Study Title: STORY: A pilot randomized controlled trial using Storytelling To prevent Obesity and encourage Responsive feeding practices in Young children

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Background, Rationale and Context

Parents commonly exert controlling feeding practices in which they pressure their child to eat or restrict the types of foods their child eats. Even when parents pressure their child to eat healthy foods and restrict unhealthy foods, this has been paradoxically associated with lower fruit and vegetable intake and increased weight gain over time. Many parents fail to establish structure around feeding, allowing their child to eat when, where, and what foods they prefer and having few meal routines. This lack of structure has been associated with increased risk of overweight/obesity. While previous studies have shown that parent education interventions are effective in improving child feeding practices, there remain barriers, such as time and provider comfort level, to implementing these interventions in clinical and community settings. It is unclear whether aspects of intervention delivery – notably who delivers the intervention and the setting in which it is delivered – impact intervention effectiveness. Narrative persuasion has demonstrated the power of storytelling to influence viewers' attitudes and beliefs, however, research by health interventionists has to date largely failed to integrate storytelling as an approach to health behavior change. **To address these gaps, our goal is to develop a novel storytelling video series to educate parents about healthy parent feeding practices and to assess feasibility and acceptability of the intervention through a pilot randomized controlled trail in diverse clinical and community settings.**

Objectives

Conduct a pilot randomized trial to assess feasibility and acceptability of STORY. We will recruit 60 parents (20 per intervention mechanism + 20 controls) of healthy 2- to 4-year-old children from pediatric primary care offices. Parents will complete a questionnaire and dyads' heights and weights will be measured. Families will be randomized to the control group or **1 of 2 intervention delivery approaches (IA)**:

IA 1. Online-only video series introduced by general pediatrician at primary care office
IA 2. Weekly classes with video viewing and group discussion led by Second Harvest Food Bank's Nutrition Services team, a community organization focused on providing evidence-based nutrition education

Parents will be given a handout (controls), links to the videos to watch independently (IA 1), or information on how they will be contacted to schedule their intervention sessions (IAs 2). After 2 videos/sessions, all parents will complete a written survey assessing their experience with the intervention and any changes made at home; the written survey will reassess baseline measures. Intervention parents will also complete a semi-structured interview to assess the family's experience with the STORY trial.

Sub aim 2a: Feasibility: number of parents approached, number of parents consented
Sub aim 2b: Adherence: number of parents who complete videos or sessions
Sub aim 2c: Acceptability to parents and providers

Aim 3: Concurrently with Aim 2, we will obtain pilot data to estimate variances (means, SD) of measures to be utilized in the larger study. We will utilize data from the pilot trial described in Aim 2. Measures include anthropometrics, parent controlling feeding practices,

child self-regulation of eating, and family mealtime practices at baseline and after STORY intervention delivery.

Methods and Measures

Design

In a pilot randomized controlled trial we will recruit parents of healthy 2–4-year-old children from three primary care offices with diverse patient populations. Participants will complete baseline questionnaires and be randomized to one of three groups. The control group will receive an educational handout at the baseline visit. The intervention will be delivered through one of two mechanisms: (1) links provided to online-only video series (2 videos) by general pediatrician at primary care office, and (2) 2 weekly group sessions with video viewing and group discussion led by Second Harvest Food Bank's Nutrition Services team, a community organization focused on providing evidence-based nutrition education. The Nutrition Services team has experience leading group classes from cooking classes and summer meal site activities for children to food demonstrations and community garden workshops.

We will assess the feasibility and acceptability of the intervention and delivery mechanisms to intervention participants and providers. After completion of the 2-week intervention we will assess the change in all participants' parental pressure to eat, child self-regulation of eating, and family mealtime practices.

Setting

We will recruit participants from academic pediatric primary care practices, including Winston East Pediatrics, The Downtown Health Plaza, and Ford Simpson Lively and Rice Pediatrics, three clinics affiliated with Atrium Health Wake Forest Baptist (AHWFB). One child per family will be recruited; if more than one is eligible, we will enroll the youngest eligible child.

Subjects selection criteria

- **Inclusion Criteria**

  Parent participants will be included if the parent is at least 18 years old and can read and write English and if the child has no medical conditions that affect development, feeding, or growth.

  Provider participants will be included if the provider leads a discussion group or refers patients into the study.

- **Sample Size**

  60 parent participants and 60 child participants will be recruited.

  20 provider participants will be recruited.

Interventions and Interactions

All participants will complete baseline questionnaires at the time of recruitment and all participants will complete follow-up questionnaires, either one month after recruitment (for controls and IA 1 participants) or after completion of their intervention (IA 2 participants). The IA 1 participants will receive an email reminder stating, "You are receiving this email because you signed up to participate in a short study during your child's visit with their doctor. This is a reminder to watch the two videos (links provided below) if you have not already done so and please know that you will receive a link to a second survey soon. Once the second survey is

completed, you will receive another $30 gift card." Additionally, IA 1 participants' email will include personalized links to videos to track those who watched the videos. Control, IA 1, and IA 2 participant groups will receive an email with the following text, "You are receiving this email because you signed up to participate in a short study during your child's visit with their doctor. You completed the first survey on a tablet during your child's visit. Here is a link to the follow-up survey. Once we have been notified that you have completed the survey we will mail you a $30 gift card as a thank you for completing the survey. If your address has changed since your child's last doctor's appointment, please let us know where you would like us to mail the gift card."

After 2 sessions, intervention parents will complete a semi-structured interview (IA 1-2). The semi-structured interview will use open-ended questions to assess the family's experience with the intervention. An interview guide will be developed, and we will test interview questions for clarity, comprehension, and face-validity via cognitive interviews with volunteers. Semi-structured interviews were chosen to allow study staff to obtain clarification, probe for detail, and allow new topics to emerge.

Links to the videos will be provided via individualized QR codes to participants. The videos can also be found at the following link:

https://youtu.be/lFS5V4lcwyA

https://youtu.be/GWodDTyzepE

Outcome Measure(s)

We will assess feasibility by evaluating the number of families who are approached for participation at primary care offices and the number consented and randomized.

We will assess adherence by evaluating the number of videos viewed (tracked through REDCap in IA 1) or sessions attended (IA 2) by each participant. Based on our experience in previous trials and what is widely accepted in behavioral interventions, we will define successful adherence to the intervention as completing 2 out of the 2 sessions (100%).

We will assess retention by evaluating the number of participants who complete the final study visit.

We will assess acceptability to *parents* by assessing: the referral experience, which aspects of the intervention were/were not helpful, barriers to completing the intervention, and barriers and facilitators to making changes to their feeding practices. This will be assessed with a brief survey after and a semi-structured interview after completion of the intervention. Finally, we will monitor time needed for intervention delivery and assessments and gather feedback on participant burden. We will assess acceptability to *providers* who introduced videos with a short survey about their experience and to group session facilitators with a semi-structured interview assessing their perceptions of the videos and its use to encourage conversation and behavior change among participants, and barriers and facilitators for participants to make changes to their feeding practices.

We will assess fidelity of intervention delivery, receipt, and enactment. Facilitators (peer leaders and Second Harvest Food Bank's Nutrition Services staff) will be given extensive training on intervention delivery and will audio record sessions. *Fidelity of intervention delivery* will be assessed through facilitator completion of key delivery components (study staff will complete

Evaluation Checklist of key points communicated during each session). To assess perceived self-competence, facilitators will respond to an open-ended question after each session to evaluate the strong and weak points of their own delivery. If perceived self-competence is low, or study staff's review of a recorded session indicates that a facilitator needs additional training, study staff will provide additional follow-up. *Receipt* will be assessed through the post-intervention survey, including whether the video content was relevant (5-point Likert scale) and expert assessment of whether the parent identified an attainable, specific, and measurable goal (yes/no). *Enactment* will also be assessed through a post-intervention survey, including expert assessment of whether the parent made a specific and measurable change in feeding practices.

Qualitative Analysis: Semi-structured interviews will be transcribed verbatim from recordings into Microsoft Word. We will analyze interviews using a thematic analysis approach which provides a systematic method for coding and analyzing qualitative data, especially useful for exploratory evaluation.[35,36] Co-investigators will read 10 transcripts to identify potential codes, first separately and then together. Transcripts will be re-reviewed by investigators to refine the common coding library and data dictionary, modifying codes as appropriate. Once a common coding scheme is developed, all transcripts will be analyzed and coded by two investigators independently. Representative quotes will be recorded, and transcript codes will be grouped into similar categories. Investigators will interpret themes and sub-themes from these categories.

Survey Measures: We will assess pressure to eat and restriction via the Child Feeding Questionnaire (CFQ). The pressure to eat subscale (4 items) of the CFQ has high internal consistency (0.7)[37] and is validated in Black and Hispanic populations.[38] The restriction subscale (8 items) has high internal consistency (0.8) and is validated in racially diverse populations.[39] Child self-regulation of eating will be assessed using three subscales of the CEBQ.[40 41] Satiety responsiveness, food responsiveness, and enjoyment of food are assessed on a 5-point scale (1=never; 5=always). Higher scores on satiety responsiveness indicate higher self-regulation; higher scores on food responsiveness and enjoyment of food indicate lower self-regulation. These subscales are valid and have good internal consistency in young black and Hispanic children in the United States.[17]

We will evaluate caregiver feeding styles using the10-item version of the Caregiver's Feeding Styles Questionnaire (CFSQ). The questionnaire assesses self-reported feeding and classifies parents using median splits, which are used in a substantial body of parenting literature and allow for direct comparison across studies, on dimensions of demandingness and responsiveness. The questionnaire is measured on a 5-point Likert scale (ranging from 1=never to 5=always). The demandingness and responsiveness scores are used to categorize parent feeding style into one of four categories: authoritative, authoritarian, indulgent, and uninvolved styles.

We will assess family mealtime practices with the Family Meal Frequency Questionnaire which assesses how many times a week the family eats dinner together, both at home and at a restaurant.[42] We will also use the Structure of Family Meals subscale of the Meals in our Household Questionnaire (10 items), which assesses whether the meal is eaten in the kitchen/dining room, whether members of the family ate the same food, and whether the meal is eaten at a regular time (never, rarely, sometimes, often, or always. This measure has been validated in preschool and school-aged children.[43]

Demographic questions will include household income and food insecurity; parents' education; and child's sex, race, ethnicity, insurance status, number of siblings, birth order, and daycare/school attendance. Parent and child weight and height will be measured by study staff. Number of siblings and birth order,[44] food insecurity,[45] and child weight status[46] have all previously been associated with parent feeding practices.

Analytical Plan

Statistical Analysis of Pilot Data: We will use this pilot data to estimate variances (means, SD) of measures to be utilized in the larger future effectiveness trial. In the analysis of this pilot data, we will use separate regression models assessing differences between each type of intervention and the control group for our outcomes of change in controlling feeding practices, child self-regulation of eating, and family mealtime structure. We will use intention to treat analyses and will adjust for child race/ethnicity, age, and sex; number of siblings; parent BMI; household income and food insecurity; and baseline feeding practice/self-regulation/mealtime structure.

Human Subjects Protection

Subject Recruitment Methods

We will recruit 60 2- to 4-year-old children and their parents from three Wake Forest Baptist Health pediatric clinics: Downtown Health Plaza (the Wake Forest School of Medicine pediatric residency clinic that sees a largely urban and minority population), Winston East Pediatrics (sees a diverse urban population), and Ford, Simpson, Lively, and Rice Pediatrics (sees primarily a suburban population). We will recruit via research personnel directly approaching parents. All patients coming to clinic will be recruited sequentially if they meet inclusion criteria. Refusal rates will be tracked, including the number of participants who decline to participate and why, but no PHI will be recorded for participants who decline to participate. Participation is voluntary and non-coercive. The research assistant will approach parents individually to discuss the study and offer participation. Approximately 2,000 2- to 4-year-old children are seen yearly. In the last few years, the English-speaking children served at these clinics were 36% black, 41% white, 20% Hispanic, and 3% other. Previous studies have been done at these clinics with successful recruitment and retention.

All pediatric providers at Downtown Health Plaza, Winston East Pediatrics, and Ford, Simson, Lively, and Rice Pediatrics who refer patients into the study will be eligible for inclusion. Additionally, providers who facilitate the discussion groups will also be eligible for inclusion in semi-structured interviews.

Informed Consent

Written consent will be obtained from parents. Assent will not be obtained from children as they are all under the age of 7 since they are unable to consent for themselves. Children under the age of 7 will have very limited understanding of the study and its procedures. The study population is children ages 2 to 4 years old. These children are unable to provide consent. After the child is placed in an individual exam room by the nurse at their clinic visit, research personnel will approach parents. The research assistant will discuss the study, assess eligibility criteria, review the consent document, and offer participation.

We will collect the name of the parent and the name and MRN of the child participants. Both name and MRN are required, because we need to maintain a record of the child's name to clarify communication with parents about which child is participating in the study, and we need to maintain a record of MRN in order to link the child's research data with their electronic health record data. We will only record names of provider participants (not MRNs) as we are not linking to their health records.

A waiver of the requirements for signed informed consent is requested for the 20 recruited providers due to research presenting no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Providers will be provide verbal consent prior to participation in the interview (see Provider Interview Guide document).

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed three years after closure of the study, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.