Title: Fit 5 Kids Screen Time Reduction Curriculum for Latino Preschoolers

NCT Number: NCT03575884

Document Date: 04/19/2024

PROTOCOL TITLE:

Fit 5 Kids Screen Time Reduction Curriculum for Latino Preschoolers: A randomized controlled trial

PRINCIPAL INVESTIGATOR:

Jason Mendoza, MD, MPH
Center for Child Health, Behavior and Development
206-884-1261
jason.mendoza@seattlechildrens.org

- **Table of Contents**

1.0 Objectives

This randomized controlled trial will be conducted in Seattle under the supervision of Dr. Jason Mendoza and Seattle Children's IRB, Yakima Central Valley under Dr. Rachel Ceballos and the IRB at Fred Hutchinson Cancer Research Center, and in Houston under Dr. Teresia O'Connor and the IRB at Baylor College of Medicine.

Calendar year		2019				2020				2021				2022				2023			
Quarter	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Wave 1 (S)	→	→	→																		
Wave 2 (S, CV, H)					→	→	→														
Wave 3 (S, CV, H)									→	→	→										
Wave 4 (S, CV, H)													→	→	→						
Analyses													→	→	→	→	→	→	→	→	→
Dissemination, Papers																	→	→	→	→	→

Key:
S=Seattle
CV =Central Valley H=Houston

1.1 Specific Aims:

1. To conduct a cluster RCT of the Fit 5 Kids curriculum to evaluate its efficacy in reducing screen time and excessive weight gain over a school year (8 months)
2. To examine mediators and moderators associated with reducing Latino preschoolers' screen time

1.2 Hypotheses:

1. Fit 5 Kids will decrease children's screen time (primary outcome), BMI z-scores and dietary energy intake, and increase moderate to vigorous physical activity (MVPA) compared to controls
2. Parents' outcome expectations, self-efficacy, and screen time parenting practices will mediate the relationship between Fit 5 Kids and changes to preschoolers' screen time
3. Parents' depressive symptoms, stress, and social support will moderate changes to child screen time

2.0 Background

2.1 **Gaps in Current Knowledge**: Childhood obesity is a major public health problem in the US. Childhood obesity and lack of physical activity (PA) are important risk factors for adult obesity, type 2 diabetes, cardiovascular disease, and multiple cancers. Since childhood PA, obesity and cardiometabolic risk track strongly into adulthood, childhood obesity prevention is necessary to reduce the lifetime risk of obesity and related chronic diseases. Due to childhood obesity inequities, interventions for PA promotion and obesity prevention are urgently needed for populations most affected by obesity. Latino children have among the highest rates of obesity, and are the largest and fastest growing minority in the US. Therefore, preventing childhood obesity among Latinos is a major US public health goal to reduce health inequities from obesity and risk of T2D in the US. However, a systematic

review identified no successful obesity prevention interventions among Latino preschoolers.

2.2 **Preliminary Data**: Studies by our group and others inform the scientific premise of this study and have linked higher screen time among preschoolers with elevated risk of obesity. Television viewing and other forms of screen time (henceforth called screen time) occupy a large part of children's awake time. Intervention studies that reduced screen time among older children have resulted in reductions to obesity, although there are few studies among preschoolers. While mechanisms linking screen time and excessive weight gain remain unclear it is thought that screen time leads to excessive dietary intake and/or inadequate PA. Among Latino preschoolers, we reported that greater screen time was associated with less PA, suggesting that reducing screen time may increase PA. Because screen time behaviors track from preschool to adolescence, the preschool years are a crucial time period to help children develop long term healthy screen time behaviors.

Our team's pilot study tested the culturally adapted Fit 5 Kids screen time reduction curriculum among Latino preschoolers in Head Start. This short term cluster randomized controlled trial (RCT) is the only successful screen time reduction program for Latino preschoolers, which reduced screen time by >25 min/day. Fit 5 Kids seeks to teach preschoolers to decrease their screen time and encourage alternative activities such as family meals, reading, and active playtime. These efforts were accompanied by substantial formative work to validate a measure of screen time and to identify correlates of obesity for Latino preschoolers. Building on this previous work, we propose a long term, efficacy cluster RCT of high scientific rigor to test the culturally adapted Fit 5 Kids among Latino preschoolers in Head Start from three sites: Seattle, Houston, and the Central Valley of Washington State.

2.3 **Significance**: Childhood obesity and lack of PA in the US are at record high levels, which elevates risk of multiple childhood diseases as well as the risk of adult obesity and thus T2D, CVD, and multiple types of cancers. Screen time is an important modifiable determinant of childhood obesity and PA. This study's scientific premise has been established by multiple studies on screen time and risk of obesity, as well as the lack of successful screen time intervention studies among Latino preschoolers. First, Latino children in the US have both high rates of screen time and obesity. RCTs whose interventions solely focused on reducing screen time have reported:

(1) reductions in BMI and other measures of obesity among older school-age children (school-based obesity prevention intervention), and

(2) significant reductions in BMI z-score among 4-7 year old children who started at or above the 75th BMI percentile.

Similar obesity prevention interventions for screen time are lacking among Latino preschoolers.

Because habitual screen time behaviors become established during the preschool years, interventions are needed to help reduce screen time among Latino preschoolers. For example, we have shown that higher screen time was significantly associated with less PA among Latino preschoolers in Head Start, this proposal's target population. Moreover,

children's PA typically declined with age such that when children entered adolescence, few met the recommended 1-hour of daily MVPA regardless of race/ethnicity; conversely, screen time increased by over 3 hours/day from childhood into adolescence, with Latino adolescents having the highest amounts of screen time.

3.0 Inclusion and Exclusion Criteria

3.1 Parents of students at 22 Head Start Centers will be sent home with study information. Should the decide to participate, they will be screened using a survey to check for eligibility criteria listed below.

3.2 **Inclusion Criteria**:

We will recruit Latino children, 3-5 years old enrolled from 22 Head Start Centers.

Their parents must read and speak English or Spanish or both.

Exclusion Criteria:

Only one preschooler per family may be enrolled to avoid clustering of variables by family.

3.3 Special Populations:

1. Individuals who are not yet adults (infants, children, teenagers). We will enroll children and their parent(s) in the study. We will enroll 3-5 year old children, who do not have the developmental capacity to make an informed decision with regard to participating in this study. Obtaining informed assent in children this young may possibly be coercive, since children of this age are highly suggestible to adults.

4.0 Study-Wide Number of Subjects

4.1 We will enroll 280 parent/child dyads in the study across all sites.

5.0 Study-Wide Recruitment Methods

5.1 When, where, and how potential subjects will be recruited:

We will use recruiting strategies that have previously been highly successful for the investigators during studies conducted in Head Start centers over the past 10-15 years. We will recruit participants from Head Start centers that serve substantial numbers of Latino families and use a combination of recruitment procedures including:

- bilingual flyers sent home with the children
- telephone calls (contact information to be collected when consent is returned)
- presentations at parent meetings (specific presentation content under development), and
- active involvement/guidance of the Head Start manager and staff in the recruitment process.

5.2 Methods that will be used to identify potential subjects:

We will send home recruitment packets with all students in the participating Head Start program. Families that wish to participate and match the inclusion criteria will return the consent form to the study staff or complete an online form with their contact information.

5.3 Materials that will be used to recruit subjects:

Students at the Head Start Schools will be sent home with the bilingual flyers and consent forms or they will be provided links to view the flyers, recruitment video, and consent forms electronically. Flyers and consent forms will also be handed out at parent meeting presentations. Extra copies of the materials will be on hand with each on-site Head Start manager.

To keep families in the intervention study engaged across three assessments throughout a period of 8 months, parents will receive a $20 incentive at Time 1 (Sept/Oct), $25 at Time 2 (Jan), and $35 at Time 3 (May/June). For wearing accelerometers, participants will receive an additional $10 incentive at each of the three assessments. For the 40 adults who participate in qualitative interviews, they will receive an additional $20 incentive. At the beginning of the school year, we will provide head start centers $400. Then, we will provide $500 per center incentive near the end of the school year.

6.0 Multi-Site Research

Conference calls will be held no less than once-a-month and will include each site investigator, coordinator, and other relevant stakeholders depending on the phase of the study. For example, during the initial planning phase individuals involved in curriculum development and training are likely to be more involved, while the coordinators and other primary staff may be included in calls during the intervention. In addition, we will designate a secure virtual site for sharing of current protocols and documents.

6.1 In order to ensure communication and uniformity between sites:

1. All sites will have the most current version of the protocol and consent document.
2. All required approvals will be obtained at each site (including approval by the site's IRB of record).
3. All modifications will be communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
4. All engaged participating sites will safeguard data as required by local information security policies.
5. All local site investigators will conduct the study appropriately.
6. All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

6.2 Methods for communicating to engaged participating sites:

1. **Problems:** Should any problems arise,
2. Interim results
3. The closure of a study

7.0 Study Timelines

7.1 Participants enrolled in the study will participate for the duration of the school year (approximately 8 months).

7.2 We expect to enroll participants in 4 waves. All participants will be enrolled by end of calendar year, 2021. The final wave of participants will finish in June of 2022.

7.3 We expect analysis to be completed by end of calendar year, 2023.

8.0 Study Endpoints

8.1 Participant involvement in the study will be complete by June, 2022. We expect preliminary analysis to be completed by end of calendar year, 2023.

8.2 Participant safety monitoring will be complete with the end of participant involvement in June, 2022.

9.0 Procedures Involved

9.1 **Study design**: The implementation of the intervention will be accomplished in four separate waves of intervention and control centers. In year 1, Dr. Mendoza will enroll two Head Start centers in the Seattle-metro area for assessments and to be randomly assigned to the intervention or control condition. In each of years 2-4, Drs. Mendoza, Ceballos, and O'Connor will each enroll two Head Start centers in their respective regions for assessments and randomization to the intervention or control condition.

The intervention schools will integrate the culturally adapted Fit 5 Kids curriculum into their standard preschool day, which may be in person or remote based on how the school educating their students and how they recommend fitting the curriculum into their program. Research staff members will be trained as interventionists to teach Fit 5 Kids by Sandra Jaramillo, the interventionist from the pilot Fit 5 Kids RCT (consultant, see letter of support). The interventionists may implement the curriculum at the head start center or develop videos for parents to share with their students. Interventionists will undergo the teacher training program developed by Dr. Mendoza and Sandra Jaramillo for the pilot Fit5Kids study. Training will consist of:

1. 1-week in person training led by Sandra Jaramillo and Dr. Mendoza and
2. Ongoing supervision of the interventionists by Ms. Jaramillo and Dr. Mendoza.

The in person training will occur prior to each region's implementation of the Fit 5 Kids curriculum, i.e., for the Seattle-based interventionist at the beginning of year 1 and for the Central Valley and Houston-based interventionists at the beginning of year 2. The in person training will provide: an overview of the Fit 5 Kids curriculum, discussion of the implementation of lessons, observation of selected lessons as taught by Ms. Jaramillo, and practice teaching opportunities of selected lessons by interventionists with feedback from Ms. Jaramillo and Dr. Mendoza. Key portions of these trainings will be video-recorded (staff only) and available for review by the interventionists throughout the study. Following the in person training, Ms. Jaramillo, Dr. Mendoza, and the co-investigators, will hold joint monthly videoconferences/telephone meetings with the interventionists, to support their teaching efforts

and answer any questions that may arise. Ms. Jaramillo, Dr. Mendoza, and the co-investigators will also be available to the interventionists by email or telephone call should the need arise.

The culturally adapted Fit 5 Kids classroom curriculum will be taught by trained research staff interventionists at each of the three study sites. Fit 5 Kids is taught over 7-8 weeks and consists of 7 weekly themes, which are

1. Increase reading,
2. Increase the time families eat meals together with the screens turned off,
3. Alternatives to screen time,
4. Too much screen time,
5. Turn off the screens week,
6. Celebrate, and
7. No more couch potatoes.

Each weekly theme is comprised of 5-6 lesson plans organized around each theme. The lesson plans include group activities as well as activities for home, which may be physically sent home with students or digitally sent to parents. The lessons are drawn from four educational disciplines:

1. Language Arts
2. Math
3. Music and Movement, and
4. Arts and Crafts.

Fit 5 Kids also includes a substantial parent component, including:

1. A weekly parent newsletter to keep them informed of the lessons and to provide home activities for the parents to complete with their preschoolers during the 7-8 week curriculum. The parent newsletter activities were adapted based on our previous work on parent self-efficacy and parent outcome expectations for limiting their preschoolers screen time as well as screen time parenting practices. Thus, these constructs will be tested as mediators of the relationship between the Fit 5 Kids intervention and changes to screen time. For parents of limited Spanish or English literacy, the take home materials will also be summarized verbally to them when they pick up their children from the Head Start center.
2. Twice monthly intercepts of parents during child drop off/pick up times for brief, child-tailored goal setting around screen time reduction strategies led by study staff. If parents are not available, we will contact them by telephone for goal setting.
3. A lending library of age-appropriate English and Spanish books (including the LeapReader Reading & Writing System), games (e.g., puzzles, Lego Duplo blocks, Magna-Tiles, Playmobile, Bristle Blocks, etc.), arts/crafts, and other projects that children can do alone or with their parents. The library resources will be available for loan

throughout the entire school year and developed with input from Head Start teachers and parents at each of the three major sites.

4. Brief text messages consisting of screen time parenting practices from the Fit 5 Kids parent newsletters and/or associated with lower child screen times. A new text message will be delivered 2-3X/week to the parents' cell phone (or email) over the 7-8 weeks of the curriculum and during the booster weeks (see below). Dr. Mendoza has experience delivering brief text messages to study participants in other PA/sedentary behavior intervention studies both ongoing (NCT02469727 and NCT02031185) and completed. The parent newsletters, goal setting, library resources, and text messages seek to increase parenting behaviors and behavioral constructs to limit their preschoolers' screen time, in synergy with the classroom curriculum which focuses on empowering preschoolers to limit their screen time.
5. Parents will also be invited to join an optional Facebook group that is private and only accessible to other study participants and members of the study team. Group members will be encouraged to share ideas related to the weekly lessons and goal setting. They are also encouraged to share any experiences and provide support to other parents around making changes related to the study and reducing screen time in their home.

Intervention booster weeks: Fit 5 Kids takes 7-8 weeks to fully teach. Given that we are interested in producing longer term behavior changes to preschoolers' screen time, we plan to add two "booster" weeks of the curriculum in late April/early May that will be delivered by each site's staff interventionist. Similar to the main Fit 5 Kids curriculum, the booster weeks will also have a take-home parent newsletter although on a daily basis (not weekly), goal setting with parents by phone or in person during child pick ups/drop offs, as well as daily text messages consisting of parenting tips on screen time reduction. The two booster weeks will mainly focus on the "Alternatives to screen time" and "Turn off the screens" lessons. Additionally, parents will be highly encouraged to borrow resources from the lending library that helps to achieve their children's goals.

Remote Intervention Delivery: In case it is not feasible to implement the Fit 5 Kids program as described above, which was originally designed for in person curriculum delivery, we will plan to implement remote intervention delivery.

1. Curriculum Video Lessons – Each lesson in the Fit 5 Kids curriculum will have a corresponding video lesson, which will be posted to a Fit 5 Kids YouTube channel, and parents will be sent links to watch the videos. These videos will be posted as "unlisted" so that only people with the link may view them.
2. Activity Material Mailings – For each week of the curriculum we will mail home materials for one activity from a lesson that week so that parents can guide their child through the activity at home.
3. Digital Lives – These are optional, as the Facebook group is. During each week of the curriculum we will offer parent and child participants the option of attending a digital live stream where we will describe the topic of each curriculum week, discuss content from the parent newsletters, and demonstrate how to do the activity we mail home to them. These will be organized by the study team and done via a YouTube

Live Stream, which will be set as "unlisted" so that only people with the link to the live stream will be able to join. Parent participants will be invited to join the live stream, which will be led by study staff.

4. Parent Newsletters – We will have a version of the newsletter that matches more with remote intervention delivery. A paper copy of each week's newsletter will be mailed alongside the activity materials being mailed home. A digital version of each week's newsletter will also be made available.
5. Books & Activities Catalog – In place of a Lending Library system, we will use a Book & Activities Catalog (similar to Lending Library Catalog), which will be mailed home with the first weeks of activity materials with a return envelope that parents can use to mail it back to us with their selections. The catalog will also be available digitally. Instead of borrowing items for a short time, participants will get to select a few items that we will mail to them to keep.
6. Text Messages for Screen Time Parenting Practices – These will generally be implemented in the same way, but a few text messages have been updated to make more sense with remote intervention delivery.
7. Goal Setting – Similar process, except we will rely more on telephone or text communication to complete goal setting. We will also aim to do goal setting weekly vs twice monthly to gauge engagement in the remote intervention.
8. Facebook – Similar process. However, we will further utilize Facebook as a platform to distribute video lessons to participants, post the newsletters, post pictures of the activities being mailed home, share information for attending the digital lives, and post the parent engagement questions from the goal setting form as another way to gauge their engagement in the remote intervention. This content will also be available to participants outside of Facebook.
9. Booster Weeks – If booster weeks are done remotely, we will follow similar procedures as outlined above. Like the in-person version of the booster weeks, parents will still receive a newsletter and text message tip daily (for each lesson). There will be 5 video booster lessons, and we will mail home activities for 4/5 of them. Parents will be invited to attend an optional Digital Live. We will set goals once for the booster week(s) period, and will still post the same type of content on Facebook.

Control condition: The control centers will not implement Fit 5 Kids but will instead provide their children with the standard Head Start preschool curriculum. This standard curriculum typically provides brief advice on healthy eating and active living, but does not go into detail about screen time reduction. As this is the standard practice of Head Start programs, there are no ethical issues to consider with the control participants.

Measurement Procedures. The investigators have experience with all proposed questionnaires and accelerometry among Latino families, ensuring high scientific rigor. All assessments and surveys measuring mediating, moderating and outcome variables as well as covariates will be assessed immediately pre-intervention (Time 1, i.e., September/October of each year), immediately after the classroom intervention (Time 2, i.e., January of each year), and 8-months after starting the

intervention (Time 3, i.e., May/June of each year). The Time 2 measurement is necessary in order to detect changes in mediators (e.g., parenting practices and parent self-efficacy) that will be expected to change prior to outcomes such as BMI z-score. The Time 2 measurement will allow for mediation analyses to better describe mechanisms underlying changes in outcomes.[98] The dietary assessment by Food Frequency Screener will occur at Time 1, Time 2, and Time 3. Research staff will collect socio-demographic and anthropometric measurements on the children and parents at their assigned Head Start center.

Table 1. Summary of study variables

10. Primary outcome: Screen time. We will measure screen time using the screen time diary that Dr. Mendoza previously validated among parents of Latino preschoolers in Head Start (see Preliminary Studies) and used in the pilot RCT of Fit 5 Kids.[40,41] The diaries will track the preschool children's screen time for a 7-day period and are divided into 15-minute blocks between 6 am and 12 am. For each block, the parent will be asked to indicate whether the study child had screen time, the type of device (television, computer, phone, tablet, etc.), the name of the program, the language of the program, and who if anyone was co-viewing with the child. These diaries will be available in English and Spanish for the parents to fill out according to their language preference. For parents of limited written literacy, the screen time diaries will only require them to mark a box next to the time their child had screen time.

11. Mediating variables: Self efficacy and outcome expectations. Social Cognitive Theory[118,119] is the most commonly applied behavioral theory for school-based childhood obesity studies[120] and for PA studies targeting Latino girls and women.[121] Given this long and successful track record, social cognitive theory was chosen to inform the design and evaluation of this behavioral intervention at the individual-level.[122] The social cognitive theory constructs of self-efficacy, i.e. one's personal sense of control for a behavior, and outcome expectations, i.e. the expected outcomes (costs/benefits) of performing the health behavior, have been well studied and have strong support for their role in children's PA behaviors.[120,121,123] We will use questionnaires that our team has developed and validated (see Preliminary Studies above) among Latino families on **parent self-efficacy (14 items) and outcome expectations** (25-items) for their preschoolers' screen time usage as mediators of the relationship between the intervention and changes to screen time.[69,70]

12. Mediating variable: Screen time (media) parenting practices. The screen time parenting practices scale, also called the TV Parenting Practices scale, consists of 15-items with the following responses: never, rarely, sometimes, or often.[66] Our team has validated these questions among Latino families, including preschool age children. Screen time parenting practices will be a mediator for the relationship between the intervention and changes to screen time.[67]

13. Anthropometric outcome: BMI z-score. Study staff will measure height and weight per standard NHANES protocol.[124] A portable stadiometer will be used to measure height (to nearest 0.1 cm), and an electronic scale to measure weight (to nearest 0.1 kg). Duplicate measures will be taken with the mean recorded as the value. A third measurement will be taken if there is >0.2 cm or 0.2 kg difference; the two closest values will be used to calculate the mean value. BMI (kg/m^2) will be calculated and BMI z-scores will be determined based on 2000 CDC growth charts[99] as per the Expert Committee Recommendations for assessment of overweight and obesity among 2-19 year olds.[125]

14. Behavioral outcome: Dietary intake by Food Frequency Screener. The preschool children's usual dietary intake over the past 6 months will be measured by the Block Kids Food Frequency Screener as reported by their parents, and screener data will be processed by NutritionQuest (Berkeley, CA), an international leader in dietary assessment and analysis. The Block Kids FFQ, available in English and Spanish, has been validated compared to 24-hour dietary recalls among children, and yielded significant correlations for energy intake (r=0.43), % energy from fat (r=0.51), % energy from carbohydrates (r=0.69), % energy from protein (r=0.55), dairy servings (r=0.74), and fruit servings (r=0.52).[55] The Block Kids FFQ estimates of fruit and vegetables significantly correlated with the objective biomarkers of children's serum carotenoids and skin carotenoids.[56,102] Total dietary energy intake will be a behavioral outcome of interest. Dr. Mendoza has led and/or substantially contributed to multiple nutritional epidemiological studies among children.[85,126-133]

15. Exploratory behavioral outcomes: fruit and vegetable intake and skin carotenoids. Several recent reviews have summarized emerging evidence linking greater screen time/television viewing with lower intake of fruits and vegetables,[134,135] including in preschool-age children.[136] While most of the evidence is observational, intervention studies focused on reducing screen time are well situated to explore this potential causal inverse relationship between screen time and fruit and vegetable intake. Because greater fruit and vegetable intake is associated with lower risk of several chronic diseases,[137,138] and increasing fruit and vegetable intake is a goal of Healthy People 2020,[53] examining whether screen time affects fruit and vegetable intake is important to inform prevention interventions and policies. Thus, we will examine fruit and vegetable intake from the Block Food Frequency Screener as an exploratory behavioral outcome of interest.

Skin carotenoids are an objective biomarker of fruit and vegetable intake in children and adults, and are responsive to changes in carotenoid intake from fruits and vegetables.[100] Skin carotenoids have been validated against plasma concentrations of carotenoids as reviewed,[100,139] Dietary intake of carotenoids as estimated by the Block Kids FFQ was significantly correlated (beta=0.87, p=0.02) with skin carotenoids among a diverse sample of children (59.8% Latino, 25.7% Black).[102] Similarly, dietary intake of total fruit (r=0.21), total vegetables (r=0.32), and total carotenoids (r=0.40) estimated by the Block Kids FFQ among preschoolers was significantly ($p<0.05$) correlated with skin carotenoids.[56] Skin carotenoids measurements are taken on the palm of participants' hands, where skin melanin is found at their lowest concentrations and do not bias results.[101,102] We will use the commercially available instrument, "BioPhotonic Scanner" (Pharmanex Global Research, Provo, UT), which was used in a previous pediatric validation study.[56] Two instruments will be provided free of charge by Pharmanex (see letter of support by Dr. Steve Wood), along with training and technical support. The Seattle and Central Valley sites in Washington State will share one instrument while the Houston site will use the other to measure preschoolers' skin carotenoids per a standard protocol at Times 1, 2, and 3. Measurements will also be compared to fruit and vegetable intake estimated by the Block Kids Food Frequency Screener, as further validation of the Food Frequency Screener among Latino preschoolers. Skin carotenoids will be an exploratory objective outcome for the present study, similar to fruit and vegetable intake via the Block Food Frequency Screener.

Table 1. Summary of study variables

Variable	Instrument	Variable type	Validation and other study references	Investigators with expertise
Screen time	Screen time diary (7-day)	1º outcome	40,41,54	Mendoza

Model of Goal Directed Behavior	Attitudes (15-item) Perceived Positive/Negative Behavioral Control (17-item) Subjective Norms (9-item) Positive and Negative Anticipated Emotions (29-item) Habits (9-item) Self-efficacy (14-item) Desires (7-item) Intentions (10-item)	Mediator	40	Mendoza
Parent outcome expectations for limiting screen time	POETV (25-item)	Mediator	68-70	O'Connor, Hughes
Screen time parenting practices	Screen time parenting practices (15 items)	Mediator	66,67	Mendoza, O'Connor, Hughes
BMI z-score	Measured height & weight	Anthropometric outcome	99	All
Dietary energy intake (for the past 6 months)	Block Kids Food Frequency Screener (40-items)	Behavioral outcome	55	Mendoza, O'Connor, Hughes
Skin carotenoids	Resonance Raman Spectroscopy	Exploratory outcome	56,100-102	Pharmanex (see LOS)
PA and sedentary behavior time	Actigraph accelerometer GT3X+	Behavioral outcome	33,40-42,57,103-110	Mendoza, O'Connor, Hughes
Maternal depressive symptoms	CES-D (20-item)	Moderator	71-73,111,112	Hughes
Maternal social support	Multidimensional Scale of Perceived Social Support (12-item)	Moderator	74,75,113	Hughes
Maternal stress	Cohen's Perceived Stress Scale (14-item)	Moderator	71,74-76,113	Hughes
Demographics	Socio-demographic survey	Covariates	33,40-42,57,103-110	All
Parent perceptions of neighborhood safety	Neighborhood disorder scale (8-item)	Covariate	40-42,114,115	Mendoza, O'Connor
Acculturation	Bidimensional Acculturation Scale for Hispanics (24-item)	Covariate	116,117	All
COVID-19 Questionnaire	Behavioral Insights, Household Pulse, Resilience	Covariate		WHO, U.S. Census Bureau

16. Behavioral Outcome: Physical activity and sedentary behavior time via accelerometry. PA will be objectively measured by the ActiGraph GT3X+ worn on a belt at the hip (Actigraph LLC, Pensacola, FL). It provides an objective measure of duration, frequency and intensity of movement over time and steps taken, thereby providing a valid and objective measure of PA in children.[48,58] These accelerometers will collect data at a raw data sample frequency of 30 Hz and later processed into 15-second epochs.[58] Preschool participants will wear the accelerometers over 7-day periods each at Times 1, 2, and 3.[58] Dr. Mendoza has used accelerometer protocols and/or analyzed data for previous and ongoing studies involving low-income and minority participants from preschool- to young adult-

age.[41,42,103,104,140,141] Accelerometers will be delivered to and picked up from participants at the Head Start centers with the option of postage-paid mailings directly to/from their homes. The accelerometer data quality standards by Troiano et al,[48] used by Dr. Mendoza and others,[104,140-142] will be used also including criteria for: non-wear and wear time (non-wear time defined as 60 consecutive minutes of zero accelerometer counts, except for 1-2 minutes of counts between 0-100, and wear time defined by subtracting non-wear time from 24 hours).[48] We will use the MVPA (420 counts/15 seconds) and sedentary cutpoints (37.5 counts/15 seconds) validated in preschoolers by Pate and colleagues.[57] At least 5-valid days of accelerometer data with three or more hours of wear time will be used in analyses to estimate habitual PA, because those criteria provided >70% reliability among preschoolers.[143,144] To maximize valid accelerometer data, participants will wear accelerometers for 24 hours/day, except for water-based activities,[145] and re-wear them for another 7-day period if they have less than 5-valid days of data at each measurement time point. This approach yielded 92.5% of participants from the analytic sample with sufficient valid accelerometer data in the pilot Fit 5 Kids cluster RCT.[40] Valid accelerometer wear time will be a covariate for analyses involving accelerometer data. The accelerometers will be provided at no cost by Dr. Mendoza.

17. Moderator: Maternal depressive symptoms. Among Head Start mothers, the prevalence of depressive symptoms can be as high as 48%.[146,147] As per a systematic review,[148] maternal depressive symptoms have been associated with greater risk of child obesity. Maternal depressive symptoms assessed using the Center for Epidemiologic Studies Depression Scale (CES-D) have also been associated with greater screen time among US children.[72,73] We will therefore measure maternal depressive symptoms using the validated CES-D, a 20-item instrument,[111] A systematic review, which examined studies by racial/ethnic groups, provided support among Latinos for the original four factor structure (depressed affect, positive affect, somatic symptoms, and interpersonal problems) by meta-analysis of confirmatory factor analysis studies.[112] Dr. Hughes used the CES-D in a previous study linking parental depressive symptoms and feeding styles among parents of Head Start preschoolers.[71] The total score for mothers' CES-D scale will be a potential moderator in analyses estimating screen time, with the hypothesis that the Fit 5 Kids intervention will have lower efficacy for reducing screen time among preschoolers of mothers with higher depressive symptoms.

18. Moderator: Maternal stress. Parental stress adversely affects parenting behaviors including setting limits on children's screen time and obesity. [74-76] Permitting their children to obtain excessive screen time may be a coping behavior used by parents in response to high stress.[76] Among a sample consisting predominantly of mothers, parenting stress was significantly associated with lower odds of setting limits on their preschoolers' screen time.[75] Maternal stress was also associated with childhood obesity in cross-sectional and longitudinal studies as reviewed.[74] To measure maternal stress, we will use Cohen's Perceived Stress Scale, a validated 14-item instrument that measures the degree to which situations in one's life are assessed and considered stressful on a 5-point Likert scale.[113] The total score for perceived stress will be a potential moderator in analyses estimating screen time, with the hypothesis that the Fit 5 Kids intervention will have lower efficacy for reducing screen time among preschoolers of mothers with higher parental stress.

19. Moderator: Maternal social support. While parental stress may adversely affect parenting behaviors and lead to greater screen time, social support is thought to moderate the impact of parental stress on parenting behaviors and health outcomes, i.e., Cohen's stress-buffering hypothesis.[149] For example in a study of low income preschoolers, social support measured by the Multidimensional Scale of Perceived Social Support moderated the adverse association between higher parental stress and higher preschoolers' screen time.[150] In a study of Head Start preschoolers, greater social support

measured by the Multidimensional Scale of Perceived Social Support was associated with parents highly restricting their preschoolers' screen time.[151] We will use the validated 12-item Multidimensional Scale of Perceived Social Support.[152,153] This scale measures perceived support from family, friends, and a significant other, and respondents rate this on a 7-point Likert scale. The total score for social support will be a potential moderator in analyses estimating screen time, with the hypothesis that the Fit 5 Kids intervention will have greater efficacy for reducing screen time among preschoolers of mothers with higher social support.

20. Covariates: Socio-demographics. Parents will complete a survey on their child's age, sex, race/ethnicity, parent education, and household income. Previous studies[40,154] have reported socio-demographics as important predictors of Latino children's screen time, physical activity, and/or BMI z-score.

21. Covariate: Perceptions of neighborhood disorder. We will use an 8-item,[114] validated neighborhood disorder scale to assess parents' perceptions of the their neighborhood in terms of safety, violence, drug traffic, and child victimization.[115] The scale showed acceptable internal consistency (Cronbach's alpha=0.95), reliability (generalizability coefficient=0.84), and validity comparing various neighborhoods ($p<0.001$).[115] In previous work led by Dr. Mendoza using this scale, neighborhood disorder was a significant correlate of Latino Head Start preschoolers' PA and adiposity (see Preliminary Studies).[41,42] Total score will be a covariate.

22. Covariate: Parent acculturation will be assessed using the previously validated 24-item Bidimensional Acculturation Scale for Hispanics. This scale consists of 3-subscales including language use, linguistic proficiency, and electronic media, which are combined into Hispanic and non-Hispanic domains.[116,117] This scale had acceptable internal consistency (alpha=0.90 and 0.96 for Hispanic and non-Hispanic domains, respectively).[116] Validity coefficients for the combined scale with generation status and the Short Acculturation Scale for Hispanics were high among the Mexican American and Latin American US sample.[116] Child acculturation will be estimated using proxy measures, including country of origin, years living in the US, and preferred language(s), which have been associated with Latino preschoolers' risk of obesity.[42]

23. Covariate: COVID-19 Questionnaire. Derived from the World Health Organization's questionnaire on behavioral insights research for COVID-19, and supplemented by additional questions relevant to our population from the 2020 Household Pulse Survey (U.S. Census Bureau), and Connor Davidson Resilience Scale 2-item. Including a COVID-19 questionnaire will allow us to adjust for how the pandemic affects both arms of the study. This may be an important covariate for physical activity and screen time outcomes given that social distancing and other stressors of the pandemic may affect mobility.

Process evaluation. We will conduct a process evaluation of the curriculum to track and ensure proper dose and fidelity across the three sites and four intervention years.[95] This process evaluation will include assessment staff directly observing class sessions and tracking teaching staff-student interactions and participation via a standard checklist. This checklist will include a measure of class time spent on each lesson, the number of children participating in the lesson with a particular emphasis on time spent on role-playing activities and reinforcement by teachers, the number of children completing lesson activities, and the number of children and parents completing take-home activities. We will also track resources used during lessons. The process evaluation's assessment of role playing in particular will provide several measures of the curriculum's application of Social Learning Theory.[96]

Role playing will directly measure modeling of behaviors by the preschool teachers for the children.[97] It will provide a measure of the children's rehearsal of behaviors, which facilitates retention of the behavior. It will also measure the number of times a teacher provides reinforcement in the form of positive prompts or praise during these behavior rehearsals. Finally, parent participation in the take home materials/lending library will be logged and also tracked by collecting assignments completed by the parent and children at home.

Post-Intervention Qualitative Interviews. We will conduct 40 semi-structured, qualitative interviews with intervention participant parents after Time 3 assessments are completed. We will follow standard qualitative procedures for data collection and thematic analysis.172,173 Interviews will explore acceptability of the Fit 5 Kids intervention and how to improve intervention efficacy. Participants will be randomly selected with balanced representation from both the intervention and control groups, and even distribution across head start centers. If there is a low response (less than 60%) to the initial invitation to complete an interview at any center, a second round of invitations will be sent to remaining parents until at least 80% of the target interviews for that center are completed.

A standardized interview script will be developed and consist of general open ended questions, followed by detailed probes and prompts to explore questions of interest. Interviews will be audio recorded, transcribed, verified, and translated (if necessary). We will use NVIVO, a qualitative software analysis program, to facilitate data coding, retrieval, and analysis. The statements in the interviews will be organized by specific questions. Using verbatim statements, each unit will be assigned a broad category and specific codes to facilitate data retrieval and analysis overall, by specific sub-categories, and participants' characteristic groups.

The multilevel Fit 5 Kids intervention consists of the classroom curriculum, weekly parent newsletters, in-person (or by telephone) goal setting on their child's screen time, a lending library of resources (books, games, arts/crafts, etc), private parent Facebook group, and text messages on screen time parenting practices offered over 7-8 weeks in the Fall semester. There will also be two "booster" weeks of classroom activities, daily parent newsletters, goal setting, and daily text messages on screen time parenting practices offered during the booster weeks in the Spring semester. The classroom component will be taught by bilingual (English/Spanish) research staff interventionists. Parent newsletters, goal setting, and text messages will be offered in English and Spanish per parent preference. The lending library of resources for parents/children will be available throughout the entire school year.

The elements unique to the proposed study include: 1) questionnaires, 2) physical activity (PA) and screen time data, 3) the Fit 5 Kids intervention, and 4) qualitative data, i.e., post-intervention qualitative interviews.

10.0 Data and Specimen Banking

N/A

11.0 Data Analysis/Management

We will conduct intent-to-treat analyses. Children will be the unit of analyses, although analyses will recognize the hierarchical nature of the data, i.e., time points nested within children, and children nested within Head Start centers. Randomization at the center level with stratification by study site should balance many observed and unobserved confounders at the center and child levels. For the primary (screen time) and other outcomes (BMI z-score, dietary energy intake, and MVPA), two sets of analyses will be performed. The first set of analysis will be separate cross-sectional analysis of T2 and T3 outcomes respectively. Given the nested structure of the data, we will apply mixed effects regression models156 to examine the effects of the intervention on each outcome while controlling for unbalanced covariates and account for correlations due to clustering. In the second set of analysis we will conduct a repeated measure analysis using outcomes from all 3 time points. For Hypothesis 2, we will assess the extent through which parent outcome expectations, self-efficacy, and screen time parenting practices exert their influence on (i.e., mediate) change in screen time via the intervention. We will use a structural equation modeling (SEM) approach:157,158 specifically, we will evaluate mediation by decomposing a total effect on the screen time slope into direct effects and indirect effects. The indirect effects represent the influence of the intervention on change in screen time via parent outcome expectations, self-efficacy, or screen time parenting practices. We will test the moderation relationships of Hypothesis 3 using mixed effects regression models as outlined for Hypothesis #1.

Power Analysis. With only two post-intervention assessments, there is limited information on trajectories of outcomes over time. Thus, our primary analysis will focus on comparisons at Time 2 (post 1) and Time 3 (post 2), respectively. We evaluated the statistical power and sample size for the proposed study using the Optimal Design Software.168 Parameter estimates saved from a pilot data analysis33,40 were used for population parameter values for data generation and coverage. We assumed an increasing attrition rate over time reflecting the likelihood that participants may drop out of the study (~15% overall); therefore if we power the study with 240 participants at Time 3, we would expect to start with approximately n=280 participants at Time 1 with attrition.

Data Management:
Each study site will be responsible for managing the data collected at that site. All staff will be informed of the need for confidentiality. All key personnel at all sites will have completed Human Subjects training and all investigators and clinical trial staff will have up to date Good Clinical Practice (GCP) training. Data containing personal information such as names, addresses, and phone numbers will be maintained in a separate locked cabinet accessible only by the study coordinator and research manager. Security access only will be permitted to each file, separately, with security limited to the projects' data manager and coordinator. Personal identification codes will be created for each participant, which can link quantitative or survey data back to an individuals' name. Data will be stored on encrypted computers and servers that are protected with passwords. All data analyses will be conducted on datasets that include only the personal identification code as a linking variable. No names or addresses will be reported in publications. Only the PIs, co-investigators, research coordinator, and research administrator have keys to the offices and locked cabinets at Seattle Children's. The semi-structured qualitative interview data will have no personally identifying information associated with the tape or the transcript, so confidentiality cannot be violated.

12.0 Confidentiality

The semi-structured qualitative interview data will have no personally identifying information associated with the tape or the transcript, so confidentiality cannot be violated. The Facebook group will be private and only accessible to other study participants who have been invited and accepted the friend request to join the group. This part of the study is also optional. All YouTube videos will be unlisted with comments inactive so that only participants with the link will be able to access them. Digital live streams will be optional as well, and will be unlisted too. Viewers will need to sign in with a gmail account in order to interact with others, which participants may do if they choose. Any paper data will be filed in locked cabinets. Data containing personal information such as names, addresses, and phone numbers will be maintained in a separate locked cabinet accessible only by the study coordinator and research manager. Security access only will be permitted to each file, separately, with security limited to the projects' data manager and coordinator. Personal identification codes will be created for each participant, which can link quantitative or survey data back to an individuals' name. Data stored on all computers and servers will be protected with passwords. All data analyses will be conducted on datasets that include only the personal identification code as a linking variable.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Prior to implementing the study, the protocols, informed consent forms, recruitment materials and evaluation procedures will be reviewed by the Institutional Review Boards (IRBs) of Seattle Children's Hospital, the Fred Hutchinson Cancer Research Center, and Baylor College of Medicine. All adverse events, breach of privacy, will be recorded and reviewed by the Principal Investigator (Dr. Mendoza, a board-certified pediatrician and a licensed physician) and the co-investigators (Dr. O'Connor, a board-certified pediatrician and a licensed physician, and Drs. Hughes, Zhou, and Ceballos). Any adverse event and the actions taken will be reported to the IRBs and NIH. As appropriate, we will refer the participant for the appropriate medical and psycho-social evaluation with the participant's primary care provider. Each adverse event will be submitted to the IRB.

This study involves minimal risk and no investigational drugs or procedures. However, the risk of an adverse event from reducing screen time, although recommended by national health authorities, warrants supervision. We have therefore appointed a Study Safety Officer, who is otherwise not associated with this research project but who has expertise in obesity prevention and treatment. Dr. Mollie Grow, MD, MPH, FAAP, a board-certified pediatrician at the University of Washington who has research and clinical expertise in pediatric obesity will provide oversight as follows: (1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and (2) assess issues concerning the continuation, modification, or termination of this study. Dr. Grow is not supervised by any of the members of the investigative team, nor has financial or other conflicts of interest with this study or its investigators. The Safety Officer, PI, co-investigators, and the Research Manager(s) will report any serious unexpected adverse event (whether associated with the intervention or not) to the IRBs and NIH within 48 hours by telephone and within 5-working days in writing. The IRBs will also determine whether the adverse event is causally related, probably related, possibly related, or unrelated to the intervention. A serious unexpected adverse event is provisionally defined as any of the following:

- death
- any acute life-threatening event or injuries
- any event requiring hospitalization or emergency department care

- any other event that warrants a designation of a "serious" event in the PIs', or Co-Is' judgements, including threats to safety or "near-miss" injury events that could have led to items a-c above

All other adverse events will be filed annually with the IRBs and the NIH. Routine monitoring for adverse events will be performed by the study staff and coordinators, the PI, and co-investigators. Since there are no investigational drugs or devices, there will be no routine post-study follow-up of participants. The NIH will be informed of any actions taken by the IRBs as a result of their continuing review of the study.

14.0 Withdrawal of Subjects

Subjects may withdraw from the study if the child or care-giver has a medical condition that makes it difficult or impossible to complete study activities. A subject may also withdraw if they cannot complete study activities for any other reason. If a subject revokes consent, information collected to that point that the subject withdraws in writing may be used if that information is necessary to complete the study. Subjects who withdraw will not be replaced.

15.0 Risks to Subjects

This proposed RCT involves minimal risk to the participants because it is focused on reducing preschool participants' screen time, which is consistent with national health recommendations such as the American Academy of Pediatrics and Healthy People 2020. Data on PA and screen time, such as measured by accelerometers or screen time diaries, are generally not considered sensitive and are similar to data on household income, education, and occupation. Participant can withdraw from the study at any time without prejudice.

15.1 The primary risks will be that a child could (1) become embarrassed from having weight measured; or (2) become embarrassed from the potential loss of confidentiality.
The primary risk for the qualitative interviews is a loss of confidentiality (privacy).

The semi-structured qualitative interview data will have no personally identifying information associated with the tape or the transcript, so confidentiality cannot be violated. The Facebook group will be private and only accessible to other study participants who have been invited and accepted the friend request to join the group. This part of the study is also optional. Any paper data will be filed in locked cabinets. Data containing personal information such as names, addresses, and phone numbers will be maintained in a separate locked cabinet accessible only by the study coordinator and research manager. Security access only will be permitted to each file, separately, with security limited to the projects' data manager and coordinator. Personal identification codes will be created for each participant, which can link quantitative or survey data back to an individuals' name. Data stored on all computers and servers will be protected with passwords. All data analyses will be conducted on datasets that include only the personal identification code as a linking variable.

15.2 We do not expect any other parts of the study to introduce risks to the participants.

15.3 There will be no risk to an embryo or fetus should the subject be or become pregnant.

15.4 There will be no risks to others that are not subjects.

16.0 Potential Benefits to Subjects

16.1 Participants may benefit from the intervention by increasing their reading, physical activity, family meals, etc., which may improve their weight status and decrease risk of chronic diseases. The proposed multilevel intervention is low cost, requires minimal project staff to implement (future iterations would train Head Start teachers themselves to teach Fit 5 Kids), and could potentially have a major public health impact on the health of Latino populations in Head Start and similar child care settings. The benefits clearly outweigh the risks, as seen by guidelines for limiting children's screen time by the American Academy of Pediatrics and US Healthy People 2020.

17.0 Vulnerable Populations

Besides the parents of the preschool children, the primary population of the proposed study will include children who are ages 3-5 years; thus, applying the NIH definition of children as ages 17 years and under, children will be a focus of this study. For this age group, which represents a developmentally important formative period towards long term screen time behaviors, intervening to promote reduction of screen time and decrease risk of obesity and related chronic diseases are national priorities. We expect 50% of child participants to be female. As we are not asking about pregnancy status, it is possible that we may inadvertently enroll women who are pregnant or become pregnant during the study. Due to the minimal risk nature of the study activities, we do not anticipate any adjustments needed for pregnant participating parents. We will not be enrolling wards of the state.

18.0 Community-Based Participatory Research

N/A

19.0 Sharing of Results with Subjects

Subjects may request aggregate data and any publications that may result from study activities. No individual data will be disseminated.

20.0 Setting

We will recruit Head Start centers in three different regions of the US, in order to increase generalizability of study findings, as well as to be inclusive of the most underserved of Latino groups, i.e., rural Latinos. We will recruit 8 Head Start centers in the Seattle-metro area, which include urban and suburban-based centers. We will recruit 6 centers from the rural Central Valley of Washington State. We will also recruit 6 centers from the Houston-metro area, which include urban-based centers.

The Puget *Sound Educational Services District (PSESD) is a state mandated educational services district in Washington State. PSESD operates 26 Head Start centers throughout the Seattle-metro area which enroll 863 Latino preschoolers. PSESD has agreed to partner with the investigators (see letter of support from Ms. Sharon Judie). In the rural Central Valley of Washington State, Inspire Centers operates 28 Head Start centers serving over 600 Latino preschoolers and will participate in this study (see letter of support from Mr. Jorge Castillo). In*

Houston, AVANCE, Inc. operates 13 Head Start centers that serve 920 Latino preschoolers and has expressed a desire to participate in this study (see letter of support from Mr. Jose Villareal).

Research staff will recruit participants from these Head Start centers. Other Head Start centers will also be invited to participate, including Denise Louie Education Centers (based in Seattle,WA) and Educational Opportunities for Children and Families (based in Vancouver, WA). Seattle Children's investigators will be conducting/overseeing the research procedures at the Head Start centers and the investigators will be acting as agents of Seattle Children's at those sites. Participants will also complete some of the study components on their own at their home.

21.0 Resources Available

The facilities and other resources at the Seattle Children's Research Institute (SCRI) include everything that is needed for the successful completion of this project in a timely manner. As described below, both the facilities and the intellectual environment contribute to an atmosphere providing research connections, which will enhance completion of this project. Investigators and research staff are supported and encouraged as they pursue their research goals. SCRI has a history of successful grant funding, timely and novel research studies, and peer-reviewed publications.

The Seattle Children's Research Institute (SCRI) is composed of seven interdisciplinary research centers that address areas central to pediatric health and use an "open lab" format to foster a rich collaborative environment. Directed by Dr. James Hendricks, SCRI is sponsored by the University of Washington Department of Pediatrics and Seattle Children's Hospital d/b/a Seattle Children's Research Institute as part of a $400 million dollar research funding initiative. Total research funding for SCRI in 2016 exceeded $100 million, which places it among the top five pediatric research centers in the US.

Drs. Mendoza (PI) and Zhou are investigators in the SCRI Center for Child Health, Behavior and Development (CHBD). CHBD is devoted to improving children's well-being in their homes, neighborhoods, schools, clinics and during hospitalization through research, including physical activity promotion and obesity treatment and prevention. Directed by Dr. Dimitri Christakis, the center uses state-of-the-art research methods to identify problems and risks for children, with a special emphasis on vulnerable populations. There are currently 68 principal investigators at CHBD with varied research interests and over $14 million in annual extramural grant support. CHBD's particular areas of interest include: obesity prevention and treatment, clinical effectiveness, health outcomes, quality of care, community-engaged research, information technology, and health informatics.

CHBD maintains its own Biostatistics, Epidemiology, Econometrics and Programming (BEEP) Core, which provides state-of-the-art statistical design, data programming, and analysis services. The BEEP Core includes both PhD and Masters level biostatisticians, epidemiologists, and programmers, who have the training, experience, and resources to handle a wide variety of statistical and programming tasks needed for clinical and health services research. The Core is directed by Dr. Waylon Howard, PhD, who ensures that all funded projects are matched with a Core member having the needed skills and experience, and who supervises the allocation of Core members across projects. Core members have access to the latest statistical and survey management software, including SPSS, SAS, Stata/SE, Mplus, R, REDCap, and DAT-STAT Illume. Core members attend a monthly journal club with faculty biostatisticians from SCRI and the UW, where they learn how to apply the latest methodological research to their activities at CHBD. Core members are skilled in

collecting, processing, and analyzing Actigraph accelerometer data. Core members also attend specialized analytic training opportunities offered by NIH, universities, and institutes.

The Research Manager will provide expertise in in protocol development and implementation, hiring and supervision of study staff, and collection and management of study data.

The study coordinator (TBN) and other research staff will be selected based on their experience working directly with children and families to obtain consent, administer questionnaires, and organize lab study visits. They will also have familiarity with protocol-based assessments and experience working with a varied participant population.

22.0 Prior Approvals

This study has undergone peer scientific review through the NIH (funding sponsor), and is also supported by a number of qualified professionals as stated in the grant letters of support.

23.0 Recruitment Methods

We will recruit 8 Head Start centers in the Seattle-metro area, which include urban and suburban-based centers. The Puget Sound Educational Services District (PSESD) is a state mandated educational services district in Washington State. PSESD operates 26 Head Start centers throughout the Seattle-metro area which enroll 863 Latino preschoolers. PSESD has agreed to partner with the investigators.

24.0 We will use recruiting strategies that have previously been highly successful for the investigators during studies conducted in Head Start centers over the past 10-15 years. We will recruit participants from Head Start centers that serve substantial numbers of Latino families and use a combination of recruitment procedures including 1) pictorial bilingual flyers sent home with the children, 2) telephone calls, 3) presentations at parent meetings, 4) active involvement/guidance of the Head Start manager and staff in the recruitment process, and 5) the use of a recruitment video. The recruitment video will be available for viewing via the same link participants will use to access and complete the electronic consent form process, and will also be available as a separate YouTube link, which school and study staff may share with potential participants in the same way the electronic consent form would be shared. At the beginning of the school year, we will provide head start centers $400. Then, we will provide $500 per center incentive near the end of the school year.

25.0 Use of Social Media

25.1 Describe the types of social media to be employed and rationale for the use of social media

As found in related studies, use of a private Facebook group was helpful for sharing information, providing support, and overall participant engagement.

25.2 Describe the measures in place to protect the privacy or confidentiality of subjects.

Access to the group will be limited to participating parents in the current intervention. Participants will be invited to join the group and will need to accept the request to then

participate and view content from other users. The group content will not be visible to the participant's other Facebook friends.

25.3 *Provide a definition of what will be considered IRB-reviewable subject matter.*

Any intervention-related content initiated by a member of the study team will first be submitted to the IRB for review and approval. We do not have any specific plans at this time for this type of content.

25.4 Describe whether user-generated content will be active, and if so, how it will be monitored and what actions will be taken to ensure subject safety and study integrity.

A member of the study team will regularly monitor participant interactions to ensure they are appropriate, respectful, and related to the intervention. Participants posting inappropriate material will receive an initial warning and reminder of the purpose of the group. A second infraction will result in removal from the group. Additionally, a member of the study team will be in 1:1 contact with any affected participants to assess the need for further action. In our experience across several studies with a range of populations this has never been an issue with this type of private group.

Post-intervention analysis will be focused on overall activity of the group and participant engagement (number of active participants, number of posts, likes, views).

26.0 Local Number of Subjects

Ten child care centers (with a minimum of 12 students in each) will be recruited in the Seattle area.

27.0 Provisions to Protect the Privacy Interests of Subjects

The primary risk in the proposed study revolves around privacy and data confidentiality. In order to protect against these risks we will do the following: risks to the participants will be fully explained during the informed consent process and repeated as needed during subsequent study visits and contact with study personnel; all the study personnel will undergo extensive, standardized training and certification with ongoing quality control monitoring; we will adhere to strict data storage and confidentiality procedures to ensure the privacy and confidentiality of the participants. In addition, study personnel will follow HIPAA regulations and be trained and certified in Human Subjects Protections. In addition, they will remind participants that they can skip any questions they are uncomfortable answering on the questionnaire.

28.0 Compensation for Research-Related Injury

N/A

29.0 Economic Burden to Subjects

There will be no costs to participants in the study.

30.0 Consent Process

Due to the minimal risk nature of the study, we will be obtaining consent from one parent or guardian prior to enrollment in the study.

1. Potential participants will first hear about the study through their child's head start center. In addition to receiving information about the study during classroom presentations, parent-teacher conferences, and home visits, the information packet (cover letter, flyer, and consent form in English and Spanish) will be sent home with the child.
2. The cover letter will provide instructions for who to contact with questions, and instructions for returning the signed consent to the school with their child or by mail with included mailing supplies and postage. The cover letter will also serve as a cover email in the event that consent forms are emailed to participants. To allow the parent sufficient time to review study materials and contact study staff with any questions, they will be given 2 weeks to review the consent form and decide if they wish to provide consent and enroll in the study. During this time, there will be ample opportunity to contact bilingual study team members to ask questions or to seek clarification. Participants will be encouraged to contact the PI or study staff should they have questions. Study staff will also be available to discuss the study in detail with participants.
3. Potential participants will be given 2 weeks to decide if they wish to consent to be in the study and speak with a study team member. In most cases participants will not have direct face-to-face contact with study staff during enrollment, so will not feel pressured to enroll in the study.

4. If at any time the participant wishes to withdraw from the study for any reason, they may do so.
5. We will be following "SOP: Informed Consent Process for Research (HRP-090)" with the following exceptions as this is a minimal risk study:
   - We will seek the consent of only one parent or guardian.
   - A formal face-to-face oral consent process will not take place. However, should participants have questions, study staff will be available to meet with participants to discuss the study in detail.

   The voluntary nature of the study will be emphasized at many points in the enrollment process including when parents receive study materials, when the study is discussed in their child's classroom or during other parent meetings, and again when they review and sign the consent (on paper or online). Once the parents enroll in the study, the study team will contact them to proceed with baseline data collection. During this contact with parents, study staff will confirm with the parents/legal guardian that they actually want to participate and ensure they understand their consent to participate in the study. Additionally, since the study activities occur over many weeks parents have the option of changing their mind at any time during the study and no longer completing study activities.

   In addition to receiving the signed consent (on paper or online), parent's understanding of the study activities and confirmation that the child's actual

parent signed the form will be informed by the parent's subsequent actions including completing the baseline surveys, and participating in at-home activities. The survey is collected from the parent before any study activities begin in the child's classroom.

Study participants will be the parent/legal guardian who signs the consent form and their child. The parent and child study participants will be the only ones that we collect data from during the study.

Some of the participants in the study may need to complete the informed consent form electronically. PHI is needed to complete the study surveys, so an alteration of HIPAA is needed. Providing participants with the option of providing consent electronically could allow more families from our target population to participate in the study. We will obtain written consent from every parent participant where it is possible, but requiring written consent for every participant may exclude some families from participating in the study. For example, some parents may want to participate in the study, but due to lack of adequate transportation might not be able to attend a classroom presentation. We would like to offer them the option of reviewing the form and providing consent and authorization electronically, with the study team available to address questions at any time. We do not want to exclude families due to barriers to completing the written consent. For families with barriers to completing written consent, we would like to offer the option of electronic consent, so we need the alteration of HIPAA for them to participate in the study. In these circumstances, it would be impracticable for the study team to conduct the research without the alteration because the research team will have no in-person contact with the families or have any contact information (not disclosed by the schools) to be able to approach the families. The research staff would rely on the families receiving the recruitment packets (with approach letter, flyer and consent forms) and have them review the content at their own pace. If they are interested in participating, they would then have the option of complete the consent form/authorization online. Our plan for protection of PHI is included in the data management and privacy protection sections of this protocol.

Paper signed consent forms will be kept in the Study Coordinator's locked office files, and online consent forms will be sent and stored via the UW REDCap database.

Waiver or Alteration of Consent/Assent/Permission
Reason for requesting a waiver or alteration of informed consent/assent/permission:

- Requesting a waiver of consent for participants who turn 18. Participants were enrolled as pre-schoolers in 2022, so none have yet turned 18.
- Participants have completed all study activities and we will not be collecting any new information (including from their medical records). The study has remained open for analysis of identifiable data and we have had no contact with

Commented [WC1]: I've tracked in the waivers into the protocol consent section. Please remove the rationale from the Mod Summary. Please review to ensure I've captured everything correctly and revise as needed for accuracy.

Commented [CT2R1]: Rationale has been removed from the mod summary.

participants for several years. The aims of the study require use of the home address to study child outcomes. Due to the length of time since the child participated, the brief duration of their involvement, and the non-sensitive and minimal risk nature of the data we are requesting a waiver of re-consent.

Consent/Assent Waiver/Alteration Criteria Justifications:

The research involves no more than minimal risk to the subjects because: The remaining study activities are limited to analysis of data with home address identifiers. Any data that is published from this analysis will be grouped such that it will not be possible to identify a given individual.

The waiver or alteration will not adversely affect the rights or welfare of the subjects because: The child will have no additional risk or benefit as a result of not re-consenting. Data provided is non-sensitive and will be grouped with data from other participants for analysis and publication. Any publication or presentation of research results would be done in a manner that would never reveal an individual's identity either directly or indirectly.

The research could not practicably be carried out without the waiver or alteration because: The funding for the grant the data was collected under has ended and participants who will turn 18 are not likely living at the same address or have the same contact information. As contacting them would not provide any additional benefit or inform of any additional risk, this would present an incredible burden on the investigator to try and track down and re-consent these participants.

If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format because: The primary aims of the study involve child health and physical activity. One factor in the analysis is the location of the home and details about the surrounding neighborhood, so it is necessary to retain home address until the analysis are completed.

Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation:
N/A

Non-English Speaking Subjects

6. Participants in the study must speak either English or Spanish. All recruitment documents, including the consent form, will be provided in both languages. All documents will be translated and back translated from English to Spanish by a certified translator. Bilingual research staff fluent in both Spanish and English will also be available should participants have questions during the consent process. As this is a minimal risk study; a formal face-to-face oral consent process will not take place. However, should participants have questions, study staff will be available to

meet with participants to discuss the study in detail. When consent activities occur for a Spanish speaking participant, the consent activities will be completed by a certified bilingual researcher.

7. This study will follow the steps outlined in the Investigator Manual.
8. Parent participants must be over the age of 18. Child participants will be age 3-5. We will not re-consent at age 18 as no participant will reach the age of 18 during the study period.
9. Planned emergency research is not applicable to this study.

Subjects who are not yet adults (infants, children, teenagers)

10. We will enroll 3-5 year old children, who do not have the developmental capacity to make an informed decision with regard to participating in this study. Obtaining informed assent in children this young may possibly be coercive, since children of this age are highly suggestible to adults. Should the child express they do not want to participate in the study at any time, the process will stop.
11. Parental permission will be obtained from:
    - One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
12. Permission will NOT be obtained from individuals other than parents.
13. Assent will NOT be obtained from any children. We will enroll 3-5 year old children.
    - The capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted.
14. Requested Waiver of consent at age of majority

Cognitively Impaired Adults

15. We will not be enrolling cognitively impaired adults.

Adults Unable to Consent

16. We will not be enrolling adults unable to provide consent.
17. No assent will be obtained as all adults enrolled will be consented.

Consent for use of HUD

18. NA.

31.0 Process to Document Consent in Writing

We will be following "SOP: Written Documentation of Consent (HRP-091). Additionally, participants will be given the option to review and sign the consent online via a secure REDCap portal. This will allow the study team to document consent while making it easier and quicker for participants to enroll. For these participants, a waiver of documentation of consent is requested as the REDCap module we are using does not meet criteria of applicable state/international law (per WA, RCW 19.34.300). In addition to having a copy of the paper

consent to review, the full content of the approved consent form will be provided online for review prior to the section where participants indicate consent by typing their name and the date. The activities in the research study are similar to what children and parents would do in their daily life and would not require consent outside of the research context.

32.0 Drugs or Devices

We will be using the commercially available instrument, "BioPhotonic Scanner" (Pharmanex Global Research, Provo, UT) to provide an objective assessment of fruit and vegetable intake via skin carotenoids. This is an exploratory outcome; we will simply examine correlations with fruit/veg intake, as a means of quality control. This is not meant to be FDA device validation, nor will it be presented as such. Additionally, we have cited several pediatric studies that have also used the device without the requirement of registering it with the FDA

33.0 Good Clinical Practice

We will conduct the described study per International Center for Harmonization of Good Clinical Practice (ICH-GCP).

REFERENCES

1. Singh GK, Siahpush M, Kogan MD. Rising Social Inequalities in US Childhood Obesity, 2003-2007. *Annals of epidemiology.* 2010;20(1):40-52.
2. Whitaker RC, Orzol SM. Obesity among US urban preschool children: relationships to race, ethnicity, and socioeconomic status. *Arch Pediatr Adolesc Med.* 2006;160(6):578-584.
3. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA.* 2014;311(8):806-814.
4. Skinner AC, Perrin EM, Skelton JA. Prevalence of obesity and severe obesity in US children, 1999-2014. *Obesity.* 2016;24(5):1116-1123.
5. World Cancer Research Fund. *Food, Nutrition, Physical Activity, and the Prevention of Cancer: a Global Perspective*: Washington, DC: AICR; 2007.
6. Friedenreich CM. Physical activity and cancer: lessons learned from nutritional epidemiology. *Nutr Rev.* 2001;59(11):349-357.
7. Friedenreich CM, Orenstein MR. Physical activity and cancer prevention: etiologic evidence and biological mechanisms. *J Nutr.* 2002;132(11 Suppl):3456S-3464S.
8. Thune I, Furberg AS. Physical activity and cancer risk: dose-response and cancer, all sites and site-specific. *Med Sci Sports Exerc.* 2001;33(6 Suppl):S530-550; discussion S609-510.
9. Poirier P, Giles TD, Bray GA, et al. Obesity and Cardiovascular Disease: Pathophysiology, Evaluation, and Effect of Weight Loss: An Update of the 1997 American Heart Association Scientific Statement on Obesity and Heart Disease From the Obesity Committee of the Council on Nutrition, Physical Activity, and Metabolism. *Circulation.* 2006;113(6):898-918.
10. Groner JA, Joshi M, Bauer JA. Pediatric Precursors of Adult Cardiovascular Disease: Noninvasive Assessment of Early Vascular Changes in Children and Adolescents. *Pediatrics.* 2006;118(4):1683-1691.
11. Amed S, Daneman D, Mahmud FH, Hamilton J. Type 2 diabetes in children and adolescents. *Expert Rev Cardiovasc Ther.* 2010;8(3):393-406.
12. Pinhas-Hamiel O, Zeitler P. Clinical presentation and treatment of type 2 diabetes in children. *Pediatr Diabetes.* 2007;8:16-27.
13. Shaw J. Epidemiology of childhood type 2 diabetes and obesity. *Pediatr Diabetes.* 2007;8:7-15.
14. Daniels SR, Benuck I, Christakis DA, et al. *Expert panel on integrated guidelines for cardiovascular health and risk reduction in children and adolescents* Washington, DC: National Heart, Lung, and Blood Institute, US Department of Health and Human Services;2012.
15. Whitaker RC, Wright JA, Pepe MS, Seidel KD, Dietz WH. Predicting obesity in young adulthood from childhood and parental obesity. *N Engl J Med.* 1997;337(13):869-873.
16. Kimm SY, Glynn NW, Kriska AM, et al. Longitudinal changes in physical activity in a biracial cohort during adolescence. *Med Sci Sports Exerc.* 2000;32(8):1445-1454.
17. Alfano CM, Klesges RC, Murray DM, Beech BM, McClanahan BS. History of sport participation in relation to obesity and related health behaviors in women. *Prev Med.* 2002;34(1):82-89.
18. Guo SS, Wu W, Chumlea WC, Roche AF. Predicting overweight and obesity in adulthood from body mass index values in childhood and adolescence. *Am J Clin Nutr.* 2002;76(3):653-658.
19. Magarey AM, Daniels LA, Boulton TJ, Cockington RA. Predicting obesity in early adulthood from childhood and parental obesity. *Int J Obes Relat Metab Disord.* 2003;27(4):505-513.
20. Camhi SM, Katzmarzyk PT. Tracking of cardiometabolic risk factor clustering from childhood to adulthood. *International Journal of Pediatric Obesity.* 2010;5(2):122-129.

21. Kumanyika SK, Obarzanek E, Stettler N, et al. Population-Based Prevention of Obesity: The Need for Comprehensive Promotion of Healthful Eating, Physical Activity, and Energy Balance: A Scientific Statement From American Heart Association Council on Epidemiology and Prevention, Interdisciplinary Committee for Prevention (Formerly the Expert Panel on Population and Prevention Science). *Circulation.* 2008;118(4):428-464.
22. Davis MM, Gance-Cleveland B, Hassink S, Johnson R, Paradis G, Resnicow K. Recommendations for prevention of childhood obesity. *Pediatrics.* 2007;120 Suppl 4:S229-253.
23. Ennis SR, Rios-Vargas M, Albert NG. *The Hispanic Population: 2010.* Suitland, MD: US Department of Commerce, Economics and Statistics Administration, US Census Bureau;2011.
24. Adepoju OE, Bolin JN, Booth EA, et al. Is diabetes color-blind? Growth of prevalence of diagnosed diabetes in children through 2030. *Population health management.* 2015;18(3):172-178.
25. Dabelea D, Mayer-Davis EJ, Saydah S, et al. Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. *Jama.* 2014;311(17):1778-1786.
26. Zhou YE, Emerson JS, Levine RS, Kihlberg CJ, Hull PC. Childhood obesity prevention interventions in childcare settings: systematic review of randomized and nonrandomized controlled trials. *Am J Health Promot.* 2014;28(4):e92-103.
27. Jago R, Baranowski T, Baranowski JC, Thompson D, Greaves KA. BMI from 3-6 y of age is predicted by TV viewing and physical activity, not diet. *Int J Obes (Lond).* 2005;29(6):557-564.
28. Mendoza J, Zimmerman F, Christakis D. Television viewing, computer use, obesity, and adiposity in US preschool children. *International Journal of Behavioral Nutrition and Physical Activity.* 2007;4(1):44.
29. Rideout VJ, Hamel E. *The media family: Electronic media in the lives of infants, toddlers, preschoolers and their parents.* Menlo Park, CA: Kaiser Family Foundation;2006.
30. Friedrich RR, Polet JP, Schuch I, Wagner MB. Effect of intervention programs in schools to reduce screen time: a meta-analysis. *J Pediatr (Rio J).* 2014;90(3):232-241.
31. Marshall SJ, Gorely T, Biddle SJ. A descriptive epidemiology of screen-based media use in youth: a review and critique. *J Adolesc.* 2006;29(3):333-349.
32. Dietz WH, Jr., Gortmaker SL. Do we fatten our children at the television set? Obesity and television viewing in children and adolescents. *Pediatrics.* 1985;75(5):807-812.
33. Dawson-Hahn EE, Fesinmeyer MD, Mendoza JA. Correlates of Physical Activity in Latino Preschool Children Attending Head Start. *Pediatric exercise science.* 2015;27(3):372-379. PMC4627590
34. Francis S, Stancel M, Sernulka-George F, Broffitt B, Levy S, Janz K. Tracking of TV and video gaming during childhood: Iowa Bone Development Study. *International Journal of Behavioral Nutrition and Physical Activity.* 2011;8(1):100.
35. Hill D, Ameenuddin N, Reid Chassiakos Y, et al. Media and Young Minds. *Pediatrics.* 2016;138(5).
36. Reid Chassiakos Y, Radesky J, Christakis D, et al. Children and Adolescents and Digital Media. *Pediatrics.* 2016;138(5).
37. Rideout VJ, Foehr UG, Roberts DF. *Generation M^2: Media in the lives of 8-18 year olds.* Menlo Park, CA: Henry J. Kaiser Family Foundation;2010.
38. Resnicow K, Baranowski T, Ahluwalia JS, Braithwaite RL. Cultural sensitivity in public health: defined and demystified. *Ethnicity & disease.* 1999;9(1):10-21.
39. Schmidt ME, Haines J, O'Brien A, et al. Systematic Review of Effective Strategies for Reducing Screen Time Among Young Children. *Obesity.* 2012;20(7):1338-1354.
40. Mendoza JA, Baranowski T, Jaramillo S, et al. Fit 5 Kids TV Reduction Program for Latino Preschoolers: A Cluster Randomized Controlled Trial. *Am J Prev Med.* 2016;50(5):584-592. PMCID: PMC5108181

41. Mendoza JA, McLeod J, Chen TA, Nicklas TA, Baranowski T. Convergent Validity of Preschool Children's Television Viewing Measures among Low-Income Latino Families: A Cross-Sectional Study. *Child Obes.* 2013;9(1):29-34. PMC3604787
42. Mendoza JA, McLeod J, Chen TA, Nicklas TA, Baranowski T. Correlates of adiposity among Latino preschool children. *Journal of physical activity & health.* 2014;11(1):195-198. PMCID: PMC3750103
43. Sallis JF, Cervero RB, Ascher W, Henderson KA, Kraft MK, Kerr J. An ecological approach to creating active living communities. *Annual Review of Public Health.* 2006;27(1):297-322.
44. O'Connor TM, Hingle M, Chuang RJ, et al. Conceptual understanding of screen media parenting: report of a working group. *Child Obes.* 2013;9 Suppl:S110-118. 3746292
45. Thompson DA, Polk S, Cheah CSL, et al. Maternal Beliefs and Parenting Practices Regarding Their Preschool Child's Television Viewing: An Exploration in a Sample of Low-Income Mexican-Origin Mothers. *Clinical Pediatrics.* 2015;54(9):862-870.
46. Flay BR. Efficacy and effectiveness trials (and other phases of research) in the development of health promotion programs. *Preventive Medicine.* 1986;15(5):451-474.
47. Courneya K. Efficacy, effectiveness, and behavior change trials in exercise research. *International Journal of Behavioral Nutrition and Physical Activity.* 2010;7(1):81.
48. Troiano RP, Berrigan D, Dodd KW, Masse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc.* 2008;40(1):181-188.
49. Robinson TN. Reducing children's television viewing to prevent obesity: a randomized controlled trial. *JAMA.* 1999;282(16):1561-1567.
50. Epstein LH, Roemmich JN, Robinson JL, et al. A randomized trial of the effects of reducing television viewing and computer use on body mass index in young children. *Arch Pediatr Adolesc Med.* 2008;162(3):239-245.
51. Nader PR, Bradley RH, Houts RM, McRitchie SL, O'Brien M. Moderate-to-vigorous physical activity from ages 9 to 15 years. *Jama.* 2008;300(3):295-305.
52. Belcher BR, Berrigan D, Dodd KW, Emken BA, Chou C-P, Spuijt-Metz D. Physical Activity in US Youth: Impact of Race/Ethnicity, Age, Gender, & Weight Status. *Medicine & Science in Sports & Exercise.* 2010;42(12):2211-2221. PMCID: PMC3242154
53. Office of Disease Prevention and Health Promotion. Healthy People 2020. US Department of Health and Human Services. Washington, DC: US Department of Health and Human Services; 2010.
54. Anderson DR, Field DE, Collins PA, Lorch EP, Nathan JG. Estimates of young children's time with television: a methodological comparison of parent reports with time-lapse video home observation. *Child development.* 1985;56(5):1345-1357.
55. Cullen KW, Watson K, Zakeri I. Relative Reliability and Validity of the Block Kids Questionnaire among Youth Aged 10 to 17 Years. *Journal of the American Dietetic Association.* 2008;108(5):862-866.
56. Nguyen LM, Scherr RE, Linnell JD, et al. Evaluating the relationship between plasma and skin carotenoids and reported dietary intake in elementary school children to assess fruit and vegetable intake. *Archives of biochemistry and biophysics.* 2015;572:73-80.
57. Pate RR, Almeida MJ, McIver KL, Pfeiffer KA, Dowda M. Validation and calibration of an accelerometer in preschool children. *Obesity (Silver Spring, Md.* 2006;14(11):2000-2006.
58. Trost SG, McIver KL, Pate RR. Conducting accelerometer-based activity assessments in field-based research. *Med Sci Sports Exerc.* 2005;37(11 Suppl):S531-543.
59. Washington State Department of Early Learning. ECEAP and Head Start. 2010; http://www.del.wa.gov/care/find-hs-eceap/. Accessed 02/15/2016.

60. Bryant MJ, Lucove JC, Evenson KR, Marshall S. Measurement of television viewing in children and adolescents: a systematic review. *Obes Rev.* 2007;8(3):197-209.
61. Dennison BA, Russo TJ, Burdick PA, Jenkins PL. An intervention to reduce television viewing by preschool children. *Arch Pediatr Adolesc Med.* 2004;158(2):170-176.
62. Mendoza JA, Barroso CS. Television viewing and physical activity among Latino children. In: Pérez-Escamilla R, Melgar-Quiñonez H, eds. *At Risk: Latino Children's Health*. Houston, TX: Arte Público Press; 2011.
63. Werner O, Campbell D. Translating, working through interpreters and the problem of decentering. In: Narroll R, Cohen R, eds. *A handbook of method in cultural anthropology*. New York: Columbia University Press; 1970:398-420.
64. Baranowski T, Beltran A, Chen T-A, et al. Psychometric assessment of scales for a Model of Goal Directed Vegetable Parenting Practices (MGDVPP). *International Journal of Behavioral Nutrition and Physical Activity.* 2013;10(1):110.
65. Hingle M, Beltran A, O'Connor T, Thompson D, Baranowski J, Baranowski T. A model of goal directed vegetable parenting practices. *Appetite.* 2012;58(2):444-449.
66. Valkenburg PM, Krcmar M, Peeters AL, Marseille NM. Developing a scale to assess three styles of television mediation: "Instructive mediation," "restrictive mediation," and "social coviewing". *J. Broadcast. Electron. Media.* 1999;43(1):52-66.
67. Chen T-A, O'Connor T, Hughes S, et al. TV parenting practices: is the same scale appropriate for parents of children of different ages? *International Journal of Behavioral Nutrition and Physical Activity.* 2013;10(1):41.
68. del Rio Rodriguez B, Hilmers A, O'Connor TM. Hispanic parents of overweight and obese children and their outcome expectations for children's television viewing: a qualitative study. *J Nutr Educ Behav.* 2013;45(6):718-722.
69. O'Connor TM, Chen TA, del Rio Rodriguez B, Hughes SO. Psychometric validity of the parent's outcome expectations for children's television viewing (POETV) scale. *BMC public health.* 2014;14:894. PMC4167499
70. Johnson L, Chen T-A, Hughes S, OConnor T. The association of parents outcome expectations for child TV viewing with parenting practices and child TV viewing: an examination using path analysis. *International Journal of Behavioral Nutrition and Physical Activity.* 2015;12(1):70.
71. Hughes SO, Power TG, Liu Y, Sharp C, Nicklas TA. Parent emotional distress and feeding styles in low-income families. The role of parent depression and parenting stress. *Appetite.* 2015;92:337-342.
72. Burdette HL, Whitaker RC, Kahn RS, Harvey-Berino J. Association of maternal obesity and depressive symptoms with television-viewing time in low-income preschool children. *Arch Pediatr Adolesc Med.* 2003;157(9):894-899.
73. Conners NA, Tripathi SP, Clubb R, Bradley RH. Maternal Characteristics Associated with Television Viewing Habits of Low-Income Preschool Children. *Journal of Child and Family Studies.* 2007;16(3):415-425.
74. Tate EB, Wood W, Liao Y, Dunton GF. Do stressed mothers have heavier children? A meta-analysis on the relationship between maternal stress and child body mass index. *Obes Rev.* 2015;16(5):351-361. Pmc4447110
75. Walton K, Simpson JR, Darlington G, Haines J. Parenting stress: a cross-sectional analysis of associations with childhood obesity, physical activity, and TV viewing. *BMC Pediatr.* 2014;14:244. Pmc4194416

76. Gable S, Lutz S. Household, Parent, and Child Contributions to Childhood Obesity*. *Family Relations.* 2000;49(3):293-300.
77. Ceballos RM, Molina Y, Malen RC, Ibarra G, Escareno M, Marchello N. Design, development, and feasibility of a spanish-language cancer survivor support group. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer.* 2015.
78. Molina Y, Thompson B, Ceballos RM. Physician and Family Recommendations to Obtain a Mammogram and Mammography Intentions: The Moderating Effects of Perceived Seriousness and Risk of Breast Cancer. *J Womens Health Care.* 2014;3(6). PMC4281937
79. Ceballos RM, Coronado GD, Thompson B. Having a diagnosis of diabetes is not associated with general diabetes knowledge in rural Hispanics. *J Rural Health.* 2010;26(4):342-351. PMC4022479
80. Knerr S, Ceballos RM. Giving samples or "getting checked": measuring conflation of observational biospecimen research and clinical care in Latino communities. *BMC Med Ethics.* 2015;16:49. PMC4504441
81. Scheel JR, Molina Y, Briant KJ, Ibarra G, Lehman CD, Thompson B. Latinas' Mammography Intention Following a Home-Based Promotores-Led Intervention. *Journal of community health.* 2015;40(6):1185-1192. PMCID: PMC4628570
82. Moralez EA, Rao SP, Livaudais JC, Thompson B. Improving knowledge and screening for colorectal cancer among Hispanics: overcoming barriers through a PROMOTORA-led home-based educational intervention. *J Cancer Educ.* 2012;27(3):533-539. PMCID: PMC3860278
83. Livaudais JC, Coronado GD, Espinoza N, Islas I, Ibarra G, Thompson B. Educating Hispanic women about breast cancer prevention: evaluation of a home-based promotora-led intervention. *J Womens Health (Larchmt).* 2010;19(11):2049-2056.
84. Murray D. *Design and Analysis of Group-Randomized Trials*. 1st ed. New York, NY: Oxford University Press; 1998.
85. Nicklas TA, Liu Y, Stuff JE, Fisher JO, Mendoza JA, O'Neil CE. Characterizing lunch meals served and consumed by pre-school children in Head Start. *Public Health Nutrition.* 2013;FirstView:1-9.
86. Hughes S, Power T, Papaioannou M, et al. Emotional climate, feeding practices, and feeding styles: an observational analysis of the dinner meal in Head Start families. *International Journal of Behavioral Nutrition and Physical Activity.* 2011;8(1):60.
87. Hughes S, Shewchuk R. Child temperament, parent emotions, and perceptions of the child's feeding experience. *International Journal of Behavioral Nutrition and Physical Activity.* 2012;9(1):64.
88. Hughes SO, Anderson CB, Power TG, Micheli N, Jaramillo S, Nicklas TA. Measuring feeding in low-income African-American and Hispanic parents. *Appetite.* 2006;46(2):215-223.
89. Hughes SO, Power TG, Orlet Fisher J, Mueller S, Nicklas TA. Revisiting a neglected construct: parenting styles in a child-feeding context. *Appetite.* 2005;44(1):83-92.
90. Hughes SO, Shewchuk RM, Baskin ML, Nicklas TA, Qu H. Indulgent feeding style and children's weight status in preschool. *J Dev Behav Pediatr.* 2008;29(5):403-410.
91. Jago R, Edwards MJ, Urbanski CR, Sebire SJ. General and Specific Approaches to Media Parenting: A Systematic Review of Current Measures, Associations with Screen-Viewing, and Measurement Implications. *Childhood Obesity.* 2013;9(Suppl 1):S-51-S-72.
92. Thompson D, Cantu D, Bhatt R, et al. Texting to Increase Physical Activity Among Teenagers (TXT Me!): Rationale, Design, and Methods Proposal. *JMIR Res Protoc.* 2014;3(1):e14. PMC3967196
93. Thompson D, Cantu D, Ramirez B, et al. Texting to Increase Adolescent Physical Activity: Feasibility Assessment. *Am J Health Behav.* 2016 (Forthcoming);40(4):472-483.

94. Pumper MA, Mendoza JA, Arseniev-Koehler A, Holm M, Waite A, Moreno MA. Using A Facebook Group As An Adjunct To A Pilot mHealth Physical Activity Intervention: A Mixed Methods Approach. *Studies in health technology and informatics.* 2015;219:97-101.
95. Baranowski T, Jago R. Understanding the mechanisms of change in children's physical activity programs. *Exercise and sport sciences reviews.* 2005;33(4):163-168.
96. Bandura A. *Social Learning Theory*. 1st ed. Englewood Cliffs, NJ: Prentice Hall; 1976.
97. Bandura A, Jeffery RW, Gajdos E. Generalizing change through participant modeling with self-directed mastery. *Behav. Res. Ther.* 1975;13.
98. Baranowski T, Anderson C, Carmack C. Mediating variable framework in physical activity interventions. How are we doing? How might we do better? *Am J Prev Med.* 1998;15(4):266-297.
99. Kuczmarski RJ, Ogden CL, Guo SS, et al. 2000 CDC Growth Charts for the United States: methods and development. *Vital Health Stat 11.* 2002(246):1-190.
100. Mayne ST, Cartmel B, Scarmo S, Jahns L, Ermakov IV, Gellermann W. Resonance Raman spectroscopic evaluation of skin carotenoids as a biomarker of carotenoid status for human studies. *Archives of biochemistry and biophysics.* 2013;539(2):163-170. Pmc3818359
101. Aguilar SS, Wengreen HJ, Lefevre M, Madden GJ, Gast J. Skin carotenoids: a biomarker of fruit and vegetable intake in children. *J Acad Nutr Diet.* 2014;114(8):1174-1180.
102. Scarmo S, Henebery K, Peracchio H, et al. Skin carotenoid status measured by resonance Raman spectroscopy as a biomarker of fruit and vegetable intake in preschool children. *Eur J Clin Nutr.* 2012.
103. Mendoza JA, Nicklas TA, Liu Y, Stuff J, Baranowski T. General versus central adiposity and relationship to pediatric metabolic risk. *Metab Syndr Relat Disord.* 2012;10(2):128-136.
104. Mendoza JA, Watson K, Baranowski T, Nicklas TA, Uscanga DK, Hanfling MJ. The Walking School Bus and Children's Physical Activity: A Pilot Cluster Randomized Controlled Trial. *Pediatrics.* 2011;128(3):e537-e544. PMCID: PMC3164094
105. Mendoza J, Watson K, Baranowski T, Nicklas T, Uscanga D, Hanfling M. Validity of instruments to assess students' travel and pedestrian safety. *BMC public health.* 2010;10(1):257.
106. Mendoza JA, Watson K, Baranowski T, et al. Ethnic Minority Children's Active Commuting to School and Association with Physical Activity and Pedestrian Safety Behaviors. *Journal of Applied Research on Children: Informing Policy for Children at Risk.* 2010;1(1):Article 4. PMCID: PMC3160673
107. Cerin E, Baranowski T, Barnett A, et al. Places where preschoolers are (in)active: an observational study on Latino preschoolers and their parents using objective measures. *The international journal of behavioral nutrition and physical activity.* 2016;13:29. PMC4772489
108. O'Connor TM, Cerin E, Robles J, et al. Feasibility study to objectively assess activity and location of Hispanic preschoolers: a short communication. *Geospatial Health.* 2013;7(2):375-380.
109. O'Connor TM, Chen TA, Baranowski J, Thompson D, Baranowski T. Physical activity and screen-media-related parenting practices have different associations with children's objectively measured physical activity. *Child Obes.* 2013;9(5):446-453. 3791041
110. O'Connor TM, Hilmers A, Watson K, Baranowski T, Giardino AP. Feasibility of an obesity intervention for paediatric primary care targeting parenting and children: Helping HAND. *Child: care, health and development.* 2013;39(1):141-149.
111. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. *Applied Psychological Measurement.* 1977;1(3):385-401.
112. Kim G, Decoster J, Huang CH, Chiriboga DA. Race/ethnicity and the factor structure of the Center for Epidemiologic Studies Depression Scale: a meta-analysis. *Cultural diversity & ethnic minority psychology.* 2011;17(4):381-396.

113. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *Journal of health and social behavior.* 1983;24(4):385-396.
114. Burdette HL, Whitaker RC. A national study of neighborhood safety, outdoor play, television viewing, and obesity in preschool children. *Pediatrics.* 2005;116(3):657-662.
115. Coulton CJ, Korbin JE, Su M. Measuring neighborhood context for young children in an urban area. *American Journal of Community Psychology.* 1996;24(1):5-32.
116. Marin G, Gamba RJ. A New Measurement of Acculturation for Hispanics: The Bidimensional Acculturation Scale for Hispanics (BAS). *Hisp J Behav Sci.* 1996;18(3):297-316.
117. Wallace PM, Pomery EA, Latimer AE, Martinez JL, Salovey P. A Review of Acculturation Measures and Their Utility in Studies Promoting Latino Health. *Hisp J Behav Sci.* 2010;32(1):37-54. 2891555
118. Bandura A. *Social Foundations of Thought & Action: A Social Cognitive Theory*. 1st ed. Upper Saddle River, NJ: Prentice Hall; 1986.
119. Bandura A. Health promotion by social cognitive means. *Health Educ Behav.* 2004;31(2):143-164.
120. Sharma M. School-based interventions for childhood and adolescent obesity. *Obesity Reviews.* 2006;7(3):261-269.
121. Sharma M. Physical activity interventions in Hispanic American girls and women. *Obesity Reviews.* 2008;9(6):560-571.
122. Ebbeling CB, Ludwig DS. Pediatric Obesity Prevention Initiatives: More Questions Than Answers. *Arch Pediatr Adolesc Med.* 2010;164(11):1067-1069.
123. Lubans DR, Foster C, Biddle SJH. A review of mediators of behavior in interventions to promote physical activity among children and adolescents. *Preventive Medicine.* 2008;47(5):463-470.
124. National Health and Nutrition Examination Survey (NHANES). Anthropometry Procedures Manual. 2007; http://www.cdc.gov/nchs/data/nhanes/nhanes_07_08/manual_an.pdf
125. Barlow SE. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics.* 2007;120 Suppl 4:S164-192.
126. Mendoza JA, Drewnowski A, Cheadle A, Christakis DA. Dietary energy density is associated with selected predictors of obesity in U.S. children. *J Nutr.* 2006;136(5):1318-1322.
127. Mendoza JA, Drewnowski A, Christakis DA. Dietary energy density is associated with obesity and the metabolic syndrome in U.S. adults. *Diabetes Care.* 2007;30(4):974-979.
128. Mendoza JA, Matshaba M, Makhanda J, Liu Y, Boitshwarelo M, Anabwani GM. Food Insecurity and CD4% Among HIV+ Children in Gaborone, Botswana. *Journal of acquired immune deficiency syndromes.* 2014;66(4):414-418. PMCID: PMC4205044
129. Mendoza JA, Paul ME, Schwarzwald H, et al. Food Insecurity, CD4 Counts, and Incomplete Viral Suppression Among HIV+ Patients from Texas Children's Hospital: A Pilot Study. *AIDS and Behavior.* 2013;17(5):1683-1687. PMCID: PMC3664131
130. Mendoza JA, Watson K, Cullen KW. Change in Dietary Energy Density after Implementation of the Texas Public School Nutrition Policy. *Journal of the American Dietetic Association.* 2010;110(3):434-440.
131. Nicklas TA, O'Neil CE, Mendoza J, Liu Y, Zakeri IF, Berenson GS. Are energy dense diets also nutrient dense? *J Am Coll Nutr.* 2008;27(5):553-560.
132. O'Neil CE, Deshmukh-Taskar P, Mendoza JA, et al. Dietary, Lifestyle, and Health Correlates of Overweight and Obesity in Adults 19 to 39 Years of Age: The Bogalusa Heart Study. *American Journal of Lifestyle Medicine.* 2012;6(4):347-358.

133. O'Donnell SI, Hoerr SL, Mendoza JA, Tsuei Goh E. Nutrient quality of fast food kids meals. *Am J Clin Nutr.* 2008;88(5):1388-1395.
134. Pearson N, Biddle SJ. Sedentary behavior and dietary intake in children, adolescents, and adults. A systematic review. *Am J Prev Med.* 2011;41(2):178-188.
135. Hobbs M, Pearson N, Foster PJ, Biddle SJ. Sedentary behaviour and diet across the lifespan: an updated systematic review. *British journal of sports medicine.* 2015;49(18):1179-1188.
136. Ford C, Ward D, White M. Television viewing associated with adverse dietary outcomes in children ages 2–6. *Obesity Reviews.* 2012;13(12):1139-1147.
137. Wang X, Ouyang Y, Liu J, et al. Fruit and vegetable consumption and mortality from all causes, cardiovascular disease, and cancer: systematic review and dose-response meta-analysis of prospective cohort studies. *Bmj.* 2014;349:g4490. PMC4115152
138. Nishida C, Uauy R, Kumanyika S, Shetty P. The joint WHO/FAO expert consultation on diet, nutrition and the prevention of chronic diseases: process, product and policy implications. *Public Health Nutr.* 2004;7(1a):245-250.
139. Institute of Medicine, Food and Nutrition Board, Panel on Dietary Antioxidants and Related Compounds. *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids*. Washington, DC: National Academies Press; 2000.
140. Mendoza JA, Watson K, Baranowski T, et al. Ethnic minority children's active commuting to school and association with physical activity and pedestrian safety behaviors. *J Appl Res Child.* 2010;1(1):Article 4. 3160673
141. Mendoza JA, Watson K, Nguyen N, Cerin E, Baranowski T, Nicklas TA. Active commuting to school and association with physical activity and adiposity among US youth. *J Phys Act Health.* 2011;8(4):488-495. 3115568
142. Tudor-Locke C, Camhi SM, Troiano RP. A catalog of rules, variables, and definitions applied to accelerometer data in the National Health and Nutrition Examination Survey, 2003-2006. *Preventing chronic disease.* 2012;9:E113. Pmc3457743
143. Hinkley T, O'Connell E, Okely AD, Crawford D, Hesketh K, Salmon J. Assessing volume of accelerometry data for reliability in preschool children. *Med Sci Sports Exerc.* 2012;44(12):2436-2441.
144. Penpraze V, Reilly J, MacLean C, et al. Monitoring of Physical Activity in Young Children: How Much is Enough? *Pediatric exercise science.* 2006;18(4):483-491.
145. Tudor-Locke C, Barreira T, Schuna J, et al. Improving wear time compliance with a 24-hour waist-worn accelerometer protocol in the International Study of Childhood Obesity, Lifestyle and the Environment (ISCOLE). *The international journal of behavioral nutrition and physical activity.* 2015;12(1):11.
146. Hall LA, Williams CA, Greenberg RS. Supports, stressors, and depressive symptoms in low-income mothers of young children. *Am J Public Health.* 1985;75(5):518-522.
147. Lanzi RG, Pascoe JM, Keltner B, Ramey SL. Correlates of maternal depressive symptoms in a national Head Start program sample. *Arch Pediatr Adolesc Med.* 1999;153(8):801-807.
148. Lampard AM, Franckle RL, Davison KK. Maternal depression and childhood obesity: a systematic review. *Prev Med.* 2014;59:60-67. Pmc4172574
149. Cohen S. *The Meaning and Measurement of Social Support*. New York, NY: Hemisphere Publishing Corporation; 1992.
150. Li K, Jurkowski JM, Davison KK. Social support may buffer the effect of intrafamilial stressors on preschool children's television viewing time in low-income families. *Child Obes.* 2013;9(6):484-491. Pmc3868299

151. Lampard AM, Jurkowski JM, Davison KK. The family context of low-income parents who restrict child screen time. *Child Obes.* 2013;9(5):386-392. Pmc3791034
152. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The Multidimensional Scale of Perceived Social Support. *Journal of personality assessment.* 1988;52(1):30-41.
153. Zimet GD, Powell SS, Farley GK, Werkman S, Berkoff KA. Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. *Journal of personality assessment.* 1990;55(3-4):610-617.
154. Ochoa A, Berge JM. Home Environmental Influences on Childhood Obesity in the Latino Population: A Decade Review of Literature. *J Immigr Minor Health.* 2016.
155. Schulz KF, Altman DG, Moher D, Group ftC. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials. *Annals of Internal Medicine.* 2010;152(11):726-732.
156. McCulloch CE, Searle SR, Neuhaus JM. *Generalized, Linear, and Mixed Models, 2nd Edition*. 2nd ed. Hoboken, New Jersey: John Wiley & Sons; 2011.
157. Brown RL. Assessing specific mediational effects in complex theoretical models. *Structural Equation Modeling: A Multidisciplinary Journal.* 1997;4(2):142-156.
158. Little TD, Card NA, Bovaird JA, Preacher KJ, Crandall CS. Structural equation modeling of mediation and moderation with contextual factors. In: Little TD, Bovaird JA, Card NA, eds. *Modeling contextual effects in longitudinal studies*. Mahwah, NJ: Lawrence Erlbaum Associates, Inc.; 2007:207-230.
159. Efron B. Better Bootstrap Confidence Intervals. *Journal of the American Statistical Association.* 1987;82(397):171-185.
160. MacKinnon DP, Lockwood CM, Williams J. Confidence Limits for the Indirect Effect: Distribution of the Product and Resampling Methods. *Multivariate behavioral research.* 2004;39(1):99-99.
161. Shrout PE, Bolger N. Mediation in experimental and nonexperimental studies: new procedures and recommendations. *Psychological methods.* 2002;7(4):422-445.
162. Little TD. *Longitudinal Structural Equation Modeling*. New York, NY: The Guilford Press; 2013.
163. Enders CK. *Applied missing data analysis*. New York, NY: The Guilford Press; 2010.
164. Graham JW, Cumsille PE, Shevock AE. *Research Methods in Psychology.* Vol 2. 2 ed. Hoboken, NJ: John Wiley & Sons; 2012.
165. Enders CK. Analyzing longitudinal data with missing values. *Rehabilitation psychology.* 2011;56(4):267-288.
166. Heck RH, Thomas SL. *An Introduction to Multilevel Modeling Techniques: MLM and SEM Approaches Using Mplus*: Routledge; 2015.
167. Raudenbush SW, Liu X. Statistical power and optimal design for multisite randomized trials. *Psychological methods.* 2000;5(2):199-213.
168. *Optimal Design Software for Multi-level and Longitudinal Research (Version 3.01) [Software]. Available from www.wtgrantfoundation.org.* [computer program]2011.
169. Cohen J. *Statistical power analysis for the behavioral sciences*: Lawrence Erlbaum; 1988.
170. Snijders TAB, Bosker RJ. *Multilevel analysis: An introduction to basic and advanced multilevel modeling*. Thousand Oaks, CA: Sage Publications Ltd.; 2012.
171. Vittinghoff E, Sen S, McCulloch CE. Sample size calculations for evaluating mediation. *Stat Med.* 2009;28(4):541-557.
172. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006;3(2):77-101.
173. Krueger R. *Developing Questions for Focus Groups: Focus Group Kit #3*. Thousand Oaks, CA: Sage Publications, Inc; 1998.

174. Archer E, Hand GA, Blair SN. Validity of U.S. Nutritional Surveillance: National Health and Nutrition Examination Survey Caloric Energy Intake Data, 1971–2010. *PLoS One.* 2013;8(10):e76632.
175. Archer E, Pavela G, Lavie CJ. The Inadmissibility of What We Eat in America and NHANES Dietary Data in Nutrition and Obesity Research and the Scientific Formulation of National Dietary Guidelines. *Mayo Clinic proceedings.* 2015;90(7):911-926. PMC4527547
176. Hebert JR, Hurley TG, Steck SE, et al. Considering the value of dietary assessment data in informing nutrition-related health policy. *Advances in nutrition.* 2014;5(4):447-455. PMC4085192
177. Davy BM, Estabrooks PA. The Validity of Self-reported Dietary Intake Data: Focus on the "What We Eat In America" Component of the National Health and Nutrition Examination Survey Research Initiative. *Mayo Clinic proceedings.* 2015;90(7):845-847.