

University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS
TEMPLATE WITH GUIDANCE

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Principal Investigator: Heather Gibbs, PhD, RD

Study Title: Nutricity: An mHealth nutrition intervention to improve diet quality among Latino children

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I. Purpose, Background and Rationale

A. Aim and Hypotheses

1. US Latino families are more likely to live in poverty with less access to education and low rates of health literacy – all of which are strong predictors of poor diet and obesity. Large health disparities exist in childhood obesity; Latino children have the highest rates among all race and ethnicities at 15.6%¹. This sets the stage for a host of chronic diseases and shorter life span. Good nutrition plays an undeniable role in the prevention of obesity, and nutrition counseling has demonstrated effectiveness for improving nutrition behaviors and diet quality²⁻⁵. However, preventive nutrition care is poorly integrated in pediatrics⁴. Routine assessment of eating habits and obesity risk are recommended in pediatric care^{4,6}, but the American Academy for Pediatrics materials provide minimal information about nutrition⁷. Little data is available to identify whether routine counseling is actually occurring. An additional gap exists in nutrition education resources for Spanish speakers.
2. The overall objective of this application is to pilot test an mHealth nutrition intervention within pediatric clinics serving Latino families and evaluate its potential for implementation. *We hypothesize the intervention will improve child diet quality and will be feasible for use within the clinic setting.* To test this hypothesis, we will pursue 3 specific aims and 1 exploratory aim:
 - a. Aim 1: Pilot Nutricity with 40 Latino families (English or Spanish speaking) vs. 40 waitlist control in primary care clinics and estimate differences in child diet quality at 3 month's post Nutricity exposure. Preliminary data will be used power in the future larger Nutricity intervention.
 - b. Aim 2: Evaluate other individual (dyad) level factors including reach, engagement, and changes in secondary effectiveness outcomes (e.g. nutrition literacy, BMI, skin carotenoid, psychosocial constructs) at 3 months post exposure.
 - c. Aim 3: Evaluate organizational-level factors (adoption, implementation, and organizational-level maintenance) in Latino-serving pediatric clinics that may support or inhibit future uptake of Nutricity. We will seek to understand the context of interventions and scalability to other clinics using mixed methods.
 - d. Exploratory Aim 1: Explore the relationship among nutrition literacy, psychosocial constructs and diet quality outcomes; and explore how engagement and satisfaction influence outcomes.

B. Background and Significance

1. **Study Significance:** Our scientific premise is that parent nutrition literacy is a key barrier to a healthy diet for children and critical for preventing obesity. Obesity affects 15.6% of 2-5 year-old Latino children⁸. While children at all BMI percentiles have the potential for adult overweight/obesity, risk for adult obesity is ~70% among those who are overweight/obese in early childhood⁹⁻¹¹. Metabolic consequences of adult obesity often begin in childhood¹². The contribution of the proposed research will be a behavior modification based, multicomponent mobile intervention to improve child diet quality and require minimal time and human resources of clinics. Such a program could be used in community programs, schools, and rural health settings and adapted for other cultural/language populations.
2. *Review of Literature.*

Poor diet quality in childhood is problematic for long-term health. Diet plays a critical role in the prevention of pediatric obesity, now considered a public health priority^{4,13}. The diets of US children continue to fall short of recommendations, resulting in excess consumption of overall kilocalories, sodium, and saturated fat and inadequate intakes of other nutrients such as iron, zinc, and fiber^{14,15}. More often facing obstacles related to the social determinants of health, Latino children tend to eat low quality diets characterized by higher intake of sugar-sweetened-beverages and fast food^{11,16-18}. While a healthy diet during this time is associated with better nutrient biomarkers¹⁹ and higher lean mass accrual at four years²⁰, a poor diet has health consequences such as higher fat mass at six years²¹, early-onset puberty²² and increased blood pressure²³. Dietary patterns established in infancy persist into preschool²⁴ and beyond²⁵, making early childhood a critical time point to set the trajectory toward a healthy diet that prevents obesity.

Parents play a key role in forming eating habits. Parents have tremendous influence on child diet quality²⁶. In early childhood, parents determine food availability and accessibility, model eating behavior, determine the context of family meals (or lack thereof), the frequency of dining out, portion sizes served and/or eaten, and exert feeding styles to influence child eating behavior²⁷. Obesogenic behaviors among Latino parents include permissive parenting style, pressure-to-eat strategies, and greater concern for underweight than overweight²⁸. On the other hand, parental feeding behavior is also influenced by child eating behavior. For example, child acceptability of vegetables is dependent upon repeated exposure, so parental response to developmentally normal neophobia (fear and rejection of new foods) when the young child is presented with a new vegetable may impair repeated exposure²⁹. Thus, children and parents work bi-directionally to form eating habits. For this reason, interventions to improve diet quality in young children need to include both parents and children. Targeting the age range of 1-5 years is ideal because parents have the most influence upon a child's diet during this time; from the transition to solid food (~1 year) until school-age (~5 years).

There is no standard of care for nutrition in pediatrics. Across health literacy levels, parents prefer to receive health information in primary care pediatric settings³⁰. Yet it is apparent that pediatricians need assistance to improve the delivery of nutrition education³¹. One study found only 13.8% of physician office visits (children and adults) included counseling about nutrition or diet³². Routine assessment of eating habits and

obesity risk are recommended for routine child visits^{4,6}, but educational materials provided by the American Academy for Pediatrics for these visits provide minimal information about nutrition⁷ and little data is available to identify whether routine counseling is actually occurring. Of 192 primary care providers for children and adolescents in the Philadelphia area, 63% felt they have limited time to discuss nutrition, 56% felt they lack sufficient education materials for preventing or treating overweight children, and 62% felt there are not enough nutritionists to assist with overweight children³³.

Rigor of prior research. RCTs examining childhood obesity prevention interventions targeting children < 5 years of age have demonstrated effectiveness for improving diet, physical activity, obesogenic behaviors at childcare facilities, and at home¹². A majority have been conducted in childcare facilities with poor parental participation, and few have been implemented within healthcare settings¹². Dietary assessment methods used within these studies have limited rigor, if done at all, and nutrition literacy of parents has not been considered. Evidence that mHealth interventions improve diet intake in children is emerging. In the Swedish MINISTOP RCT, a 6-month smartphone delivered intervention for parents of 4-yr old children, the intervention group had higher odds of increased diet/activity composite scores (OR:1.99; P=.008), mostly explained by increased fruit/vegetable intake³⁴. Similarly, frequency of vegetable intake increased in the Food4toddlers mHealth intervention in Norway (0.46 times/d, p=.02)³⁵ and discretionary food intake was reduced (estimate -1.36; P=.004) in those receiving the 6-month Time2bHealthy intervention in Australian parents of 2-5 year-olds³⁶.

C. Rationale

1. *Formative work*³⁷: We recruited 30 parents of 1-5 year-old children from two urban clinics to use Nutricity in English (n=15) or Spanish (n=15) for 30 minutes and provide feedback via 14-item survey³⁸. Our sample was predominantly Hispanic/Latino (63%) with low income and low education with 60% of parents completing high school or less. Most demonstrated nutrition literacy deficits, with 33% (n=10) with a "likelihood of poor nutrition literacy" and 43% (n=13) a "possibility of poor nutrition literacy." Parents rated a series of statements about Nutricity on a 5-point Likert scale (1=poor, 5 = good). Importantly, likability did not differ between language groups (4.6 and 4.5, English and Spanish, respectively; p=0.45) or nutrition literacy scores (r=-0.001, p=0.997). Pediatricians (n=7), nurse managers (n=3) and one nurse from 4 KC metro clinics were interviewed to assess the feasibility of implementing Nutricity within their clinics. All welcomed a Nutricity intervention and confirmed that standard nutrition care is insufficient in meeting patient needs. Wait times in the exam room are estimated at 20-30 minutes or more. Regarding feasibility, most shared similar sentiments such as "They are already using smartphones and tablets, so they may as well be doing something worthwhile."

Proof-of-Concept Pilot Study. We worked with clinic staff at two pediatric primary care clinics with university affiliation to trial the integration of Nutricity in the clinics. Resource constraints limited recruitment to English speakers only. We enrolled 18 dyads, losing only 1 to follow-up. Importantly, this pilot was not adequately powered to determine effectiveness; yet we established protocols and feasibility for measuring the pre-post primary (child diet quality) and secondary outcomes of our proposed trial. Improvements

were seen in two HEI component scores, including dairy (+1.2 pts, $p=0.055$) and seafood & plant proteins (+1.3 pts, $p=0.046$). Our sample maintained a low reported intake of added sugars throughout the intervention (8.7/10 pts). Most ($n=15$) participated in text messages for ≥ 10 weeks, while website usage averaged 4 weeks. At completion, participants rated overall likeability of Nutricity as 4.1 on a 5 point scale (5=good). A common emergent theme was need for more individualized text messages.

2. *Anticipated Outcome.* Completion of the proposed work will produce a behavior modification based, multi-component mobile intervention to improve diet quality among young Latino children. If pilot data are positive, we will propose a large randomized controlled trial (RCT) to evaluate the effectiveness of Nutricity to improve child diet quality versus waitlist control. We will conduct our RCT in pediatric exam rooms to introduce the Nutricity content to English and Spanish speaking families. Our future study will build on and refine pilot study procedures, as a full-scale effectiveness-implementation "Hybrid Type 1 trial"³⁹, using the iPARIHS framework⁴⁰ to guide implementation strategy and the RE-AIM framework⁴¹ for overall evaluation.

II. Research Plan and Design

A. Study Objectives: The long-term goal of this research is to improve child diet quality for obesity and chronic disease prevention. The overall objective of this application is to pilot test an mHealth nutrition intervention within pediatric clinics serving Latino families and evaluate its potential for implementation.

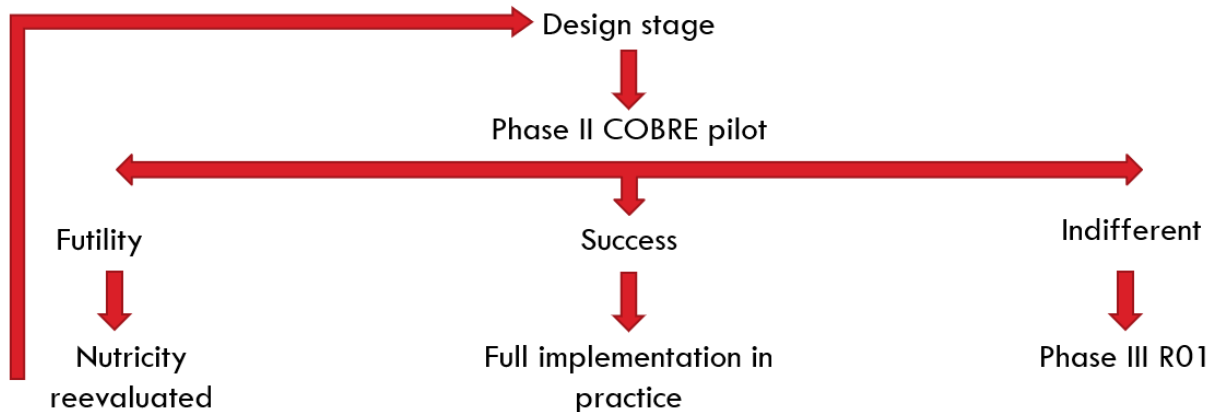
- a. Aim 1: Pilot Nutricity with 40 Latino families (English or Spanish speaking) vs. 40 waitlist control in primary care clinics and estimate differences in child diet quality at 3 month's post Nutricity exposure. *Preliminary data will be used in a future larger Nutricity intervention.*
- b. Aim 2: Evaluate other individual (dyad) level factors including reach, engagement, and changes in secondary effectiveness outcomes (e.g. nutrition literacy, BMI, skin carotenoid, psychosocial constructs) at 3 months post exposure.
- c. Aim 3: Evaluate organizational-level factors (adoption, implementation, and organizational-level maintenance) in Latino-serving pediatric clinics that may support or inhibit future uptake of Nutricity. We will seek to understand the context of interventions and scalability to other clinics using mixed methods.
- d. Exploratory Aim 1: Explore the relationship among nutrition literacy, psychosocial constructs and diet quality outcomes; and explore how engagement and satisfaction influence outcomes.

B. Study Type and Design: Randomized controlled trial (pilot) with a seamless Phase II-III adaptive design. Phase II will be the COBRE portion of the design, and all participants will be used in Phase III. The phase III portion will comprise a proposed R01.

C. Sample size, statistical methods, and power calculation

1. After consent, participants will be randomized with ratio of 1:1 in each block through the study database (REDCap).

2. The research team will not be blinded to randomization.
3. A maximum of 165 dyads (parent and child) will be enrolled in each group, intervention or waitlist control.
4. The first year interim analyses will occur after at least 30 subjects have enrolled into the trial. Subsequent interims will be conducted every 52 weeks and will continue beyond full accrual. Since interims are defined by calendar time, the total number of planned interims is random and will depend on the rate at which subject accrue to the trial. The accrual rate is expected to be 5 participants/month.
5. Seamless Phase II-III design uses the Bayesian adaptive approach to reduce sample size while preserving the operating characteristics of a traditional two-stage design.



D. Subject Criteria (See Vulnerable Populations appendix, if applicable): We will study a maximum of 330 dyads of 1) parents who are >18 years old and have a child aged 1-5 years, and 2) the 1-5-year-old child.

1. Inclusion criteria: Individuals are eligible if they meet the following criteria:
 - E. Age (of parent) > 18 years;
 - F. Parent or guardian of a child between 1-5 years old;
 - G. Hispanic/Latino;
 - H. English or Spanish speaking;
 - I. Primary food decision-maker for the home;
 - J. Internet connectivity at home (smart phone is adequate);
 - K. Owns a device for accessing internet at home.
2. Exclusion criteria: Individuals will be **ineligible** if any of the following criteria are present:
 - E. Overt cognitive or psychiatric illness;
 - F. Visual impairments that preclude viewing educational materials and using a tablet/device;
 - G. Child illness requiring a highly restrictive diet, such as type 1 diabetes, renal disease, celiac disease, etc.;
 - H. Child BMI $\geq 95\%$ ile (obese children are referred for more intensive therapy).
3. Withdrawal/Termination criteria: N/A
4. Subjects may not participate in another research study that involves nutrition, nutrition education, or weight management.

E. Specific methods and techniques used throughout the study

1. Laboratory tests: None
2. Study Procedures: Research appointments will occur at baseline and at 3 months for collecting measures described below. Participants could be enrolled via different methods-
 - a. Potential participants will be introduced to the study by their provider at their well-child appointment. Participants will make a study appointment at the Nutrition Literacy Lab (KUMC main campus) for measures and to be introduced to Nutricity tools. Waitlisted participants (control) will receive Nutricity after 3 months of control, but they will not be followed after Nutricity introduction due to resource and time constraints. Introduction consists of identifying a username and password for website login and cell phone number for text messaging. The parent is guided through the login process on their personal device and sent the initial text message during the visit, allowing the researcher to confirm that the parent can access the tools. Parents are given a handout with recorded login information, trouble-shooting tips, and researcher contact information. Children are given the device and encouraged to play Nutricity games while their parent completes surveys.
 - b. Participants will be introduced to Nutricity tools at their well-child appointment while waiting to see their provider. Waitlisted participants (control) will receive Nutricity after 3 months of control and final study visit, but they will not be followed after Nutricity introduction due to resource and time constraints. Nutricity mobile tools (website and text messages) will be introduced to parents and children at the well-child visit, a process requiring <5 minutes. The researcher will coordinate with the nurse to determine when Nutricity introduction best fits into the patient visit schedule, which often depends upon physician availability and clinic demands. Generally, introduction will occur just after the patient is roomed, weighed, and measured. Introduction consists of identifying a username and password for website login and cell phone number for text messaging. The parent is guided through the login process on their personal device and sent the initial text message during the visit, allowing the researcher to confirm that the parent can access the tools. Parents are given a handout with recorded login information, trouble-shooting tips, and researcher contact information. Children are given the device and encouraged to play Nutricity games while waiting for the physician.

Measures: All measures are submitted for review in English. Spanish versions of all surveys and participant-facing materials will be developed by the research team by native Spanish speakers using the consensus translation process. Final versions of these materials will be submitted as a modification to the IRB protocol before recruitment into the study begins.

- c. Child Diet quality. Child diet quality is the primary research interest, and the change from baseline of diet quality is the primary outcome. Considered the “gold standard” for diet assessment, we will obtain two 24-hour recalls from parents in observation of the child’s diet at baseline and at 3 months’ post-Nutricity introduction. For those children who eat meals at daycare/preschool, we will use the Comstock method for visual observation in which parents will be given forms for day care providers to record meals and consumption of 0%, 25%, 50%, 75% or 100% for each individual meal item. Recalls will be entered into Nutrient Data

System for Research (NDS-R; University of Minnesota, Minneapolis, MN; version 2017) and the combined total of the recalls will calculate a Healthy Eating Index (HEI) score (i.e. the child diet will eventually be measured by HEI score-2015). Total score for HEI-2015 has a possible range of 0 – 100. Though NDS-R software includes a wide variety of Latin American dishes and foods, we anticipate not all reported foods will be found in the database. We will collect food labels and ingredient information of missing products at local stores and manufacturer website. We will create user recipes for homemade or restaurant recipes that are missing from the database⁴². To decrease the bias of self-reported dietary intake alone, we will also collect skin carotenoid content via resonance Raman spectroscopy (described below) at baseline and 3 months in children.

- d. Parent diet. To *characterize* parent diet, we will also screen parent fruit, vegetable, fat and fiber intake at baseline and 3 months using NCI's multifactor screener.
- e. Parent Nutrition Literacy: measured by the self-administered Nutrition Literacy Assessment Instrument (NLit) at baseline and 3 months post-Nutricity introduction. Both Spanish and English versions measure nutrition literacy comprehensively and are comprised of six domains (nutrition and health, energy sources in food, household food measurement, food labels/numeracy, food groups, and consumer skills). Scoring interpretation is based upon correlated Healthy Eating Index-2010 scores: $\leq 28/42$ correct is "likelihood of poor nutrition literacy"; scores from 29-38 is "possibility of poor nutrition literacy"; and scores ≥ 39 is "likelihood of good nutrition literacy." The endpoint will be the percentage correct in improvement in NLit scores from pre- to post-Nutricity
- f. Skin Carotenoid Content (Children): *Biomarker*. Collection of skin carotenoid content increases the rigor of this study, providing a biomarker of fruit and vegetable intake, effectively decreasing the bias of self-reported dietary intake alone. Resonance Raman spectroscopy ("Veggie Meter," Longevity Link Corporation) uses gentle pressure applied to the pad of the fingertip to put in close contact with light to detect and measure carotenoid molecules in the blood. Three, 10-45 second measurements are taken and averaged for the recorded score. This approach has been validated in children. The endpoint is change in skin carotenoid from baseline to 3 months.
- g. BMI. Collected at baseline (parents and children) and 3 months (children)
 - i. Parents/caregivers: BMI (18.5-24.9 Normal; 25.0-29.9 Overweight; >30.0 Obese), age (18-25 yrs; 26-40 yrs; >40 yrs); and sex (male vs. female). Parent BMI will be treated as a covariate.
 - ii. Children: Weight for height assessments (for 1 year-old: Weight-for-length %ile; for 2-5 year-old: BMI %ile); age; and sex (male vs. female). Change in BMI z-score will be calculated.
- h. Exposure to Nutricity/fidelity. Each dyad will receive a unique login for accessing Nutricity. Upon login, users will identify as parent or child. Once logged in, website activity will be measured via website usage reports, identified by date and length of time engaged. Attrition will be evaluated by week of drop-out, identified by Nutricity website usage reports, response to weekly SMS, and/or research appointment absence. Using these data points to identify weekly participation, we will measure the dosage of Nutricity received for each dyad. Full dosage is considered weekly login to Nutricity AND weekly goal setting confirmed via text message.
- i. Demographics. Age, sex, education, acculturation, language spoken at home, country of origin will be collected from parents via questionnaire at baseline.

- j. Reach. EMR records will be used to identify all eligible participants from the respective participating clinics, in order to report the % of eligible participants who agree to participate. We will also track the number of participants excluded. We will identify high vs. low users according to website usage reports and response to text messages to evaluate for differences in attaining primary and secondary effectiveness outcomes.
 - k. Interviews. Structured interviews with a small sample of parent-child dyads will be conducted after study participation by a trained research team member who was not involved in previous data collection and/or participant interaction to assess parent and child engagement, usability, barriers to participation, and recommendations for improvement.
 - l. Feeding behaviors of parents and children will be measured at baseline and 3 months using the Behavioral Pediatrics Feeding Assessment Scale (BPFAS). The BPFAS is a 35-item validated survey completed by parents that identifies problem mealtime behavior of children and parental responses to problem behaviors.
 - m. Parent-child communication. Specifically, the constructs of active mediation and co-playing Nutricity, will be measured at baseline and 3 months by modifying an 8-item survey instrument. Active mediation, assessed with 3 items, measures the frequency with which parents' comment positively on the media content with their child ($\alpha=.72$). Co-playing, assessed with 5 items, describes the extent to which parents play the game with their child ($\alpha=.85$).
 - n. Self-efficacy. Self-efficacy for healthy child feeding will be measured at baseline and 3 months using a valid 9-item survey, grouping parents into 3 categories (0- <1.5 not at all/slightly confident; 1.5 - <2.5 very confident; 2.5 - 3 extremely confident).
 - o. Parent nutrition attitudes. Attitudes of parents toward healthy eating will be measured at baseline and 3 months using an 8-item measure, scored on a range of -2 to +2, with positive scores corresponding with positive attitudes.
 - p. Food Security. Food security will be measured using the 18-item USDA Household Food Security Survey at baseline and 3 months. Households with either high or marginal food security are considered food secure, while those with low or very low food security are considered food insecure.
3. All data will be collected for research purposes and are not billable to insurance.
4. mHealth tools (Nutricity Intervention). Based on the premises and gaps established above, we developed *Nutricity*³⁷. Nutricity is a bilingual (English/Spanish) mobile website supplemented by an automated text-messaging system. Drawing upon Social Cognitive Theory⁴³ (SCT), Nutricity utilizes strategies such as goal setting, self-monitoring, and feedback commonly used among successful digital interventions focused on diet behavior⁴⁴. The website uses clear communication techniques^{45,46}, to address five components of nutrition literacy our previous research has identified. These components include 1) ability to comprehend nutrition text, 2) portioning foods appropriately, 3) using food labels to make nutrition decisions, 4) grouping foods into like categories, and 5) choosing between similar foods (consumer skills). Content is organized similar to a conversation map design⁴⁷, allowing users to choose the environmental context for interacting with food and nutrition information. Map locations include community spaces in which nutrition decisions are commonly made for/with children including the grocery store, home, and restaurants. For each location, Nutricity provides a 3-pronged approach: 1) information and behavioral strategies provided via short videos to form a nutrition base. 2) games for kids relating to content that parents can play alongside, and 3) practice nutrition skills via quizzes that provide feedback to answers. Companion text

messaging is used to encourage behavior modification and use of the Nutricity website. The text messaging library (SMS) drives interaction with participants on a weekly basis, setting 1 nutrition-related behavioral goal/week, and directing participants to the website for information and skill-building activities that relate to goals. SMS messages will be delivered using Mosio, a service that interfaces with our research database (REDCap) and is compliant with HIPAA requirements. Nutricity content addresses many factors as depicted in Figure 1, known to influence child eating behavior including (A) family characteristics, (B) parent characteristics, (D) child characteristics, food parenting practices, and (D) child behavior⁴⁸.

Nutricity website content

Environment	Relevant Nutrition Literacy Constructs	Instructional Concepts Important to Construct	Educational Content	Practice/Skill Reinforcement
Grocery Store	Food Label Reading Consumer Skills	Finding nutrient information on food labels; Interpreting healthfulness of food labels; How to use ingredients lists	"Food Fits! Grocery Store Tour" Video Food Label Video (FDA)	<u>Parents:</u> Check Your Skills Quiz (choose between similar food items using product information, feedback provided) <u>Children:</u> "Good Groceries" game
Home	Nutrition & Health Food Groups Household Food Measurement Feeding Behaviors	Understanding dietary guidelines and nutrition terms; Identifying food group categories; Building a healthy plate; Recommended portion sizes; „Division of Responsibility" of parent/child eating roles	"Food Fits! Food Groups" video "Feeding Children Well" Video	<u>Parents:</u> Check Your Skills Quiz (terms, food groups, division of responsibility; feedback provided) <u>Children:</u> Interactive MyPlate game
Restaurant	Nutrition & Health Food Groups Household Food Measurement	Building a healthy plate at restaurants; Recommended portion sizes; Understanding menus	"Food Fits! Healthy Eating When Dining Out" Video	<u>Parents:</u> Check Your Skills Quiz (menu selection) <u>Children:</u> Find the Fruits & Veggies (Digital Seek & Find)

5. Timeline of measures collected:

Participant Assessed	Measures: All collected in-person	Time required	Baseline	3 months
Parents	Nutrition Literacy Assessment Instrument	22 minutes	X	X
Parents	Height/Weight	5 minutes	X	X

Parents	Demographic Questionnaire	5 minutes	X	
Parents	NCI multifactor screener (fr/veg, fat, fiber)	5 minutes	X	X
Parents	Behavioral Pediatrics Feeding Assessment Scale	15 minutes	X	X
Parents	Parent-child communication questionnaire	3 minutes	X	X
Parents	Self-efficacy questionnaire	3 minutes	X	X
Parents	Parent nutrition attitudes questionnaire	3 minutes	X	X
Parents	USDA Household Food Security Survey	5 minutes	X	X
Children	24-hr recall (as provided by Parent using Comstock method)	20 minutes*	X	X
Children	Resonance Raman Spectroscopy (skin carotenoid)	5 minutes	X	X
Children	Height/weight	5 minutes	X	X

- F. Risk/benefit assessment: There are minimal risks for participants involved in this study.** The research may include risks to the privacy and confidentiality of self-reported health information or participant weight. Risks associated with short message services (SMS, or text-messaging) used within a clinical trial is the possibility of an unauthorized 3rd party obtaining personally identifiable health information (PHI). In this study, the seriousness of this risk is low because SMS will not be used to collect PHI, and several steps will be taken to ensure confidentiality, including but not limited to adequate training of personnel with human subjects' responsibility. All field computers will be password protected. Further, based on the high security of university network computers, the likelihood of these risks is low.
1. Physical risk. Possible risks associated with the skin carotenoid assessment include temporary discomfort and the unlikely possibility of soreness.
 2. Psychological risk. It is possible that completing questionnaires could cause stress or anxiety for some participants. All university research assistants will be trained to deal with this anticipated anxiety and each individual will always have the right to refuse to participate or to answer any questions on the questionnaires.
 3. Social risk. None anticipated
 4. Economic risk. None anticipated
 5. Potential benefit of participating in the study
 - a. There are no significant direct benefits to individual participants. They may enjoy participation in the experience and learn about nutrition information from study materials.
 - b. The population of parents of young children may benefit if the findings lead to a nutrition literacy intervention aimed at parents of young children.
 - c. Society may benefit from the findings of this study which may lead to nutrition literacy intervention work aimed at parents of young children.

G. Location where study will be performed: Participating sites are all clinical entities of either the University of Kansas Medical Center and/or Children's Mercy Hospital including general pediatrics clinics of KUMC and CMH. If preferred, participants can complete study visits in a private location at the pediatric clinic after a clinic appointment, or at a separate appointment for research only. Research appointments could be offered at the Clinical Research Center in Fairway, or in the Nutrition Literacy Lab (CCHD G021) at the KUMC main campus. All data collected in print (consent form and any questionnaires the participant

prefers to complete in hard copy form) will be stored in a locked file in the PI's locked lab. All electronic data will be stored on the KUMC REDCap server and/or KUMC-supported network drive.

H. Collaboration (with another institution, if applicable): Children's Mercy Hospital and Clinics

I. Single IRB Review for a Multi-site study (if applicable):

1. For which sites will KUMC serve as the IRB of record? All sites, including KUMC and CMH clinics
2. All study procedures will be identical across study sites.
3. A member of the research team will be present in the clinic setting for data collection purposes.
4. Lead investigators will communicate with and disseminate new information to study via training meetings and regularly-scheduled conference calls
5. We do not anticipate any AE's for study participants while participating in study, but any problems reported to the study team from the research will be documented and reported to the PI and within 24 hours.
6. Name the member of the KUMC study team who will be the point of contact to coordinate oversight and communication with the sites. Heather Gibbs, PI

J. Community-Based Participatory Research (if applicable)

1. Participants and the nature of their involvement: A community advisory board of six native Spanish-speaking individuals will be formed under the direction of Juntos director, Mariana Ramirez, to provide feedback from community members in the cultural tailoring of Nutricity tools (website and text messaging) and review of participant-facing study materials. Research data will not be collected from community advisory board members. Community advisory board members will not collect or analyze study data.

K. Personnel who will conduct the study, including:

1. Indicate, by title, who will be present during study procedure(s):
2. Primary responsibility for the following activities, for example:
 - a. Determining eligibility: Study coordinator, GRA, PI
 - b. Obtaining informed consent: Study coordinator, GRA, or PI
 - c. Providing on-going information to the study sponsor and the IRB: PI
 - d. Maintaining participant's research records: Study coordinator, GRA, PI
 - e. Completing physical examination: N/A
 - f. Taking vital signs, height, weight: Study coordinator, GRA, and/or PI
 - g. Drawing / collecting laboratory specimens: N/A
 - h. Performing / conducting tests, procedures, interventions, questionnaires: Study coordinator, GRA, or PI
 - i. Completing study data forms: Study coordinator, GRA, or PI
 - j. Managing study database: Study coordinator, GRA, or PI

L. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. Study presents no more than minimal risk
2. The PI, Co-I's, Study Coordinator, and internal medical monitor, Dr. Stephen Lauer, will meet at mid-enrollment to discuss the following areas: 1)Review of study protocol to ensure it meets the highest level of science, considering any new evidence concerning human subjects protections for obesity prevention in children 5 years and younger; 2)Review of recruitment activities, including study eligibility determination issues and to enhance study enrollment of participants in a timely manner; 3)Study progress on recruitment, retention, adherence to the protocol, study assessment completion rates, quality assurance activities related to delivery of the interventions and collection of study data, adverse events, and interpretation of study outcomes; 4) Discuss continuation, termination, or other modifications of the study based on observed beneficial or adverse effects of experimental treatments; and 5)Ensuring the confidentiality of study data and the results of monitoring.

III. Subject Participation

A. Recruitment:

1. Three major recruitment strategies will be used: 1) A partial waiver of HIPAA privacy authorization is included to review electronic medical records for potential eligibility (i.e. child age, language preference, absence of excluded diagnoses) to derive a list of potential participants; physician review of potential list to flag patients who should not be contacted; postcards will be sent to potential participants describing the study; research personnel will follow up by phone after 1 week of sending letter to screen potential participants for additional eligibility factors (listed below), and then scheduled for a research appointment at KUMC. Alternatively, 2) Potential subjects will be identified by clinic referral through pediatric clinics of the University of Kansas Medical Center (KUMC) and Children's Mercy Hospital and Clinics. Clinic personnel, who introduce the study to potential participants, will notify the research team of patient interest via REDCap survey. Interested participants who qualify will then be contacted by research staff, screened by phone as described above, and scheduled for a research appointment at KUMC. Flyers will also be located in participating clinics for self-referral to the study team. 3) Potentially eligible participants at KU Pediatrics will be identified using Epic/O2 reporting workbench report via Research Informatics and will be informed of the study opportunity via MyChart message or postcard if MyChart is inactive. Study team members will follow up with potential participants by phone.

B. Screening Interview/questionnaire: Screening process described above. Consent to participate in the screening process is conferred when potential participants self-refer or (within the clinic setting) agree to discuss potential participation with research personnel.

C. Informed consent process and timing of obtaining of consent

- 1 The principal investigator and study coordinator will maintain records of human subject's training completed for all key research personnel (principal investigator, co-investigators, research staff, and graduate research assistants). Informed consent will be collected from all parent/caregiver participants for their participation and on behalf of the child.

The age of children included in this study (≤ 5 years), is deemed too young to collect assent. However, research personnel collecting consent will be trained to explain study involvement using plain language, and any questions posed by a child present during consent will be answered.

- 2 Once a potential participant has been identified as being eligible for the study, the preference for the timing and location of the research study appointment will be offered and scheduled with the potential participant. Consent will take place at the beginning of the research appointment in a private space, providing adequate oral and written information regarding the research activities.
- 3 The Study Coordinator or GRA will determine eligibility based upon inclusion and exclusion criteria above asked of the potential participant. Exclusion criteria include those with overt cognitive impairments.

D. Alternatives to Participation: N/A

E. Costs to Subjects: N/A

F. How new information will be conveyed to the study subject and how it will be documented: N/A

G. Payment, including a prorated plan for payment: Participant time will be compensated in the form of a ClinCard (the VISA debit card preferred for participant compensation by the KUMC Research Institute) including \$40 at baseline, \$60 at 3-months. If participants don't have a SSN or TIN, then they will receive study payments in pre-paid Visa gift cards. These amounts are modest, but appropriate for the time required to complete research tasks. Clinic advisory team members will be compensated \$25 each for each monthly meeting.

H. Payment for a research-related injury: No research-related injuries are anticipated resulting from this minimal risk study.

IV. Data Collection and Protection

A. Data Management and Security:

1. Only persons listed in the HSC protocol will have access to identifiable study data.
2. Data will be maintained in a password-protected file of KUMC encrypted network for 7 years after completion of the research.
3. The consent form will be the only data collected that is personally identifiable.
4. PI and GRAs will maintain and have access to the key for data coding.
5. All records will be indexed by an alphanumeric code assigned to each participant. Names and other personally identifying information will be stored separately from the actual data records.
6. All data collected in print (consent form and any questionnaires the participant prefers to complete in hard copy form) will be stored in a locked file in the PI's locked lab. All electronic data will be stored on the KUMC REDCap server and/or KUMC-supported network drive.
7. Under supervision of trained research personnel, participants will use KUMC password protected devices to complete electronic questionnaires via REDCap. Participants will be given a non-personally identifiable alphanumeric user name and password to login to the Nutricity website using their own mobile device. The Nutricity website is login protected

and is housed on the University server. Each participant will receive a unique alphanumeric login for purposes of tracking website usage (number and date of logins, website locations visited, time viewing content). No personal data will be collected about participants via the website or text messaging. KUMC Teaching & Learning Technologies will provide usage reports of the website by alphanumeric code to identify frequency of activity, date of last activity, most and least viewed portions of the website. SMS messaging will be managed via Mosio, a HIPAA-compliant system that interfaces with the REDCap study database. Using this system, all messages sent to participants will be free of personal health information. Further, an individual's responses to SMS are directly digitally recorded in the database within the individual's numerically coded record.

8. No identifiable data will be sent outside of KUMC.

B. Sample / Specimen Collection: N/A

C. Tissue Banking Considerations: N/A

D. Procedures to protect subject confidentiality: Risks associated with short message services (SMS, or text-messaging) used within a clinical trial is the possibility of an unauthorized 3rd party obtaining personally identifiable health information (PHI). In this study, the seriousness of this risk is low because SMS will not be used to collect PHI, and several steps will be taken to ensure confidentiality, including but not limited to adequate training of personnel with human subjects responsibility. All field computers will be password protected. Further, based on the high security of university network computers, the likelihood of these risks is low.

E. Quality Assurance / Monitoring

1. For online questionnaires, participants complete these themselves, thus most data is entered by the participants. PI and GRAs will review the completion of questionnaires, identifying any incomplete items and giving participants the option to complete missing items. 24 hour recalls, height, and weight, and skin carotenoid assessments will each be collected by trained research personnel and verified for accuracy by a second trained researcher.
2. Third party monitoring is not necessary.

V. Data Analysis and Reporting

A. Statistical and Data Analysis: Change in diet quality (HEI) is the primary outcome measured by Bayesian t-tests for within and between group comparisons. Using Bayesian multiple linear regression models, we will also explore differences in each primary (child diet quality) and secondary (parent nutrition literacy and child BMI) outcome by age, sex, income, education, language preference, country of origin, 'dose' of Nutricity (weeks' participation), parent-child communication, self-efficacy, attitudes, and food security. All predictors are either continuous or binary, so Bayesian multiple linear regression is appropriate. The adaptive design report shows more details of the trial design.

B. Outcome:

- i. Aim 1, Estimate differences in child diet quality after 12 weeks Nutricity exposure between intervention vs. waitlist control: The difference of change from baseline in diet quality (HEI score-2015) between the intervention and waitlist groups will be analyzed by t-test. The first year interim will occur after at least 30 subjects have enrolled into the trial. Subsequent interims will be conducted every 52 weeks and will continue beyond full accrual. Since interims are defined by calendar time, the total number of planned interims, I , is random and will depend on the rate at which subjects accrue to the trial. Throughout the trial, decisions may be based on the following quantities:

$$Pr(\theta_d > \theta_0) \text{ for } d = \text{Intervention}$$

$$Pr(\theta_d - \theta_0 > 1) \text{ for } d = \text{Intervention}$$

1. **Stopping for Futility.** For interims 1- I , the trial may stop accrual for futility if any of the following criteria are satisfied:

$$Pr(\theta_d - \theta_0 > 1) < 0.1 \text{ for } d = \text{Intervention}$$

If a futility stopping rule is met at an interim analysis, then subject follow up will be discontinued, and the final evaluation criteria will be applied to the currently available data.

2. **Stopping for Expected Success.** For interims 1- I , the trial may stop accrual for expected success if all of the following criteria are satisfied:

$$Pr(\theta_d > \theta_0) > 0.995 \text{ for } d = \text{Intervention}$$

If a success stopping rule is met at an interim analysis, then a final analysis will be conducted after all currently enrolled subjects have been followed to their final endpoint.

3. **Final Evaluation Criteria.** No final futility criteria have been defined for this trial. At the final analysis, the trial will be considered successful if all of the following criteria are satisfied:

$$Pr(\theta_d > \theta_0) > 0.955 \text{ for } d = \text{Intervention}$$

- ii. Aim 2, Evaluate reach, engagement, and secondary effectiveness outcomes at the dyad level:

1. Analysis of secondary outcomes (change from baseline of Parent Nutrition Literacy and BMI in children): We will use Bayesian multiple linear regression models to explore the differences in each outcome by BMI in parents, age, sex, income, education, language preference, race, country of origin, and dose of Nutricity. All

predictors are either continuous or binary, so multiple linear regression is appropriate.

2. Analysis of reach: We will perform descriptive statistics of demographics of parents agreeing to participate and those who do not. Differences between groups will be evaluated by income estimates based upon zip code, educational attainment, race, and language preference. We will perform descriptive statistics of parents' completing the intervention and those who do not. Differences in groups will be evaluated by zip code-based income estimates, educational attainment, race, and language preference.
 3. Engagement: Attrition will be evaluated by week of intervention drop-out, identified by Nutricity website usage reports and/or research appointment absence. Descriptive statistics of usage reports will evaluate high vs. low Nutricity users. Transcripts from interviews will be analyzed using the constant comparative method and data triangulation to identify recurrent themes. To limit bias, two research trained in qualitative methodology will code the transcripts separately and then meet to discuss major themes and reach consensus.
- iii. Aim 3, Evaluate organization-level factors in Latino-serving pediatric clinics that may support or inhibit future uptake of Nutricity. We will perform descriptive analysis of the following:
1. Adoption. Percent and characteristics of settings that agreed to participate. All data associated with the study are collected by the research team at study visits, but clinic personnel will introduce participants to Nutricity when they arrive for their scheduled clinic visit. However, because introduction is critical to study participation, a member of the research team will also be present. We will track recruitment and participation by clinic personnel at each respective clinic location to identify differences in the contribution of non-research staff to the completion of the intervention. We will also record when Nutricity was introduced within the flow of the clinical encounter. We will record the role of the Nutricity facilitator and record detailed minutes from monthly clinic advisory meetings to evaluate implementation barriers and facilitators.
 2. Implementation. Extent to which intervention is implemented as planned. We will record the time required for Nutricity introduction within the exam room, time dyads using Nutricity tools while waiting for care, and interview the clinic advisory committee members 1 x/year for barriers and facilitators.
 3. Organizational Maintenance. Extent to which the intervention is likely to be sustained over time. We will use the Organizational Readiness to Change (ORCA) Instrument to evaluate Nutricity's potential for integration into the pediatric clinic system. The ORCA consists of 77 items, with 19 subscales designed to measure 3 major scales of the PARIHS framework including 1) evidence for implementation, 2) context for implementation, and 3) facilitation of implementation. Each item measures degree of agreement (1=strongly disagree; 5=strongly agree) with the item statement.

- iv. Exploratory Aim, Explore the relationship among nutrition literacy, psychosocial constructs, diet quality outcomes, and explore how engagement and satisfaction influence outcomes. Differences in measures will be evaluated by Bayesian t-tests between the intervention and waitlist groups. Multiple linear regression models will be used to explore differences in child diet quality, parent nutrition literacy, and child BMI each by dose of Nutricity, feeding behaviors, parent-child communication, self-efficacy, parent nutrition attitudes, and food security. The research team anticipates using results of Bayesian linear regression models to develop a structural equation model for testing in a larger-scale study.
- v. Power and sample size for seamless Phase II-III is summarized here. The seamless design considers two phases of the traditional design as one. We pause accrual after 78 weeks up to 104 weeks in the seamless design to emulate the traditional design that assumes a stop for Phase II results processing and report submission. In both designs, we expect to enroll 5 patients a month. The traditional design Phase II trial will require 80 completers and 82 weeks. Phase III will require 250 completers and 232 weeks. Assuming the expected effect of a 5-point difference we estimate 99% power for a seamless design that matches 99% power for a 1-sided t-test done under the traditional design. We observed a noticeable reduction in trial duration (153 weeks) and sample size (157 subjects). The assumed 3.5 difference scenario showed 91% power for seamless design compared to 87% power for the traditional design with some savings in the duration (212 weeks) and sample size (225 subjects). Both designs provided 5% Type 1 error, but we have a 50% chance of stopping early under seamless design. That translates to 234 subjects and 213 weeks needed across simulations. In the unlikely scenario of the intervention arm performing worse than the control, we estimate a 77% chance of stopping early and will need 182 subjects and 165 weeks.

C. Study results to participants: If a study subject is interested in their result on the Nutrition Literacy Assessment Instrument or analysis of reported nutrient intake, this will be shared with them. If requested, a summary of results can be provided to any interested participant.

D. Publication Plan: Research results will be disseminated through academic means, abstracts/posters, oral presentation, publication as appropriate.

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