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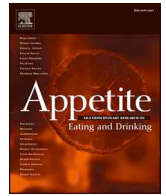
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## Cluster randomized control trial promoting child self-regulation around energy-dense food

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### ABSTRACT

Children with lower inhibitory control have greater weight gain over time and consume more snack food. Our goal was to test whether a pilot program based on enhancing self-regulation in preschool children could decrease consumption of energy-dense foods. Ninety-two preschool children were randomized to the intervention or control group. The intervention was a three-week, play-based program that focused on enhancing executive function skills and decreasing consumption of energy dense snack foods. Controls met for a similar length of time, but focused on dental hygiene, good sleep habits/routines, and physical activity. Primary outcome included calories consumed during the post-intervention “Eating in the Absence of Hunger” paradigm, controlling for baseline calories consumed. Inhibitory control was assessed using the “Day/Night” and “Less is More” tasks. There were no differences in post-intervention calories consumed between groups ( $p = 0.42$ ). However, post-hoc analysis revealed a significant interaction between group and weight status ( $p = 0.04$ ). In the intervention group, overweight/obese and healthy weight children consumed a similar number of calories (118.0 kcals vs. 124.1 kcals respectively,  $p = 0.64$ ). However, in the control group, overweight/obese children consumed more than normal weight children (155.9 kcals vs. 103.6 kcals respectively;  $p = 0.01$ ). With regards to inhibitory control, post-hoc analysis revealed a significant interaction between group and age ( $p = 0.03$ ), with younger children in the intervention group scoring higher than younger children in the control group (0.93 vs 0.78 respectively,  $p = 0.007$ ). No differences were observed between groups among older children (0.93 vs 0.96,  $p = 0.42$ ). These types of programs for preschool children may help to temper consumption of excess calories among overweight/obese children. Further development and investigation of pediatric programs that prevent consumption of excess calories are warranted.

*Trial registration:* Clinicaltrials.gov: [NCT02077387](https://clinicaltrials.gov/ct2/show/study/NCT02077387).

### 1. Introduction

Executive functions (EF) are neurocognitive processes that assist individuals in making appropriate choices among a myriad of options for the purpose of goal attainment, guiding behavioral responses to complex tasks or demands, and supporting social-emotional competencies (Kochanska, Murray, & Harlan, 2000; Miyake et al., 2000). The primary EFs are thought to be inhibitory control (the ability to control and regulate impulsive behaviors), working memory (the ability to update and monitor working memory content), and cognitive flexibility (the ability to shift attention between tasks) (Lehto, Juujarvi, Kooistra, & Pulkkinen, 2003; Miyake et al., 2000; Miyake & Friedman, 2012).

These functions are thought to be developing in preschool age children (Carlson & Moses, 2001; Diamond & Taylor, 1996), and may become more stable as children enter adolescence and adulthood (Friedman et al., 2016; Friedman, Miyake, Robinson, & Hewitt, 2011). While EF may not be directly related to intelligence per se (Friedman et al., 2006), there have been studies to suggest that certain dimensions of EF (like inhibitory control) are associated with school readiness and academic success (Allan & Lonigan, 2011; Blair & Diamond, 2008; Diamond, Barnett, Thomas, & Munro, 2007; Johnstone et al., 2011; McClelland et al., 2007; Mischel, Shoda, & Peake, 1988).

Inhibition is defined as the act of deliberately overriding a dominant or prepotent response (Miyake et al., 2000). With regards to obesity

*Abbreviations:* EF, Executive functions; EAH, Eating in the Absence of Hunger; BMI, body mass index; OW/OB, overweight/obese

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risk, inhibition may be particularly important as individuals try to stop a response to tempting food cues or resist distracting foods and impulses. Several studies have shown that obese children have less inhibitory control than normal weight children (Nederkoorn, Braet, Van Eijs, Tanghe, & Jansen, 2006; Nederkoorn, Coelho, Guerrieri, Houben, & Jansen, 2012; Reinert, Po'e, & Barkin, 2013). Other studies have shown that children with lower levels of inhibitory control measured between the ages of 3–5 years had greater weight gain over time or higher weight status by the age of 11 or 12 years (Francis & Susman, 2009; Seeyave et al., 2009). In addition to predicting weight status, one study demonstrated that the ability to delay gratification (i.e., the ability to inhibit immediate responses to a desirable food) may be acting as a critical mediator of the relationship between chronic life stressors and increase in BMI percentile in children between the ages of 9 and 13 years (Evans, Fuller-Rowell, & Doan, 2012). Furthermore, inhibitory control could act as a moderator of obesity risk. For example, fourth grade children who scored lower on overall EF were shown to have increased consumption of snack foods (Riggs, Spruijt-Metz, Chou, & Pentz, 2012; Riggs, Spruijt-Metz, Sakuma, Chou, & Pentz, 2010) which could put them at risk for greater weight gain over time. Finally, impulsivity appears to moderate the effect of weight control interventions such that children high in impulsivity had less weight loss during treatment and were the most overweight at the end of treatment (Nederkoorn, Jansen, Mulken, & Jansen, 2007).

Combined, this emerging body of literature suggests that lower levels of EF, particularly inhibitory control, may play a role in the increased risk of obesity in part by increasing caloric consumption. As a result, programs to improve inhibitory control skills around food are being tested in adults and children. Among adults, computer-based inhibitory control tasks such as the Go/No-go task (Verbruggen & Logan, 2008a) and the Stop Signal Task (Logan, Schachar, & Tannock, 1997; Verbruggen & Logan, 2008b) have been modified to promote inhibitory responses to highly desired foods (e.g., chocolate, chips, beer), and were successful at decreasing consumption of these foods (Houben, 2011; Houben & Jansen, 2011; Houben, Nederkoorn, Wiers, & Jansen, 2011). For children, a computerized game-world was developed to train 9–14 year-old children with obesity who were completing an inpatient weight loss program to increase inhibitory control and working memory skills (Verbeken, Braet, Goossens, & van der Oord, 2013). Children in the intervention group demonstrated improvements in working memory tasks, but not inhibitory control tasks, and were more successful at maintaining their weight loss eight weeks after discharge. Unfortunately, other brief efforts to train children in response inhibition using a computer game have not been successful at limiting caloric intake (Guerrieri, Nederkoorn, & Jansen, 2008). Recently, Folkvord and colleagues (Folkvord, Anschutz, Nederkoorn, Westerik, & Buijzen, 2014) tried to reward children to refrain from eating after playing a game that promoted energy-dense snacks. Interestingly, those children who were highly impulsive did not benefit from this condition while those who were low impulsive consumed less when rewarded not to eat. While this approach may not be effective for all children, additional efforts to develop inhibitory control skills or more comprehensive treatment programs to address impulsivity, that are also developmentally appropriate for younger children, are worth exploring to help combat the issue of childhood obesity.

The Tools of the Mind program (Bodrova & Leong, 2007), based on the social development theory of Vygotsky (Vygotsky, 1978), focuses on the development of child self-regulation through multiple activities, and suggests that social and cognitive development in young children relies on social interaction and a knowledgeable other who can interact with and share experiences that promote higher-level thinking and cognitive skills. While the concept of self-regulation stems from social and personality psychology literature, many of the skills relevant to self-regulation and EF are similar (Hofmann, Schmeichel, & Baddeley, 2012). In the Tools of the Mind program, mental and physical learning tools such as dramatic play, self-talk, and visual and verbal scaffolding

(supports that act as reminders to promote a behavior) help regulate behavior and thought and allow for planning and creation of solutions to complex problems. Use of these tools also employ many EF skills. For example, with dramatic play, working memory is needed to remember the rules and stories that are being used during the game, cognitive flexibility is needed as one switches roles, games, or stories, and inhibitory control is needed to inhibit basic responses or impulses and stay in character. Therefore, the Tools of the Mind program was viewed as a more developmentally appropriate way to train young children in EF skills. Furthermore, the Tools of the Mind program has been shown to improve inhibitory control, decrease internalizing/externalizing behaviors, and improve receptive/expressive vocabulary and letter/word identification in preschool children (Barnett et al., 2008; Diamond et al., 2007). This program has also been shown to be more successful than direct instruction (e.g., simply telling children that they should refrain from behaving in a certain manner) in developing EF (Diamond et al., 2007), and can assist with long-term learning and socio-emotional competence (Bodrova & Leong, 2007). At this time, programs that promote EF in preschool children have not been adapted to address food stimuli. Considering the role of inhibition in overeating and obesity, it may be important to adapt these programs to focus on the development of EF in young children to prevent excessive weight gain.

To fill this gap, we adapted the Tools of the Mind program (Bodrova & Leong, 2007) to promote food-based self-regulation in preschool children and decrease their consumption of energy-dense snack foods. The goal of this study was to pilot test the effect of a play-based intervention on preschool children's self-regulation and inhibitory control skills around energy-dense snack foods. Given that the intervention would be implemented in the preschool setting, a cluster randomized design was utilized, randomizing at the level of the classroom. Our primary outcome of interest however, was caloric intake of energy-dense snack foods when sated as measured in the Eating in the Absence of Hunger (EAH) free-access paradigm (L. L. Birch, Fisher, & Davison, 2003; Fisher & Birch, 2002) and assessed at the level of the individual. We also assessed inhibitory control skills using age-appropriate tasks. We hypothesized that children enrolled in the intervention would show decreased consumption of energy-dense snack foods when sated compared to those children in the control group. We also hypothesized that inhibitory control skills would improve among those children in the intervention group.

## 2. Materials and methods

### 2.1. Study design

The study was a cluster randomized control trial conducted in preschool settings over a three-week period. Within each school, age-matched classrooms were randomized to the intervention or control group. The intervention was delivered in three preschool sites in San Diego County from June 2014 to November 2015. Each of these preschools had 60 to 62 children at their site in the 4–6 year old age range. These were racially and ethnically diverse preschools: 55% Caucasian, 17% Asian/Pacific Islander, 14% African American, and 14% Mixed/other; 45% reported Hispanic ethnicity.

### 2.2. Recruitment

Families with children aged 4–6 years old were provided with an information packet describing the study and invited to an informational meeting during their regularly scheduled parent-teacher night at the preschool. During the meeting, parents were told that the study was focused on helping children make healthy eating and activity choices. Parents who were interested and were deemed eligible to participate (see eligibility criteria below), completed the consent process with trained research staff and were given questionnaires to complete at home. Questionnaires assessed basic demographic information, medical

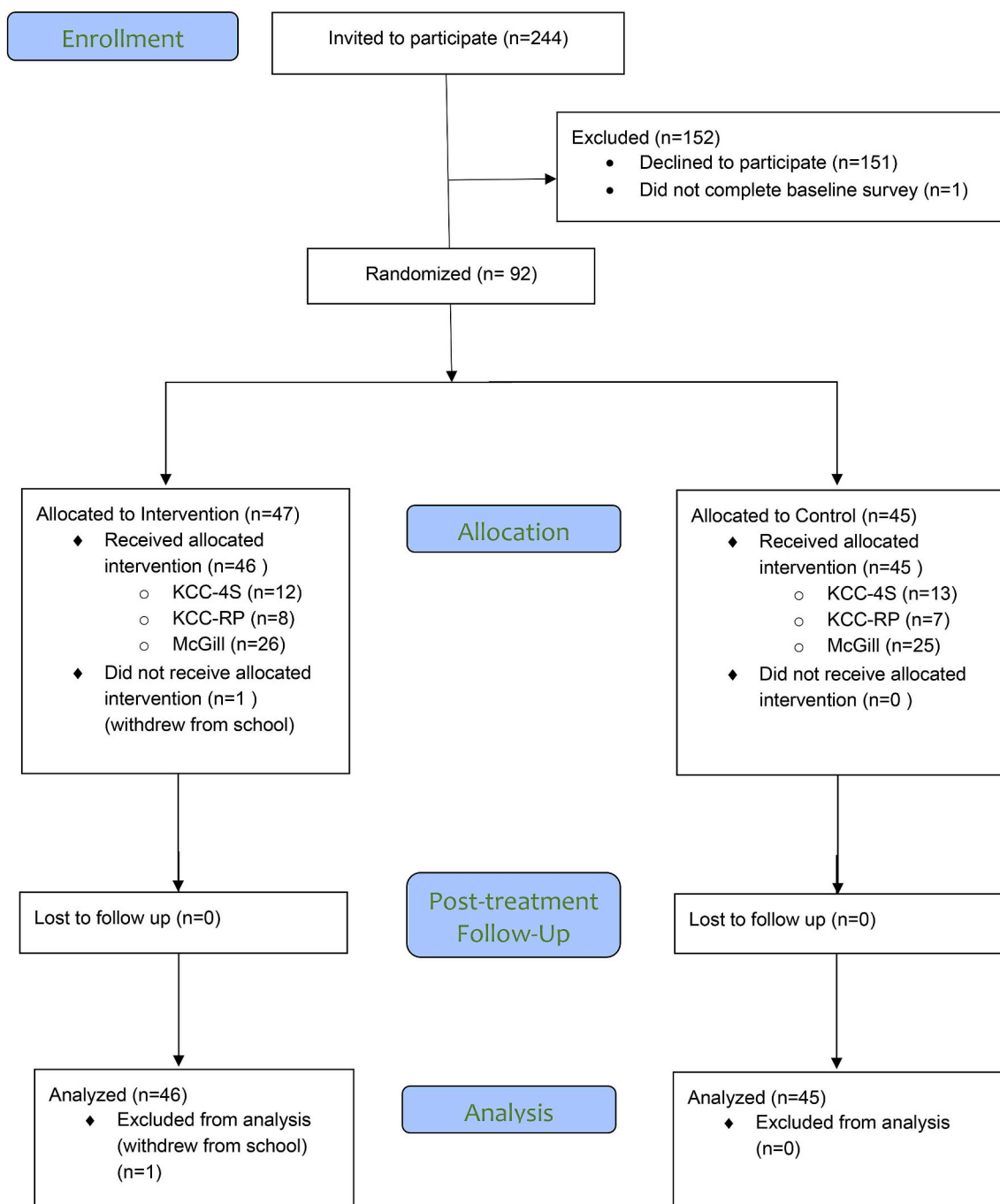


Fig. 1. Consort diagram.

history, and child eating and activity behaviors. Questionnaires were returned to school prior to the start of the study; parents received a \$25 gift card upon completion of the surveys. This protocol was approved by the Institutional Review Board of the University of California, San Diego, and registered in [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT02077387).

### 2.3. Eligibility

Inclusion criteria included children aged 4–6 years old, enrolled in one of the three preschools, with a body mass index (BMI)  $\geq$  5th %ile, and active parent consent. Children with a BMI < 5th %ile are considered underweight based on CDC growth charts (Kuczmarski et al., 2002) and were excluded from the study. Other exclusion criteria included parent-reported child with a major psychological diagnosis,

developmental delay, or other medical disorder that affected weight, eating behaviors, and cognition. Those with food allergies to the foods used in the study and plans to leave the preschool within the timeframe of the study were also excluded (Fig. 1: Consort Diagram).

### 2.4. Intervention arms

On the first day, all children received an introductory lesson (puppet show) on the unhealthy effects of energy-dense snack foods. Children were then randomized to the intervention or the Control Condition (CC) in clusters based on their classroom. Age-matched classrooms were randomly assigned by the study statistician to be in the intervention or control arm, and all consented children in that classroom received the allocated treatment. This was done to decrease the risk of cross-

**Table 1**  
Intervention descriptions.

	Play-based Program (Intervention)	Attention Control Condition (CC)
Week 1	<ul style="list-style-type: none"> <li>Children introduced to the concept of high- and low-energy density foods in the form of a puppet show.</li> <li>Using the book <i>The Very Hungry Caterpillar</i>, children were asked to describe what they felt like if they ate too many energy-dense snack foods or only healthy foods. (WM)</li> <li>Interventionist discussed:               <ul style="list-style-type: none"> <li>Limiting the amount of energy-dense snack foods they consumed</li> <li>What happens to their body (how their body feels) when they eat too many energy-dense snack foods</li> <li>Introduced them to the idea of satiety/fullness</li> <li>Encouraged them to limit consumption of food when they are physically full</li> </ul> </li> <li>Children practiced sorting food images into healthy or unhealthy groups. (WM)</li> <li>Children created photographs with a “larger than life caterpillar” who was filled with either unhealthy or healthy foods. Children demonstrated how they would feel if they ate the foods the caterpillar had eaten. These photos were used as reminders during snack time. (WM)</li> <li>Engaged in these discussions and activities three times during week 1, prior to morning or afternoon snack.</li> </ul>	<ul style="list-style-type: none"> <li>Children were introduced to the concept of high- and low-energy density foods in the form of a puppet show.</li> <li>Day 1: Children were introduced to the importance of healthy teeth, the role teeth play in their health, and what behaviors help teeth stay strong.</li> <li>Day 2: Children learned proper flossing techniques using model teeth (legos and string).</li> <li>Day 3: Children learned proper brushing techniques using egg cartons with food drawn on them (with dry-erase marker) and a brush with water.</li> </ul>
Week 2	<ul style="list-style-type: none"> <li>Children were paired with other children to engage in several dramatic plays: (WM, CF, IC)               <ul style="list-style-type: none"> <li>Going on a picnic with friends</li> <li>Shopping at the grocery store and avoiding energy-dense snack foods</li> <li>Eating at a restaurant and avoiding energy-dense food items</li> </ul> </li> <li>Interventionist monitored their play and offered assistance to those who could not stay in their role, were not talking, or were forgetting the theme of the play.</li> <li>Interventionist offered suggestions to resolve disputes and provided other themes that could be woven into their play if needed.</li> <li>Engaged in dramatic play three times during week 2.</li> </ul>	<ul style="list-style-type: none"> <li>Children were taught about the benefits of physical activity</li> <li>Day 1: Children participated in activities and exercises that promoted movement from head to toe.</li> <li>Day 2: Children participated in an obstacle course.</li> <li>Day 3: Children participated in an art activity that involved being physically active.</li> </ul>
Week 3	<ul style="list-style-type: none"> <li>Reviewed “MyPlate” recommendations for a complete and balanced meal.</li> <li>Children learned to play a card game that allowed them to practice “throwing away” energy-dense snack food items. (IC, WM)</li> <li>Each child was dealt five food cards from a deck of 50 cards.</li> <li>Each child takes turns discarding any card that had a picture of energy-dense foods on it into a “trash can”.</li> <li>Each child can only discard one card per turn and pick up a new card from the center pile.</li> <li>The goal is to create a hand of 5 cards with only healthy food pictures.</li> <li>Game continued until all children had a hand of five healthy food items.</li> <li>Interventionists assisted by talking about how healthy the foods were (i.e., whether or not they were energy-dense) and answering questions.</li> <li>Game was played three times during week 3.</li> </ul>	<ul style="list-style-type: none"> <li>Day 1: Children learned about the importance of sleep on the body, mind, and mood.</li> <li>Children learned about the importance of having a routine before going to sleep.</li> <li>Day 2: Children participated in an art activity making masks to represent their moods when they do and do not get enough sleep.</li> <li>Day 3: Children created a personalized sleep routine (e.g., take a bath, brush teeth, read a story, good night kiss, turn off the light, stay in bed until morning) to take home.</li> </ul>

WM – Working memory.

CF – Cognitive Flexibility.

IC – Inhibitory control.

contamination between children. Children in the CC did not receive any further information about food. Their activities centered around dental hygiene, good sleep habits/routines, and physical activity.

The 3-week intervention included key components of the Tools of the Mind program including: 1) dramatic/pretend play to exercise inhibitory control, working memory, and cognitive flexibility; 2) visual and verbal scaffolding to support and remind children of their goals or behaviors; 3) games to help children work on increasing working memory and inhibitory control; and 4) self-talk as a means to remind children of their goal behaviors. The primary goals of the play-based intervention was to educate children about energy-dense snack foods (defined as foods high in fat or added sugar that are energy dense (calories/gram of food > 4)), appropriate healthy snack options, and train them to inhibit responses to high energy-dense snack foods. The interventions occurred three times a week, for 30 min each session, over a three-week period, equaling a total of 4.5 h of intervention time. Program details are presented in Table 1.

Control children attended similar length sessions during the three-week period to match treatment intensity of the play-based program. Control sessions focused on educating children about proper dental hygiene (including brushing teeth and flossing), good sleep habits/routines, and the importance of being physically active. Children did not engage in any inhibition training which utilized components of the

Tools of the Mind program. Separate protocols were developed for the intervention and control arms to ensure treatment fidelity.

During the program, parents received one-page handouts describing the skills and behaviors that their children were learning that week, along with an activities packet to help them engage in these behaviors at home. Parents in the control arm received similar materials, but centered around the topics of dental hygiene, good sleep habits/routines, and physical activity. All parent/child materials were translated into Spanish to enhance dissemination in the San Diego area.

Prior to the start of the program, the interventionists and research assistants spent 3 day at the preschool to acquaint themselves with the teachers and children and reduce stranger effects. Children enrolled in the study completed baseline assessments prior to the start of the intervention. Post-assessments were done at the end of the three-week intervention. All child assessments were conducted at the school to reduce parent burden. Assessments were conducted by research staff who were blinded to treatment condition.

Treatment staff attended two 3-h trainings with KR and SK to learn study materials. Treatment staff followed protocols to deliver the intervention and could not be blinded to intervention conditions. Study staff were aware of the goals to improve healthy eating and activity behaviors, but not to the details of the study. Assessment staff were separate from the treatment staff and were blinded to group assignment.



## 2.5. Measures

All tasks and anthropometric assessments were completed at baseline and post-intervention. The primary outcome was absolute calories consumed in the Eating in the Absence of Hunger (EAH) paradigm (L. L. Birch et al., 2003; Boutelle et al., 2011; Faith et al., 2006; Fisher & Birch, 2002). EAH measures how much children eat when physiologically satiated and has been associated with longitudinal weight gain (Fisher & Birch, 2002). Each child was asked to rate his/her hunger on a 3-point scale (hungry, half-full, full) prior to the assessment. If children rated themselves as hungry or half-full, they were provided with a 100-calorie granola bar and asked to rate their hunger again 10 min later. Only when children reported that they were no longer hungry, were they allowed to start the assessment. Each child was taken into a secluded area where they were asked to rate their preferences for the 10 snack foods. They were provided with a small amount of each food (10 g or less) for this taste test. After the taste test, these foods were available to them in generous proportions. These snacks foods were previously weighed and included: Cheetos® (72.7 g), Ruffles® (37.4 g), Doritos® (49.2 g), Choco Chips (68.1 g), Frosted Animal Cookies (100.9 g), Gummy Bears (205.4 g), Skittles® (193.1 g), and M&M® (191.8 g). Several electronic books, toys, and games were also available in the room for children to play with. After the child rated the foods, the research assistant told the child that he/she could play with the toys or eat the foods while she did some work in the adjacent room for 10 min. After 10 min of free access to the snack foods, the amount of remaining food items were weighed, and total calories consumed by each child was calculated (Institute of Medicine (U.S.). Panel on Macronutrients. & Institute of Medicine (U.S.). Standing Committee on the Scientific Evaluation of Dietary Reference Intakes., 2005).

Tests of inhibitory control included the “Day/Night” and “Less is More” tasks. Both tasks represent conflict tasks in that children are required to inhibit a dominant or impulsive response and provide a new or conflicting response in order to receive a reward. Both of these tasks also require working memory to perform correctly. Day/Night is a Stroop-like task that was created and validated for preschool age children (age 4–7 years old) and uses symbols of the sun, moon and stars (Gerstadt, Hong, & Diamond, 1994). First, children are asked to identify the pictures on the cards and confirm that the sun appears during the day and the moon and stars appear at night. Then they were told to say “day” when they saw the black card with a picture of the moon and stars, and to say “night” when they saw the white card with a picture of the sun. The RA conducted two practice trials with the child (showing the sun card and moon/stars card once each) and confirmed understanding of the task afterwards. Then the RA conducted 16 test trials in a fixed random order. Final scores were represented as the proportion of trials the child answered correctly. Scores range from 0 to 16 with higher scores representing better performance (memory and inhibitory control) (Gerstadt et al., 1994). Final scores were represented as the proportion of trials the child answered correctly. Reaction time was not assessed since previous studies have demonstrated that reaction times in this age group did not vary significantly (Gerstadt et al., 1994).

Less is More is a reverse-reward contingency task where children need to point to the smaller amount of treats in order to receive the larger amount (Carlson, Davis, & Leach, 2005). This task assesses inhibitory control skills by using real objects as opposed to symbols, requires working memory, and has been validated for use in this age group (Carlson et al., 2005). Briefly, in this task, children were told that they were going to play a game with a naughty chipmunk puppet. The chipmunk was naughty because he did not like to share his treats. Children were shown several treats and asked to identify one that they liked (mini marshmallows or mini Oreos®); this treat was used during the task. Children were told to point to a bowl of treats (containing either 2 or 5 treats) and the puppet would get those treats in his clear plastic bag. The child, on the other hand, would receive the treats from the other bowl (the bowl that he/she did not point to), and save them in

his/her bag. Children engaged in three practice trials with the RA, and the RA conducted a verbal rule check after each of these trials. Then the RA conducted 16 test trials, 8 trials with the child's bag on the right and another 8 trials with the child's bag on the left to control for side biases. Scores ranged from 0 to 16 with higher scores representing better performance (Carlson et al., 2005). Final scores were represented as the proportion of trials where the bowl with fewer treats was picked. Less is more has good internal validity among preschool age children and correlates with other measures that assess both inhibitory control and working memory (Carlson et al., 2005).

Covariates included child age, sex, and school site. Heights and weights for each child was obtained at school following standard protocols. Children were asked to take off their shoes and jackets and were weighed in kilograms on a Tanita Digital Scale (model WB-110A). Weights were recorded twice to the nearest 0.1 kg, and the average value used for analysis. Height was also obtained using a portable Schorr height board (Schorr Inc, Olney, MD). Height was recorded twice to the nearest 0.1 cm, and the average value used for analysis. BMI percentile for each child was calculated based on CDC growth charts (Kuczmarski et al., 2002). Children with a BMI > 5th percentile and < 85th percentile were considered normal or healthy weight, while those with a BMI ≥ 85th percentile were considered overweight/obese. Parents were asked to complete demographic information regarding their own race/ethnicity and income. Race/ethnicity was categorized as non-Hispanic White, Hispanic, or Other. Income was dichotomized at the median.

## 2.6. Statistical power

Sample size was calculated for a two-group design with an end-point analysis of calories consumed as the primary outcome. Since experimental studies of inhibitory control around food in young children have not been published, we based the expected effect size on two recent studies where inhibitory control of eating behavior was manipulated in college students (Houben, 2011; Houben et al., 2011; Houben & Jansen, 2011). These studies had standardized effect sizes of  $d = 0.87$  to  $0.81$ . Since this is a new intervention applied to young children, we used  $d = 0.70$  as a conservative and meaningful expected effect size. Anticipating no more than 10% attrition (since children enrolled at the preschool center and participated in the intervention there), sample size for a two-tailed between group test with alpha set at 0.05 and 80% power required a total sample size of 72 participants ( $n_1 = n_2 = 36$ ).

## 2.7. Statistical analysis

Descriptive statistics were performed on baseline and demographic data. Ten clusters of classrooms were randomized to receive the intervention or CC, with 8–10 children per group. Intraclass coefficient using mixed effects modeling was calculated to be  $< 0.01$ . Therefore, repeated-measures regression analysis was used to examine differences in post-treatment calories consumed during EAH and post-treatment inhibitory control scores between groups, controlling for baseline scores. A school effect was added to account for the design effect of delivering the intervention and control conditions in three schools. All models assessing post-treatment calories controlled for baseline EAH calories consumed and child age, sex, and parent race/ethnicity. Similarly, baseline inhibitory control scores were entered as a covariate in all models assessing post-treatment inhibitory control, as well as child weight status, sex, and parent race/ethnicity. Repeated-measures regression analysis was also used for post-hoc analyses exploring group by sub-population interactions. We specifically examined differences by weight status category and by age group since previous literature has suggested that these groups may have different characteristics with regards to caloric intake and inhibitory control (Carlson, 2005; Nederkoorn et al., 2006, 2012). Age groups were dichotomized at the median (5.2 years). Analyses were run in RStudio version 1.0.136.

**Table 2**  
Sample characteristics at baseline.

No. (%)	Treatment (n = 44)	Control (n = 47)	Total (n = 91)
Age (years), Mean (SD)	5.34 (.68)	4.88 (.72)	5.11 (.73)
Sex			
Girls	19 (21%)	23 (25%)	42 (46%)
Boys	25 (27%)	24 (27%)	49 (54%)
Race/Ethnicity			
Hispanic	19 (21%)	22 (24%)	41 (45%)
Non-Hispanic White	10 (11%)	11 (12%)	21 (23%)
Other	15 (16.5%)	14 (15.5%)	29 (32%)
Weight status, Mean (SD)			
BMI	16.35 (2.43)	16.68 (2.66)	16.52 (2.54)
BMI Percentile	58.22 (31.81)	57.84 (35.05)	58.03 (33.24)
Overweight/Obese	13 (14%)	17 (19%)	30 (33%)
Age (years), Mean (SD)	34.98 (5.72)	34.16 (6.57)	34.56 (6.14)
Sex			
Women	39 (43%)	40 (44%)	79 (87%)
Men	5 (5%)	7 (8%)	12 (13%)
Race/Ethnicity			
Hispanic	15 (16.5%)	20 (22%)	35 (38.5%)
Non-Hispanic White	8 (9%)	17 (18.5%)	25 (27.5%)
Other	21 (23%)	10 (11%)	31 (34%)
Weight			
Overweight/Obese	24 (27%)	19 (21%)	44 (48%)
Household Income (\$100,000 +)	17 (18.5%)	17 (18.5%)	34 (37%)
Marital Status (Married)	28 (31%)	32 (35%)	60 (66%)
EAH, Mean (SD)	84.63 (85.85)	90.34 (103.24)	87.58 (94.75)
Day/Night, Mean (SD)	0.81 (0.26)	0.75 (0.25)	0.78 (0.28)
Less is More, Mean (SD)	0.84 (0.21)	0.76 (0.30)	0.80 (0.23)

EAH = Eating in the Absence of Hunger paradigm.

**3. Results**

A total of 92 children were enrolled in the study. However, one child left the school and did not complete the intervention; 91 children were included in the analysis. Half (54%) were male, with a mean age of 5.11 years (S.D. 0.73), and a mean BMI percentile of 58.03% (S.D. 33.24) (Table 2). There were no differences between intervention and CC groups.

**3.1. Calories consumed**

At baseline, children in the intervention and control groups consumed a similar number of calories in the EAH paradigm (84.6 kcals (S.D. 85.9) vs. 90.3 kcals (S.D. 103.2), respectively,  $p = 0.78$ ). At the end of the three-week intervention, the mean calories consumed in both groups increased (mean increase = 32.6 kcals, S.D. 102.0), but there were still no differences between groups in the number of calories consumed, controlling for age, sex, school, parent race/ethnicity, and baseline EAH calories consumed ( $p = 0.42$ ) (Table 3a).

We conducted post-hoc analyses to determine if there were effects among certain sub-populations. There was a significant interaction between group and weight status (overweight/obese vs. healthy

**Table 3a**  
Main effect of group on calories consumed.

	b	S.E.	t	p
Group	-15.90	19.41	-0.82	0.42
Baseline EAH Calories Consumed	0.38	0.09	4.14	< 0.001
Child Age	-32.37	22.39	-1.44	0.15

S.E. = Standard Error; EAH = Eating in the Absence of Hunger paradigm. Effect sizes: Across groups  $d = 0.36$ , 95% CI [0.07, 0.66]. Intervention  $d = 0.45$ , 95% CI [0.01, 0.88]; Control Condition  $d = 0.30$ , 95% CI [-0.011, 0.72].

**Table 3b**  
Interaction between group and weight status on calories consumed.

	b	S.E.	t	p
Group	-41.39	21.66	-1.91	0.06
Weight Status (OW/OB vs. NI)	-13.02	27.33	-0.48	0.64
Baseline EAH Calories Consumed	0.38	0.09	4.28	< 0.001
Child Age	-34.16	21.80	-1.57	0.12
Group x Weight Status	74.59	36.23	2.06	0.04

S.E. = Standard Error; OW/OB = Overweight/Obese; NI = Normal weight; EAH = Eating in the Absence of Hunger paradigm.

Effect sizes: NI-Intervention  $d = 0.39$ , 95% CI [-0.17, 0.95]; NI-Control Condition  $d = 0.08$ , 95% CI [-0.51, 0.68]; OW/OB-Intervention  $d = 0.36$ , 95% CI [-0.72, 1.44]; OW/OB-Control Condition  $d = 0.70$  95% CI [-0.10, 1.50].

weight) ( $b = 74.59$ ,  $SE = 36.23$ ,  $p = 0.04$ ) (Table 3b). Following the intervention, children with overweight/obesity in the intervention group consumed a mean of 118.0 kcals (S.D. 97.5) while healthy weight children consumed a mean of 124.1 kcals (S.D. 83.0) ( $b = 13.02$ ,  $SE = 27.33$ ,  $p = 0.64$ ). However, overweight/obese children in the control group consumed a mean of 155.9 kcals (S.D. 92.6) while healthy weight children consumed a mean of 103.6 kcals (S.D. 74.0) ( $b = -61.57$ ,  $SE = 23.93$ ,  $p = 0.01$ ) (Fig. 2).

**3.2. Inhibitory control**

At baseline, children in the intervention and control group exhibited similar percent correct in both the Day/Night (0.81 (S.D. 0.26) vs. 0.75 (S.D. 0.30), respectively,  $p = 0.34$ ) and Less is More tasks (0.84 (S.D. 0.20) vs. 0.76 (S.D. 0.25), respectively,  $p = 0.11$ ). At the end of the three-week intervention, there were no differences between groups in either Day/Night ( $b = 0.05$ ,  $SE = 0.06$ ,  $p = 0.40$ ) or Less is More ( $b = 8.87E-4$ ,  $SE = 0.03$ ,  $p = 0.98$ ), with all models controlling for age, sex, school, parent race/ethnicity, and baseline EF task scores.

Post hoc analyses revealed a significant interaction between group and age ( $b = 0.10$ ,  $SE = 0.04$ ,  $p = 0.03$ ) in the Less is More task (Table 4). Younger children in the intervention group had higher post-intervention scores than younger children in the control group after controlling for baseline scores (0.93 vs. 0.78,  $p = 0.007$ ) (Fig. 3). Among older children, scores were similar between the intervention and control group (0.93 vs. 0.96,  $p = 0.42$ ).

**4. Discussion**

Interest in improving executive functions (EF) and inhibitory control skills around food stimuli has increased over the past several years in response to evidence that impaired inhibitory control may be associated with increased caloric intake (Guerrieri et al., 2008; Riggs et al., 2010, 2012). We adapted strategies from the Tools of the Mind program to promote decreased consumption of energy-dense snack foods among preschool age children. While there were no intervention effects in the overall group, we found that the intervention might have had some effect when stratifying children by weight status. Children with overweight/obesity in the intervention group consumed similar amount of calories as healthy weight children in the intervention group at the post intervention time point, while children with overweight/obesity in the control group ate more than healthy weight children in the control group. These results suggest that the play-based program may have helped overweight/obese children consume calories at a level that is more on par with children who are normal weight. This type of intervention may be particularly apropos for young children who are easily distracted by highly rewarding stimuli such as sweets and fatty foods, and are therefore at risk for excess weight gain. Since EF (Carlson & Moses, 2001; Diamond & Taylor, 1996) and eating behaviors (L. L. Birch, PhD & Fisher, 1998) are developing during the preschool years, implementing this type of intervention may allow us to dampen the

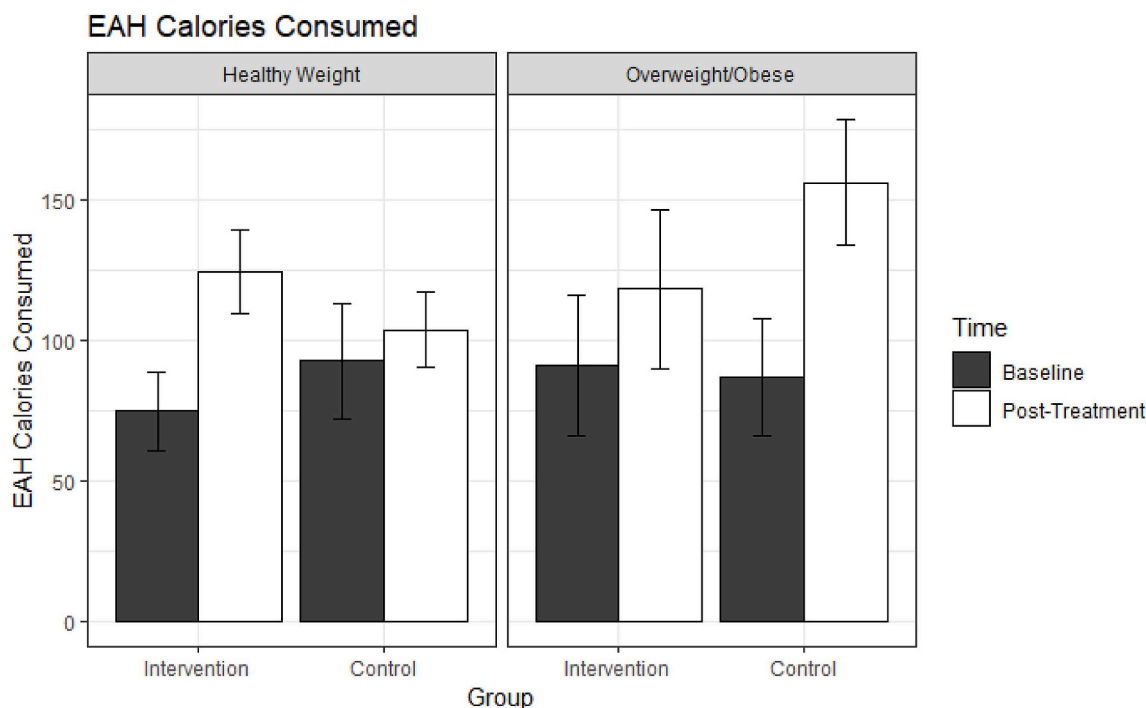


Fig. 2. Interaction between Group and Weight status on Caloric Intake.

Fig. 2 represents the mean pre-intervention and post-intervention calories consumed by children in the intervention and control group. Standard errors are represented on the graph.

Table 4  
Interaction between group and age on inhibitory control scores.

Day/Night	b	S.E.	t	p
Group	-0.39	0.39	-1.01	0.32
Child Age	-0.01	0.08	-0.15	0.88
Weight Status (OW/OB vs. NI)	0.07	0.06	1.11	0.27
Baseline Day/Night	0.06	0.10	0.56	0.58
Group x Child Age Interaction	0.09	0.08	1.15	0.25

Less is More	b	S.E.	t	P
Group	-0.51	0.23	-2.18	0.03
Child Age	0.09	0.05	1.95	0.06
Weight Status (OW/OB vs. NI)	-0.01	0.03	-0.30	0.77
Baseline Less is More	0.20	0.07	2.86	0.005
Group x Child Age Interaction	0.10	0.04	2.20	0.03

S.E. = Standard Error; OW/OB = Overweight/Obese; NI = Normal weight.  
**Effect Sizes:** Day/Night. Younger-Intervention  $d = 0.09$ , 95% CI [-0.63, 0.81]; Younger-Control Condition  $d = 0.29$ , 95% CI [-0.23, 0.81]; Older Intervention  $d = 0.006$ , 95% CI [-0.56, 0.55]; Older-Control Condition  $d = 0.43$ , 95% CI [-0.33, 1.19].  
**Effect Sizes:** Less is More. Younger-Intervention  $d = 0.57$ , 95% CI [-0.17, 1.30]; Younger-Control Condition  $d = 0.18$ , 95% CI [-0.33, 0.69]; Older-Intervention  $d = 0.46$ , 95% CI [-0.09, 1.01]; Older-Control Condition  $d = 0.66$ , 95% CI [-0.11, 1.42].

increased caloric intake of at-risk children.

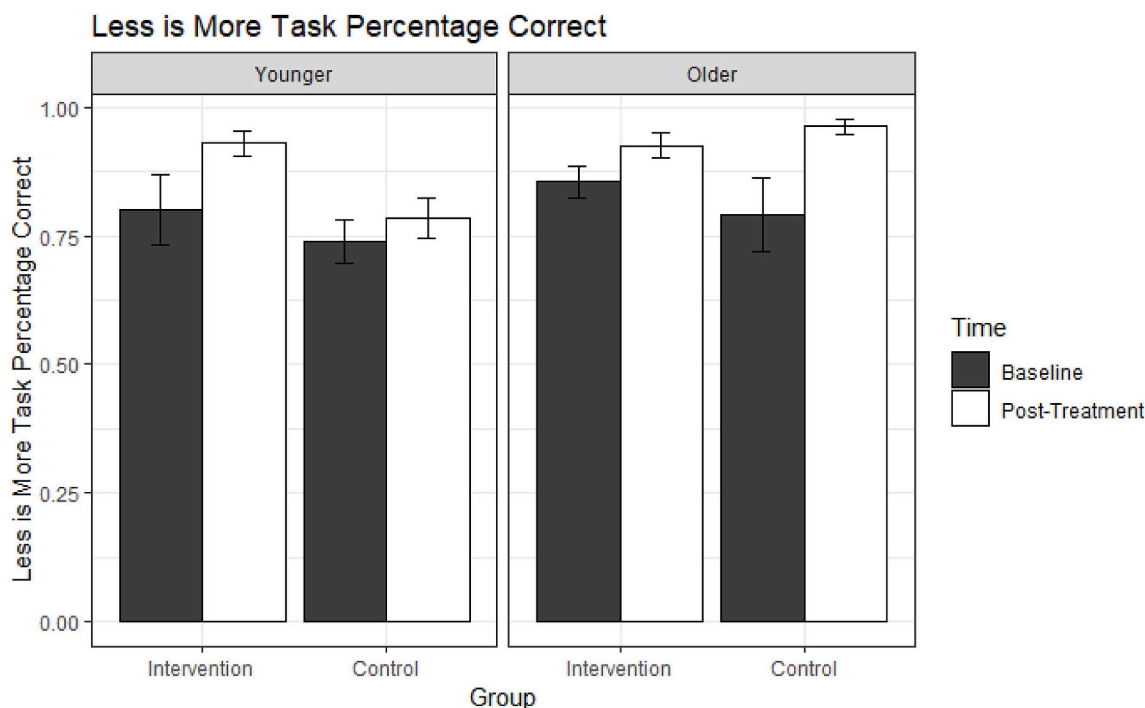
While the Tools of the Mind curriculum is thought to focus on the development of child self-regulatory skills and the ability to control one's behaviors, thoughts, and feelings, executive functioning is still highly relevant to these skills and important to consider when assessing the impact of this program. Executive functioning is described as being critical to the development of self-control, reflecting the cognitive aspects of self-control, while self-regulation reflects the behavioral and emotional aspects of self-control (Blair & Ursache, 2011; Hofmann et al., 2012). EFs such as inhibitory control are therefore likely necessary in the self-regulation of behaviors. Of note, EFs are typically

assessed via cognitive tasks while self-regulation is assessed via observation or surveys regarding the child's behaviors. Few studies have been conducted to assess EFs in the Tools of the Mind curriculum. However recently, Solomon, et al. conducted a cluster randomized trial in Canadian preschoolers to assess the effect of this curriculum on self-regulation (Solomon et al., 2017). Interestingly, they assessed EF with the Day/Night task and 'Head to Toe' task (Pontitz, McClelland, Matthews, & Morrison, 2009), a behavioral measure of EF. While there was no main effect of the intervention, they found that those with higher risk (i.e., higher levels of hyperactivity and inattention) had greater gains in the Head to Toe task. These results suggest that the curriculum in this intervention had some effect on self-control, particularly among those who entered with lower self-regulatory or cognitive skills. However, assessing a wide range of EFs and assuring that the intervention provides sufficient self-regulatory or EF training has been difficult in these studies. Additional studies that tease apart the mechanism of action of these programs, and whether they are primarily working through cognitive means or behavioral means should be further investigated.

When testing EF skills in our study, we found that younger children in the intervention group had significantly increased scores at the post-intervention time point compared to younger children in the control group, as assessed by the Less is More task and after controlling for baseline scores. Of note, their post-intervention scores were similar to the post-intervention scores of older children in both the intervention and control groups. These results suggest that the intervention may be having an effect on self-regulation, particularly in younger children (i.e., those who presumably come in with less developed skills). While it appears that the intervention did not have an effect on older children, others have reported that a ceiling effect may exist in these tasks as children get older (Carlson, 2005). Therefore, we might not have been able to accurately measure the effect of the intervention on these children with the tasks used in this study.

It is interesting to note that we did not find any results with the Day/Night task. It has been suggested that the Less is More task is a test of "hot" executive functions that apply to the appetitive reward system,





**Fig. 3.** Interaction between group and age on inhibitory control skills score.

Fig. 3 represents the mean pre-intervention and post-intervention inhibitory control score by children in the intervention and control group. Standard errors are represented on the graph.

while tasks like Day/Night are “cool” tests that highlight more symbolic cognitive functions (Carlson, 2005; Carlson et al., 2005). Therefore the Less is More task may have been a more valid test in this setting since the intervention focused on consumption of energy-dense snack foods. Furthermore, the Less is More task requires working memory as well as inhibitory control skills, both of which were addressed in this intervention. Therefore, this test may have been a more appropriate measure of intervention effects. Given the limited nature of inhibitory control testing that was conducted in this study, additional age-appropriate tasks that measure the range of EF domains and both hot and cold EFs should be conducted in future pediatric weight control programs to determine possible mechanisms of action.

It is interesting to note that children across the board demonstrated greater caloric intake in the post-treatment EAH assessments, whether or not they were in the intervention or control group. While the EAH assessment has been used in numerous studies to demonstrate changes in caloric intake over time (Fisher & Birch, 2002; Kral et al., 2012), it is not typically used for follow-up assessments within this short period of time. We have seen this type of effect in other studies (Boutelle, Kuckertz, Carlson, & Amir, 2014), and there are a number of reasons why this could have occurred. First, children may be more comfortable with the assessment and the assessors at time two, and eat more because of the familiar situation. We also suspect that conducting EAH assessments close in time primes the children to eat more the second time (i.e., “I’m excited to do this taste test again”). Unfortunately, there are no objective measures of eating behavior in children that do not have this effect so close in time. Nevertheless, there was a difference in caloric intake among preschool children with overweight/obesity, suggesting that the intervention may have had some impact despite these practice effects.

While this type of intervention shows promise, there were some limitations to this study. The intervention was relatively brief and did not involve parents in a significant manner. Better integration of these types of interventions into the school and/or home setting could potentially improve the effects. Increased parent involvement at home would have also allowed for greater reinforcement and potential

mastery of these skills. A larger sample size with additional mid-point assessments would have also allowed us to conduct mediational or moderator analyses to determine which phenotypic or demographic characteristics were responsive to this type of intervention, and whether changes in inhibitory control or self-regulation mediated the effect of treatment. While all families in the preschools were invited to participate, parents who did not complete baseline surveys were not able to participate, thus limiting our sample size. Future studies conducted in larger samples, over a full school year, and with greater parent involvement should be done to further understand the impact of such interventions.

## 5. Conclusion

Self-regulation training among preschool children may be an effective means of limiting caloric intake in this early time period. While the effects of this intervention were small (in the 50 calorie range), reductions at this level, particularly in young overweight/obese children, could result in considerable slowing of the weight gain trajectory and prevent roughly 5 lbs. of excess weight gain per year. Considering the relationship between inhibitory control and obesity, it is possible that training in EF or self-regulation could inoculate preschoolers against the obesogenic environment. Efforts to develop additional self-regulation and inhibitory control skills training programs among preschool age children is a burgeoning field that will allow us to create new and innovative treatment strategies for overweight/obese children.

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Dr. Rhee conceptualized and designed the study, supervised the implementation of the intervention, interpreted the data, and wrote the first draft of the manuscript. Dr. Boutelle contributed to the design of the study, analysis of data, and critically reviewed the manuscript. Ms. Kessl contributed to the design and implementation of the study, participated in data collection, and critically reviewed the manuscript. Mr. Manzano was responsible for data analysis and interpretation, and

critically reviewed the manuscript. Dr. Strong contributed to the design, analysis and writing of the manuscript. All authors have reviewed the final manuscript and approved the submission. Drs. Rhee and Strong had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The authors have no conflicts of interest or relevant financial disclosures to report. This work was supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Grant R21HD074987 to Dr. Rhee. They did not contribute to the study design, data collection, analysis or interpretation of the data, or writing of the manuscript.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.appet.2018.10.035>.

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