Maintenance Following a Randomized Trial of a Clinic and Home-based Behavioral Intervention of Obesity in Preschoolers

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Objective To assess maintenance of improved weight outcomes in preschoolers with obesity 6 and 12 months following a randomized clinical trial comparing a home- and clinic-based behavioral intervention (Learning about Activity and Understanding Nutrition for Child Health [LAUNCH]) to motivational interviewing and standard care.

Study design Randomized controlled trial with children between the ages of 2 and 5 years above the 95th 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, were followed 6 and 12 months post-treatment. Child and caregiver weight, height, and caloric intake, child physical activity, and home environment were assessed. The primary outcome was maintenance of greater reduction of percent over the 50th percentile body mass index (BMI%50th) by LAUNCH compared with motivational interviewing and standard care at the 6- and 12-month follow-up.

Results Significantly lower child BMI%50th was maintained for LAUNCH compared with motivational interviewing at 12-month follow-up and to standard care at the 6-month follow-up; however, the effect sizes were maintained for comparison with standard care at 12-month follow-up. LAUNCH had significantly lower daily caloric intake compared with motivational interviewing and standard care at both follow-ups and maintained significantly fewer high-calorie foods in the home compared with standard care at 6 and 12 months and compared with motivational interviewing at 12 months. However, caloric intake increased by 12% from post-treatment. LAUNCH caregivers did not maintain improved BMI at follow-up.

Conclusions LAUNCH showed success in reducing weight in preschoolers. However, maintaining treatment gains post-treatment is more difficult. Treatment may need to last longer than 6 months to achieve optimal results. *(J Pediatr 2019;213:128-36).*

Trial registration Clinicaltrials.gov: NCT01546727.

Addressing overweight and obesity effectively early in life has the potential to halt the growing obesity epidemic and prevent associated negative health consequences that often present in adolescence and adulthood.[1] Empirical support for interventions during this age range is limited to only 6 weight-management studies using a randomized controlled trial design with preschoolers who were already overweight or obese.[2-7]

Multicomponent, family-based behavioral treatments consistently have demonstrated significant differences between treatment and control conditions.[3,5,6,8] Despite these positive findings, few studies have longer-term data to assess weight status maintenance after treatment ends.[5,9] Our pilot of a family-based, behavioral clinic and home intervention (Learning about Activity and Understanding Nutrition for Child Health [LAUNCH])[3] demonstrated strong maintenance of treatment effects 6 months after treatment with an average body mass index z score (BMIz) difference between LAUNCH and standard care of −0.59 (±0.17).

BMI	Body mass index
BMI%50th	Percent over the 50th percentile BMI
BMI%95th	Percent over the 95th percentile BMI
BMIz	Body mass index z score
LAUNCH	Learning about Activity and Understanding Nutrition for Child Health
MVPA	Moderate-to-vigorous physical activity

The current study examines the maintenance of LAUNCH on weight and secondary outcomes (mechanistic factors of diet and physical activity and environmental factors of parent weight and diet and the home food environment) at the 6- and 12-month follow-up from our large randomized clinical trial comparing LAUNCH for preschoolers with obesity with motivational interviewing and standard care.[8] Since the design of the primary study, several studies have been published indicating that the primary outcome of the trial, BMIz, is less sensitive to reductions in adiposity in populations of children over the 97th BMI percentile due to artificial ceiling effects in the Center for Disease Control and Prevention BMI z scores and compression in variability in z scores across age strata for 2- to 4-year old children.[10] As the average BMI for the participants in our clinical trial was ≥98th percentile, we analyzed our follow-up data using 2 measures of adiposity demonstrated to be more sensitive to change in children above the 97th percentile BMI, percent over the 50th BMI percentile[11] and percent over the 95th BMI percentile[12] for age and sex. Percent over the 50th BMI percentile was chosen as the primary outcome to be comparable with other published weight-management studies with preschoolers.[6,9] BMIz also is presented to be consistent with our original trial design. In addition, we present a reanalysis of our baseline to post-treatment data using percent over the 50th BMI percentile. Based on the maintenance seen in our pilot study,[3] we hypothesized that children receiving LAUNCH would be lower on percent over the 50th BMI percentile compared with children in the motivational interviewing and standard care arms of the trial.

Methods

This study was a randomized controlled trial comparing LAUNCH with motivational interviewing and with standard care. We report the primary and secondary outcomes at the 6- and 12-month follow-up. The previously reported methodology[8,13] is described as follows.

Families of children were recruited through 27 independent pediatric practices and referrals from 7 practices in a unified health system between March 12, 2012, and June 8, 2015, and followed through December 21, 2016. The study was approved by institutional review board at the primary medical center where the study was conducted, and written informed consent was obtained from caregivers. Initial chart reviews were conducted to screen for child inclusion criteria (active patient, aged 2-5 years, and BMI percentile ≥95th) and exclusion criteria (developmental disability, medical condition promoting obesity or condition that precluded full participation, weight affecting medication, enrolled in a weight-management program, or non-English speaking).

Families of children meeting initial screening criteria were sent a letter describing the study and an "opt-out" postcard. Families not returning the opt-out postcard within 10 days were called by study personnel to invite participation and conduct a phone screening for eligibility. Families meeting eligibility and expressing interest were scheduled for clinic and home baseline visits. Only families completing both baseline visits were randomized to a study arm and intent-to-treat was defined a priori as attending the first intervention session (LAUNCH or motivational interviewing) or being reached for treatment assignment (standard care).

Families were recruited in cohorts of 12-18. After all baseline visits were complete for a cohort, children were stratified by BMIz and race/ethnicity and randomized to a study arm by the statistician (see Stark et al[8,13] for additional details). A priori power estimates on our original outcome, BMIz, indicated we would have at least 80% power to detect baseline to posttreatment mean group difference of 0.67 with a sample size of 43 per intervention arm. However, no a priori power was estimated for maintenance of treatment effect or the outcomes presented in this paper, percent over the 50th BMI percentile, and percent over the 95th BMI percentile.

LAUNCH and motivational interviewing were designed to follow the Expert Committee Recommendations[14] for reducing obesity in preschoolers by either stabilizing or slowing the rate of children's weight gain or producing a gradual weight loss of 1 lb/month. On the basis of the Expert Committee Recommendations, both LAUNCH and motivational interviewing targeted: (1) limiting portion size; (2) limiting consumption of energy-dense foods; (3) limiting eating out; (4) consumption of ≥5 servings of fruit and vegetables per day; (5) minimizing or eliminating sugar-sweetened beverages; (6) limiting screen time to ≤2 hours per day, and no TV in room where child sleeps; and (7) achieving ≥1 hour of moderate-to-vigorous physical activity (MVPA) per day. LAUNCH and motivational interviewing were delivered over 18 sessions (weekly in months 1-3; every other week in months 4-6).

LAUNCH was a family-based, behavioral intervention delivered in sessions that alternated weekly between group clinic sessions (90 minutes) at a medical facility and individual home visits (60 minutes). The clinic sessions included simultaneous parent and child groups. Parent-group sessions provided nutrition education, problem-solving around/monitoring of dietary intake for children and parents and physical activity changes, and child behavior-management strategies (across all sessions) 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. Child groups provided nutrition education about healthy eating, opportunities to try new foods during a structured meal, and engagement in MVPA. Home visits were designed to support the generalization of the clinic-taught skills to the home including parenting skills

and changing the home environment. Parent clinic group sessions were conducted by a PhD-licensed psychologist. The child group and home visits were conducted by a post-doctoral fellow in pediatric psychology or nutrition.

Motivational interviewing was conducted with care-givers and targeted improvement in the child's dietary and activity behaviors. At the first visit, caregivers met with a pediatrician trained in motivational interviewing, at which time they completed questionnaires to assess their values and motivation for change and were given informa-tion about their child's weight and BMI percentile and a packet of publicly available materials/brochures from the American Academy of Pediatrics "Let's Go" program. Following the tenets of motivational interviewing, care-givers were asked about their concern with their pre-schoolers' weight, diet, and physical activity and asked about their desired child outcome, motivation, and confi-dence to make changes in any area of concern. If receptive, they were asked to select a nutrition or physical activity behavior as a primary target of discussion from a menu of the American Academy of Pediatrics recommendations and the "Let's Go" materials. Subsequent motivational in-terviewing intervention sessions were delivered by a licensed clinical psychologist trained in motivational inter-viewing in either the family's home (3 sessions) or over the telephone (14 sessions). These sessions consisted of a dis-cussion of previous goals selected by the caregiver, explora-tion of the caregiver's perception of their success in reaching these goals, determination of caregiver's confi-dence and willingness to continue working on existing goal(s) vs establishing new behavioral goals, enhancement of motivation to address ambivalence and readiness to change behaviors in the caregivers, and identification of self-selected strategies for goal attainment.

Participants in the standard care group received routine care from their pediatrician and were only seen by the study team at the assessment visits.

All participating families received $50 to offset costs associated with completing each assessment visit at base-line, 6 months (postintervention), and 6 and 12 months post-treatment. Recruitment cycles 7 and later were located further from the medical center where visits took place, and thus, families traveling ≥20 miles to complete assessment visits were given an additional $25 to help offset travel costs.

Anthropometrics

Caregiver and child weight and height were collected at base-line (caregiver height only assessed at baseline), postinterven-tion (6 months), and follow-up (6 and 12 months post-treatment) following a standard protocol by assessors who were unaware of the participants' treatment assignment as previously described.[8] Percent over the 50th (BMI%50th) and over the 95th BMI (BMI%95th) percentiles and absolute weight gain were calculated, with BMI%50th as the primary outcome. To be consistent with our original trial design and pre-post outcomes paper, BMIz also was calculated.

Secondary Outcomes

Secondary outcomes included mechanisms hypothesized to be associated with reduction in adiposity including child di-etary intake, physical activity, their environment including home food environment and presence of a TV in their bedroom, and parent dietary intake. Measures are briefly described here (for complete description see Stark et al[13]). Child dietary intake was assessed via three 24-hour recalls with caregivers. Physical activity was assessed using Acti-Graph accelerometer (model GT3X+; ActiGraph, Pensacola, Florida). The home food environment was assessed via a direct observation measure developed in our previous studies,[3,15] where the availability of fruits, vegetables, bever-ages (high-calorie/low-nutrient were defined as red bever-ages), and high-calorie/low-nutrient foods (defined as red foods) were recorded. This measure also included assessment of whether a TV was present in the child's bedroom. Parent dietary intake was assessed via the Block Food Frequency Questionnaire.[16]

To examine group differences in BMI%50th at 6 and 12 months post-treatment, intent-to-treat analysis using regression-based ANCOVA models were conducted in Stata version 15 (StataCorp LLC, College Station, Texas). Baseline BMI%50th was included as a covariate in the analysis. Two dummy variables were created to compare LAUNCH with motivational interviewing and LAUNCH with standard care (both with LAUNCH as the reference category). Both of these dummy variables were included in the models to compare treatment groups on BMI%50th at each time point. Standardized effect sizes estimates of the group differences at each time point (ie, Cohen d) are presented in addition to statistical significance. The same models were used to examine BMI%95th, BMIz, weight gain, and secondary out-comes at each time point. Logistic regression models were used to examine differences between the odds of a child hav-ing a TV in their bedroom between the groups at each time point. Maximum likelihood estimation on the full random-ized sample (N = 151) was used to address missing data for all models. This estimator does not require the deletion of participants with any missing data but instead uses all avail-able information when computing the model parameters.[17] Previously reported baseline and post-treatment child weight[8] and dietary[18] outcomes are presented to provide a context for maintenance of the follow-up data.

Results

Figure 1 (available at www.jpeds.com) shows the participant flow through the study and follow-up. As previously reported, 92% of the participants randomized to treatment and meeting intent-to-treat criteria were retained at posttreatment[8] and 85.4% and 84.1% were retained at the 6- and 12-month follow-ups, respectively. Attrition did not differ between the groups on our primary outcome at posttreatment (P = .98), 6-month (P = .16), or 12-month follow-up (P = .35). No covariates (sex, race, ethnicity, socioeconomic status) were correlated with missing data or

outcomes r >.40,[17] and therefore no covariates, other than baseline BMI%50th, were included in the analyses. Families did not differ on any demographic variables or weight across the 3 groups at baseline (Table I; available at www.jpeds.com); however, children of families who dropped out at posttreatment ($P = .02$), 6 month ($P < .001$), and 12-month follow-up ($P = .001$) had significantly greater BMI %50th at baseline.

Change in BMI%50th, BMI%95th, and child weight gain from baseline to posttreatment and 6- and 12-month follow-up are shown in Figure 2. As shown in Table II, LAUNCH participants were significantly lower than motivational interviewing group participants on BMI%50th at posttreatment ($P < .001$, d = 0.33), not significant at the 6-month follow-up ($P = .053$, d = 0.03), but significantly lower again at the 12-month follow-up ($P = .034$, d = 0.15). Similarly, the LAUNCH group was significantly lower than the standard care group at posttreatment ($P < .001$, d = 0.33) and 6-month follow-up ($P = .016$, d = 0.20) and, although not statistically significant, maintained a similar effect size at the 12-month follow-up ($P = .061$, d = 0.25). Similar results are shown for BMI%95th. LAUNCH participants also continued to have statistically significant lower absolute weight gain than motivational interviewing ($P = .045$, d = 0.15) and standard care ($P = .021$, d = 0.09) groups at 6-month follow-up, and compared with motivational interviewing at 12-month ($P = .049$, d = 0.22) and, although not statistically significant compared with standard care at the 12-month follow-up, an increased effect size from 6 months was found ($P = .054$, d = 0.17).

The previously reported significant decrease in average total daily calorie intake for children in LAUNCH[18] compared with children in standard care was maintained at both the 6-month ($P = .006$) and 12-month follow-up ($P < .001$) and compared with motivational interviewing at 6-month ($P = .006$) and 12-month follow-up ($P = .002$) (Table II).

As shown in Table III, the previously reported decrease in high-calorie foods in the LAUNCH homes compared with motivational interviewing and standard care homes at posttreatment[18] was maintained at the 6- and 12-month follow-up for LAUNCH compared with standard care but only at the 12-month follow-up for LAUNCH compared with motivational interviewing. The significantly greater presence of fruits and vegetables in the LAUNCH homes compared with motivational interviewing homes at posttreatment[18] was not maintained at either the 6- and 12-month follow-up. No other home food environment variables were significantly different between LAUNCH and motivational interviewing or standard care at any assessment point.

As shown in Table IV (available at www.jpeds.com), children in all conditions were achieving approximately 90 minutes/day of MVPA and close to 25 minutes in vigorous activity with no difference between groups. Posttreatment, children in LAUNCH had decreased their minutes of MVPA to 72 minutes/day and their vigorous

activity to 20 minutes/day; both were significantly less than the average minutes per day for motivational interviewing, $P = .008$, and for standard care, $P < .001$. At the 6- and 12-month follow-ups, the groups were no longer significantly different, with all achieving 82-89 minutes/day of MVPA and 22 minutes/day of vigorous activity. A logistic regression analysis for TV in a child's bedroom showed that children in standard care were 5 times more likely ($P < .05$) and 6 times more likely ($P < .05$) to have a TV in their bedroom at the 6-month and 12-month follow-up, respectively, compared with LAUNCH.

As shown in Table V, the differences in caregiver BMI previously reported to be statistically significant baseline to posttreatment[8] were no longer significant at the 6- or 12-month follow-up for LAUNCH compared with motivational interviewing (6 months: $P = .17$; 12 months: $P = .21$) or to standard care (6 months: $P = .16$; 12 months: $P = .39$). Although caregivers in LAUNCH lost significantly more weight (-2.7 kg) compared with caregivers in motivational interviewing ($+1.3$ kg) and standard care ($+0.60$ kg) baseline to posttreatment (Table V), there were no significant differences between the groups for change in caregiver weight at the 6- or 12-month follow-up. Caregivers in LAUNCH reported a statistically significant lower average daily calorie intake compared with motivational interviewing at posttreatment ($P = .013$) and at the 12-month follow-up ($P = .015$) but not at the 6-month follow-up ($P = .06$). Caregivers in LAUNCH also reported significantly lower daily caloric intake compared with standard care at posttreatment ($P < .001$), that was maintained at the 6-month ($P = .033$) and 12-month follow-up ($P = .007$).

Discussion

The weight-management literature for preschoolers is small yet evolving. LAUNCH adds to this literature by demonstrating the effectiveness of multicomponent behavioral treatment in reducing obesity in preschoolers and the promise of this intervention in maintaining improvements in weight after treatment ends. Participants in LAUNCH were found to gain significantly less weight than participants in motivational interviewing or standard care over the year following treatment, and this resulted in LAUNCH participants maintaining a lower percent over the 50th percentile BMI than motivational interviewing and standard care. Although these differences were not statistically significant at the 6-month follow-up compared with motivational interviewing and at the 12-month follow-up compared with standard care, effect size estimates indicate that LAUNCH is superior to motivational interviewing and standard care 12 months following treatment.

These weight outcomes mirror the change and maintenance in the mechanistic factor of diet, but not physical activity in this study. The children in LAUNCH showed a significantly greater decrease in average daily caloric intake
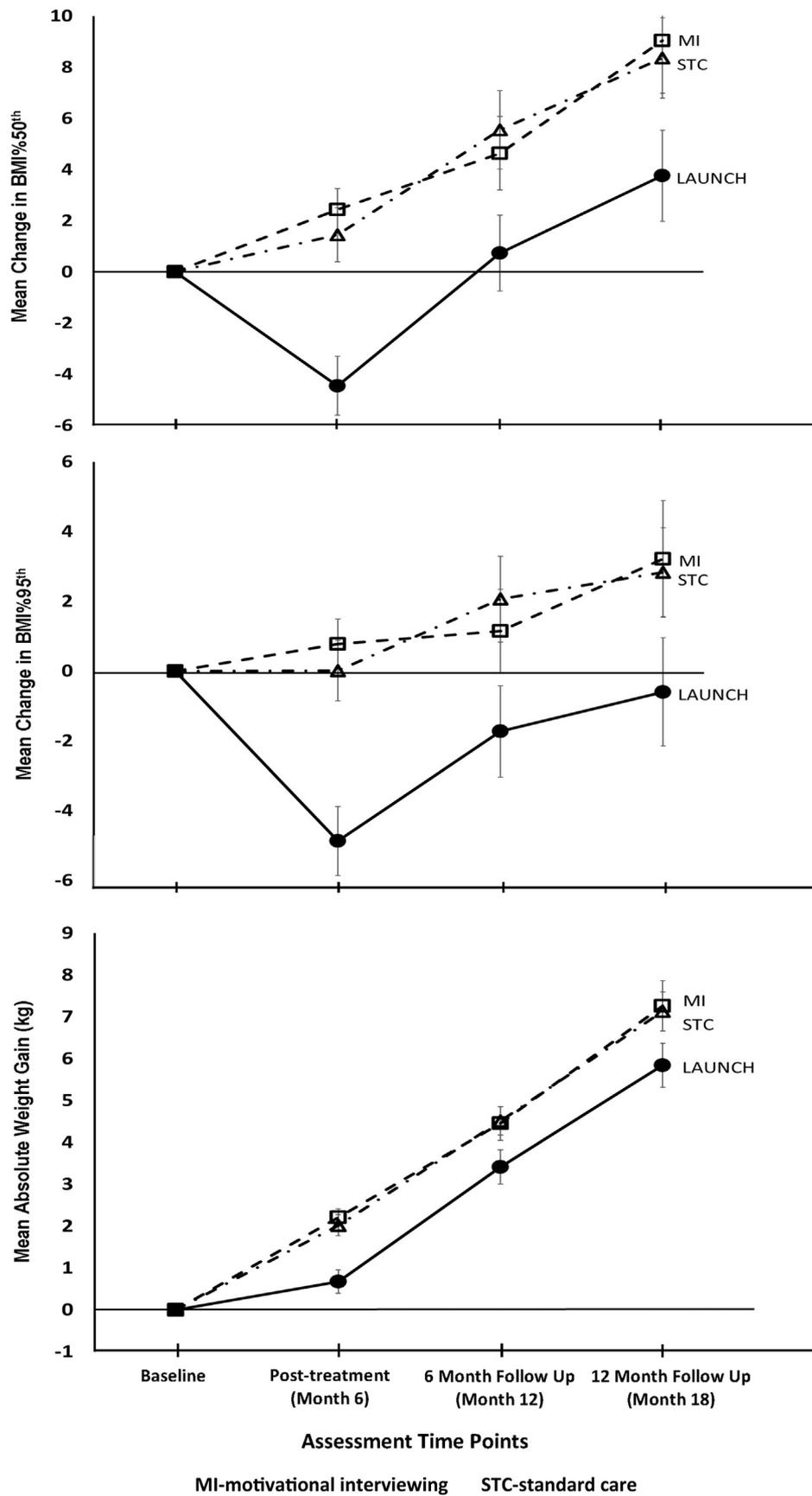
Figure 2. Mean change in BMI%50th, BMI%95th, and absolute weight gain in kilograms for LAUNCH, motivational interviewing, and standard care from baseline to post-treatment, 6-month follow-up, and 12-month follow-up.

Table II. Change in child BMI%50th, BMI%95th, weight, BMI percentile, BMIz, height, and caloric intake from baseline to post-treatment, baseline to 6-months post-treatment, and baseline to 12-months post-treatment by treatment assignment

Outcome measure	Baseline Mean (SD)	Post-treatment Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P	6-month follow-up Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P	12-month Follow-up Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P
BMI%50th													
LAUNCH	35.64 (17.21)	30.43 (17.80)	−4.45 (7.55)			35.16 (19.51)	0.74 (9.70)			37.39 (19.95)	3.76 (11.40)		
Motivational interviewing	34.18 (15.76)	36.07 (16.72)	2.43 (5.62)	**6.89 (4.02, 9.74)**	**<.001**	35.72 (15.67)	4.64 (8.97)	4.12 (−0.06, 8.30)	.053	40.34 (19.82)	9.04 (12.80)	**5.45 (0.43, 10.47)**	**.034**
Standard care	36.21 (17.23)	36.33 (17.83)	1.45 (7.49)	**5.90 (3.10, 8.70)**	**<.001**	39.06 (20.07)	5.55 (10.46)	**4.87 (0.89, 8.84)**	**.016**	42.19 (18.89)	8.36 (10.78)	4.57 (−0.22, 9.37)	.061
BMI%95th													
LAUNCH	114.72 (13.134)	109.35 (14.01)	−4.87 (6.48)			112.15 (15.25)	−1.73 (8.58)			112.66 (14.95)	−0.60 (9.95)		
Motivational interviewing	113.79 (13.08)	114.15 (14.10)	0.77 (4.90)	**5.64 (3.22, 8.05)**	**<.001**	112.17 (12.98)	1.15 (7.47)	2.99 (−0.54, 6.51)	.097	114.60 (16.29)	3.21 (10.46)	3.86 (−0.35, 8.07)	.072
Standard care	115.27 (14.40)	114.10 (14.57)	0.01 (6.12)	**4.88 (2.52, 7.25)**	**<.001**	115.03 (16.29)	2.06 (8.41)	**3.82 (0.48, 7.17)**	**.025**	116.07 (15.18)	2.83 (8.79)	3.43 (−0.58, 7.44)	.094
Weight													
LAUNCH	26.15 (6.16)	26.71 (6.18)	0.67 (1.86)			29.18 (6.98)	3.42 (2.68)			31.32 (7.79)	5.84 (3.38)		
Motivational interviewing	25.91 (5.02)	28.16 (5.45)	2.21 (1.35)	**1.54 (0.87, 2.22)**	**<.001**	30.10 (5.42)	4.46 (2.49)	**1.06 (0.02, 2.09)**	**.045**	32.88 (6.63)	7.26 (3.77)	**1.39 (0.01, 2.77)**	**.049**
Standard care	25.97 (5.47)	27.76 (6.05)	2.03 (1.75)	**1.37 (0.70, 2.03)**	**<.001**	29.79 (6.36)	4.52 (2.33)	**1.16 (0.18, 2.15)**	**0.021**	32.58 (6.94)	7.13 (3.12)	1.30 (−0.02, 2.62)	.054
BMI%ile													
LAUNCH	98.60 (1.22)	96.56 (3.64)	−2.00 (2.92)			96.90 (3.41)	−1.64 (3.04)			96.80 (3.87)	−1.77 (3.52)		
Motivational interviewing	98.52 (1.31)	98.23 (1.80)	−0.20 (1.24)	**1.84 (1.00, 2.67)**	**<.001**	97.60 (2.52)	−0.66 (1.93)	1.03 (−0.03, 2.10)	.057	97.43 (2.78)	−0.87 (2.03)	0.99 (−0.19, 2.17)	.099
Standard care	98.57 (1.30)	97.75 (2.68)	−0.76 (1.94)	**1.25 (0.43, 2.06)**	**.003**	97.77 (2.67)	−0.67 (2.33)	0.99 (−0.03, 2.00)	.057	97.64 (3.09)	−0.82 (2.53)	0.99 (−0.13, 2.12)	.083
BMIz													
LAUNCH	2.41 (0.53)	2.08 (0.62)	−0.32 (0.33)			2.19 (0.70)	−0.20 (0.54)			2.16 (0.67)	−0.20 (0.60)		
Motivational interviewing	2.41 (0.55)	2.35 (0.54)	−0.05 (0.27)	**0.31 (0.14, 0.48)**	**<.001**	2.17 (0.48)	−0.12 (0.31)	0.09 (−0.12, 0.29)	.397	2.17 (0.52)	−0.16 (0.32)	0.08 (−0.12, 0.29)	.428
Standard care	2.48 (0.70)	2.31 (0.63)	−0.13 (0.31)	**0.23 (0.07, 0.40)**	**.006**	2.28 (0.59)	−0.13 (0.40)	0.12 (−0.07, 0.32)	.217	2.25 (0.54)	−0.17 (0.45)	0.09 (−0.10, 0.29)	.359
Height													
LAUNCH	111.02 (8.71)	114.74 (8.38)	3.64 (0.90)			117.74 (8.41)	7.13 (1.60)			120.78 (8.43)	10.50 (2.11)		
Motivational interviewing	111.62 (8.04)	115.85 (7.56)	3.89 (0.91)	0.28 (−0.07, 0.63)	.120	119.96 (6.96)	7.39 (1.22)	0.38 (−0.23, 1.00)	.222	123.04 (7.09)	10.68 (1.70)	0.31 (−0.45, 1.07)	.427
Standard care	110.77 (7.92)	114.64 (7.78)	3.79 (0.91)	0.14 (−0.21, 0.48)	.430	117.66 (7.47)	7.25 (1.65)	0.10 (−0.48, 0.68)	.731	121.47 (7.71)	10.81 (1.68)	0.33 (−0.40, 1.06)	.376
Average caloric intake per day													
LAUNCH	1456 (301)	1144 (217)	−293 (318)			1316 (292)	−127 (346)			1313 (262)	−141 (361)		
Motivational interviewing	1425 (356)	1411 (334)	−34 (357)	**260.89 (151, 371)**	**<.001**	1482 (320)	0 (375)	**149.10 (29, 269)**	**.015**	1518 (379)	57 (339)	**201.14 (75, 328)**	**.002**
Standard care	1323 (274)	1409 (337)	99 (268)	**321.59 (212, 431)**	**<.001**	1413 (315)	−129 (269)	**165.38 (47, 284)**	**.006**	1509 (336)	227 (28)	**284.09 (160, 408)**	**<.001**

Bolded values indicate those that were statistically significant.

Table III. Change home food environment from baseline to post-treatment, baseline to 6-months post-treatment, and baseline to 12-months post-treatment by treatment assignment

Outcome measure	Baseline Mean (SD)	Post-treatment Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P	6-month Follow-up Mean (SD)	Change From baseline Mean (SD)	β (95% CI)	P	12-month Follow-up Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P
Average number of high-calorie foods in home													
LAUNCH	13.0 (2.7)	10.7 (2.9)	-2.8 (2.8)	**2.11 (1.06, 3.16)**	**.000**	11.6 (2.9)	-1.8 (2.5)	1.02 (-0.03, 2.07)	.058	11.6 (2.6)	-2.0 (2.6)	**1.48 (0.54, 2.42)**	**.002**
Motivational interviewing	12.0 (3.7)	11.9 (3.2)	-0.2 (3.1)	**1.78 (0.76, 2.81)**	**.001**	11.9 (3.1)	-0.1 (3.2)	**1.24 (0.24, 2.23)**	**.015**	12.3 (2.9)	-0.4 (2.9)	**1.43 (0.54, 2.33)**	**.002**
Standard care	13.0 (2.9)	12.2 (2.9)	-0.8 (2.6)			12.6 (2.4)	-0.2 (2.8)			12.7 (2.3)	-0.1 (2.4)		
Average number of high-calorie beverages in home													
LAUNCH	2.4 (1.4)	1.8 (1.1)	-0.7 (1.1)	0.31 (-0.12, 0.74)	.153	2.2 (1.0)	-0.3 (1.5)	-0.07 (-0.58, 0.44)	.779	2.1 (1.1)	-0.5 (1.7)	-0.16 (-0.69, 0.36)	.544
Motivational interviewing	2.3 (1.4)	2.0 (1.1)	-0.2 (1.6)	0.32 (-0.11, 0.75)	.142	2.1 (1.32)	-0.1 (1.6)	-0.12 (-0.61, 0.37)	.631	1.9 (1.3)	-0.3 (1.8)	0.19 (-0.32, 0.70)	.466
Standard care	2.3 (1.2)	2.1 (1.0)	-0.3 (1.3)			2.0 (1.2)	-0.3 (1.6)			2.2 (1.2)	0.0 (1.5)		
Average number of vegetables in home													
LAUNCH	10.6 (4.5)	11.5 (4.6)	0.4 (2.7)	**-1.56 (-2.87, -0.24)**	**.021**	10.6 (4.4)	-0.9 (3.7)	0.03 (-1.59, 1.65)	.971	10.4 (3.8)	-1.2 (3.5)	-0.35 (-2.13, 1.44)	.702
Motivational interviewing	10.2 (4.4)	9.4 (4.0)	-1.0 (3.7)	-0.89 (-2.20, 0.42)	.182	10.2 (4.6)	-0.6 (4.2)	-0.07 (-1.63, 1.50)	.933	9.6 (4.3)	-1.1 (5.4)	0.36 (-1.38, 2.10)	.685
Standard care	10.8 (4.8)	10.2 (4.8)	-0.3 (3.6)			9.8 (5.1)	-0.6 (3.9)			10.2 (5.2)	-0.3 (4.6)		
Average number of fruits in home													
LAUNCH	6.0 (3.0)	6.4 (3.0)	-0.1 (2.5)	-0.65 (-1.73, 0.43)	.241	6.2 (3.2)	-0.3 (3.1)	-0.23 (-1.56, 1.11)	.740	5.4 (3.1)	-1.1 (3.0)	0.40 (-0.78, 1.58)	.508
Motivational interviewing	5.9 (3.0)	5.6 (3.2)	-0.6 (2.9)	-0.29 (-1.37, 0.79)	.601	5.8 (3.5)	-0.5 (3.4)	0.19 (-1.11, 1.49)	.772	5.7 (3.2)	-0.5 (3.1)	0.05 (-1.11, 1.20)	.937
Standard care	5.9 (3.1)	5.8 (3.3)	-0.1 (3.2)			6.0 (3.3)	0.2 (3.9)			5.2 (3.0)	-0.7 (3.2)		

Bolded values indicate those that were statistically significant.

at posttreatment and the 6- and 12-month follow-up compared with motivational interviewing and standard care. They also showed a significant reduction in high-calorie foods in the home from baseline to post-treatment compared with motivational interviewing and standard care, and this was maintained at the follow-up assessments. Child participants in LAUNCH were also significantly less likely to have a TV in their bedrooms at the follow-up assessments than children in standard care. Similar to our pilot work, LAUNCH did not increase children's physical activity. Lack of effect on physical activity may be due to our sample having a particularly high MVPA of >90 minutes/day at baseline and thus were meeting the recommended ≥60 minutes/day of MVPA. Alternatively, it maybe that increasing physical activity is difficult in this age group because of the need for adult supervision for outdoor play—a primary barrier anecdotally reported by caregivers. Although physical activity is a cornerstone of obesity treatments, more research is needed to better understand the role of physical activity in weight management of preschool age children.

Despite the success of the current intervention in reducing the percentage overweight of preschool children, as a group, the children continued to be overweight and obese. Although the children in LAUNCH showed a significantly greater decrease in average daily caloric intake from baseline (1455 cal/d) to the 6- and 12-month follow-up compared with motivational interviewing and standard care, they increased their caloric intake by almost 12% from posttreatment (1147 cal/d) to the 6- and 12-month follow-up (1300 cal/d). Together these, data indicate that treatment may need to be longer than 6 months or that active boosters may be required in the maintenance phase to maintain improvement on caloric intake and continue to reduce absolute weight gain to achieve a healthy weight as the children grow in height.

There are aspects of the study that limit generalization of the findings beyond the population tested. Despite efforts to recruit low-income and minority populations by partnering with Federally Qualified Health Centers and holding treatment sessions at locations near these Federally Qualified Health Centers practices, the sample was primarily white and middle class. And although we surpassed our targeted enrollment of Hispanic and Latino families of 2%, based on census data on our area, achieving 6%, we only enrolled of 9% of African Americans compared with our targeted enrollment of 14% to reflect the census of the city in which the study was conducted. Finally, participation rate was only 26.5% of those identified as eligible via a chart review and who could be contacted about the study and thus represents only a small proportion of the overall population. Recognition of overweight and obesity in young children is a primary barrier to recruitment.[19] We have shown previously the opt-out strategy of the current study is superior to an opt-in where parent initiate the call to the study[20]; however, a warm hand off from the pediatrician to study personnel in the pediatrician office has the highest enrollment rates (70%) reported in the literature[6] and should be used in future studies.

Table V. Change in parent BMI, weight, and average daily caloric intake from baseline to post-treatment, baseline to 6-months post-treatment, and baseline to 12-months post-treatment by treatment assignment

Outcome measure	Baseline Mean (SD)	Post-treatment Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P	6-month Follow-up Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P	12-month Follow-up Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P
Parent BMI, kg/m²													
LAUNCH	38.9 (8.8)	37.8 (8.8)	−1.0 (1.8)	**1.43 (0.59, 2.27)**	**.001**	38.7 (9.1)	−0.3 (2.2)	0.81 (−0.36, 1.97)	.175	38.6 (9.7)	0.0 (2.4)	0.79 (−0.44, 2.02)	.210
Motivational interviewing	35.7 (7.1)	36.6 (7.8)	0.4 (1.6)			35.8 (8.0)	0.4 (2.8)			36.3 (7.8)	0.7 (2.4)		
Standard care	35.8 (7.8)	36.5 (8.4)	0.2 (1.9)	**1.21 (0.42, 2.00)**	**.003**	36.9 (8.5)	0.4 (2.2)	0.77 (−0.31, 1.85)	.163	37.0 (8.6)	0.5 (2.6)	0.49 (−0.63, 1.60)	.392
Parent weight, kg													
LAUNCH	106.9 (24.1)	104.1 (24.0)	−2.7 (5.0)	**4.04 (1.68, 6.39)**	**.001**	106.0 (24.6)	−0.8 (6.0)	2.35 (−0.83, 5.52)	.147	105.7 (26.3)	0.1 (6.5)	2.04 (−1.36, 5.44)	.240
Motivational interviewing	102.7 (24.4)	106.7 (26.5)	1.3 (4.9)			104.6 (28.8)	1.4 (7.9)			105.9 (27.3)	2.1 (7.1)		
Standard care	98.5 (26.8)	101.1 (28.5)	0.6 (5.1)	**3.39 (1.19, 5.60)**	**.003**	102.3 (29.1)	1.1 (5.9)	2.08 (−0.88, 5.04)	.168	102.6 (28.8)	1.2 (6.9)	1.18 (−1.93, 4.28)	.457
Average parent caloric intake per day, kcal/d													
LAUNCH	1523 (567)	1170 (390)	−358 (601)	**259.15 (55, 464)**	**.013**	1247 (495)	−294 (428)	225.82 (−9, 461)	.059	1213 (453)	−329 (456)	**272.43 (52, 493)**	**.015**
Motivational interviewing	1796 (957)	1551 (619)	−286 (679)			1587 (658)	−192 (728)			1599 (622)	−188 (772)		
Standard care	1757 (787.1)	1602 (559.0)	−119 (664)	**355.93 (163, 549)**	**.000**	1551 (671)	−125 (706)	**239.44 (19, 460)**	**.033**	1514 (596)	−76 (554)	**279.07 (75, 483)**	**.007**

Bolded values indicate those that were statistically significant.

Our study demonstrates the importance of identifying the outcome measure that best measures change in adiposity in children at the high end of obesity. Since the design of our trial, several studies have demonstrated that BMIz is not accurate for measuring change in children ≥97th BMI percentile,[12] especially in children ages 2-5 years of age[10] where the theoretical maximum BMIz changes from greater than 5 among 2- to 4 year-old children to approximately 3 for children between 6 and 12 years. Thus, children with a wide range of very high BMIs could map to similar z scores due to ceiling effects.[10] In the current study, we chose the 50th percentile BMI as the primary outcome to be comparable with previous studies of preschool children[6,9] and found similar results, but a more uniform reporting of outcome measures would advance the emerging research in this area. Research continues to be needed to advance our knowledge of how to design durable treatments that promote achievement of healthy weight, diet, home food environments, and physical activity among families of our youngest children with obesity. ∎

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Data Statement

Data sharing statement available at www.jpeds.com.

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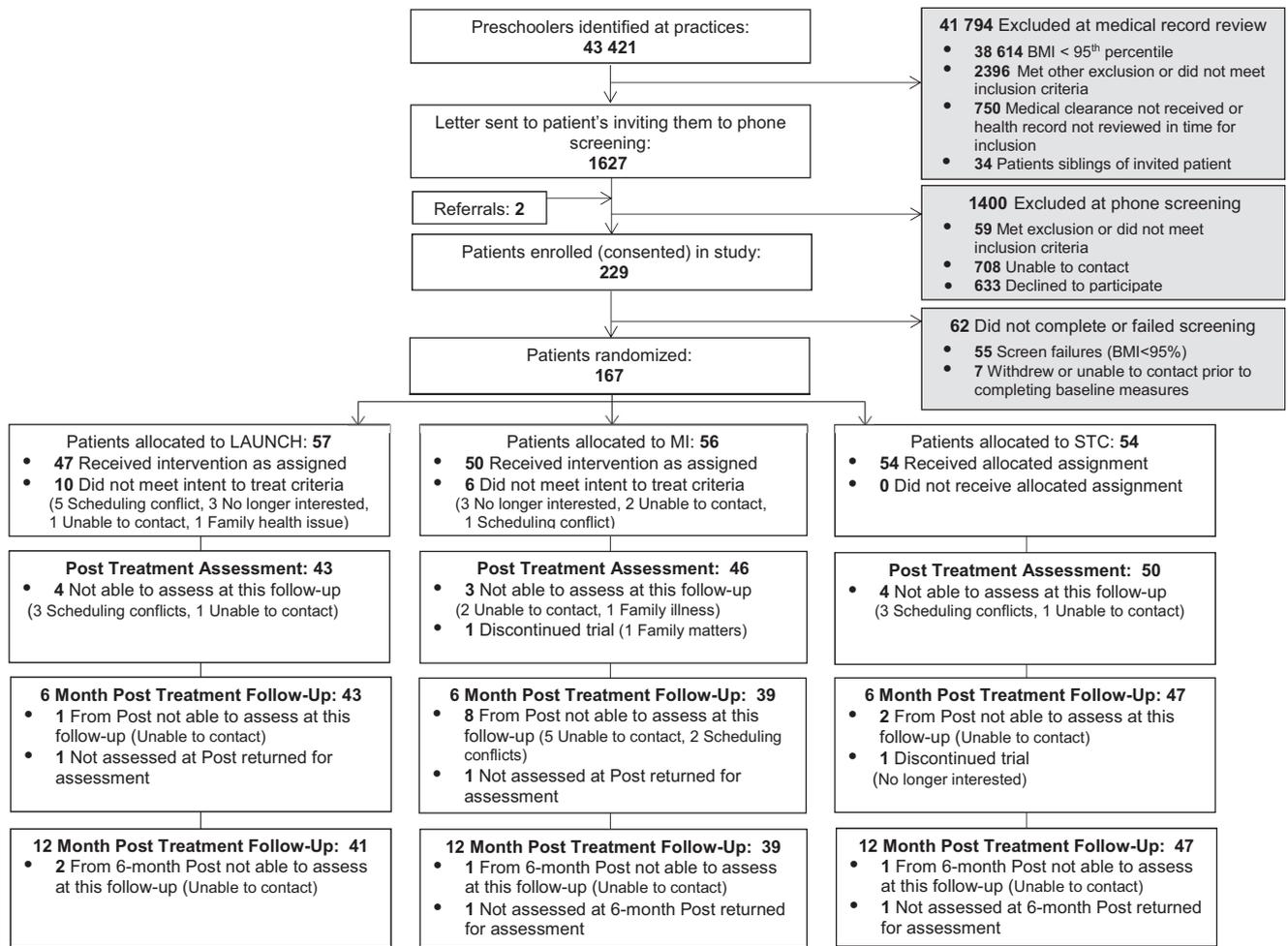
Figure 1. CONSORT flow diagram of participants to LAUNCH, motivational interviewing, and standard care.

Table I. Baseline characteristics of children and caregivers meeting intent-to-treat criteria in LAUNCH, motivational interviewing, standard care, and overall sample

Demographics	Overall (n = 151)	LAUNCH (n = 47)	Motivational interviewing (n = 50)	Standard care (n = 54)
Child				
Age, mo*	55.14 (11.19)	55.10 (12.07)	55.00 (10.67)	55.30 (11.06)
Sex (female), n (%)*	86 (56.95)	25 (53.19)	29 (58.00)	32 (59.26)
Race, n (%)*				
Black	14 (9.27)	3 (6.38)	6 (12.00)	5 (9.26)
White	115 (76.16)	37 (78.72)	38 (76.00)	40 (74.07)
More than one/other	22 (14.57)	7 (14.89)	6 (12.00)	9 (16.67)
Ethnicity, n (%)*				
Hispanic or Latino	9 (5.96)	1 (2.13)	3 (6.00)	5 (9.26)
Non-Hispanic	142 (94.04)	46 (97.87)	47 (94.00)	49 (90.74)
Weight, kg	26.01 (5.52)	26.15 (6.16)	25.91 (5.02)	25.97 (5.47)
Height, cm	111.13 (8.17)	111.02 (8.71)	111.62 (8.04)	110.77 (7.92)
Child BMIz*	2.44 (0.60)	2.41 (0.53)	2.41 (0.56)	2.48 (0.70)
BMI%50th*	35.36 (16.66)	35.64 (17.21)	34.18 (15.77)	36.21 (17.23)
Child BMI percentile*	98.57 (1.28)	98.60 (1.23)	98.52 (1.31)	98.57 (1.30)
Caregiver				
Age	35.42 (6.55)	35.36 (6.56)	34.78 (5.95)	36.07 (7.09)
Relationship to child, n (%)				
Mother	136 (90.07)	42 (89.36)	47 (94.00)	47 (87.04)
Father	11 (7.28)	4 (8.41)	2 (4.00)	5 (9.26)
Grandparent	3 (1.99)	1 (2.13)	1 (2.00)	1 (1.85)
Other	1 (0.66)	—	—	1 (1.85)
Caregiver education, n (%)				
Less than high school degree	2 (1.32)	—	—	2 (3.70)
High school graduate/GED	16 (10.60)	5 (10.64)	5 (10.00)	6 (11.11)
Some college/specialized training	53 (35.10)	21 (44.68)	17 (34.00)	15 (27.78)
College degree	55 (36.42)	15 (31.91)	20 (40.00)	20 (37.04)
Graduate degree	25 (16.56)	6 (12.77)	8 (16.00)	11 (20.37)
Family income, n (%)*				
<$30k	16 (10.60)	4 (8.51)	8 (16.00)	4 (7.41)
$30k-49.9k	23 (15.23)	9 (19.15)	5 (10.00)	9 (16.67)
$50k-99.9k	77 (50.99)	25 (53.19)	23 (46.00)	29 (53.70)
≥$100k	34 (22.52)	9 (19.15)	14 (28.00)	11 (20.37)
Not reported	1 (0.66)	—	—	1 (1.85)
Hollingshead score*	43.03 (11.68)	43.21 (11.12)	42.24 (12.73)	43.59 (11.31)
Marital status, n (%)				
Single	31 (20.53)	10 (21.28)	11 (22.00)	10 (18.52)
Married	108 (71.52)	35 (74.47)	34 (68.00)	39 (72.22)
Divorced	6 (3.97)	2 (4.26)	2 (4.00)	2 (3.70)
Separated	3 (1.99)	—	2 (4.00)	1 (1.85)
Widowed	1 (0.66)	—	1 (2.00)	—
Cohabit, not married	2 (1.32)	—	—	2 (3.70)
Caregiver weight status, n (%)				
Healthy weight (BMI <25)	19 (12.58)	6 (12.77)	8 (16.00)	5 (9.26)
Overweight (BMI 25 to <30)	25 (16.56)	7 (14.89)	7 (14.00)	11 (20.37)
Obese (BMI ≥30)	101 (66.89)	33 (70.21)	32 (64.00)	36 (66.67)
Pregnant	6 (3.97)	1 (2.13)	3 (6.00)	2 (3.70)
Self-reported prepregnancy BMI	32.32 (6.02)	33.59 (—)	34.05 (3.47)	29.07 (11.19)

GED, General Education Development.
*$P > .05$.

Table IV. Change in child physical activity from baseline to post-treatment, baseline to 6-months post-treatment, and baseline to 12-months post-treatment by treatment assignment

Outcome measure	Baseline Mean (SD)	Post- treatment Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P	6-month Follow-up Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P	12-month Follow-up Mean (SD)	Change from baseline Mean (SD)	β (95% CI)	P
Average minutes in vigorous activity per day													
LAUNCH	25.8 (14.3)	19.9 (9.3)	−6.1 (12.4)			22.5 (10.7)	−3.2 (12.8)			22.3 (12.8)	−2.1 (12.1)		
Motivational interviewing	26.5 (11.9)	25.1 (11.7)	−2.0 (9.9)	**4.29 (0.51, 8.07)**	**.026**	23.5 (10.1)	−3.0 (9.2)	0.49 (−3.57, 4.55)	.814	23.1 (12.3)	−4.4 (10.1)	−1.31 (−5.28, 2.66)	.517
Standard care	23.7 (11.0)	27.0 (13.0)	3.20 (9.1)	**8.25 (4.61, 11.89)**	**.000**	21.8 (10.1)	−1.3 (10.0)	0.64 (−3.29, 4.56)	.751	22.0 (8.4)	−1.6 (9.2)	0.05 (−3.73, 3.83)	.979
Average minutes in MVPA per day													
LAUNCH	90.6 (33.1)	72.7 (26.5)	−17.8 (28.7)			82.7 (28.2)	−8.4 (30.0)			80.7 (33.1)	−6.8 (27.5)		
Motivational interviewing	94.6 (31.8)	89.1 (30.2)	−5.9 (30.1)	**13.97 (3.65, 24.28)**	**.008**	88.4 (28.3)	−5.5 (28.6)	4.55 (−6.10, 15.20)	.402	83.6 (30.8)	−12.5 (26.5)	−2.01 (−12.33, 8.32)	.703
Standard care	92.7 (31.0)	96.2 (32.8)	5.0 (24.8)	**23.08 (3.19, 32.97)**	**.000**	84.4 (25.8)	−5.8 (28.4)	2.16 (−8.09, 12.41)	.680	84.1 (20.5)	−7.0 (27.6)	1.48 (−8.33, 11.29)	.767

Bolded values indicate those that were statistically significant.