practices were farther from the medical center) families traveling  $\geq 20$  miles were given an additional \$25 to help offset travel costs. Intervention arms are briefly described below and fully elsewhere.<sup>18</sup>

LAUNCH is an 18-session clinic and home family-based behavioral weight management intervention, consisting of a 3-month intensive treatment phase (weekly sessions) followed by a 3-month maintenance phase (every other week sessions). Intervention sessions alternated between clinic (10 sessions) and home (8 sessions) visits.

Parent clinic-based group sessions were 90 minutes each and led by a licensed clinical psychologist. Sessions consisted of education and problem-solving around parent and child diet, dietary and physical activity changes, and child behavior management strategies such as differential attention (eg, ignoring complaints about food, praising trying vegetables), contingency management (eg, rewarding healthy behaviors), limit setting, effective use of time-out to manage tantrums, shaping (eg, gradually introducing change), and exposure to introduce new foods, and implementing stimulus control measures to improve food choices and physical activity. Sessions 1-7 focused on dietary changes (with dietary tracking conducted throughout treatment), Sessions 8-10 focused on changing sedentary and physical activity, and sessions 11-18 focused on bringing all the skills together and problem-solving barriers to recommended lifestyle changes. A simultaneously held

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