

Document Cover Page

Official Title of the Study: Improving Parent-Child Interactions to Enhance Child Health

NCT Number: NCT03982511

Date of Document: 4/5/2023

Study Protocol and Statistical Analysis Plan (SAP)

Study Protocol

After determining eligibility, potential participants will be invited to the Center for Children, Families, and Communities (CCFC) to provide consent and complete baseline measures. Following completion of clinic-based baseline measures, participants will be instructed on how to complete home-based baseline measures (e.g., family mealtime recordings, Actigraphs). One week later, research assistants will obtain home-based assessments from families' homes. After these assessments are completed, research assistants will inform families whether they have been randomly assigned to intervention or waitlist control condition. Random assignment will be determined by random number generator and stratified by child sex. See Table 1 for assessment protocol and timeline. Participants in the intervention condition will receive PCIT-Health and participants in the waitlist control condition will be offered the intervention after 6-month post-intervention measures are completed (i.e., 10 months after they have enrolled in the study). After baseline, assessments will occur: (1) at completion of PCIT-Health intervention and (2) at 6-months post-intervention completion. All participants (regardless of condition) will complete these additional assessments after baseline. In other words, all participants will complete three different assessments.

PCIT-Health Intervention

Given that the pandemic necessitated virtual delivery of treatment, a telehealth version of PCIT-Health was delivered. See Domoff et al. (2022) for how PCIT-Health (Domoff & Niec, 2018) was adapted to be delivered through virtual conferencing. PCIT-Health consists of three phases: Child-Directed Interaction (CDI), Parent-Directed Interaction (PDI), and Health-Directed Interaction (HDI; Domoff & Niec, 2018). During CDI, parents learn child-centered play/interaction skills to enhance the parent-child relationship. During PDI, parents learn age/developmentally- appropriate discipline skills. In the HDI teaching session, we provide psycho-education about beneficial parenting practices in areas specific to children's weight-related behaviors: parental feeding practices and parenting around screen time (i.e., media parenting). Three coaching sessions (guided and reinforced implementation of skills learned in the teaching session) focus on two primary contexts where children are socialized around eating and activity: (1) family mealtime and (2) unstructured child play/free time (see Domoff et al., 2022 & Domoff & Niec, 2018 for more comprehensive descriptions of the sessions).

References:

Domoff, S. E., & Niec, L. N. (2018). Parent-child interaction therapy as a prevention model for childhood obesity: A novel application for high-risk families. *Children and Youth Services Review*, 91, 77-84.

Domoff, S. E., Overton, M. M., Borgen, A. L., & Niec, L. N. (2022). Adapting PCIT-Health for Telehealth Delivery: A Case Study. *International Journal of Environmental Research and Public Health*, 19(14), 8352.

Measures

Feasibility and Acceptability Measures (AIM 1)

Feasibility and acceptability measures will be administered once, at treatment completion. The acceptability of PCIT-Health will be measured by the Abbreviated Acceptability Rating Profile (AARP) and Therapy Attitude Inventory (TAI), which assesses parents' satisfaction with parent training interventions. Both measures have strong psychometric properties. The Barriers to Treatment Participation Scale (BTPS) will be administered as well.

Primary (AIM 2) and Secondary (AIM 3) Outcome Measures

The following measures will be assessed at each time point (baseline, post-treatment, and 6-month follow-up). There has been increasing recognition of need for observational measures of parenting; as such, we will assess secondary outcomes of PCIT-Health (e.g., parent-child relationship quality, and parent behavior management skills in general and obesity-specific contexts) using both observational and parent-report measures (see below and Table 1 for assessment visit activities).

Child Anthropometrics

Change of child BMI z-score from baseline to (1) completion of PCIT-Health and (2) six-month follow-up will be calculated as the primary outcome variable (**AIM 2**). Child height and weight will be measured by trained research assistants, using a Detecto Portable Scale Model and a Seca portable stadiometer. Children will be weighed twice and if the two readings differed by more than 0.1 kg, the child will be weighed two more times. For the height measurement, the child's position and posture will be checked, and height will also be measured twice. As with weight, if measurements differ by more than 0.5 cm, two more measurements will be taken. BMI will be calculated and the child BMI z-score will be derived using age- and sex-specific norms.

Child Self-Regulation

Emotion Regulation Checklist (ERC) is a 24-item parent-report measure that assesses parents' perception of their child's affective regulation and emotionality. Two subscales are calculated based on parent responses. The first, Emotion Regulation,

Table 1. Protocol	
Time	Activity
Clinic Assessments	
4pm	Instructions for Clinic Visit
4:15	Parent completes questionnaires
5:15	DPICS protocol
5:45	Child and caregiver anthropometry
5:55	Instructions for home based measures
Home Assessments	
Frequency/Description	
3 dinners	Family Mealtime Recordings
7 days	Actigraph assessments

assesses a child's adaptive regulation and expression or emotion. The second, Lability/Negativity, assesses a child's emotional intensity, negative reactivity, and dysregulation of positive emotions.

Child Weight-Related Behaviors

Child Screen Time. Caregivers will report on children's typical weekday and weekend screen time (including TV, tablet, computer, video game use). Items request caregivers to give estimates based on different parts of the day (e.g., "How many hours did your child [watch TV/videos/use mobile device/use computer/play video games] from the time he/she wakes up until going to [daycare/preschool]" to facilitate recall. Parents will also report on Problematic Media Use (Domoff et al.,2019).

Child Physical Activity. Objective measures of habitual physical activity will be monitored by a wGT3X-BT Actigraph accelerometer (ActiGraph of Ft. Pensacola, FL) and analysis with ActiLife6 software (ActiGraph of Ft. Pensacola, FL). Participants will be asked to wear the device for seven consecutive days while they are awake and to remove it while swimming or bathing. Any block of time greater than or equal to 60 minutes where the activity count is equal to zero will be considered time when the monitor was not worn. Each minute of accelerometer data will be coded based on the recorded activity counts for that minute associated with sedentary, moderate, moderate-to-vigorous, and vigorous physical activity as previously described in children.

Parent-Child Relationship Quality

Dyadic Parent-Child Interaction Coding System-IV (DPICS-IV). The DPICS is a standardized, behavior observation measure of parent-child interactions during three situations in which parents must exert increasing control over their children. It provides a reliable measure of parenting behaviors (e.g., child-centered skills, positive and negative physical interaction, use of contingent reinforcement).

Parenting Stress Index, Fourth Edition, Short Form (PSI-4/SF). The PSI-4/SF is a 36-item self-report measure assessing parenting distress in parents of children 3 months to 12 years of age. Three subscales are included: Parental Distress assesses distress related to a respondent's role as a parent; Parent-child Dysfunctional Interaction assesses distress associated with a parent's relationship with a target child; Difficult Child (DC) assesses distress associated with a target child's difficult behaviors. The PSI has demonstrated good to excellent reliability and validity, including internal consistency, test-retest reliability, and discriminant and factorial validity. Scores on the Parent-child Dysfunctional Interaction subscale will be used as the parent-report of parent-child relationship quality.

Parent Behavior Management Skills in General and Obesity-Specific Contexts

Parent behavior management skills in general (non-obesity specific contexts) will be measured by the DPICS-IV. Parent behavior management skills in obesity-specific contexts will be measured in the domains of feeding and screen media use. Parents will

complete self-report measures (detailed below) and research assistants will code recordings of family mealtime observations to assess behavior management skills in the obesity-specific context.

Parent feeding practices and styles. How caregivers feed their children will be measured by parent report on the subscales of Pressure to Eat and Restriction on the Child Feeding Questionnaire (CFQ) and Caregivers' Feeding Styles Questionnaire, Emotional feeding (using food to help regulate child's emotions) and instrumental feeding (using food as a reward) will be measured with respective subscales on the Parental Feeding Style Questionnaire.

Media parenting practices. Parenting practices related to children's media exposure and screen time will be measured by self-report, using the Parental Mediation Scale. This Scale measures three types of media parenting: active mediation, co-viewing, and restrictive mediation and has strong psychometric properties. Caregivers will also report on other aspects of media parenting practices related to child obesity risk, including the number of screens in the home and in the child's bedroom.

Observational Coding of Parenting during Mealtime. Family mealtime characteristics and interactions will be assessed through coding of recorded family mealtimes. Caregivers will be provided a videorecorder and tripod and instructed how to record three typical dinnertime meals in the home. These video recordings will be coded for a variety of behaviors. **Parent feeding behaviors** will be coded using an adapted version of the Mealtime Interaction Coding System. **Media parenting practices** (e.g., presence of screen media, type(s) of screen media present, TV on) during mealtime will be coded.

Statistical Analysis Plan

Aim 1. To assess the acceptability and feasibility of the PCIT-Health intervention delivery and assessment methods.

To address Aim 1, descriptive statistics (e.g., means and frequencies) of the parent-report measures assessing acceptability of PCIT-Health (e.g., AARP, TAI, and BTPS) will be calculated. Proportions of treatment completers to enrollees will be calculated as well as frequencies of total sessions attended. In addition we will use multivariate regression models to identify factors that increase/decrease PCIT-health participation. Such information would be valuable and will be used to enhance participation in the program.

Aim 2. To test the preliminary efficacy and estimate the effect size of PCIT-Health in parent-child dyads randomly assigned to PCIT-Health or wait-list control on change in child BMI z-score (primary outcome) from baseline to (1) treatment completion and (2) 6-month post-intervention follow-up.

Repeated measure ANOVA will be used for testing change in child BMI z-scores between (1) baseline and post-intervention and (2) baseline and 6 month follow up will

be conducted. Given that the sample size is not very large for this study, we will report both statistical significance as well as the effect size. The magnitude of the effect size would show the potential effect of PCIT-Health when applied to a larger population.

Aim 3. To explore the effect of PCIT-Health on the following secondary outcomes: (1) child self-regulation, (2) child eating behaviors, (3) physical activity, and (4) child screen media use.

Similar to Aim 2, repeated measure ANOVA will be used for testing change in secondary outcomes between (1) baseline and post-intervention and (2) baseline and 6 month follow up will be conducted. Both the significance level and the effect size will be reported to fully understand the magnitude of the treatment effect.