**Study Protocol and Statistical Analysis Plan**

# Adapting a Parenting Intervention to Promote Healthy Screen Time Habits in Young Children with Behavior Problems

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## Study Protocol

### Background

The sharp rise over the past decade in young children's access to mobile devices (e.g., smartphones, tablets) has posed new and significant challenges to parents in managing their children's screen media use.[1,2] For parents of young children with externalizing behavior problems, managing children's time with screen media ("screen time") is especially important and represents a significant public health priority. Studies have identified early externalizing behavior problems as a risk factor for increased screen time in young children,[3,4] and increased screen time is associated with higher levels of externalizing behavior problems and other negative outcomes (e.g., sleep problems, obesity).[5,6] Thus, in the current project, we propose to develop and examine the initial efficacy of a screen time intervention designed for parents of children with externalizing behavior problems, which will have the potential for high impact and broad dissemination. This project will focus on adapting a group-based parenting intervention, the School Readiness Parenting Program (SRPP).

### Objectives

1) Develop the screen time adapted parenting intervention for parents of preschool-aged children with externalizing behavior problems to intervene more directly around screen time, including:
   a. Adapting the existing manual for the targeted behavioral parenting intervention (SRPP) to infuse intervention strategies around screen time.
   b. Implementing an open trial to collect initial data on utility, feasibility, and acceptability of the screen time adapted parenting intervention.
   c. Revising the manual based on: (i) data from the open trial, and (ii) feedback from an experts in behavioral parenting interventions and early media use, as well as community stakeholders, including parents and parenting interventions providers.
2) Examine the feasibility, acceptability, and initial efficacy of the screen time adapted parenting intervention in a pilot randomized controlled trial. We expect that, in comparison to controls receiving the standard intervention, families receiving the screen time adapted intervention will show increased reported use of use of positive technology-related parenting strategies for managing child screen time (e.g., monitoring, limit-setting), decreased frequency of overall child screen time, and increased proportion of child screen time that is educational.

### Study Design

The study took place over two years and was divided into two phases. In phase 1, we developed a manual to infuse SRPP with key screen time intervention components without extending the length of the intervention or reducing the focus on externalizing behavior problems. We developed detailed session guides, parent handouts, and revised fidelity checklists. Following development, we conducted an open trial with 10 families recruited from participants of a summer camp for children with behavior disorders (Summer Academy). The Summer Academy program runs for 8 weeks (June-August) each summer and includes a once weekly (on Wednesdays) parent intervention group using the SRPP model. Parents choose to participate in a morning group (after child drop-off) or an afternoon group (before child pickup). Open trial participants participated together in one group on Wednesday morning (the more popular time slot in past years of Summer Academy), simultaneously and for the same length of time as the original parenting groups (1.5-hour group sessions weekly over 8 weeks). We

collected data on feasibility, fidelity, and parent satisfaction, as well as pre-, post-, and 1-month follow-up measures of child screen media use and parent behavior. The manual was revised based on feedback from parents and expert consultants. In phase 2, we conducted a pilot RCT using the revised manual by randomly assigning 20 families to receive the adapted intervention and 20 families to the control group receiving the original SRPP. Two pairs of clinicians with master's level training, supervised by Co-I Hart, led each group. The intervention for both study arms was delivered in 1.5-hour group sessions weekly for 8 weeks, with parents within each arm choosing whether to attend a morning or afternoon session. Group composition within each arm could change week to week, consistent with the standard practice for Summer Academy. Group size in each session was approximately 10 parents. We offered makeup group sessions later in the same week for parents who missed the weekly session, consistent with the standard practice for Summer Academy.

**Recruitment, Screening, and Eligibility**

Participants for the open trial and the pilot RCT were recruited from families attending Summer Academy, an 8-week summer camp for 50 preschoolers with externalizing behavior problems. The program included a classroom-based curriculum targeting child school readiness skills (i.e., academic and social-emotional) and a mandatory once-weekly group parenting intervention (i.e., SRPP). Eligibility criteria for the summer program included elevated externalizing behavior problems, child general cognitive ability of 70 or above on the Differential Ability Scales II, and one parent able to attend the weekly group sessions. Based on past demographics of summer program participants, study participants were low-income and largely Black/African American. For the 2019 Summer Academy program, 89% of families were Black/African American, and the median reported annual income range of the primary caregiver was $23,493 - $27,827. Families were recruited through partnerships with local preschools and Head Start programs. Teachers shared information about the program with parents of students they identified as having behavioral concerns. Interested parents contacted Summer Academy staff, and the parent and child completed screening for eligibility. For the open trial, we invited parents who had been accepted into the Summer Academy program to participate in the adapted curriculum and complete additional measures of screen time and satisfaction. We had a sample target of 15 families for the open trial, but as overall camp attendance had declined after COVID-19, the final sample for the open trial was 10. For the pilot RCT, all parents completing the consent process were informed that new elements on managing children's screen time were being tested in the program, and they might or might not be assigned to a group that contained these elements. 34 families were originally recruited for the RCT, though 3 did not begin participation in the summer camp, and therefore did not receive any intervention.

**Intervention**

The screen time adapted parenting intervention was an adaptation of the School Readiness Parenting Program (SRPP), which is an 8-week evidence-based parenting program for parents of preschool-aged children with externalizing behavior problems. The SRPP is designed to target child externalizing behavior problems specifically, as well as to help parents promote their children's school readiness skills (early academics and social-emotional/behavioral functioning). The SRPP contains traditional aspects of behavioral management strategies (e.g., improving parenting skills and the parent-child relationship; discipline strategies such as time out) that have historically been implemented and found efficacious in behavioral parenting intervention programs. The SRPP follows a group Parent-Child Interaction Therapy (PCIT) model and also

uses motivational interviewing and modeling problem-solving approaches. The SRPP utilizes a large group format (10-15 parents) with weekly sessions lasting 1.5 hours. Parents received initial didactic information on skills involving positive parent-child interaction (i.e. the child-directed interaction or “special time” skills) and use of effective commands and time out for discipline (i.e. parent-directed interaction). Parents then broke into subgroups of 3-4 parents for skill practice. During subgroup activities, parents practiced their newly acquired skills with their own children while the other parents in the subgroup observed, recorded, and provided feedback on the parents’ performance. Parents rotated through actually practicing the skills and serving as the observers. In this manner, parents were being trained in how to be the “therapist” in terms of knowing what to look for, providing feedback, and then trying the skill themselves. The therapist’s role during these subgroup activities was to help the parents who were observing as well as provide feedback to parents who were practicing their skills. In addition to a focus on improving the parent-child relationship and reducing externalizing behavior problems, specific sessions of the SRPP also directly targeted parental interactions during children’s learning activities. Setting up homework and household structure and routines to support behavioral and academic functioning (e.g., through good sleep hygiene) was also addressed. In its original form, SRPP did not address management of children’s screen time.

To adapt the SRPP intervention, we first reviewed the literature on how screen media use affects children’s behavior and academic outcomes, as well as previous screen media interventions, to guide the content of the adapted parenting intervention. Four major themes were identified: (1) setting screen media routines, (2) monitoring and limiting screen time, (3) choosing educational content, and (4) encouraging positive caregiver-child media interactions. Changes were made to session objectives and materials to include these themes without lengthening sessions. For example, screen media was integrated into discussions on reward systems and behavioral strategies like differential attention. Key adaptations included: (1) using media-relevant examples for behavioral principles, (2) adding discussions on media routines alongside other daily routines (e.g., sleep), and (3) incorporating media-related check-ins during existing progress reviews.

Experts in child media use and parenting reviewed both the initial draft of the intervention protocol and the results of the open trial and changes were made based on their suggestions. Changes made included adding content around caregiver modeling of healthy screen habits, addressing the harms of using media to soothe children, and discussing developmental changes in media routines. The revised intervention protocol was then used for the pilot RCT, with the original SRPP curriculum serving as the control condition.

The parent group for the open trial was led by a master’s-level clinician with previous experience as a group leader of SRPP, along with Co-PI Griffith, who had extensive experience delivering parent training interventions. Before the open trial, Co-PI Griffith and the clinician attended the clinician trainings for SRPP held before the start of Summer Academy each year, with Co-I Hart (co-developer of the SRPP). Co-PI Griffith, the clinician, and Co-I Hart also met for 4 additional hours of training before the start of the open trial to review and discuss the adaptations to the SRPP program in the adapted manual, and weekly during the open trial for supervision. Any potential adaptations to the SRPP training needed in addition to the adapted session guides were noted at this phase for use in the pilot RCT. For the pilot RCT, two master’s level clinicians with experience delivering parent training interventions were recruited to lead the

screen time adapted parenting intervention groups, while two others led the original SRPP (control) groups.

**Outcomes and Assessment**

Study outcomes were assessed in both trials at a baseline (pretest), posttest (immediately after the 8-week intervention), and approximately 2 months following the end of the intervention (follow-up0. The primary caregivers were compensated $25 at the baseline timepoint, $50 at the posttest timepoint, and $45 at the follow-up time point for their completion of measures. Caregivers in the open trial who completed an additional semi-structured interview were compensated $50. The pre- and post-test questionnaire measures were completed by parents during intake and exit appointments with Summer Academy. Families were contacted 1 month after the post-test to complete measures online or by phone, to avoid the burden of an in-person appointment.

**Program feasibility and satisfaction.** We used measures of parent enrollment, attendance at sessions and homework completion between sessions, and clinician adherence to the protocol coded from videotapes to assess feasibility. Parent satisfaction was measured using the Treatment Attitude Inventory (TAI), which is a widely used measure of satisfaction with parenting programs. The TAI was administered at the posttest. Caregivers in the open trial were additionally invited to complete a semi-structured interview about their experiences and thoughts on the adapted intervention at the follow-up time point.

**Screen media use patterns.** At each time point, caregivers were asked to report for the most recent weekday and the most recent weekend day: (1) the child's total amount of screen time, (2) the proportion of screen media content that the child watched that was educational (3) the shows, movies, or apps used; and (4) whether the parent co-used screen media with the child on those days. Caregivers in the open trial were also asked to submit screenshots of the app use summary page from the inbuilt Screen Time (iOS) or Digital Wellbeing (Android) tools of any device the child used, from which information about total daily use of that device and the name and duration of each app used over the previous week (7 days) was gathered. They received $10 for each set of screenshots (up to $30 over all timepoints).

**Technology-related parenting skills.** Technology-specific parenting skills were measured using items from the Technology-related Parenting Scale (TPS), which assesses parents' use of screen time rules and enforcement strategies. Parents' perceived efficacy in using electronic media and managing children's screen time was assessed using the Perceived Parental Efficacy subscale of the Parent Perceptions of Technology Scale (PPTS). The TPS and PPTS were given at the pretest, posttest, and follow-up assessments.

**Child behavior.** Child externalizing behavior problems were measured using the total score for externalizing behavior on the Behavior Assessment Scale for Children (BASC).

## Statistical Analysis Plan

The primary goal of the proposed open trial was to inform the revision of the adapted intervention to be used in the pilot RCT, while the primary goal of the pilot RCT was to inform the design of future appropriately powered trials. As such, we acknowledged that the pilot RCT was underpowered for complex statistical inferences. Instead, sample size for the pilot RCT was determined based on published guidance by Whitehead et al.,[7] of 10 to 20 participants per arm for pilot studies with a targeted small effect size. Consistent with expert recommendations, we did not rely on one data point but rather a convergence of data to determine if it was feasible and clinically meaningful to pursue further examination of this intervention. Decisions concerning future development relied upon several factors, including treatment adherence, statistical and clinical significance of outcomes, effect size estimates, treatment satisfaction, and dropout rate.

**Acceptability/feasibility.** Descriptive statistics were used to inspect participant attendance, homework completion, and parent satisfaction measures (TAI), as well as treatment integrity and fidelity for the intervention. Scores of 80% or higher on percentage of treatment components delivered were considered evidence of feasibility for the delivery of the treatment. These thresholds were based on attendance rates recorded for previous SRPP groups and other group-based PCIT treatments, as well as typical treatment fidelity score targets for standard PCIT.

**Improvement in outcomes.** Preliminary outcome data for the open trial were explored using examination of effect sizes and paired samples t-tests on scores for technology-related limit setting and self-efficacy, total amount of screen time, and proportion of screen time that was educational. For the pilot RCT, we conducted ANCOVAs with pretest scores as a covariate for the posttest and 1-month follow-up scores, to explore the effect of the adapted intervention on outcomes from pretest to posttest and follow-up, compared to the control condition. We also included covariates for relevant demographic variables known to impact both screen media use and parenting treatment effects, including annual household income and household size (to approximate income-to-needs ratio) and caregiver education. We also added externalizing behavior as a control variable because children who received the standard SRPP had significantly higher levels of externalizing behavior at pre-test on the BASC-3, $t(28) = -2.156$, $p = .04$, compared to children who received the adapted SRPP intervention. We also examined effect sizes for change in each group. We hypothesized that parents in the adapted group would report decreased screen time, increased proportion of screen time that was educational, increased scores on technology-related parenting skills, and increased frequency of co-use of media with children.

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