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Rationale and Design of the Feeding Dynamic Intervention (FDI) Study for Self-Regulation of Energy Intake in Preschoolers

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Abstract

In 2011, the Institute of Medicine Early Childhood Prevention Policies Report identified feeding dynamics as an important focus area for childhood obesity prevention and treatment. Feeding dynamics include two central components: (1) caregiver feeding practices (i.e., determining how, when, where, and what they feed their children) and (2) child eating behaviors (i.e., determining how much and what to eat from what food caregivers have provided). Although there has been great interest in overweight and obesity prevention and treatment in young children, they have not focused comprehensively on feeding dynamics. Interventions on feeding dynamics that reduce caregivers' excessive controlling and restrictive feeding practices and encourage the development of children's self-regulation of energy intake may hold promise for tackling childhood obesity

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especially in the young child but currently lack an evidence base. This manuscript describes the rationale and design for a randomized controlled trial designed to compare a group of mothers and their 3-to 5-year old children who received an intervention focused primarily on feeding dynamics called the Feeding Dynamic Intervention (FDI) with a Wait-list Control Group (WLC). The primary aim of the study will be to investigate the efficacy of the FDI for decreasing Eating in the Absence of Hunger (EAH) and improving energy compensation (COMPX). The secondary aim will be to examine the effect of the FDI in comparison to the WLC on maternal self-reported feeding practices and child satiety responsiveness.

Keywords

feeding; children; satiety; obesity

1. Introduction

In 2011–2012, 22.8% of preschoolers in the United States were overweight or obese [1]. To address this significant health concern, prevention and treatment efforts have traditionally centered on food restriction. However, this approach can be ineffective or even counterproductive given its connection to food preoccupation, eating in the absence of hunger, weight regain, and inability to self-regulate food intake (i.e., recognizing and using internal hunger and satiety cues to guide eating behavior) [2–4].

One alternate approach with a strong potential to prevent and treat early childhood overweight and obesity is feeding dynamics [3], which targets the roles, interactions, and balance of control and power between caregivers and children. Ellyn Satter [5–7] first identified a feeding dynamic approach that she named the “trust model”, with a primary emphasis on Division of Responsibility of feeding. The trust model proposes that caregivers and children divide feeding roles and responsibilities: caregivers decide “what” food is offered, “where” food is eaten, and “when” food is made available to eat, whereas children decide “how much” and “what” of the offered food to eat. Satter posited that when caregivers and children each have an appropriate level of control and autonomy during feeding, children learn to trust and develop a healthy relationship with food, enjoy a wide variety of nutritious food, and preserve their ability to self-regulate food intake. Whereas excessive food restriction and control disrupts children’s recognition of their internal hunger and satiety cues [2, 4, 8, 9], following a feeding dynamic approach is theorized to enhance children’s attention to these cues, which should, in turn, help prevent their eating in the absence of hunger [1]. Eating in the absence of hunger (EAH), a research procedure used to determine satiety responsiveness is defined as eating in response to the presence of palatable foods in the absence of physiological hunger” [10, 11]. Children who eat in the absence of hunger have higher BMIs and a greater likelihood of becoming obese [2].

Realizing the potential for feeding dynamics to prevent and treat childhood overweight and obesity, scholars have called for interventions targeting feeding interactions between caregivers and children [3, 12–14]. Despite this call, such interventions remain to be created and validated. Therefore, our group developed the Feeding Dynamic Intervention (FDI); a 6-

session curriculum based largely on a feeding dynamic approach and recognizes the current obesogenic environment [15] by incorporating nutrition and physical activity components to guide caregivers on healthy food choices and activity opportunities for their children. The FDI was developed and evaluated in stages [16–18].

A 90-minute class covering the core topics was piloted among 17 mothers of 2-to 5-year-old children, who reported the curriculum topics as acceptable and provided feedback after a 4-week trial period. Their responses assisted the development of the final 6-session FDI by a research team of two dietitians, a physician, a curriculum expert, and psychologist. A nine-person team of three dietitians, five health educators, and a public health specialist from the university extension program in eight rural and urban Ohio counties conducted the initial program evaluation, while a team of five that included two parents, dietitians and a curriculum expert carried out the second review. Their feedback helped further refine the presentation and content. Finally, the full FDI was piloted with eight mothers. All but one participant responded well to the FDI; as this mother felt that the content conflicted with her cultural approach to food. The rest of these mothers, however, implemented FDI recommendations such as reducing their restrictive feeding behaviors and dividing feeding responsibilities.

In this paper, we describe the rationale and protocol for a pilot randomized controlled trial (RCT) designed to compare a group of mothers and their 3-to 5-year old children who will receive the FDI with a Wait-list Control Group (WLC). We will examine improvements in children's self-regulated eating, energy compensation (the ability to regulate intake based on metabolic need) [19], satiety responsiveness (the ability to adjust oral intake in response to physiologic hunger and fullness cues) [20] and caregivers' feeding practices, as well as calculate effect sizes based on change in BMI z-score for a subsequent large RCT.

2. Study-design

Eighty-four mother-child dyads will be recruited over a 15-month period. All child participants will be at or above the 85th percentile of body mass index (BMI), report low satiety responsiveness, and be 3- to 5-years-old at the time of their first study visit. The primary aim of the study is to investigate the efficacy of the FDI for improving energy compensation (COMPX) and decreasing Eating in the Absence of Hunger (EAH) in comparison to the Wait-list Control Group (WLC). For the secondary aim, the team will examine the effect of the Feeding Dynamic Intervention (FDI) on maternal self-reported feeding practices and child satiety responsiveness in comparison to the WLC. The tertiary aim will be to calculate effect size estimates for changes in BMI z-score to determine sample size requirements for a subsequent multicenter randomized controlled trial evaluating the efficacy of the FDI as an overweight and obesity treatment and prevention strategy. The conceptual model for the trial is depicted in Figure 1 and the study timeline in Figure 2.

3. Recruitment Strategies

Recruitment will be from primary care and dental clinics, referrals to a pediatric obesity treatment program, WIC (Women's, Infants and Children) programs, Head Start programs

and local child care centers using a combination of website advertisement, in-person recruitment, flyers and social media.

3.1. Screening, inclusion and exclusion criteria

Participants interested in the study will contact the Research Associate (RA) via phone to inquire about the study. The RA will provide information about the study using a script and those interested in participating will be screened for eligibility. Initial inclusion criteria will be parent-reported child BMI at or above the 85th percentile (to be confirmed at the baseline visit) and child age between 3–5 years old. During the screening call, the parent will complete the Child Eating Behavior Questionnaire Satiety Responsiveness subscale (CEBQ-SR) [21]. This subscale consists of six questions which assess the mother's report of the child's appetite and how easily the child is satiated [21, 22]. Higher BMI z-scores have been associated with lower mother-reported child satiety responsiveness in the preschool age range [23]. A parent-reported child CEBQ-SR score ≤ 2.8 will be considered poor satiety responsiveness [22]. This criterion is included to increase the power of the study to detect an effect given satiety responsiveness is a key outcome measure and related to self-regulation of energy intake. Adult enrollment will be limited to mothers, because they tend to be the primary caregiver responsible for feeding children [17], and the extant literature on feeding practices has been largely conducted with mothers [4, 23]. Finally, we are focusing on the preschool age range as it is also a sensitive period for food preference formation [24–28] and the development of long-lasting eating habits and autonomy [28–32] under the guidance of a still significant caregiver role.

Other inclusion criteria include that the mother be fluent in English because the study materials are only available in English and the mother will be the primary legal guardian and have primary physical custody of the child. Children may attend a child care center. The tenets of the FDI are typically used in these centers (e.g., structured times for meals and food provided meet the US Department of Agriculture Child and Adult Care Food Program standard for nutritious meals). Children will be excluded if they are in an unlicensed non-parental child care or home child care for more than 10 hours per week because feeding practices may be inconsistent in these settings and this exposure would dilute the effect of the intervention. Children will also be excluded if they have a medical condition or take medications that affect appetite, eating, or growth; food allergies or dietary restrictions; or a developmental or behavioral diagnosis (e.g., cognitive impairment, language delay, or autism) that might affect their ability to respond to a behavior-based intervention.

3.2. Consent

Participants will be mailed a consent document prior to their baseline visit to provide them with the opportunity to read the document and call the RA with questions. When participants arrive for their baseline study visit, they will be escorted to a private room in the Clinical Research Center (CRC) where the RA will review the consent document. The study visit will begin once all questions about the study and consent document are answered, the consent document is signed by both the mother and the RA and a copy is given to the mother. Given the age of the children, formal assent will not be obtained. The RA will explain the study to the child using age appropriate language.

4. Randomization

Participants will be randomized in blocks of 8 to 10 participants to one of two groups: 1) Wait-list Control Group (WLC) or 2) Feeding Dynamic Intervention (FDI). Using a random number generator, each block will randomly assign 4–5 participants to each group, depending on the number recruited for the block [33]. Group assignment will be recorded in a sealed yellow envelope labeled on the outside with the corresponding number (1 through n). These envelopes will be presented in numeric order to each subject at the final baseline measurement. The RA will be unaware of the assignments in the envelope.

5. Intervention

5.1. Delivery of the Feeding Dynamic Intervention and fidelity

The FDI will be delivered in a closed-group setting and will consist of six intervention sessions lasting 75 minutes each (Table 1). Each class will be taught by a registered dietitian, who will be trained in the delivery of the FDI but blinded to the study hypotheses. For each FDI cycle, two sessions will be randomly selected to be videotaped, and the RA will complete a checklist developed by the study team to guarantee session fidelity to lesson content. The process evaluation will include documentation of any deviation from the curriculum and the extent to which the FDI was successfully implemented.

5.2. Description of FDI classes and wait-list control

Mothers in the intervention group (FDI) will be required to attend the FDI classes on their own (i.e., without a partner or child) once every other week, for a total of six classes in a 12-week period. Mothers will receive \$10 for every class attended to defray the cost of child care during the FDI class. The FDI classes will be didactic, but include hands-on activities, video clips from contemporary reality shows, and designated time for discussion (Table 1). The overarching goals of the FDI are to teach mothers to: (a) help their child recognize satiety cues, (b) serve a variety of foods for family meals, (c) feed their child in an authoritative manner by providing healthy and balanced meals while acknowledging the child's food preferences and eating patterns, and (d) help their child develop a trusting relationship with food. A section reviewing mothers' responsibilities for encouraging their child's physical activity and limiting TV viewing (e.g., providing opportunities for physical activity and promoting the child's motor development) will be included to provide a comprehensive approach for overweight and obesity prevention and treatment (Table 1). Mothers in the WLC group will have the opportunity to participate in the classes free of charge after they have completed the study. Both groups will receive newsletters and non-weight related educational materials typically provided by pediatricians as anticipatory guidance at Well Child visits (e.g., water safety) three times during the study period.

5.3. Use of three-dimensional stomach model to teach hunger and satiety cues

For each FDI lesson, a section on understanding hunger and satiety cues will be included and will focus primarily on how to recognize feelings of being “hungry,” “full,” or “stuffed”. The concepts will be first taught and demonstrated by the RA to the child and mother at the first baseline visit. The concepts will then be reinforced and elaborated in

further detail with a visual model within the first FDI lesson. More specifically, each mother- in the FDI group will be given a 3-dimensional model to use to assess hunger and satiety cues before meal and snack times in the home. The model, similar to that used by Johnson in her study with preschoolers, has three stomachs made of soft pink felt material sewn and stuffed to depict “hungry,” “full,” and “stuffed” stomachs mounted on a small wooden board [9, 19]. Children will be encouraged to pick the stomach that is the closest to how they would describe their sense of hunger and satiety before and after a meal after being taught these concepts by the RA at their baseline visit and their mother following the first FDI class. After each subsequent FDI lesson, mothers will complete a series of questions to evaluate how they taught the hunger and satiety concepts with their child using the model, the frequency to which they used the model, and the child’s response to the use of the model.

6. Outcome measures

Participants will complete the outcome measures at baseline (pre-intervention), three months and six months from the start of treatment. The estimated time between the initial study visit for the baseline evaluation period (which consists of three visits over 3–4 weeks) and the first FDI class will be six weeks. This will ensure participants in each group will have time to complete the three study visits before randomization. Primary outcome measures will include two behavioral eating protocols: Eating in the Absence of Hunger (EAH) and the Energy Compensation Test (COMPX). Additional outcome measures include BMI and BMI z-score, as well as scales that assess mother-reported feeding behaviors and child satiety responsiveness.

6.1. Eating in the Absence of Hunger (EAH)

Children who eat in the absence of hunger have higher BMIs and a greater likelihood of becoming obese [2]. Higher levels of EAH have been reported among children of parents who use restrictive feeding practices [2, 8] and parents who are overweight [2, 8]. We will measure children’s propensity to eat in the absence of hunger [2], following the methods of Birch, which has garnered considerable reliability and validity evidence [2]. The EAH will be conducted in an observation suite that is outfitted with an unobtrusive video system so that the room can be viewed and recorded remotely at all times.

6.1.1. EAH component: Satiety doll—Once seated, the RA will present the child participant with a “satiety doll” developed by our team to assist in measuring self-reported satiety in children. The satiety doll is plain and gender-neutral with three detachable stomachs: a “hungry” stomach, a “full” stomach, and a “stuffed” stomach, similar to the stomach model used for the FDI intervention (see section 5.3 above). The RA will then introduce the concept of the three stomachs with the child using a script, with examples provided. For instance, waking up in the morning and before breakfast will be given an example of when the child may have a “hungry” stomach and how it feels to have one. This discussion is interactive, with the child responding to questions and the RA probing for understanding. The RA will use the satiety doll immediately prior to the lunch (see 6.1.2

below) by asking the child how his or her stomach is feeling and will record the answer. The RA will then serve lunch to the child and mother.

6.1.2. EAH component: Lunch—Participant lunches will be pre-ordered from a local sandwich franchise and pre-weighed using a TEOIC digital scale. Lunch for the child will include a child-sized sandwich (turkey, ham, roast beef, tuna or vegetarian), with apples, Sun Chips®, milk (8 oz)/juice (6.76 oz), and a sugar cookie. The goal for the child's lunch will be to provide enough food so that the child can eat until satiated. The meal will also provide enough variety with a combination of salty and sweet food items to reduce the impact of sensory-specific satiety. This occurs when an individual develops decreasing satisfaction for flavors that she or he is currently consuming and increased appetite for new flavors [34, 35]. The mother's meal will include a six-inch sandwich and a drink (water, Diet Coke® [20 oz] or Diet Sprite® [20 oz]). Mothers will be instructed to not share food with their child. The mother and child will be left alone during lunch; however, the RA will observe and record the meal from a remote location which will allow the RA confirm that food is not shared between mother and child. After the child indicates that they are finished eating, the RA will come back into the room with the satiety doll and again assess the child's satiety rating using the three stomachs. If the rating is "full" or "stuffed," the mother and child will be escorted into a waiting room. If the child endorses she/he is still hungry, additional food items will be provided from the original meal content until the child indicates that she/he is "full" or "stuffed." Within 10–15 minutes following completion the EAH lunch, the RA will bring the child into the EAH procedure room alone, leaving the mother in the waiting room or a room nearby but without access to the child (depending on the comfort of the child).

6.1.3. EAH component: EAH—The RA will set-up the EAH procedure room with a variety of snacks and toys. There will be six snack containers which contain the following items: gummy candy treats (141 g $\pm$ 3g), Cheez-Its® (61g $\pm$ 1g), Chips Ahoy® cookies (106 g $\pm$ 7g), pretzels (53 g $\pm$ 2g), Froot Loops® (46 g $\pm$ 2g), and Ritz® crackers (59 g $\pm$ 3g). Again, specific sweet and salty snacks will be used to counteract sensory-specific satiety. The toys will include a puzzle, three books, building blocks, and an Etch-a-Sketch®. The RA will then leave the room. The child will spend 10 minutes in the room, and the RA will check on the child after five minutes and restate the instructions. The RA will observe and take notes (e.g., time of first bite) on the child's actions through offsite video portal. Immediately following the visit, the RA will weigh each of the remaining snack food items twice to ensure accuracy. If the two measures are more than one gram apart, the RA will re-measure. However, if they are within 1g apart, the RA will average the two weights for a final measure. The number of grams remaining across the six snack foods will be subtracted from the total grams originally placed into the containers. The sum of the weight of the eaten snacks in kilocalories will represent the *EAH score*. Higher EAH scores will represent more food eaten in the absence of hunger.

6.2. COMPX Procedure

The COMPX procedure will be used as a measure of the child's ability to self-regulate energy intake following a caloric preload [26]. More specifically, this procedure will assess

a child's energy compensation when lunch is consumed following beverage preloads of varying caloric density [25, 26]. Participants will complete two sets of COMPX trials, one at baseline and one at three months post-intervention, but not at six months post-intervention due to financial constraints. Each COMPX trial will consist of two visits, approximately one week apart, to the Clinical Research Center (CRC). Prior to the visit, the mother will be instructed that the child should have a typical breakfast on the day of each visit, and then avoid food and drink after breakfast until the visit time, a 3-hour time span. A recall of the breakfast will be collected (with assistance from the mother), as well as the time of the child's last food and beverage. The child will then be provided with a beverage preload, followed by a 30-minute waiting period. During the waiting period, the mother will complete surveys and the child will be provided with sedentary, child-friendly entertainment (for example, coloring books or a popular cartoon DVD without food references).

6.2.1. Preload—Prior to lunch, one of two beverage preloads (high energy-density or low energy-density) will be given at each COMPX visit in random order. The high-energy preload will be prepared with 8g of sweetened Kool-Aid® powder, 19g granulated sugar, 11g maltodextrin, and 118g water (150kcal or 628 kJ). The low-energy preload will be prepared with 0.5g unsweetened Kool-Aid® powder, 7g granulated sucralose-based artificial sweetener (Splenda®), and 118g water (0 calories). Both drinks will be matched for flavor, mass (173g) and volume (3oz), and served in identical cups. The CRC staff administering the test will be blinded to the type of preload. The child will be instructed to consume the entire 3oz drink.

6.2.2. Lunch—After the 30-minute waiting period, the CRC staff will bring in a lunch tray (Table 2) and the time will be recorded. The child will be instructed that she or he may eat anything off of the lunch tray and can refuse any food she or he does not like. The CRC staff will also explain that the child may ask for as many additional servings as desired. The CRC staff will remain in the room with the child throughout the lunch period, interacting with the child only if the child initiates conversation. However, the CRC staff will abstain from conversations around food and will not use the words “hungry” or “full”, in order to avoid drawing added attention to the child's natural hunger or fullness cues. If additional servings are requested, the food items will be delivered to the room. If the child appears to be losing interest in the food, the RA will ask the child if she or he is finished eating. When the child states that she or he is finished (with or without prompting), the time will be recorded, and the child will be given a small toy as compensation for participating in the COMPX trial. After the lunch period, all foods left on the tray will be reweighed and recorded.

6.2.3. Calculation of the COMPX score—The COMPX score will be calculated as follows^{1–3}:

$$\%COMPX = \left[\frac{EI_{lowED} - EI_{highED}}{Preload_{highED} - Preload_{lowED}} \right] \times 100$$

where EI_{lowED} is the energy intake at the lunch meal following the low energy-density preload, and EI_{highED} is the energy intake at the lunch meal following the high energy-

density preload. A COMPX score of 100% will represent perfect energy compensation. A score <100% will represent overeating or undercompensation and a score >100% will represent undereating or overcompensation.

6.3. Body Mass Index (BMI) z-score and Weight Status

BMI, the most commonly used measure of body density, has a relatively high correlation with gold-standard measures of body fatness [34]. Weight and height will be measured using standardized procedures detailed below, child and maternal BMI will be calculated, and BMI z-score will be derived based on age- and sex-specific norms from the US Centers for Disease Control National Center for Health Statistics growth charts [36]. We will measure maternal weight and height at each evaluation period and define maternal obesity as a BMI > 30, and overweight as a BMI 25 <30. Height will be measured using an Ayrton Stadiometer Model S100. Prior to stepping on the stadiometer, participants and their mothers will remove their shoes and stand on the stadiometer base with their backs straight against the pole. The RA will make sure the perpendicular piece of the stadiometer is well above the participant's head, and then the RA will slide it down until the bottom of it touches the top of the participant's head. The RA will then ask participant to step away from the stadiometer. The RA will record height in centimeters (cm) to the nearest tenth of a cm. If the second measurement differs from the first by more than 0.5 cm, the RA will record these heights and obtain two more height measurements according to the aforementioned procedure. Weight will be measured using a Seca electronic column scale (Model 220). Prior to stepping on the scale, participants will be asked to remove shoes and other bulky articles of clothing. The scale will be calibrated to kilograms and zero-balance of scale will be checked. The participant will then step on the scale. After the first weight is taken, the RA will repeat the weight by asking the participant to step off the scale, re-checking the zero balance and asking the participant to step back on each time. If the second measurement differs from the first by more than 0.1kg, the RA will record these weights and obtain two more weights according to the aforementioned procedure. The final measures for weight and height will be the average of the two (or two closest) measures obtained.

6.4. Surveys

Mothers will complete surveys at each evaluation period (i.e., baseline, three months and six months from the start of treatment). Measures of maternal feeding behaviors will be assessed using the Child Feeding Questionnaire (CFQ) [37] developed by Leann Birch and colleagues, in which 31 items generate seven subscales (Pressure to Eat, Restriction, Monitoring, Perceived Feeding Responsibility, Perceived Child Overweight, Perceived Parent Overweight, and Concerns about Child Overweight). The range of each subscale is 1 to 5, with higher scores reflecting more of the identified characteristic. The CFQ is the most commonly used maternal-report measure of parents' feeding behavior and has demonstrated reliability and validity in different ethnic groups [36–38]. In another study of mothers with 2–5 year olds, the internal consistency estimates (Cronbach's alphas) were .73 for Restriction, .82 for Pressure to Eat, and .73 for Monitoring [18].

To address caregiver and child roles in feeding, mothers will complete the Caregiver Feeding Responsibility Scale (CFRS), an 11-item instrument which measures whether

caregivers adhere to feeding dynamic roles [39]. Specifically, items ask mothers the extent to which they perform their responsibilities (e.g., feed their child at regular times, serve meals with a variety of foods, ensure that the family eats together without distractions such as TV) and allow their child to perform their responsibilities (i.e., decide what or how much to eat of what has been offered). The range of each response scale is 1 to 5, with higher scores indicating greater adherence to the feeding dynamic approach [14]. The CFRS factor structure is unidimensional, demonstrates internal consistency reliability ($\alpha = .70$), test-retest reliability over a 5-week period ($r = .80$), and construct validity among mothers of 2- to 5-year-old children [18].

The Child Eating Behavior Questionnaire (CEBQ), a parent-completed 35-item survey, has established reliability and validity [21, 22] and will be used to measure a child's eating behaviors [21]. The CEBQ contains eight subscales: Food Responsiveness, Emotional Over-eating, Enjoyment of Food, Desire to Drink, Satiety Responsiveness, Slowness in Eating, Emotional Under-eating, and Food Fussiness. Although we will administer the full CEBQ, we will only calculate and analyze the Satiety Responsiveness subscale. Higher Satiety Responsiveness subscale scores are associated with less eating in the absence of hunger [22].

6.5. Additional survey items

Finally, other survey items that will be used as covariates and moderators will include demographic information, household routines, level of family chaos (state of confusion and disorganization in the home examined using social and physical factors) [40–42], maternal health status and eating behaviors [43], food insecurity [44], and food-related tantrums [45]. Food-related tantrums will be captured with a series of questions used in prior work by Agras [45], as well as in our own current work [46]. Mothers will be asked to report, during the last four weeks, how often (1) the child asked for something to eat; (2) the mother told the child he/she could not have something to eat; (3) the child became upset in response; (4) the child had a tantrum in response. Additional data on number of visits to a healthcare provider and exposure to any lifestyle information and counseling during the period of the study will also be documented. Mothers in both the FDI and the WLC group will complete a pre- and post-curriculum survey to assess their knowledge, perception, self-efficacy, acceptability and frequency of use of the FDI recommendations.

6.6. Compensation for completing outcome measures

Participants will be compensated \$75 for completing outcome measures at each evaluation point (i.e., baseline, three months and six months from the start of treatment). Thus, in total, participants will be paid \$225.

7. Analysis plan and statistical power

Caregiver and child demographics and outcome measures will be summarized by descriptive statistics; means and standard deviations will be calculated for continuous variables and frequencies and percentages for categorical variables. The primary outcome analyses (EAH and COMPX) will be based on the intention-to-treat (ITT) analysis principle. All

participants, including participants who drop out of the study, will be included in the final analysis based on the randomized group rather than their participation in the assigned group. The ITT analysis therefore will maintain the randomization as well as estimate the efficacy of the intervention. The outcome measures for participants who will drop out of the study will be imputed using a last observation carried forward (LOCF) approach where the missing outcome is imputed using the baseline value assuming no intervention effect for the dropout. We will include only participants who complete 75% of each measure to compare between group differences. Data that are missing at random are not problematic when conducting the analyses that will be performed in this study. We will further determine whether variables such as treatment group (FDI vs. WLC), demographic variables, and maternal characteristics are associated with the rate of missing data. All statistical analyses will be conducted using SPSS version 22.

A repeated measure analysis of covariance (RM-ANCOVA) will be used to compare differences in outcome measures outlined above between the FDI and WLC groups from baseline, three months and six months after the treatment. The impact of relevant covariates (e.g., demographics, household routines, maternal weight status, level of chaos, maternal eating behaviors), while controlling for treatment group, will also be investigated. We will perform RM-ANCOVA with intervention type (FDI vs. WLC), time (baseline, three months and six months from the start of treatment) and their interaction for each of the outcome measures (i.e., controlling for relevant covariates). We will follow-up significant analyses with either nonparametric Wilcoxon two-sample tests or t-tests when it is appropriate. The Holm-Bonferroni method will be used to adjust p-values for multiple comparisons. This method uses a stepwise algorithm to control the Family-wise error rate; it is more powerful than and not as conservative as the Bonferroni correction method.

7.1 Statistical power

We will estimate attrition rate at 15% and have included rigorous protocols to improve retention (e.g., structured phone calls, emails, use of newsletters). With a two-tailed p-value of .05 and 42 participants in each group, we will have 80% power to detect a Cohen's *d* effect size of .67 (a moderate effect) between the FDI and WLC for our primary (EAH and COMPX) and secondary (maternal feeding behaviors and maternal-reported child satiety responsiveness) outcomes. A moderate effect allows for reasonable sample sizes necessary for a pilot study. We acknowledge that non-statistically significant smaller effect sizes may occur for some of the other outcome measures. Given the preliminary nature of this study, we anticipate to use these effect size findings in calculating the sample size necessary for a subsequent large randomized controlled trial.

8. Discussion

This study is designed to test the efficacy of a Feeding Dynamic Intervention (FDI) with overweight preschoolers to increase their responsiveness to satiety and reduce eating in the absence of hunger. The FDI is delivered to mothers and focused on improving children's self-regulated eating, energy compensation, satiety responsiveness and caregivers' feeding practices. The ultimate goal of the FDI is to treat and prevent overweight and obesity in

preschool-aged children by improving self-regulation. At the completion of this study, we expect to know: (1) the degree to which children can be taught to respond appropriately to satiety cues, improve energy compensation, and reduce eating in the absence of hunger in response to a parent-directed intervention; (2) the effect of the FDI on maternal self-reported feeding practices among overweight and obese children; and (3) the estimated effect size of the intervention for changes in the outcome measures. The ultimate goal of the study is to demonstrate proof of concept, feasibility, and effect size that will lead to a subsequent large-scale multicenter trial. The proposed research will test an innovative intervention for addressing overweight and obesity among young children and advance our understanding of whether and how accurate self-regulation of energy intake among young children can be shaped by parenting behaviors.

There are several strengths of this study. First, there has been a long-standing hypothesis within the scientific community and within the lay press and clinical practice guidelines [13] that a key intervention approach to preventing obesity in young children is to reduce parental feeding behaviors that are overly controlling or intrusive (both with regard to pressuring children to eat more as well as restricting children from eating too much) [12]. Many studies have shown associations between overly controlling feeding behaviors and excessive increases in child body mass index or obesity [2, 47–49]. To our knowledge, there has been just one prior study examining in a randomized controlled trial the effect of an intervention focused on reducing overly controlling parental feeding behaviors among young children, a key caregiver role in the feeding dynamic approach [50]. In that study, 62 children between 2- and 4-years-old with at least one overweight or obese parent were randomized to either an intervention focused on the division of responsibility in feeding, or a control group which received education regarding increasing the intake of vegetables, decreasing fats and sweetened beverages, decreasing television exposure and increasing physical activity. Outcome measures were the Child Feeding Questionnaire [38] subscale scores of Pressure to Eat and Restriction. The study found that parents in the division of responsibility intervention reduced self-reported pressure on the child to eat; there was no intervention effect on restrictive feeding practices. The trial currently being undertaken differs in several important ways from this single prior study. Specifically, there is uncertainty in the literature regarding whether parental pressure on children to eat and restriction of children's eating actually causes, or at even precedes, maladaptive child eating behaviors or the development of child overweight [4, 51]. Examining self-reported parental feeding practices only is a relatively proximal outcome. The trial will be the first to our knowledge to test whether an intervention focused on division of responsibility will actually change children's observed eating behaviors, specifically, accurate down-regulation of energy intake in response to a caloric preload and a reduction in eating in the absence of hunger. If the results of this trial are promising, ultimately a trial with a larger sample size will test the conceptual model that the intervention reduces overly controlling parent feeding behaviors, which lead to improvements in children's eating behaviors, which lead to a reduction in excessive increases in body mass index and the treatment of overweight and obesity.

There are several limitations to the study. A key question in the literature that is receiving increasing attention is variability in appetitive drive in children. Specifically, child obesity

interventions that focus on reducing parental over-control necessarily assume that all children possess an innate ability to accurately self-regulate energy intake that would operate perfectly and prevent obesity if only parents did not interfere and override this innate, finely tuned system. This notion has been generated by a long-standing but sparse literature indicating that children demonstrate relatively stable caloric intake despite variability between meals [52–54]. More recent work has demonstrated that the risk allele of the FTO gene is associated with a greater risk of childhood obesity, reduced parent-reported child satiety responsiveness [55], and more child self-reported episodes of loss of control in eating [56]. In other words, it is possible that some children are innately less responsive to satiety cues and are more predisposed towards eating in the absence of hunger. For such children, an intervention that reduces parental provision of external controls over the child's eating could actually result in a greater likelihood of excessive weight gain. In summary, because obesity is such a complex trait with a multifactorial etiology, it is unlikely that there is a “one-size fits all” efficacious intervention [3]. However, the trial currently underway will provide the first evidence regarding whether, for at least some children, there is an obesity prevention effect of reducing parental overcontrol in feeding.

If the intervention is found to have a beneficial effect on children's observed eating behaviors in the current trial, there are many additional questions that may be answered in future research. Specifically, recent work has emphasized factorial designs in randomized controlled trials [57], which allow the evaluation of which component of a multi-component intervention is actually predictive of the desired outcome. This type of work would lead to an improved understanding of the mechanism of the interventions focused on division of responsibility. In the current trial, the mechanism of effect could be improved structure, reducing pressure to eat, reducing restriction, “the where,” “the when,” or “the what” (Table 1). Identifying which component of the intervention actually provides the intervention effect would lead to both more efficacious future interventions as well as improve the understanding of mechanisms and causal pathways. Another area for future work involves the more specific phenotyping of maternal feeding behaviors. Although a strength of the trial currently underway is the observational assessment of child eating behavior, the study does not include the observational assessment of maternal feeding behavior. There are very few observational studies of maternal feeding behavior currently described in the literature [4, 49]. As opposed to relying on maternal self-report of feeding practices, future work might videotape mother-child feeding interactions in the home or in a structured laboratory setting and employ observational coding to measure maternal feeding style and practices [58]. Future studies may also evaluate whether any intervention effect is moderated by pre-existing features of the child's eating behavior that are perhaps genetically driven. For example, the intervention may only be effective among children without the risk allele of the FTO gene or without high appetitive drive. Indeed, these types of differences may be observable even in infancy – a vigorous sucking pattern in the first months of life has been associated with a higher likelihood of being obese at school age [46]. In the current trial, mothers are taught both to alter their feeding practices, but also to teach the child about hunger and satiety cues. If teaching children to be more attentive to their own hunger and satiety cues is effective, this component of the intervention may be more widely disseminated if it could be delivered directly to children themselves in preschool or school

settings. Finally, there is a need to understand whether the intervention effects, if present in the short term, are also sustained and have long-term effects on the risk of becoming obese.

In summary, the trial currently underway will provide valuable data regarding the efficacy of an oft-cited intervention frequently promoted among the lay public. The results may also provide a path towards understanding inter-individual differences in the intervention effect and mechanism of effect. In the context of the current obesity epidemic, the trial will therefore provide critical practical knowledge regarding the value of one intervention approach, but will also inform the understanding of the surely diverse etiologies of the early development of obesity within the population.

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Figure 1.
Conceptual framework of the Feeding Dynamic Intervention (FDI) study

Figure 2.
Timeline for the Feeding Dynamic Intervention (FDI) study

Table 1

Content of each lesson in the Feeding Dynamic Intervention

<p>1. Parent's Role in Feeding and Child's Role in Eating</p> <p>Explore beliefs about mothers' eating, process of feeding children, and past experiences with eating. Instruct and discuss roles in feeding/ eating, rationale and benefits for defining roles and application in relation to parenting styles. Introduce continuum of hunger and satiety. Mothers learn and teach their children to recognize hunger and satiety using a 3-D model of empty and full stomachs (i.e., differences between hunger, fullness, and being "stuffed").</p> <p>2. Limiting Where and When Food is Eaten-"the Where and When"</p> <p>Watch video of a Supernanny episode that highlights an under-supported and chaotic eating environment. This video also shows a family with a young child and illustrates the where, when and what aspects of the division of responsibility. Teach concepts on application using parenting strategies. Discuss benefits of "where" and "when" in daily living. Introduce hunger and satiety cues in children in relation to the "where" and "when." Discuss opportunities to decrease grazing, the importance of family meals, and the selection of snacks. Problem solve challenges surrounding "the where and when." Reinforce approaches to teaching child to recognize hunger and satiety.</p> <p>3. Parenting Styles: Family Meals/Balanced Meals-"the What, When and When"</p> <p>Watch video and discuss parenting styles. Complete parenting style survey. Discuss the authoritative parenting style and implementing the feeding dynamic approach. Problem solve challenges surrounding parenting and feeding. Reinforce approaches to teaching child to recognize hunger and satiety.</p> <p>4. Nutrition – "the What": Practice Meal and Menu Planning</p> <p>Compose meals (starch, protein, fat, fruit/vegetable and dairy) using the balanced plate concept while offering variety. Perform activity on "worst meal scenario" and illustrate that certain inexpensive foods can be used to design balanced meals. Emphasize convenient foods rather than convenience meals. Problem solve challenges surrounding "the what." Serving size vs. portion size, recipes, and food labels. Reinforce approaches to teaching child to recognize hunger and satiety.</p> <p>5. Problem Solve "the What" Scenarios and Introduce Physical Activity</p> <p>Discuss menu planning. Problem solve challenges around cooking, offering variety, eating out, nutrient quality, and parenting struggles. Introduce parent and child roles for physical activity. Reinforce approaches to teaching child to recognize hunger and satiety.</p> <p>6. Physical Activity and Wrap Up</p> <p>Discuss parental responsibility and physical activity. Discuss how to reduce sedentary behaviors and increase physical activity. Provide suggestions for reducing TV viewing time. Address why parents are key to reducing TV viewing time. Share and problem solve experience with FDI. Wrap up.</p>
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Table 2

Food composition of the energy compensation (COMPX) tests

COMPX Item	Weight per serving (g)
Macaroni and cheese	133.0
Cheese stick	28.88
Grapes	113.0
Green beans	105.63
Graham crackers	29.25
Milk	257.36
Carrots	35.0
Water	236.8