Study Protocol and Statistical Analysis Plan

Identifiers: NCT02723916

Title: Parent Training in Pediatric Care: A Self Directed Tablet-Based Approach

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The **specific aims** are:

Aim 1. Test the direct effects of the 6-module *e*CPP on parenting outcomes (parenting behavior, self-efficacy, and stress) and child outcomes (child problem and prosocial behavior) compared to an enhanced usual care control condition among low-income parents with young children seen in primary care.

HYPOTHESIS 1A: Relative to parents in the control condition, parents in the *e*CPP condition will report greater improvements in parenting and child outcomes at the 3-month assessment.

HYPOTHESIS 1B: The improvements in parenting outcomes and child outcomes the *e*CPP condition relative to the control condition will be maintained through the 6- and12-month assessments.

Aim 2. Compare the cost-effectiveness of the *e*CPP relative to control for parenting and child outcomes. **HYPOTHESIS 2**: The *e*CPP is cost-effective relative to control for parenting and child outcomes.

Aim 3. Quantify the levels of program implementation of the *e*CPP in primary care using the RE-AIM framework. **RESEARCH QUESTION 3:** What is the degree of Reach, Efficacy, Adoption, Implementation, and Maintenance of the *e*CPP intervention in pediatric primary care

Study Design. The study will be a person-randomized clinical trial comparing the effects of the *e*CPP tablet-based intervention to an enhanced usual care control condition (Table 1). Parents (*n* = 312) of 2- to 5-year-old children will be recruited from 4 primary care practices and randomly assigned to either the *e*CPP or control condition. Randomization will occur within sites at the participant level. Intervention parents (*n* = 156) will complete the 6 modules of the *e*CPP over a period of 3 months (~2 weeks/module; intervention phase) with ongoing access to the program (reference phase) throughout the remainder of the study period. Control condition parents (*n* = 156) will receive tablet-based parenting materials that they would normally receive at their primary care practice (e.g., information regarding nutrition, immunization, and exercise) and have access to the materials over the same intervention time period. Data collection in both conditions will occur at baseline and at 3, 6, and 12 months post-baseline. A descriptive design will be used to evaluate implementation of the *e*CPP from the perspective of practice sites, clinicians, and parents. Guided by the RE-AIM framework, we will use surveys, electronic health records, data usage metrics, and post-implementation assessments to evaluate the implementation process over the study period.

Measures.

Aim 1: Randomized Control Trial. All measures are written at the 5th grade reading level and administered on an Android tablet as computer assisted, self-interviews (CASIs). An audio option (audio-CASI) is available if parents prefer to listen to the questions. All control and outcome data are obtained by parent self-report and will be collected at each of the 4 data collection time points (baseline, 3, 6, and 12 months post baseline). Previous findings from RCTs of the group-based CPP have found significant findings across three sources of data: parent self-report, teacher report and parent-child observation.[14,24] In these studies, the parent self-report findings have consistently agreed with other methods of measuring parent and child outcomes. For this reason, the source of parenting and child outcome data for this study will be parent self-report alone.

Control variables. We will collect information on social determinants of health that may affect parenting and child behavior outcomes. The social determinants of health are: general demographics, income and economic hardship, and neighborhood and community characteristics.[69] Demographics (e.g., age, race/ethnicity, household structure) will be collected using a 21-item demographic inventory. Income and economic hardship will be assessed with a 9-item income inventory and an economic hardship scale (7 items).[70] In our current study, Cronbach's alpha for the economic hardship scale was .68. Neighborhood and community characteristics will be collected using 9 items from the National Survey of Children's Health.[71] Questions include perceived neighborhood social support, condition, and safety.

Outcome variables. Primary parenting outcome variables include parenting behavior, self-efficacy, and stress. The primary child outcomes are child behavior problems and prosocial behavior. All survey data are obtained by parent self-report and will be collected at each of the 4 data collection time points (baseline, 3, 6, and 12 months post baseline). Parenting behavior will include parenting discipline strategies and positive parenting

behavior. Parenting discipline strategies will be measured using the 40-item Parent Questionnaire (PQ). Three scales – warmth, follow-through on discipline, and corporal punishment – using a 5-point scale measure how parents discipline their children. Cronbach's alpha for the three subscales are .84, .80, and .68, respectively.[14] The PQ is a valid measure of parenting behavior and discipline skills in African American and Latino families.[14,72] Positive parenting behavior will be assessed using the 21-item Parenting Young Children (PARYC) measure using a 7-point scale. There are three subscales for the PARYC: supporting positive behavior, setting limits, and proactive parenting. Cronbach's alpha for the three scales are .78, .79, and .85, respectively.[73] Parenting self-efficacy will be evaluated using the 17-item Parenting Sense of Competence Scale (PSOC). The PSOC has two subscales using 6-point scales: satisfaction (person's liking of the parenting role) and efficacy (person's perceived competence in the parenting role). Cronbach's alpha for the total scale, satisfaction, and efficacy subscales are .79, .80, and .80, respectively.[74,75] The PSOC is correlated with other measures of family life and child behavior, and the satisfaction subscale is strongly correlated with measures of child behavior, parent well-being, and parenting style.[74,76] Parenting stress will be assessed with the Parenting Stress Index-Short Form (PSI-SF). The PSI-SF is a 36-item survey with three scales using a 5-point scale: parental distress, parent-child dysfunction, difficult child.[77] Cronbach's alpha is .90 for the total scale, .79 for parental distress, .80 for parent-child dysfunction, and .78 for difficult child.[78] The PSI-SF is a valid measure of parenting stress in multicultural samples and for parents from lower socioeconomic groups.[79,80]

We will measure child behavior problems using the Eyberg Child Behavior Inventory (ECBI).[81] The ECBI is a 36-item scale designed to measure the presence and intensity of problem behavior. Each item is measured on two scales: the Problem Scale (dichotomous) and Intensity Scale (7-point). The ECBI is a valid measure of child behavior problems, with established convergent validity across racial and ethnic populations and economically and linguistically diverse samples.[81-83] Cronbach's alpha reliabilities of the Intensity and Problem Scale scores are.92 and .99.[24] In addition, the Strengths and Difficulties Questionnaire (SDQ) will provide a measure of child behavior problems and prosocial behavior. The 25-item SDQ has a five-factor structure (emotional, conduct, hyperactivity-inattention, peer, and prosocial) using a 3-point scale. Mean Cronbach's alpha for the SDQ is .73.[84] The SDQ has been validated in multiple cultures and socioeconomic levels.[85]

Aim 2: Cost effectiveness analysis. Data for the cost effectiveness analyses will be drawn from invoices, staff report, study records, EHR, and *e*CPP electronic time stamps (Table 4). Resources used for the intervention include the *e*CPP costs (e.g., tablet, tech support, and maintenance costs), modification of the EHR, orientation for clinicians, and time for the clinician to introduce the study to parents during well-child visits. Participant costs are primarily the parents' opportunity costs, representing the value of their time spent in the intervention or control condition, respectively. Participant costs include time spent completing the *e*CPP. Resources used will be translated into costs by multiplying the number of units with the cost per unit for each cost category.

Table 4. Description of Resource and Cost Measures

Cost Category	Source	Unit of Measure	Translation to Costs
***e*CPP costs**			
*e*CPP delivery costs	Invoice	Participant	Average cost/participant
Orientation delivery costs			
EHR modification	Programmer report	Minutes/site	Programmer average hourly wage
Clinician time receiving study orientation	Study records	# of clinicians Minutes/clinician	Clinician average hourly wage
Time to lead orientation	Study records	Minutes	Study staff average hourly wage
Clinician costs			
Time to introduce study*	EHR	Minutes/ participant	Clinician average hourly wage
Parent costs			
Time spent learning about the study*	EHR	Minutes/ participant	Parent average hourly wage
Time spent completing *e*CPP modules	digital time logs	Minutes/ participant	Participant average hourly wage

EHR = Electronic Health Record; *time for introducing and learning about the study includes all parents (non-participants and participants), averaged across the # of participants.

Aim 3: RE-AIM data collection. Process tracking forms will be created to record the evaluation data, if not already part of the RCT outcome data (Table 5). These data will be collected monthly by study staff at each site during the recruitment phase from the 4 primary care practice sites, clinicians, and participants.

Table 5. Data and Source for RE-AIM Evaluation

RE-AIM component	Data and Source
REACH: Proportion and characteristics of parents from the practices that were introduced to and enrolled in the study.	# of monthly well-child visits for children aged 2-5 over course of study recruitment (source: EHR) # of parents who were introduced to the study during a well-child visit (source: EHR) # of parents who enrolled in the study (consented/randomized) # of parents who were not introduced to the study and reason (source: EHR) Characteristics of parents enrolled in the study (source: demographics [C.5.a], Technology Inventory[a])
EFFICACY: Evaluation of intervention efficacy.	Efficacy of the *e*CPP intervention is assessed as part of the RCT arm of the study by changes in parenting and child behavior. **[Specific Aim 1- RCT (Hypothesis 1a)]**
ADOPTION: Characteristics of clinicians and practices oriented and agreeing to deliver the intervention (e.g., introduce the study to eligible parents).	Clinician characteristics: MD or NP, specialty, years in practice, and current practices of managing parenting and child behavior concerns (source: Primary Clinician Survey[b]). Site characteristics: # of patients aged 2-5, average time of well-child visits (source: EHR). # of orientation sessions per practice site and proportion of clinicians that attend the orientation (source: attendance records).
IMPLEMENTATION: Assessment of the delivery of the introduction of the study by clinicians and associated costs.	Proportion of clinicians that introduce the study to parents of patients aged 2-5 at well-child visits (source: EHR). Tracking and monitoring any implementation adaptations by the clinicians (source: clinicians). **NOTE:** Evaluation of implementation-related cost will occur as part of data collection and analysis of Aim 2 **[Specific Aim 2- cost-effectiveness analysis].**
MAINTENANCE: Evaluation of the practice site maintenance of implementation procedures and participant level maintenance of behavior change.	Evaluation of maintenance of procedures across the study period at the practice sites (source: recruitment rates, # of parents introduced to the study monthly). # of follow-up orientation sessions for clinicians. Assessment of implementation challenges and facilitators, and sustainability of activities in clinical practice (source: post-implementation interviews with clinicians). Maintenance of behavior change over time will be assessed as part of the RCT arm of the study. **[Specific Aim 1- RCT (Hypothesis 1b)]**.

EHR = Electronic Health Record. [a]The Technology Inventory includes 18 items for parents to respond to about their use and ownership of technology. [b]The Primary Clinician Survey[86] is a 25-item measure developed by Metzler and colleagues for their 2014 NIH-funded grant "Parenting Help Online Study" to assess pediatric primary care clinicians' current practices in helping parents with child behavior problems and parenting concerns. The measure will be used with permission by the authors; no reliability data has been reported. (Appendix B)

Analytic plan.

Aim 1. Test the direct effects of the 6-module *e*CPP on parenting outcomes (parenting behavior, self-efficacy, and stress) and child outcomes (child problem and prosocial behavior) compared to an enhanced usual care control condition among low-income parents with young children seen in primary care. **HYPOTHESIS 1A:** Relative to parents in the control condition, parents in the *e*CPP condition will report greater improvements in parenting and child outcomes at the 3-month assessment. **HYPOTHESIS 1B:** The improvements in parenting outcomes and child outcomes the *e*CPP condition relative to the control condition will be maintained through the 6- and12-month assessments.

All analyses for Aim 1 will be performed on an intent-to-treat basis. As multiple dependent variables are being examined, a repeated-measures multivariate analysis of variance (assessment x intervention condition) will be conducted to ensure control of experiment-wise Type-I error, and to perform an initial assessment of intervention effects. We will then test intervention efficacy using multilevel growth models[90-92] with three levels (assessments [Level 1] within parent [Level 2] within primary care practice site [Level 3]). Intervention condition will be dummy coded (*e*CPP vs. control) at Level 2, and covariates at site-level (e.g., clinic size) or parent-level (e.g., age, race/ethnicity) will be included at the appropriate level of analysis. By including baseline measures of the outcome variable being tested as a covariate at Level 2 (parent level) and setting the intercept at the 3-month assessment, we will be able to test Hypothesis 1A (intervention effects between baseline and 3-month assessment) as the main effect of intervention condition (i.e., controlling for baseline level of the outcome being tested). The condition x time interaction will then serve to test differential change in outcome measures following the 3 months of active intervention, and planned contrasts will be estimated to test Hypothesis 1B (maintenance of intervention effects at 6 and 12 months).

Aim 2. Compare the cost-effectiveness of the *e*CPP intervention relative to control for parenting and child outcomes. **HYPOTHESIS 2**: The *e*CPP is cost-effective relative to control for parenting and child outcomes.

We will assess cost-effectiveness of *e*CPP from the societal perspective, including costs borne by the program, health care system, and parent. We will conduct additional analyses from the program, health care system, and parent perspectives separately. For the cost measurement, quantities of resources used and their associated prices will be collected for the *e*CPP (either prices paid or value of the clinician time) and participant (i.e., value of participant's time to use the *e*CPP). Program and parent costs will be calculated for the 12-month study duration and summed to calculate total cost per parent. All costs will be valued in 2015 dollars.

For the effectiveness measurement, effectiveness will be measured using the parenting and child outcomes. Cost-effectiveness will be evaluated by combining the mean total cost per parent with effectiveness (parenting and child behavior outcomes). We will calculate the incremental cost-effectiveness ratio (ICER) for *e*CPP compared to the control condition, such that $ICER = (C_1 - C_0)/(E_1 - E_0)$, where C is cost and E is effectiveness. Subscript 1 denotes *e*CPP and subscript 0 denotes the control condition; 95% confidence intervals for the ICERs will be calculated to evaluate the uncertainty in these results.[93-95] We will conduct one-way and multi-way sensitivity analyses for the key parameters to evaluate whether the ICERs are sensitive to plausible changes in their values. The sensitivity analysis is a check on the robustness and will determine the key parameters impacting the ICERs. We will also plot acceptability curves based on varying threshold (willingness to pay) values for adherence and change in parenting and child behavior outcomes.

Aim 3. Quantify the levels of program implementation of *e*CPP in primary care using the RE-AIM framework. **RESEARCH QUESTION 3:** What is the degree of Reach, Efficacy, Adoption, Implementation, and Maintenance of the *e*CPP intervention in pediatric primary care?

Descriptive statistics will be calculated to identify achievements across each level of RE-AIM for each primary care site. We will develop a demographic, income, and technology use profile for the populations reached (i.e., parents enrolled in the study). We will use contingency table analyses and independent *t* tests to compare the demographic and income profiles to the characteristics of the population of the primary care sites service catchment communities using data from the U.S. Census. This analysis will allow us to assess the extent to which we are either over- or under-representing our priority populations (low-income families) from the local catchment area in this study. Technology ownership and use will be compared to data from national data sets from the Pew Research Center's Internet and American Life Project.[96]

To determine the effectiveness of the implementation strategy and inform dissemination of the *e*CPP, a cascaded probability model will be constructed.[97,98] This will be developed based on the following proportions: (a) the likelihood of clinician adoption at the site [*proportion 1 (pr 1)*], (b) the likelihood of implementation (study introduction) by clinicians at the site [*pr 2*], (c) the likelihood of parent enrollment in the study [*pr 3*], and (d) the likelihood of maintenance of behavior change by the *e*CPP participants [*pr 4*]. *Pr 4* is defined as the proportion of participants whose parenting and child behavior outcomes are the same or improved at the 12-month data collection compared to the 6-month data collection. The estimated likelihood of parents being introduced to the program will be the product of *pr1* and *pr2*. Second, the compound likelihood of parent enrollment in the study will be the product of *pr1, pr2,* and *pr3*. Finally, we will estimate the compound likelihood of maintaining behavior change by examining the product of *pr1, pr2, pr3,* and *pr4*. This analysis will provide us with two important pieces of information: (1) the probable benefits of the program in terms of how likely it is for parents to achieve maintenance of behavior change and (2) inform us of the phase of the implementation process (as operationalized by *pr1, pr2, pr3,* and *pr4*) which is likely to interfere with the dissemination of the *e*CPP.

We will conduct a content analysis of the post-implementation interviews with the clinicians. We will use a coding-based system of content obtained from the interviews using the notes taken during the interview using Atlas.ti software. Atlas.ti allows for the identification, organization, and systematizing of codes that can then be assessed in the context of the clinician interviews. Themes will be summarized by site and used to inform the development of processes and procedures to support the implementation and dissemination of the *e*CPP in pediatric primary care practice sites.

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