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Treating Obesity in Preschoolers: A Review and Recommendations for Addressing Critical Gaps

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SYNOPSIS

Developing interventions targeting obesity reduction in preschoolers is an emergent area. While intensive, multi-component interventions appear a promising approach to preschool obesity reduction, the current review identifies three critical gaps (poor reach to families from low-income and minority backgrounds, do not provide sufficient evidence to determine the most effective and efficient treatment components and approaches to treating obesity in early childhood, and lack consensus on how best to discern intervention effectiveness) in the extent preschool obesity intervention literature. Approaches for addressing each gap are discussed.

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Keywords

Preschool; Obesity; Intervention

Introduction

Twenty-three percent of 2–5 years-old in the United States (US) are estimated to be overweight (BMI 85th percentile) or obese (BMI 95th percentile).¹ Although rates have decreased over the past decade, these changes have not been experienced equally, and disparities persist for preschoolers from low-income and minority backgrounds.^{1,2} Excess weight gain in early childhood remains a significant public health concern given immediate physical and psychosocial health consequences (e.g., high blood pressure, run/walk difficulties, peer stigmatization, lower health-related quality of life),^{3–6} its persistence into adolescence and adulthood,^{7–9} and the implications for morbidity and mortality in adulthood even when controlling for adult weight status.¹⁰ Early intervention (before age 6) is important because the incidence of new onset obesity is greater during kindergarten than any other time in childhood,¹¹ because children overweight at kindergarten are 4 times more likely to become obese later in childhood,¹¹ and because prevention efforts have unclear benefits for preschoolers who already overweight and obese.^{12–14}

A recent comprehensive review of the preschool obesity intervention literature by Foster and colleagues¹⁵ concluded multidisciplinary, intensive behavioral programs appear most promising for achieving the goal of obesity reduction in children <6 years-old. The purpose of this paper is to move beyond examining efficacy to explore the current state of the preschool obesity treatment literature by critically evaluating the sociodemographic characteristics of *who* preschool obesity interventions are reaching (i.e., who is enrolling), *which* lifestyle behaviors and behavior change strategies are most efficient and effective for yielding improvements in preschooler weight status, and *how* to best evaluate program effectiveness. Integrated into this discussion is a call to focus on early stage intervention development to address critical gaps in each domain and to concentrate efforts on developing programs for families from low-income and minority backgrounds. The same criteria for intervention inclusion as Foster and colleagues¹⁵ were applied for this review: 1) enrolled children ages 0–6 years-old (or tailoring to preschoolers if sample included older children), 2) included measure of weight status, 3) only included children with BMI 85th percentile. We identified one additional publication¹⁶ than Foster and colleagues, bringing the total number of studies included to seven.

Reach of Preschool Weight Control Trials

Preschool obesity interventions should be designed to maximize reach so eligible families are aware of the intervention and participate.¹⁷ Understanding enrollment rates, sociodemographic characteristics of *who* is enrolling, *which* strategies are most effective in recruiting families, and barriers (e.g., transportation, perception of health problem) to participation are important first steps in evaluating the progress of the preschool obesity treatment literature. In this section, we evaluate each trial to discern answers to these

questions. Recruitment details and characteristics of intervention arms are summarized by trial below and detailed in Tables 1 and 2.

Two trials were conducted within established pediatric obesity clinics where participants had already been referred by a pediatrician or healthcare provider and agreed to receive treatment.^{18,19} Both trials were conducted outside of the United States and neither provided information on sociodemographic characteristics of participating families. In the first study by Bocca and colleagues,¹⁸ all but three referred families met eligibility criteria and were randomized to receive either a 4-month, 25-session multidisciplinary program or usual care. In the second study by Kelishadi and colleagues,¹⁹ all 120 referred families enrolled and were randomized to one of three 6-month, 6-session interventions: energy restriction, dairy-rich, or education only (control).

Three trials examined intensive behavioral interventions;^{16,20,21} all required one caregiver with overweight for participation. Two iterative pilot randomized control trials by Stark and colleagues^{16,20} examined the efficacy of a 6-month, 18-session clinic and home-based intervention targeting obesity reduction in preschoolers *and* caregivers compared to an enhanced standard of care session with a pediatrician. Clinic visits were group-based. The second iteration¹⁶ also included a third intervention arm (9-sessions, clinic only program). Prescreened families of preschoolers with obesity were randomly selected to receive a study invitation letter and opt-out postcard from their pediatrician. The research team called all families who did not return opt-out postcards within 10 days of the mailings. Across the trials, 51% of families reached refused participation. Reasons for refusal were only documented in one trial,²⁰ with the majority of caregivers citing time/scheduling (61%) or not perceiving preschooler as obese (29%). Twenty-six percent of eligible families enrolled, of which 18% were from minority backgrounds and 16% reported an annual income \$50,000 (the lowest income bracket assessed). All enrolled families in the trial by Quattrin and colleagues^{21,22} received a primary care-based program (12 months, 13 in-person sessions plus 10 coaching calls between group visits). Only the program for intervention families included behavior modification and child management skills training and targeted weight management for preschoolers and caregivers. Study recruiters were embedded within the primary care clinic and met with interested families immediately following well-child visits. Twenty-five percent of families referred by pediatricians declined to meet with recruiters. Eighty-one percent of eligible families enrolled, of which 26% were from minority backgrounds and 8.3% reported an annual income of \$20,000 (the lowest income bracket assessed).

In two trials, randomization occurred at the clinic or provider level. Interventions tested were less intensive (10 sessions over a year) and occurred within the primary care setting.^{23,24} Taveras and colleagues²³ randomized pediatrician offices to deliver a one-year program consisting of 4 office visits and 3 phone calls (intervention) or continue with usual care. An invitation letter opt-out procedure like Stark and colleagues^{16,20} was used for recruitment. Twenty-one percent of families contacted by phone declined participation. Similar to Stark and colleagues,²⁰ families cited time (66%) and not perceiving child as overweight or obese (27%) as the top reasons for refusal.²⁵ Caregivers with a college degree were also significantly less likely to enroll their family than those without a college degree. Forty-

seven percent of eligible families enrolled, of which 43% of families were from minority backgrounds and 29% reported an annual income of \$50,000 (the lowest income bracket assessed in the study). In the second trial, Van Grieken and colleagues²⁴ randomized Youth Health Care teams (YHCT) within nine Youth Health Care Centers (YHCC) to provide a 12-month, 4 session motivational interviewing plus counseling intervention or usual care to families of 5 year-old *overweight* preschoolers. Rates of refusal, the total number of eligible families, and sociodemographic characteristics for families with overweight preschoolers is unclear as study participation was offered to families irrespective of child weight and recruitment flow was not presented by preschooler weight status. A total of 637 families with overweight preschoolers enrolled.

In summary, rates of enrollment (26%–81%) and refusal (21–51%) into preschool weight control trials are variable. Families from low-income (8.3–29%) and minority (18–43%) backgrounds are underrepresented within these trials (see Table 1), which is concerning given the persistence of obesity disparities. Only two studies provide information on barriers to participation. Although interventions differed in intensity and structure, time and not believing preschooler weight is problematic were the most commonly barriers to enrollment.^{20,25} While Taveras and colleagues found lower enrollment for families with more highly educated caregivers,²⁵ they did not evaluate whether income or race/ethnicity differentiated families who refused participation. All trials recruited families from medical settings. Excluding the two trials where families had accessed services in a weight management clinic before being invited to participate in research,^{18,19} enrollment was highest when recruitment was initiated by pediatricians, occurred entirely in-person, and when interventions were implemented within primary care settings.^{21,23,24}

Future Directions to Improve Reach

Based upon limitations described above, three recommendations are provided to improve reach of preschool obesity interventions. First, strategies are needed to increase accuracy of caregiver perceptions of child weight status and their motivation for change. Higher rates of misperception among families from low-income²⁶ and minority^{27,28} backgrounds, and their lower rate of enrollment in extant preschool weight control trials, highlights this barrier may be particularly relevant for underserved populations. Inaccuracy may also reflect that pediatricians are less likely to talk about weight or diagnose obesity in preschoolers compared to older pediatric age groups.^{29,30} Color-coded BMI charts are one tool that has effectively facilitated more frequent weight discussions with pediatricians and improved caregiver accuracy in perception of child weight status, particularly among families of preschoolers from low-income and minority backgrounds.^{31,32} Dawson and colleagues³³ also found 76% of families who received weight feedback using color-coded BMI charts enrolled into a 2-year preschool weight control trial. Although a control group was lacking, this enrollment rate is impressive as slightly over half of caregivers were not aware of their preschooler's weight status prior to the feedback session.³³ Culturally tailored weight rulers are an additional tool that show promise in improving accuracy of caregiver perceptions of preschooler weight status and were preferred over color-coded BMI charts by families from low-income and minority backgrounds.³⁴

Second, expanding recruitment beyond medical settings may improve recruitment of families from low-income and minority backgrounds. Emergency departments are one setting that could be explored for its recruitment potential given their frequent use by low-income and minority populations for routine healthcare.³⁵ Lynch and colleagues also recently found significantly higher ED utilization by overweight and obese children compared to those who were of a healthy weight.³⁶ Researchers should also establish partnerships with The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and Head Start as these federally funded programs serve 4.7³⁷ and 1 million³⁸ preschoolers from low-income backgrounds, respectively. Further, over 40% of families receiving services from WIC and Head Start are from racial and ethnic minority backgrounds. Preschool obesity trials are currently underway that may provide insight on the recruitment potential of collaborating with these community-based organizations.^{39,40} Finally, YMCAs should be considered given their general emphasis on health promotion and because pediatric weight control programs have been successfully delivered in this setting.⁴¹

Third, even if caregiver motivation increases and recruitment is extended beyond medical settings, families may still be reluctant to enroll in preschool weight control trials if they do not perceive the intervention as feasible and acceptable. A substantial number of families contacted by Stark and colleagues²⁰ and Taveras and colleagues²³ reported time as a barrier to enrollment. Interventions tested in each study varied on intensity, dose, and treatment setting, which suggest additional intervention characteristics than time may serve as enrollment barriers (see Table 2). Ongoing trials may provide insight on whether innovative components improve enrollment, especially among low-income and minority populations. For example, three studies are testing programs led by community health workers^{39,40,42} and two of these studies are home-based.^{40,42} Examining enrollment characteristics *de novo* can provide information on feasibility and acceptability but may slow progress and is costly because trials must be completed prior to analysis. Recently, the Obesity-Related Behavioral Intervention Trials (ORBIT) work group published a four-phase model for developing health behavioral interventions⁴³ that encourages completion of two formative phases prior to conducting comparative effectiveness trials. Involving members of the targeted population from the start of program development (user-centered approach) is encouraged to maximize intervention feasibility and acceptability. Only one trial,³⁹ which is currently underway, involved their target population (WIC families) in the formative steps of intervention development. Specifically, semi-structured qualitative interviews were completed with families of overweight and obese preschoolers to discern why they felt it was important to address weight in early childhood and the feasibility and acceptability of extent preschool obesity interventions.⁴⁴ Information gleaned from interviews was applied to develop the 4-month (14 session), community and home-based preschool weight control intervention that is currently being pilot tested. A full example of how the NIH ORBIT model can be applied to complete the formative steps of developing interventions for low-income and minority populations via increasing feasibility and acceptability is presented in Table 3.

Treatment components

Identifying *which* lifestyle behaviors or combination of behaviors are most salient to reducing obesity in preschool-aged children and how to best help families achieve behavior

changes is a second important step to advancing the preschool obesity treatment literature. In this section, we review what is currently known about lifestyle behaviors contributing to excess weight gain in early childhood (e.g., diet, activity, sleep), the unique challenges to modifying these behaviors for preschoolers, and evidence for what strategies are effective in changing behaviors associated with increased obesity risk in early childhood. Table 4 provides an overview of behaviors targeted, specific recommendations, if and how behavior change was measured, and changes reported.

Diet—Preschoolers are estimated to consume an average of 1,537 calories daily,⁴⁵ which exceeds the 1,000–1400 calories recommended based upon age and sex.⁴⁶ Palatable foods like pasta, desserts, milk (whole and reduced-fat), and fruit juice are the largest contributors to daily caloric intake for preschoolers,⁴⁷ with slightly less than half meeting daily fruit and vegetable recommendations.⁴⁸ Sugary drinks (e.g., soda, fruit drinks) and snacks are estimated to account for approximately 10%⁴⁷ and 27%⁴⁹ of preschoolers' daily caloric intake, respectively. While caregivers of preschoolers have more control over their child's dietary intake than perhaps at any other pediatric age-group, normative preschool behaviors present a challenge to dietary modification. Since children innately prefer salty and sweet tastes,⁵⁰ foods that do not have these properties (e.g., vegetables) are often rejected.⁵¹ Food neophobia, the rejection of novel or unknown foods,⁵² peaks during the preschool years.⁵³ Tantrumming for food is also commonly reported by caregivers of preschoolers and associated with increased obesity risk.⁵⁴ Caregivers frequently discontinue exposure to new foods after three to five trials⁵⁵ instead of the 12–15 necessary for new food preferences to develop.⁵⁶ Caregivers of preschoolers also report frequently using food to manage child behaviors, providing palatable foods as rewards for good behavior and to terminate disruptive behaviors.^{57–59}

Managing negative food-related behaviors appears especially challenging for caregivers with preschoolers who are overweight and obese as they report uncertainty in how to encourage consumption of new foods, feeling like they are depriving children if unhealthy foods are limited, and difficulty managing tantrums resulting from restricting access to unhealthy foods.^{60,61} Strategies caregivers employ to encourage healthy eating may also have the opposite of their intended effects. For example, restricting access to highly palatable foods is associated with greater intake of those foods when accessible, even in the absence of hunger,⁶² and higher weight.^{62–64} Similarly, pressuring children to eat certain foods (e.g., vegetables), is associated with decreased preference for those foods,⁶⁵ picky eating,^{66,67} and lower weight.⁶⁸

In light of these patterns and challenges, it is not surprising dietary modification is a component of all preschool weight control interventions included in this review. However, there is significant variability in which behaviors are targeted and how (see Table 4). Decreasing caloric intake is the most common dietary recommendation. Four^{16,18–20} of five^{16,18–21} studies including this component report outcome data. Although caloric intake decreased for intervention preschoolers in all four studies, this change was significantly greater than control or alternate treatments only in studies by Stark and colleagues.^{16,20} Stark and colleagues also document the only maintenance of caloric decreases achieved during intervention participation at a 6-month follow-up assessment. Decreasing sugary

drink (SD) intake and increasing fruit and vegetable (FV) intake are the second most common dietary targets.^{16,20,21,23} Outcome data were reported for two^{23,69} of three interventions including recommendations for one or both these behavior changes. Taveras and colleagues²³ found modest decreases in SD and increases in FV for preschoolers irrespective of group assignment but neither achieved the recommended amount. Kuhl and colleagues⁶⁹ collapsed data for two iterative trials examining their clinic and home-based behavioral intervention. Intervention preschoolers experienced a small and non-significant decrease in SD; this change was consistent with recommendations. FV intake increased significantly but not to recommended levels. Only Taveras and colleagues²³ specifically targeted fast food consumption, finding marginally larger changes for preschoolers in the intervention compared to control group. Additional dietary changes for which no outcome data was reported include eating breakfast daily,²⁴ portion control,^{21,24} and limiting snacking.²⁴ Across the seven trials, only Kuhl and colleagues⁶⁹ specifically examined the relationship between dietary changes (calories, FVs, SD, sweet and salty snacks) and weight outcomes, finding decreases in caloric intake were the only significant dietary predictor of BMI z-score (BMI_z) reductions for intervention preschoolers.

Strategies taught for achieving dietary changes include self-monitoring,^{16,18,20,21,23,24} shaping,^{16,20,21} stimulus control,^{16,20,21} modeling,^{16,20,21} an interactive website with recipes,²³ vegetable taste tests,^{16,20} positive feeding practices,^{16,20} and child behavior management strategies.^{16,20,21,24} However, data on participant use of these strategies and the relation between strategy implementation and behavior changes are lacking. Stark and colleagues^{16,20} provide the only outcome data on use of behavior change strategies and this report is limited to stimulus control within the home food environment. Providing education and engaging families in “home clean-outs” at home visits yielded significantly greater reductions in high-calorie foods for families in the intervention compared to control groups that were maintained to the 6-month follow-up. While significantly greater increases in FVs and decreases in SD were evident for intervention compared to control families at post-treatment, changes were not sustained at the 6-month follow-up.

Physical activity (PA)—Similar to diet, unique challenges to modifying PA are evident during the preschool years. Unlike older pediatric age groups and adults, preschoolers are physically active in isolated and sporadic spurts^{70,71} that can range from a fraction of a second to 9 minutes.⁷² Because only a small portion of activity spurts reach the moderate to vigorous activity level, it can take over 11 hours for preschoolers to meet the recommended 60-minutes of daily moderate to vigorous physical activity (MVPA).⁷² Parent-reported barriers to increasing preschooler PA include lack of knowledge about what constitutes MVPA, difficulty measuring daily activity, outdoor safety, inability to monitor or engage in PA with their child, parent dislike of PA, and inclement weather.^{73,74} Caregivers may overestimate the amount of PA their preschoolers are getting at (pre)school or daycare,⁷⁵ which may further hinder encouraging PA at home. While homes of obese preschoolers have been found to have fewer PA devices,^{76,77} studies have not consistently found preschoolers with overweight or obese engage in lower levels of PA than their healthy weight peers.⁷⁸ However, an inverse association between vigorous PA and overweight in preschoolers has been found.⁷⁹

While PA was included as a component within all published preschool obesity interventions, the type of activity targeted varied. Stark and colleagues^{16,20} found MVPA remained stable and consistent with program recommendations across all assessment time points with no between groups differences. While all preschoolers in the trial conducted by Bocca and colleagues¹⁸ increased their daily step count, increases were only significant for those in the control condition and there were no between group differences. Kelishadi and colleagues¹⁹ reported energy expenditure increases (not significant) for all preschoolers in their trial from pre to post-treatment and at the follow-up assessments across 3 years. Of the two studies to recommend increases in outdoor play, only Taveras and colleagues²³ reported outcome data, finding small increases irrespective of group assignment. Similar to diet, only Kuhl and colleagues⁶⁹ evaluated the relationship between activity changes and weight outcomes. MVPA was not a significant predictor of BMIz change. Specific strategies targeting PA changes included self-monitoring,^{16,18,20,21} pedometers,^{16,18,20} working with families to modify the home environment to support PA,^{16,20} structured PA sessions,¹⁸ and inclusion of child²¹ or family-based activity during in-person intervention sessions.^{16,20} No outcome data was reported on use of these strategies.

Sedentary activity (SA)—Preschoolers are estimated to spend 52–70% of their waking hours engaged in SA.^{72,80} While many developmentally appropriate activities for this age-group are sedentary in nature (e.g., coloring, playing with blocks), preschoolers also regularly engage in screen activities like watching television, using computers, and playing video games.⁸¹ Exceeding 2 hours of television daily nearly triples the risk of overweight in preschoolers⁸² and having a television present in the bedroom increases weekly viewing time⁸³ and obesity risk.^{77,84} Despite short and long-term associations of preschooler screen use to obesity,^{82,85} caregivers report difficulty modifying this lifestyle behavior because children enjoy it, screens are a good “babysitter,” and screens are a “go-to” activity during inclement weather.^{60,86,87}

While reducing sedentary activity was included as a component in five preschool obesity interventions,^{16,20,21,23,24} outcome data are only available for two studies.^{23,69} Stark and colleagues⁶⁹ report screen use for families randomized to their clinic and home-based intervention only. While significant reductions in television use from pre to post-treatment were observed, this change was not a significant predictor of BMIz decreases.⁶⁹ Taveras and colleagues²³ found significantly greater reductions in screen use for preschoolers in the intervention compared to control condition but no group differences on removal of televisions from preschoolers’ bedrooms. Screen use reductions achieved by intervention preschoolers did not meet recommendations in either study. In contrast to diet and PA, preschool obesity interventions encourage generalization of a broader set of child behavior management (e.g., ignoring, time out)^{16,18,20,21} and behavior change skills (e.g., self-monitoring, stimulus control)^{16,20,21,23,24} rather than provide specific strategies to aide families in efforts to reduce preschooler screen use. Taveras and colleagues also offered television allowance units.²³

Sleep—Preschoolers are currently sleeping an average of 11.5–12 hours per day,⁸⁸ which is within the recommended 10–13 hours.⁸⁹ Sleep *duration* is more variable (9.1–14.2 hours)⁸⁸

and concerning given its association with concurrent and later obesity.⁹⁰ Some research suggests that compared to older age groups, the risk for subsequent overweight and obesity may be particularly high among young children with inadequate sleep. Preschoolers who get less than 10-hours of sleep have 1.5⁹¹ to greater than 5 times⁹² the odds of subsequent overweight and obesity compared to preschoolers who sleep 11 hours,⁹³ with evidence of this risk tracking into adulthood.⁹⁴ Although the risks for obesity are multifactorial, inadequate sleep may be a particularly strong predictor. Short sleep (8 hours) was found the strongest of 22 identified risk-factors for preschool obesity⁹⁵ while adequate sleep (10-hours) was the only significant predictor of decreased obesity risk in a model including three additional protective factors for obesity (frequent family meals, 2 hours screen use daily, and no television in the bedroom).⁹⁶ In a longitudinal cohort study of preschoolers, a dose-response association between sleep and weight was reported: each additional hour of sleep at ages 3–5 years (average of 11 hours) was associated with nearly a half unit reduction in BMI and reduced risk of being overweight at age 7 years.⁹⁷ Similarly, Clifford and colleagues⁹⁸ found in a sample of preschoolers with obesity, each hour of nighttime sleep (mean of 10 hours) was associated with a reduction in BMIz of 0.14 units.

Barriers to adequate sleep are more frequently reported for preschoolers with obesity.^{99,100} One of the most common barriers noted is lack of a consistent bedtime routine.¹⁰¹ The predictability of routines allows children to transition between activities more easily¹⁰² and decreases the likelihood of other sleep related problems that lead to insufficient sleep.¹⁰¹ Preschoolers with obesity are more likely to have bedtimes later than 9 PM,¹⁰⁰ which is associated with 48 minutes less nighttime sleep.¹⁰³ While the body of research linking sleep to obesity risk is rapidly growing, sleep is not included as a component of any published preschool obesity interventions.

In sum, all preschool obesity interventions evaluated within the context of published randomized controlled trials to date are multicomponent, which reflects the multiple behavioral risk factors for obesity in early childhood. While diet, PA, and SA are included as components in the majority of interventions, sleep has not been included in any interventions despite consistent and compelling evidence for its association with obesity in preschoolers. Understanding which combination of diet and activity behaviors is most salient to preschool obesity reduction is complicated due to variability in the specific diet and activity behaviors targeted and what recommendations were provided to families. Further, the majority of weight control trials do not include outcome data for lifestyle behaviors targeted within the interventions with only one study evaluating the differential impact of lifestyle behavior changes on preschooler weight outcomes. Decreasing caloric intake appears the most consistently addressed and achieved behavioral recommendation. Changes to preschooler PA were low and not significantly different from preschoolers in control conditions despite intervention preschoolers experiencing significantly greater obesity reductions. Findings in three studies^{16,18,20} that preschoolers were already meeting PA recommendations at baseline also call into question whether recommendations are sufficient to yield obesity reductions. Reductions in screen-use did not equate to adherence to recommendations and few families removed televisions from preschooler bedrooms may reflect the significant challenge to making these changes for young children.

Future Directions to Optimize Preschool Obesity Interventions

While the literature suggests multicomponent interventions are a promising approach to preschool obesity reduction,¹⁵ research is needed to identify *which* behavioral components should be included in multi-component programs, *the degree* of change targeted, and the most effective and efficient approaches for achieving recommended lifestyle changes and subsequently preschool weight control. The Multiphase Optimization Strategy (MOST)^{104–107} and Sequential Multiple Assignment Randomized Trials (SMART)^{107–109} are two innovative approaches with distinct advantages for advancing the preschool obesity treatment literature (See Table 5). At present, no published studies have applied MOST or SMART to develop preschool obesity interventions. However, Brophy-Herb and colleagues¹¹⁰ are applying MOST to examine individual and interactive effectiveness of 6 different strategies (meal delivery, ingredient delivery, community kitchen, healthy eating classes, cooking demonstrations, provision of cookware) on increasing frequency of family meals and the quality of foods served at those meals. Outcomes will be used to develop an obesity prevention program for preschoolers participating in Head Start.

Determining Intervention Effectiveness

Understanding what defines clinically significant improvements in obesity reduction is a third important step for gauging progress of the preschool obesity treatment literature. In adult studies, a loss of at least 5% of excess body weight is associated with clinically meaningful improvements in long-term health outcomes, with even greater health benefits following a loss of 10–15% of body weight.¹¹¹ At present, no guidelines exist for determining clinically meaningful change when intervening on obesity in preschool-aged children.¹⁵ In this section, we synthesize available data on markers of intervention effectiveness and provide recommendations for future research directions to move towards defining clinically meaningful change in preschool-aged children.

Obesity Reduction—Within the preschool obesity treatment literature the metrics used to assess weight are variable (see Table 2). Standardized BMI score (BMI_z or BMI SDS) is the most common metric but others include waist circumference,^{19,112} percent body fat,^{18,19} BMI percentile,^{16,20} percent over BMI²¹. Within the six trials reporting standardized BMI score, only four achieved significantly greater pre to post-treatment (16-weeks to 12-months) mean reductions in BMI_z for intervention compared to control arms^{16,18,20,22,112} In these trials, mean change in BMI z-score for intervention preschoolers at post-treatment ranged from −0.37 to −0.50.^{16,18,20,22} Outcomes were maintained at follow-up time points 6-months post-treatment for two trials^{16,20} and 12- and 24-months post-treatment for one trial.²² Additionally, while Kelishadi and colleagues¹⁹ did not find significant between group differences from pre- to post-treatment, significant between group differences were observed at 24-months post-treatment. Further, in a prospective study of the association between childhood weight trajectories and adult weight status, De Kroon and colleagues¹¹³ reported a mean reduction in BMI-SDS of −0.36 relative to −0.10 between 2 and 6 years of age to distinguish adults with normal weight from adults with obesity.

Although there continues to be much debate over the best metric for examining change in weight-outcomes,^{114,115} research with older children (aged 6–17 years) with overweight or

obesity suggests reductions in BMI_z or BMI-SDS of 0.25–0.50 are associated with clinically meaningful improvements in biomarkers of cardiovascular (CVD) risk at 6- and 9-months post-treatment.^{116,117} However, among this same age range, other research has documented improvements in CVD biomarkers with even smaller reductions in BMI_z<0.10 at 12-months post-treatment.¹¹⁸ Within this review, the interventions to treat obesity in preschool-aged children achieve short- (–0.37 to –0.50) and long- (–0.1 to –0.50) term reductions in BMI_z and BMI-SDS consistent with parameters of clinically meaningful change for older children and suggest the effects of intervention on obesity reduction in preschool-aged children may be greater and more enduring.

Cardiovascular risk reduction—In addition to measures of weight, effect on chronic disease risk reduction is a second marker of clinically meaningful change for obesity interventions. Obesity during the preschool years not only increases the risk for the early emergence of precursors to CVD (e.g., large waist circumference, indicators of insulin resistance, and elevated glucose, lipids, blood pressure, markers of inflammation) during the preschool years,¹¹⁹ but also increases the risk for CVD in adulthood.¹²⁰ For example in one of the few studies to examine the long-term implications of CVD factors during the preschool-years, Juhola and colleagues¹²¹ found abnormal levels of CVD risk in children 3–9 years old was associated with approximately two to over four times the risk of abnormal levels of CVD risk factors 27-years later. Further evidence of persisting risk from childhood into adolescence¹²² and adulthood has been documented in prospective studies with older children.¹²³ Clustering of CVD risk factors as early as age 6 is associated with nearly five times the odds for clustering of CVD risk in adolescence.¹²² Similarly clustering of CVD risk factors at 6–19 years of age (mean age=12.9 years) is associated with six times the odds for later clustering of risk factors and over 14 times the odds of CVD in adulthood.¹²³ Findings that each 10-point change in age-and-sex specific BMI percentile from childhood to adulthood was associated with a 24% change in risk for clustering of CVD risk factors in adulthood illustrate the broader health impact of intervening on obesity early in childhood¹²³

Within the preschool obesity treatment literature, only two studies examined the impact of obesity reduction on CVD risk. Bocca and colleagues¹⁸ explored short-term effects (16 weeks; post-treatment) of their interventions on preschooler CVD risk. Although no between-groups differences were evident at post-treatment, the treatment group demonstrated significant improvements in low-grade inflammation. When the treatment and control were collapsed, improvement in percent body fat was positively correlated with improvements in glucose metabolism and lipid profile. Improvements in percent body fat, BMI_z, waist-circumference z-score, and visceral fat were also each significantly associated with improvements in leptin concentrations. Second, Kelishadi and colleagues¹⁹ found significant improvements at post-treatment (6-months) for lipid [triglycerides (TG) and HDL-cholesterol] and glucose metabolism values (insulin and HOMA-R) across the three arms in their trial, but these changes were not maintained at the 6–24 month follow-up assessments. For the dairy treatment group only, CVD risk factor values continued to show improvement over baseline values until the 12-month follow-up for TG, insulin, and HOMA-R values and significant until the 24-month follow-up for HDL-cholesterol. There were no significant changes observed in measures of blood pressure, fasting blood glucose,

or indicators of inflammation and associations with measures of weight change were not reported. Prospective research looking at the long-term implications of change in adiposity on CVD risk among preschool-aged children with overweight and obesity is largely lacking from the current body of research and warrants future investigation.

In addition to the positive effects of weight reduction on CVD risk, evidence suggests change in the health behaviors linked to obesity in preschoolers may have important implications on long-term weight-management as well as clinically meaningful improvements in CVD risk. For instance, in a three-year, cluster randomized controlled trial targeting diet and CVD risk for preschoolers in Head Start,^{124–126} treatment had no effect on child weight but preschoolers at intervention sites experienced significantly greater improvements in diet (total caloric intake, calories from saturated fat, and grams fat) and CVD risk compared to children at control sites 1-year after the start of treatment.¹²⁵ Among children in the treatment group, reductions in CVD risk at year 1 were also associated with significant reductions in BMI at the 1-year post-treatment follow-up.¹²⁷ These findings suggest while reduction in caloric intake may be particularly important for weight reductions in the short-term,⁶⁹ changes in nutritional content may also be important for short- and long-term health outcomes.

While interventions included in this review did not have significant effects on PA, research with school-aged children who participated in an intervention to increase PA demonstrated significantly greater change in percent overweight compared to children in the control group at 5 and 10-years, suggesting PA may have important implications on long-term weight-management.¹²⁸ In a separate study, school-aged children were followed for 7-years, and those with the lowest initial fitness levels (lower VO₂peak) experienced greater clustering of CVD risk factors 7-years later relative to children who were more fit.¹²² Similar to the larger body of preschool obesity treatment literature, research examining associations between change in specific health behaviors and improvements in preschooler obesity are limited, while investigations of associations with improvements in CVD risk factors are currently lacking. Therefore, research is not only needed to better understand the short- and long-term implications of specific health behaviors changes on obesity and associated comorbidities, but research is also needed to determine the amount and duration of changes needed to achieve clinically-meaningful change.

In sum, the literature to date suggests intensive, multicomponent behavioral lifestyle interventions are the most efficacious approach to reducing overweight and obesity in preschool-aged children.⁵⁸ The magnitude of treatment effects on measures of excess weight in preschoolers may also have important implications for reducing short- and long-term CVD risk, which has the potential to reduce the extraordinary annual economic costs (approximately \$300 billion) resulting from obesity and obesity-related illness.¹²⁹

Future Directions to Increase Understanding of Intervention Effectiveness

While clinically meaningful change for BMIz has been identified in older children,^{116–118} this threshold has not been identified for preschool children. Additional research is needed to identify the most important metric(s) for identifying the change that is considered clinically meaningful for children between the ages of 2 and 5 years-old. Studies measuring biological

outcomes are also needed to examine the impact of changes in weight and health behaviors on short and long-term CVD and metabolic functioning. Bugge and colleagues¹²² reported lower retention of participants for data points involving more invasive procedures including VO2 peak analysis and biological measures. The combined use of BMI and waist circumference may provide an acceptable alternative to measuring and tracking obesity related health risks¹¹⁹ as research has also found BMI and waist circumference in 3- to 6-year olds predicted the same CVD risk factors in this young age group.

Conclusions

Despite recent declines, excess weight gain during the preschool years is prevalent and problematic with persistent disparities among children from low-income and minority backgrounds.^{1,2} While multidisciplinary, intensive behavioral interventions may be a promising approach to preschool obesity reduction,¹⁵ our review reveals preschool weight control trials have had poor reach to families from low-income and minority backgrounds, do not provide sufficient evidence to determine the most effective and efficient treatment components and approaches to treating obesity in early childhood, and lack consensus on how best to discern intervention effectiveness. Addressing these three critical gaps is necessary to advance the preschool obesity treatment literature and eliminate early childhood obesity disparities. In addition to exploring alternative recruitment settings that may increase reach to families from low-income and minority backgrounds and identifying strategies for improving accuracy of caregiver perceptions of preschooler weight status, completion of formative work that integrates user-centered design may improve enrollment. Applying innovative designs like MOST^{104–107} and SMART^{107–109} will allow researchers to efficiently determine the most effective behavioral targets, the most efficient approaches and strategies for yielding behavior change, and whether and how interventions should be modified so they are optimized for families from different sociodemographic backgrounds. Including outcome measures for *all* behaviors targeted and recommended change strategies targeted is also necessary to build empirically-supported treatments. Finally, assessment of changes in risk-factors for cardiovascular disease and other physical and psychosocial health consequences of obesity is important for reaching consensus on a definition of clinically meaningful obesity reduction for preschoolers.

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KEY POINTS

- * Nearly one quarter of preschoolers are overweight or obese, with persistent disparities among those from low-income and minority backgrounds.
- * Developing interventions effective at obesity **reduction** in early childhood is imperative given the immediate physical and psychosocial health consequences of excess weight gain and its persistence to adulthood if not addressed.
- * Poor reach to families from low-income and minority backgrounds, insufficient evidence to determine the most effective and efficient treatment components and approaches to treating obesity in early childhood, and lack consensus on how best to discern intervention effectiveness are three critical gaps in the extent preschool obesity treatment literature.
- * Addressing these gaps is imperative to eliminating preschool obesity disparities and reducing the overall prevalence of obesity in early childhood.

Box 1**Barriers and recommendations for improving reach of preschool obesity interventions**

<u>Barrier/Challenge</u>	<u>Recommendation</u>
<ul style="list-style-type: none"> Inaccurate perception of child weight status 	<ul style="list-style-type: none"> Increased discussion of weight with pediatrician Increased frequency of diagnosing overweight and obesity by pediatrician Use of tools to increase accuracy of caregiver perception of child weight status (e.g., Weight Rulers and Color-coded BMI charts)
<ul style="list-style-type: none"> Recruitment limited to medical settings (weight management clinics and pediatrician offices) 	<ul style="list-style-type: none"> Expand recruitment to other settings frequented by families with overweight and obese children such as the emergency department Partner with community organizations, especially those serving predominately low-income and minority families
<ul style="list-style-type: none"> Failure to include families of overweight and obese preschoolers in the treatment development process 	<ul style="list-style-type: none"> Formative studies to explore with families of obese preschoolers what they want and need in programs targeting obesity reduction Emphasis on understanding needs of families from low-income and minority backgrounds given these populations are underrepresented in the preschool obesity treatment literature despite being at greater obesity risk.

Box 2**Considerations for Developing Optimized Preschool Obesity Interventions**Developmental barriers to lifestyle modification in preschoolers

- Neophobia
- Tantrums (preferred foods and activities)
- Desires for autonomy
- Activity in sporadic bursts
- Short attention span
- Developmentally appropriate activities are often sedentary (e.g., playing with blocks)
- Need for supervision
- Challenges to playing/staying occupied independently

Promising components

- Decreasing caloric intake⁶⁹
- Increasing vigorous activity⁷⁹
- Increasing sleep duration⁹⁰⁻⁹⁴
- Stimulus control for home food environment^{16,20}

Important steps to developing optimized preschool obesity interventions

- Measurement of and reporting outcome data for all components and strategies
- Determine what rate of lifestyle behaviors is associated with preschool obesity reduction
- Implement efficient designs like MOST and SMART

Table 1

Recruitment and sample characteristics

Study	Number attempted/invited	Number eligible	Number (percent) of eligible enrolled	Sample characteristics [M(SD)/n(%)]
Kelishadi et al., 2009 ¹⁹	120	120	120 (100%)	Child Age ^b : 5.6±0.5 BMI-SDS: Dairy-rich diet=2.4±0.01 Energy-restricted diet=2.3±0.04 Control=2.4±0.01 BMI: Dairy-rich diet=22.1±0.09 Energy-restricted diet=22.7±0.8 Control: 22.4±0.5
Stark et al., 2011 ²⁰	109	56	18 (32%)	<u>Child</u> BMI Percentile: Intervention=99±0.9 ESC=97.7±2.5 Age: Intervention=4.4±0.92 ESC=3.9±1.1 Sex (female): Intervention=2 (25%) ESC=4 (40%) Minority: Intervention=3 (25%) ESC=1 (10%) Hispanic: Intervention=2 (25%) ESC=1 (10%) <u>Caregiver^a</u> Age: Intervention=36±3.61 ESC=35±4.24 Education (college degree): Intervention=5 (62.5%) ESC=6 (60%) Income (\$50,000 annually): Intervention=8 (100%) ESC=8 (80%)
Taveras et al., 2011 ²³	3253	1008	475 (47%)	<u>Child</u> Age: Intervention=4.8±1.2 Usual Care=5.2±1.1 Minority: Intervention=135 (53%) Usual Care=58 (30%) BMI z-score: Intervention=1.88±0.69 Usual Care=1.82±0.56 BMI: Intervention=19.2±2.6 Usual Care=19.2±2.0 <u>Caregiver</u> Obese: Intervention=154 (61%) Usual Care=84(44%) Education(college): Intervention=147 (58%) Usual Care=127 (66%) Income (\$50,000 annually): Intervention=160(64%) Usual Care=153(80%) Marital Status (married): Intervention=187(75%) Usual Care=151(79%)
Bocca et al., 2012, 2014 ^{18,112}	78	75	75 (100%)	<u>Child</u> Age: Intervention=4.6±0.8 Usual Care=4.7±0.8 Sex(female): Intervention=28(70%) Usual Care=12(30%) BMI: Intervention=21.2±2.9 Usual Care=21.0±2.7 BMI z-score: Intervention=2.7±1.0

Study	Number attempted/invited	Number eligible	Number (percent) of eligible enrolled	Sample characteristics [M(SD)/n(%)]
				Usual Care=2.7±1.0
Quattrin et al., 2012, 2014 ^{21,22}	171	147	105 (71%)	<p><u>Child</u></p> <p>Age: Intervention=4.6±1.1 Control=4.4±1.1</p> <p>Sex(female): Intervention=31(67%) Control=33(66%)</p> <p>Minority: Intervention=13(28%) Control=13(26%)</p> <p>BMI z-score: Intervention=2.2±0.8 Control=2.1±0.7</p> <p>% Over BMI: Intervention=32.4±22.4 Control=29.8±17.1</p> <p><u>Caregiver</u></p> <p>Age: Intervention=37.2±5.0 Control=36.4±5.0</p> <p>Sex(female): Intervention=33(72%) Control=39(78%)</p> <p>Minority: Intervention=12(26%) Control=8(16%)</p> <p>Income: Median=\$65,729 <\$20,000=8 (8.3%)</p> <p>BMI: Intervention=37.2±8.3 Control=36.2±6.9</p>
van Grieken et al., 2013 ²⁴	13792 ^c	unknown	637 ^d	<p><u>Child</u></p> <p>Age (months): Intervention=68.65±4.98 Control=69.64±5.37</p> <p>Sex(female): Intervention= 214(61.3%) Control=179(62.3%)</p> <p>Minority: Intervention= 80(24.2%) Control= 56 (19.4%)</p> <p>BMI: Intervention=18.6±0.63 Control=18.10±0.61</p> <p><u>Mothers</u></p> <p>Age: Intervention=35.8±4.23 Control=35.92±4.37</p> <p>Education (mid-high/High): Intervention=333(66.7%) Control=197(68.5%)</p> <p>BMI (overweight/obese) Intervention= 155 (44.5%) Control= 135 (43.4%)</p>
Stark et al., 2014 ¹⁶	277	153	42 (27%)	<p><u>Child</u></p> <p>Age: ESC=4.8±0.7 LHV=4.7±1.3 LC=4.2±1.1</p> <p>Sex(female): ESC=8(67%) LHV=8(80%) LC: 7(64%)</p> <p>Minority: ESC=3(25%) LHV=1(10%) LC=1(9%)</p> <p>BMIz: ESC=2.4±0.4 LHV=-2.1±2.1 LC=2.5±2.5</p> <p>Family Income (\$50,000 annually): ESC=10 (83%) LHV=8 (99%) LC: 9 (82%)</p>

ESC=enhanced standard of care, LHV=LAUNCH with home visits, LC=LAUNCH clinic only

^aSample characteristics are for mothers only as few fathers were primary caregiver targeted for intervention [Mothers=7 (87.5%); Control=9 (90%)]

^bAge only reported in the manuscript for sample as a whole

^cNumber reflects all families invited as recruitment information was not presented by preschooler weight status

^dPercent enrollment cannot be determined because recruitment flow was not differentiated by preschooler weight status

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Table 2

Preschool Weight Control Trial Characteristics

Study	Trial Arm	Length	Dose	Session Location	Session Length	Interventionist(s)	Format
Kelishadi et al.(2009) ¹⁹	Healthy Lifestyle Education + Dairy-Rich	6 months	6 monthly	Obesity Research Center	Did not report session length	Pediatrician and Nutritionist	Group
	Healthy Lifestyle Education+ Energy Restriction	6 months	6 monthly sessions	Obesity Research Center	Did not report session length	Pediatrician and Nutritionist	Group
	Healthy Lifestyle Education (Control)	6 months	6 monthly sessions	Obesity Research Center	Did not report session length	Pediatrician and Nutritionist	Group
Stark et al. (2011) ²⁰	Control	1 session	1 session	Academic medical center (50 miles from homes of participating families)	45–60 minutes	Pediatrician	Individual
	Intervention	6 months	18 sessions (weekly for 3 months, biweekly for 3 months)	Same academic medical center as control and homes of participating families	Group visits=90 minutes; home visits=60–90 minutes	PhD level psychologist (parent groups); pediatric psychology post-doctoral fellow and research coordinator (child groups); pediatric psychology post-doctoral fellow (home visits)	Group and individual sessions
Taveras et al.(2011) ²³	Intervention group	One year	Four in-person sessions and three phone calls	Pediatrician's Office	25 minute in-person sessions and 15 minute phone sessions	Pediatric nurse practitioners	Individual families
	Usual Care	One year	One well-child visit	Pediatrician's Office	Did not specify length	Pediatricians	Individual families
Bocca et al. (2012, 2014) ^{18,112}	Intervention	4 months	25 sessions (Behavioral Therapy; 6 sessions; Physical Activity; 12 sessions; Dietary advice; 6 sessions	Groningen Expert Center for Kids with Obesity (GECKO)	30 hours – Behavioral therapy sessions: 120 minutes; Physical activity sessions: 60 minutes; Dietary advice: 30 minutes	Psychologist, Physiotherapist; Registered Dietitian	Group
	Control	4 months	3 sessions	GECKO	30–60 minutes	Pediatrician	Group
Quattrin et al.(2012, 2014) ^{21,22}	Intervention	6 months	10 sessions (4 weekly, 2 bimonthly, 4 monthly); 8 phone calls in between meetings	Primary Care	Sessions each lasted 60 minutes	Patient Enhancement Assistants and project manager=group leaders; Pediatricians reviewed progress	Group
	Information Control	6 months	10 sessions (4 weekly, 2 bimonthly, 4 monthly); 8 phone calls in between meetings	Primary Care	Sessions each lasted 60 minutes	at 3 and 6 months Group leaders trained to deliver intervention; Pediatricians reviewed progress at 3 and 6 months	Group

Study	Trial Arm	Length	Dose	Session Location	Session Length	Interventionist(s)	Format
Van Grieken et al. (2013) ²⁴	Intervention	One year	Up to 4 sessions	Youth Healthcare Centers (YHC)	Did not specify	Physician-Nurse Teams, Mostly Physicians	Individual
	Usual Care Control	One Year	One Session	YHC	Did not Specify	Physician-Nurse Teams, Mostly Physicians	Individual
Stark et al. (2014) ¹⁶	Control	1 session	1 session	Academic medical center (50 miles from homes of participating families)	45–60 minutes	Pediatrician	Individual
	Intervention-clinic and home	6 months	18 sessions (weekly for 3 months, biweekly for 3 months)	Same academic medical center as control and homes of participating families	Group visits=90 minutes; home visits=60–90 minutes	PhD level psychologist (parent groups); pediatric psychology post-doctoral fellow and research coordinator (child groups); pediatric psychology post-doctoral fellow (home visits)	Group and individual sessions
	Intervention-clinic only	9 months	9 sessions (biweekly for 3 months, monthly for 3 months)	Same academic medical center as control	90 minutes	PhD level psychologist (parent groups); pediatric psychology post-doctoral fellow and research coordinator (child groups)	Group only

Table 3

Example of how to apply the NIH ORBIT model⁴³ to complete formative steps of developing a preschool obesity intervention for underserved populations

Phase	Example
1: Design	
1a: Define	<ul style="list-style-type: none"> - Review guidelines and empirical literature to identify promising behavioral targets, change strategies, and intervention approaches/structure - Semi-structured qualitative interviews or focus groups with targeted population to complete needs assessment and determine feasibility and acceptability of extant interventions
1b: Refine	<ul style="list-style-type: none"> - Semi-structured qualitative interviews or focus groups with targeted population provide feedback on content, structure, dose, delivery setting/method, etc. of beta version of intervention developed from information collected in “define” stage - Ideally would include having members of the targeted population complete a particular session and/or utilize a specific strategy (e.g., new self-monitoring tool) for a shortened period of time - Adapt and modifying intervention based upon feedback from participants
2: Preliminary Testing	
2a: Proof-of-Concept	<ul style="list-style-type: none"> - Open trial (small n) where members of the targeted population complete the intervention. - Include qualitative methodology to gather in-depth feedback from families on their intervention experience. - If possible, and needed, complete interviews with families who drop out to understand what (if anything) could be done differently to promote retention - Adapt and modifying intervention based upon feedback from participants and outcome data - Repeat until intervention achieves clinically significant reduction in preschooler obesity status
2b: Pilot Studies	<ul style="list-style-type: none"> - Pilot randomized controlled trial with adequate control group (e.g., treatment-as-usual in primary care or WIC). - Include qualitative methodology to gather information on intervention feasibility and acceptability with all or randomly selected subset of intervention completers. - If possible, and needed, complete interviews with families who drop out to understand what (if anything) could be done differently to promote retention - Adapt and modifying intervention as warranted based upon feedback from participants and outcome data - Repeat until intervention achieves significantly greater reduction in preschooler obesity status compared to the control condition.

Table 4

Summary of Components and Behavior Change Data

Study	Behaviors Targeted	Recommendation/Daily Goal	How Change Measured	Baseline Post-treatment	Baseline to 12 months ^a
Kelishadi et al. 2009 ¹⁹	Caloric Intake	NS	Diary (3-day)	MNR	MNR
	Calcium Intake	NS	Diary (3-day)	MNR	MNR
	Activity	NS	Parent Report	MRN	MNR
Stark et al., 2011 ²⁰	Caloric Intake	1000–1400 ^b	24-hour dietary recalls	LHV = -218±354 ESC = 322±280	LHV -214±327 ESC = 311±372
	FVs	5 servings	24-hour dietary recalls	NR ^c	NR ^c
	MVPA	60 minutes	Accelerometer	NR ^c	NR ^c
Taveras et al., 2011 ²³	Screen Use	2 hours	Parent report	NR ^c	NR ^c
	Sugary drinks	Reduce/Eliminate	24-hour dietary recalls	NR ^c	NR ^c
	Sugary Drinks	<4 ounces	Parent Report	I = -0.59±0.10 C = -0.33±0.06	N/A
	Fast Food	1 outing per week	Parent Report	I = -0.22±0.05 C = -0.02±0.06	
	Screen Use	1 hour	Parent Report	I = -0.53±0.09 C = -0.07±0.09	
	Television in bedroom	Remove	Parent Report	I = -25 (10%) C = -9 (5%)	
	FV	5 servings	Parent Report	I = 0.22±0.09 C = 0.16±0.11	
	Outdoor Active Playtime	60 minutes	Parent Report	I = 0.06±0.10 C = 0.20±0.13	
	Caloric Intake ^d	Normocalorie diet	Diet Diary	I _{Baseline} = 1434±252 I _{Post-treatment} = 1323±200	I _{Follow-up} = 1369±244
Bocca et al., 2012, 2014 ^{18,112}	Activity ^d	60 minutes	Pedometer (step count)	C _{Baseline} = 1504±316 C _{Post-treatment} = 1327±220	C _{Follow-up} = 1429±265
				I _{Baseline} = 11998±3031 I _{Post-treatment} = 13823±2711	I _{Follow-up} = 12455±3185
				C _{Baseline} = 9862±2729 C _{Post-treatment} = 1327±220	C _{Follow-up} = 1429±265
Quattrin et al., 2012, 2014 ^{21,22}	Caloric Intake	1000–1400 ^b	Diary	NR	NR
	Activity	60 minutes	Diary	NR	NR

Study	Behaviors Targeted	Recommendation/Daily Goal	How Change Measured	Baseline Post-treatment	Baseline to 12 months ^a
van Grieken et al., 2013 ²⁴	TV/Screen Time	<2 hours	Diary	NR	NR
	Playing Outdoors	1 hour daily	NA	NR	NR
	Eating breakfast	<2 glasses	NA	NR	NR
	Reducing sweet drinks	<2 hours	NA	NR	NR
	Screen activity		NA	NR	NR
Stark et al., 2014 ¹⁶	Caloric Intake	1000–1400 ^b	24-hour dietary recalls	LHV: -465±292 LC: -243±567 ESC= -65±724	LHV: -518±315 LC: -249±592 ESC= -3±620
	FVs	5 servings	24-hour dietary recalls	NR ^c	NR ^c
	MVPA	60 minutes	Accelerometer	NR ^c	NR ^c
Kuhl et al. 2014 ⁶⁹	Screen Use	2 hours	Parent report	NR ^c	NR ^c
	Sugary drinks	Reduce/Eliminate	24-hour dietary recalls	NR ^c	NR ^c
	Caloric Intake	1000–1400 ^b	24-hour dietary recalls	LHV: -72.48±351.93	N/A
	FVs	5 servings	24-hour dietary recalls	LHV: 1.16±3.03	
	MVPA	60 minutes	Accelerometer	LHV: 4.37±18.13	
	Screen Use	2 hours	Parent report	LHV: -26.96±69.34	
	Sugary drinks	Reduce/Eliminate	24-hour dietary recalls	LHV: -1.82±4.22	

NS=not specified; MNR=means not reported (data available only in graphical form); NR=not reported; FV=fruit and vegetable; MVPA=moderate and vigorous activity; LHV=LAUNCH Home Visits; LC=LAUNCH clinic only; ESC=enhanced standard of care; I=intervention; C=control

^aWhile 3 studies included follow-up assessments at 1 up to 3 years post-treatment, outcome data on behavior changes was either not reported^{22,112} or means could not be discerned from graphs.¹⁹

^bDaily calorie recommendations based up preschooler age and sex: 2–3 years-old=1,000, 4–6 year-old girls=1200, 4–6 year-old boys=1400.

^cOutcomes for preschoolers randomized to LHV collapsed across iterative trials and reported in Kuhl et al., 2014⁶⁹

^dChange scores not reported

Table 5

Overview of the Multiphase Optimization Strategy (MOST) and Sequential Multiple Random Assignment Trials (SMART)

MOST^{104–107}

What it is

- A framework for developing optimized interventions, or those that include only components and combinations of components
- Emphasizes *resource management principle*: strategic use of resources to gain the most knowledge in a reliable and efficient manner. Design experiments by prioritizing what information is most important for moving science forward.
- Emphasize *continuous optimization principle*: next round of experimentation begins when the previous is completed; the goal is for each successful round to be a better product.
- Three phases
 - Conceptualization
 - Optimization
 - Evaluation

Example

Conceptualization phase

- Establish the theoretical model: social cognitive theory of change^{16,20}
- Identify components to test: decreasing caloric intake,⁶⁹ increasing sleep duration^{90–94} and vigorous activity⁷⁹
- Conduct pilot/feasibility work: e.g., pilot test whether home food environment modification with interventionist is more effective than prescription for completion by caregivers on modifying home food environment.
- Identify the optimization criterion: BMIz decrease of 0.50 at 6 months^{116,117}

Optimization phase

- Factorial design to examine each component and whether individual effects are strengthened or damped when combined.
- Refine effective component(s) to discern optimal level and dose for by SES and racial/ethnic background.
- SMART trials (see below)

Evaluation phase

- Compare the optimized intervention to standard of care

How it's different from traditional intervention development approaches

- Instead of testing a package first and then dismantling, MOST begins by examining the individual and combined effectiveness of components first. A comparative effectiveness trial is not conducted until the optimized intervention including only effective components is developed.
- Through use of factorial designs, researchers can answer questions about what components or combinations are the most effective in 1 study rather than a series of studies that would examine 1–2 components to a control

Advantages

- Factorial designs are the only approach that allows investigators to obtain information on individual AND combined effects.
- Use of factorial designs necessitates fewer participants than if the same questions were answered over the course of multiple RCTs
- Effect sizes for components and combinations of components are obtained at each step of development

SMART^{107–109}

What it is

- Implemented to develop staged treatments that adapt in response to specific criteria over time
- Design that has multiple randomizations that are sequenced over time

- Randomizations occur at critical treatment decision points and seek to evaluate two or more treatment options at that decision point
- Type of factorial experiment
- Can be integrated within the MOST framework (during optimization stage, refining step)

Example

- Randomization 1: weekly sessions of motivational Interviewing versus behavioral intervention
- Randomization 2: at 1 month
 - Critical decision: weight loss or maintenance at 1 month=responder
 - If respond, then randomize to relapse prevention or termination
 - If do not respond, then randomize to continue with initial treatment approach or switch to whatever approach was not received first
- Questions that can be answered from this SMART design:
 - What is the best first treatment approach?
 - What is the second line treatment?
 - Is relapse prevention necessary for maintenance?
 - What baseline (e.g., age of preschooler) or stage 1 characteristics (e.g., caregiver high or low adherence to monitoring) facilitate second stage treatment sequence tailoring

How it's different from traditional approaches to intervention development

- 1 Multiple randomizations within a single trial
- 2 Comparative effectiveness trial is not conducted until optimized intervention sequence is determined (no randomization at this phase)

Advantages

- 1 Efficient approach to answering questions about treatment sequencing
 - 2 Fewer participants needed than if each randomization was a separate trial because participants are “recycled” across randomizations
 - 3 Can gather information within the context of the study to help with refining tailoring variables (e.g., what is the optimal sequence for families with high versus low motivation for changing preschooler lifestyle behaviors)
 - 4 Increased likelihood of reducing cohort effects
-