ADAPTIVE TRIAL OF PARENT EMPOWERMENT AND COACHING IN EARLY INTERVENTION

PEACE FOR IMPACT STUDY

Research Protocol
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Adaptive Trial of Parent Empowerment and Coaching in Early Intervention: PEACE for ImPACT Study RESEARCH PROTOCOL

BACKGROUND

Caregiver-mediated interventions are considered an evidence-based practice (EBP) for young children with autism. **Caregiver coaching is key to efficacious caregiver mediated early intervention (EI) for autism**. Caregiver-mediated interventions include caregivers as partners in delivering EI services through explicit caregiver coaching. Coaching caregivers increases parents' use of intervention strategies, and caregivers overwhelmingly appreciate getting coached (Abouzeid et al., 2020; Siller et al., 2022). Families of toddlers who received caregiver coaching used fewer services than families receiving usual community-based services, suggesting significant cost savings (Tsiplova et al., 2022). Coaching is an interactive process between a provider and a caregiver involving observation, reflection, and action to promote the caregiver's ability to support their child's participation at home and in their community. **Despite policies supporting caregiver coaching, early intervention providers rarely coach caregivers of children with ASD** (Campbell & Coletti, 2013; Douglas et al., 2020; Salisbury et al., 2012)**.** Instead, they usually work directly with the child (Campbell & Coletti, 2013; Campbell & Sawyer, 2007). In contrast to university-based studies of caregiver-mediated interventions, community early intervention outcomes tend to be poor, especially in low-income communities (Nahmias et al., 2019). Poorer outcomes may be due in part to a lack of effective parent coaching.

The Philadelphia EI system launched a system-wide initiative to train EI providers in **Project ImPACT**, an evidence-based caregiver coaching model for families of young children with autism (Ingersoll & Dvortcsak, 2019). However, our previous evaluations indicated that intervention fidelity was low, meaning most providers did not implement the intervention as designed. We partnered with the EI system to evaluate the reasons for low intervention fidelity, and we developed an implementation toolkit called Parent Empowerment and Coaching in Early Intervention (**PEACE**) to improve the implementation of caregiver coaching for families of young children with autism. We conducted a pilot study of the PEACE toolkit and our pilot test indicated that the PEACE toolkit shows promise for improving providers' use of caregiver coaching, increasing parents' responsive parenting, and improving child outcomes. However, the sample was small, and some providers required additional implementation support. **The goal of this study is to test the impact of PEACE and determine the level of implementation support needed to improve provider fidelity to caregiver coaching, which will subsequently improve caregiver and child outcomes.**

RESEARCH PLAN

We will use a Hybrid Type 3 implementation-effectiveness trial (Curran et al., 2012) using a SMART design (Almirall et al., 2018; Nahum-Shani & Almirall, 2019) to efficiently test the effect of increased implementation support for providers who demonstrate sub-threshold levels of coaching adherence. A SMART design provides a systematic and principled way to monitor and rapidly improve providers' caregiver coaching adherence. Rapid assessment of coaching

adherence and assignment to increasing implementation support will enable the rapid support for families whose providers are not meeting the standard for implementation, providing them with an immediate step-up in their care. This study will address four aims:

Aim 1: Identify the level of implementation support needed to rapidly improve providers' use of caregiver coaching with a sample of 200 EI providers.

Aim 2: Assess caregiver and child outcomes for families receiving caregiver coaching through Project ImPACT for a sample of 400 families,

Aim 3: Identify provider and family characteristics associated with the need for increasing implementation support

Aim 4: Evaluate the cost and cost-effectiveness of tiered implementation strategies.

Setting

In Philadelphia, children less than five years of age with or at high risk for developmental disabilities are eligible for publicly funded early intervention. Each year, approximately 1,700 children with ASD receive early intervention through agencies that contract with the County to provide these services. Services are delivered in the family's home or preschool/daycare setting.

Participants

Providers: We will recruit 200 providers from participating EI agencies across four years. All providers have a Bachelor's or Master's degree in a relevant field (e.g., psychology, education, speech pathology). They often are independent contractors. We will recruit providers in years 1-4 (~50 per year) by randomly sampling without replacement from each agency, to evenly distribute providers across agencies each year. Inclusion criteria for providers are: 1) employed by a Philadelphia EI agency and 2) have $\geq$ 5 children with/at risk for ASD on their caseload.

Children and Families: We will recruit 400 children and one caregiver per child (2 parent-child dyads per provider). Inclusion criteria are that children must: 1) be receiving EI services from a participating provider; 2) have a classification of ASD or high ASD risk as determined by the EI system; 3) caregiver speaks English or Spanish (Project ImPACT materials are available in Spanish); and 4) have a caregiver willing to participate in weekly coaching sessions.

Methods.

Intervention – Project ImPACT: Project ImPACT is a manualized, caregiver-mediated, naturalistic developmental behavior intervention that includes two core components: (1) a child-directed curriculum to guide caregivers in supporting their child's social communication; and (2) guidelines to help EI providers coach caregivers. Project ImPACT training includes a 6-hour self-paced e-course and 14-hr interactive workshop on the child-directed Naturalistic Developmental Behavioral Intervention components of the program, the scope and sequence of the curriculum, data collection and progress monitoring strategies, and strategies to support caregivers in learning the intervention strategies.

PEACE Implementation Toolkit Description: The PEACE Toolkit is a theory-informed, modular toolkit of strategies that map onto identified implementation barriers to caregiver coaching. The

PEACE toolkit has three parts:

Tier 1: PEACE online resource library. The PEACE online resource includes self-paced training modules that cover the foundations of caregiver coaching, caregiver perspectives towards coaching, strategies for aligning with caregivers and gaining buy-in for coaching, evidence-based strategies to empower caregivers from marginalized backgrounds, and strategies to improve collaboration and cohesion among providers working with the same child. Each module includes brief example videos, easy-to read infographics, tip sheets, and checklists to guide implementation. A virtual communication application, Slack, facilitates frequent communication, enhances social networks among providers, and creates social norms related to the use of caregiver coaching. Providers can post questions or suggestions, share resources, and receive updates about other providers' accomplishments. Consultants frequently post encouraging messages and progress updates to increase motivation and shared norms for coaching.

Tier 2: Weekly group facilitation meetings. PEACE also includes facilitation meetings to improve provider self-efficacy and fidelity to caregiver coaching strategies. Facilitation comprises interactive problem solving and support, a shared understanding of need for improvement, and a supportive interpersonal relationship. Effective facilitation has been linked to improved implementation outcomes (Powell et al., 2015). Providers participate in 12 weekly group facilitation meetings for one hour virtually with an expert consultant focused on auditing providers' fidelity to caregiver coaching through role-play and performance feedback. Each group meeting aligns with content from the PEACE online resource library modules.

Tier 3: Individual Facilitation Meetings. Individual facilitation is delivered virtually for one hour each week for eight weeks with a consultant focused on reflection and problem solving any identified implementation barriers, as well as practice and performance feedback.

Aim 1: Examine the effectiveness of PEACE at tiered implementation levels.

Research Question: How can we optimize implementation supports for EI providers to implement caregiver coaching with fidelity?

Overview

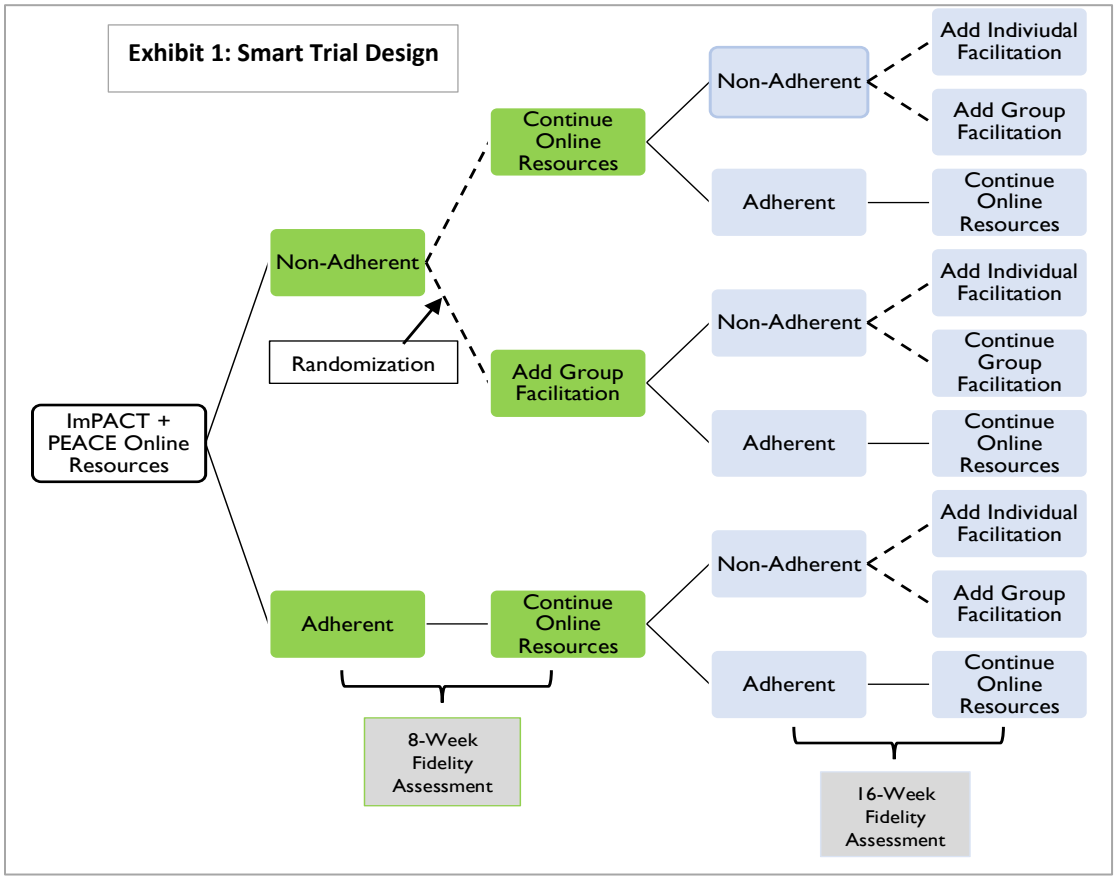
Our primary aim is to evaluate the effectiveness of tiered levels of implementation support in increasing providers' caregiver coaching adherence using the PEACE implementation toolkit components (i.e., PEACE online resource library and chat, PEACE group facilitation, PEACE individual facilitation). We will conduct two sets of comparisons, based on randomizations to increasing implementation support and on the embedded support sequences, to evaluate the optimal implementation support needed to improve providers' caregiver coaching adherence, our primary outcome of interest. We also will collect measures of acceptability, feasibility, and appropriateness of the PEACE implementation toolkit as secondary implementation outcomes.

Tier 1: PEACE online resource library: All providers will have access to the PEACE Online resources following completion of Project ImPACT training.

Tier 2: PEACE Group Facilitation: After eight weeks (see **Exhibit 1),** providers with low

coaching adherence will be randomized to continue with online resources or to participate in weekly group facilitation.

Tier 3: PEACE Individual Group Facilitation: After 16 weeks, providers may be randomized to receive individual facilitation with an expert coach.



Design.

The SMART design uses two evaluations of provider coaching adherence, at eight weeks and 16 weeks of intervention (**Exhibit 1**). For the first eight weeks, all providers will have access to the PEACE online resource library and virtual chat space and will implement Project ImPACT as usual. At eight weeks, we will rate each provider's caregiver coaching adherence, separately for each child, using the PEACE Caregiver Coaching Fidelity Tool. If a provider has a caregiver coaching adherence score < 80%, for either child, the provider will be randomized 1:1 to receive either 1) PEACE weekly group facilitation to improve fidelity; or 2) to continue without support, through the 16-week time point. Providers adherent for all children at eight weeks will continue without support through 16-weeks. At the 16-week time point, all providers will be evaluated again, and non-adherent providers will be randomized 1:1 to receive either 1) PEACE weekly group facilitation, or 2) PEACE individual facilitation through the 24-week time point; again, providers who demonstrate coaching adherence ≥ 80% will continue without additional support.

Measures

Providers' caregiver coaching adherence, the primary outcome, will be assessed using the *PEACE Caregiver Coaching Fidelity Tool* from video recorded observations of community-based EI sessions. The tool consists of 25 items, rated on a 5-point scale with a rating of 4 or 5 indicating acceptable adherence. A score of 80% indicates adherence on the overall measure (i.e., 80% of the items rated at 4 or 5). Trained research assistants will code caregiver coaching adherence from video recordings. We will assess adherence at 8-week intervals for 6 months to allow a sufficient length of intervention to observe changes in parent and child outcomes (i.e., 8, 16, and 24 weeks of intervention).

Acceptability, Appropriateness, and Adoption of the PEACE toolkit will be measured using a measure which specifically queries for respondents views about the usefulness, acceptability, and the extent to which they used the components of the toolkit. Respondents rate the toolkit's acceptability, appropriateness, and their use of the components on a 5-point scale. We will collect this measure after 6 months of intervention from all providers.

Statistical analyses. The design allows for two sets of comparisons, one based on the two randomizations, and one based on the embedded support sequences.

Randomization Comparisons: Our *primary comparison* concerns the (non-adherent) providers randomized at eight weeks, and tests whether providing group support at 8 weeks yielded improved fidelity at 16 weeks and 24-weeks. We will compare the groups using a linear mixed-effects model (Molenberghs & Verbeke, 2001; Verbeke, 1997), with the lower of the provider's two fidelity scores at 16 weeks, and at 24-weeks, as the repeated responses, and randomization group (no support vs PEACE group facilitation) as the main explanatory variable. The model will also include a binary factor for time (16 vs 24 weeks), and a group by time interaction to account for possibly differing effects at weeks 16 and 24.

Our *secondary comparisons* will be based on the providers randomized at 16-weeks. They will examine the effect of the 16-week randomizations on the fidelity scores at 24 weeks, using linear regressions models with the worst 24-week fidelity score as response, and the 16-week randomization group (PEACE individual facilitation vs group facilitation) as the explanatory variable. In further analyses, we will examine the effects of providers' 8-week status (adherent vs non-adherent, group facilitation vs no support) on the 24-week fidelity outcome, by extending the models to include 8-week adherence and support (group vs none) as binary factors and examine their interactions with 16-week randomization group.

For our primary comparison of the 24-week fidelity responses, we will use a linear regression model on this expanded dataset, possibly after transforming the response to reduce skewness. The explanatory variable of primary interest will be a four-level categorical indicator of adaptive support sequence. The model will provide an overall test of differences in the distribution of fidelity score across the four sequences, and provide contrasts between subsets of the sequences. Our main interest is in pairwise comparisons between sequence 1, which is a "control" sequence, and the other three sequences.

Power: Based on preliminary data, we anticipate high rates of non-adherence at week 8, so differences between sequences will be largely due to differences among the providers randomized at eight weeks. We base power calculations on the methods of Seewald et al

(Seewald et al., 2020; Formula (10), Design II). If 140 providers are randomized at week 8, and that the correlations between fidelity scores within a given provider over time are at least 0.5, and that 30% of the providers randomized to continuing online support are adherent at 16 weeks compared to 60% of those randomized to group support, then the design provides 80% power to detect effect sizes of Cohen's d=0.52 or higher.

Aim 2: Assess caregiver and child outcomes for families receiving caregiver coaching.
Research Question 1: Does improved EI provider coaching fidelity lead to improvements in caregivers' responsive interaction strategies with their child?
Research Question 2: Does improved caregiver use of responsive interaction strategies lead to improvements in their child's social-communication skills?

Overview

We will use validated measures of caregiver responsiveness and children's social communication skills to assess changes in caregiver and child outcomes associated with improvements in providers' caregiver coaching fidelity. These measures have been used by the research team in similar community-based evaluations of parent-mediated interventions and are sensitive to change in caregiver and child outcomes following intervention.

Measures

Caregiver responsiveness will be assessed using the *Parenting Interactions with Children: Checklist of Observations Linked to Outcomes* (PICCOLO: (Roggman et al., 2013). The PICCOLO is a checklist of 29 observable, developmentally supportive parenting behaviors with children ages 10-47 months; it has been used to effectively measure changes in caregiver responsiveness with caregivers of children with autism and developmental disabilities through five years of age (Alquraini et al., 2019; Innocenti et al., 2013). The PICCOLO has four domains: Affection, Responsiveness, Encouragement, and Teaching. Total scores on each domain are used to monitor change in parenting behaviors. It is a strengths-based measure of parenting interactions that predicts children's early social, cognitive, and language development with solid psychometrics and has been successfully used to assess changes in parent responsiveness with families of children with disabilities and from diverse ethnic backgrounds (Roggman et al., 2013; Vilaseca et al., 2019), and was sensitive to changes with large effect sizes in a community-based sample of families receiving Project ImPACT (Stahmer et al., 2020). A brief (10 minute) parent-child interaction will be video recorded at baseline and after 6 months of intervention to assess changes in parent responsiveness; members of the research team blind to study arm or time point will score the checklist from the video recorded interaction.

Children's Social Communication Skills will be measured using the *Autism Impact Measure* (Kanne et al., 2014) and the *Social Communication Checklist*. The *Autism Impact Measure* is a 25-item parent report questionnaire designed to track incremental change in frequency and impact of core ASD symptoms (Mazurek, Carlson, Baker-Ericzén, Butter, Norris, & Kanne, 2020). It has excellent construct validity, test-retest reliability, convergent validity and structural validity and is sensitive to change in children's ASD core symptoms in response to intervention (Houghton et al., 2019; Mazurek, Carlson, Baker-Ericzén, Butter, Norris, Barr, et al., 2020; Mazurek, Carlson, Baker-Ericzén, Butter, Norris, & Kanne, 2020). Changes in children's social

communication skills will be assessed using the AIM at baseline and after 24 weeks of the intervention. The *Social Communication Checklist (SCC)* is a 47-item parent report checklist that is used as part of the Project ImPACT program to help parents set their child's social communication goals and assess child progress. An initial psychometric evaluation suggests that it is reliable, sensitive to change after intervention, and strongly related to well-established measures of social-communication functioning (Wainer et al., 2017). The SCC will be collected at baseline and week 24.

Statistical Analyses. We will address Research Questions 1 and 2 in the context of comparisons of embedded sequences. For each question, we may have more than one parent, or more than one child, providing responses for a given provider. To account for this nesting of parents and children within provider, we will use the weighted regression methods of NeCamp et al., (2017). The responses are continuously distributed, so we will use linear models. The explanatory variable of primary interest will be a four-level categorical indicator of adaptive support sequence, and the baseline version of the response will be included as a covariate.

Aim 3: Identify provider and family characteristics associated with the need for increasing implementation support.

Research Question 1: Are provider and family characteristics associated with coaching fidelity?
Research Question 2: Among randomized providers, are provider or family characteristics associated with response to implementation support?
Research Question 3: Does the PEACE toolkit engage targeted implementation barriers?

Overview: We will gather preliminary data regarding the association between provider and family characteristics and provider fidelity. These secondary and exploratory analyses will identify potential levers for personalized implementation supports. In addition, we will conduct qualitative interviews with providers purposively sampled from each support sequence to assess whether PEACE has engaged the intended target implementation barriers (see Exhibit 3).

Measures
Provider demographics will be measured at baseline through a brief questionnaire that asks questions regarding degree, discipline (e.g., instructor, speech therapist), years in the field, experience with children with autism and experience with Project ImPACT components.

Parent demographics will be assessed at baseline using 1) a socio-demographic survey that includes demographics, family composition, education and financial resources using relevant US Census Survey questions, and 2) The *Confusion, Hubbub, and Order Scale (CHAOS)* (Matheny et al., 1995), a validated parent-report measure of disorder and chaos in the home will be used to measure home environmental factors that may interfere with the use of caregiver coaching.

Qualitative Interviews will be conducted individually with 20% of providers purposively sampled from each randomized support sequence each year upon completion of the PEACE toolkit (at week 24). We will adapt the semi-structured interview guide used in our previous work to identify the targeted implementation barriers. Standardized probes will be included in the interview guide so that consistency across interviews is maintained. The interview protocol will allow us to assess how PEACE engaged the targeted implementation barriers. Specifically,

we will query around: 1) providers' perceptions about whether the PEACE toolkit addressed the targeted implementation barriers; 2) if providers experienced additional implementation barriers that were not adequately addressed by the PEACE toolkit (to inform potential adaptations); and 3) providers' perceptions about the appropriateness, benefits, and challenges of the levels of implementation support they received. Interviews will be digitally recorded, professionally transcribed, and loaded into Nvivo 12.0 software for data management and analysis.

Data Analyses

Quantitative Statistical Analyses.

For Research Question 1, the responses will be the provider's caregiver coaching fidelity score, for each child, at week 8, prior to any implementation support. We will use linear mixed effects models to accommodate correlations between scores within the same provider. We will include the provider's discipline (e.g., ABA therapist, Speech Therapist, instructor), years of experience, experience with ASD, and caseload size, as provider-level explanatory variables. For family/child characteristics, we will include the family education, income, composition, and chaos score, and the baseline child scores on each of the four subdomains (restrictive behavior, language/communication, social reciprocity, atypical behavior) of the *Autism Impact Measure.*

To address Research Question 2, we focus on the providers who were non-adherent at week 8. Our response will be the change in provider's caregiver coaching fidelity score from 8 weeks through 16 and 24 weeks, and we will use the same provider and family/child characteristics described in Research Question 1 above. First, we will address the possible moderating effects of the characteristics on the effects of the week eight randomization (group support vs continued online support). We will use linear mixed effects models, with the week 16 and week 24 change scores for each child as repeated responses, and with binary factors for group and week (16 vs 24). The models will include the provider and family/child characteristics, and the week eight caregiver coaching fidelity score, as main effects and as interactions with randomization group. To test for possibly differing moderation effects at weeks 16 and 24, we will include group by week interactions, and group by week by characteristic interactions. Next, to examine the effects of the week 16 randomizations (group vs individual supports), we will focus on the set of doubly randomized providers, and use similar models to test for moderating effects of the characteristics on the change in fidelity score from week 16 through week 24.

Qualitative & Mixed Methods Data Analysis. We will use qualitative and mixed methods analyses to evaluate Research Question 3 and to assess whether PEACE has engaged the intended target implementation barriers. We will analyze transcripts using an iterative process based upon an integrated approach that incorporates inductive and deductive features (Bradley et al., 2007). Both *a priori* codes (codes that are developed before coding the data) and grounded theory codes (codes for ideas that emerge while reading what the respondents actually say) will guide codebook development based on a close reading of the first three transcripts. A priori attributes of interest include the extent to which providers describe how PEACE impacted their attitudes toward caregiver coaching, their perceptions of caregiver coaching norms, and their confidence (self-efficacy) in their ability to deliver effective coaching. Twenty percent of transcripts will be double coded and we will use the interrater reliability function in NVivo to generate Kappa scores to estimate agreement among coders. If there is less than 90% agreement, the coders and investigators will discuss discrepancies and resolve them through consensus.

After coding, we will read through all codes to examine themes and produce memos of examples and commentary. Mixed methods will analyze themes as a function of provider characteristics to identify patterns of responding, consistent with best practices in mixed methods research (Dowding, 2013).

Aim 4: Evaluate the cost and cost-effectiveness of tiered implementation strategies.

Research Question 1: What are the costs and cost-effectiveness (CE) of the PEACE implementation toolkit and increasing levels of implementation support?

Overview

We will conduct two sets of cost and CE comparisons, one based on the two randomizations, and one based on the four embedded strategies. Our cost analysis will take a payer (i.e., Philadelphia EI system) perspective focusing on programmatic costs and use Time-Driven Activity-Based Costing (TDABC), a well-established micro-costing method, based on process mapping (Kaplan & Anderson, 2003). This method has been applied to implementation science by co-I Dr. Cidav in other work (Cidav et al., 2020, 2021).

Measures

We will determine total labor and non-labor costs associated with study conditions and embedded strategies. For labor costs, first, as per TDABC, we will create process maps in which we will discretely outline the activities performed within each randomization group and embedded strategy and determine the personnel involved in each activity (e.g., provider, coach). Core implementation activities are use of PEACE online library, attending group facilitation meetings, attending individual facilitation meetings, and assessing provider fidelity. Second, we will determine frequency and average duration of each of these activities during the study period.

For group facilitation meetings, individual facilitation meetings, and provider fidelity assessment, frequency, average duration, and personnel involved will be directly observed and documented in real time as part of the trial administrative records. For example, during each group facilitation meeting, we will have one staff assigned to record date, start and end time of the meeting, and who was present. For use of the online resource library, since continuous documentation is burdensome and infeasible (e.g., providers recording each virtual communication), we will administer activity time logs by which the providers will record their time spent on using the online library over a pre-determined period (e.g., staff records virtual communication over a randomly selected 1-week period at different time points during the study period). Providers will report their online resource library and chat use by a self-report survey.

Once we determine how many times personnel participated in each activity and the average duration of the activity, multiplying frequency and duration will yield total time spent by the specific personnel on a given activity. Multiplying this by the personnel's hourly wage rate (including benefits) will yield total cost incurred by the personnel to perform that specific activity. The total cost of an activity is the sum of costs incurred by each personnel who participated in that activity. Adding up the cost of each activity within a specific randomization group/embedded strategy will yield the total labor cost for that randomization group/embedded strategy. For non-labor resources, we will itemize consumable equipment and supplies (training materials, assessment and evaluation materials, office supplies, etc.). Cost of each item will be

determined from the project budget and administrative records. Labor and non-labor costs will be added together to determine overall costs for each randomization group/strategy.

Statistical Analysis

Total and per-provider costs for each randomization group and strategy during the study period will be determined. We will examine activity, personnel and agency-level variation in costs and its determinants. We will conduct sensitivity analyses to estimate the potential costs under alternative scenarios where we assume hypothetical modifications (e.g., effects on costs of increasing frequency of individual facilitation meetings).

Finally, we will combine the outcomes of different study arms and embedded strategies with their respective costs to provide a measure of relative cost-effectiveness. The effects will be improvements in provider implementation fidelity. Incremental cost-effectiveness ratios (ICER) will be computed as the ratio of the difference in mean costs (incremental cost) to the difference in mean effects (incremental effect). We will compare the ICERs for each randomization group/strategy to each other to assess which approach is most cost-effective. Using non-parametric bootstrapping procedures (Glick et al., 2014), we will construct confidence intervals for the ICERs and cost-effectiveness acceptability curves to study cost-effectiveness based on different monetary threshold values attached to the improvement in implementation fidelity.

PROTECTION OF HUMAN SUBJECTS

Research will not begin until the Institutional Review Boards of the University of Pennsylvania and the City of Philadelphia approve the proposed study.

Characteristics of Population

Participants will be providers in the Philadelphia EI system, children ages 18 months to 5 years being treated by these providers, and their parents. All primary data collection will be conducted based on informed consent. Two distinct groups of participants will be recruited in the study (EI providers and families). Separate recruitment and consent strategies will occur for each group of participants.

Providers: We will recruit 200 providers. All providers have a Bachelor's or Master's degree in a relevant field (e.g., psychology, education, speech pathology). Inclusion criteria are: 1) employed by a Philadelphia EI agency; and 2) have $\geq$ 5 children with/at risk for ASD on their caseload. Based on data from the Philadelphia early intervention system, we anticipate that the sample of providers will be 90% female and 10% male. With regard to race/ethnicity, we anticipate the following breakdown for providers: 63% Caucasian, 23% African American, 12% Hispanic/Latino, 1% Asian, and 1% American Indian/Alaska Native.

Children and Families: We will recruit 400 caregiver and child dyads (2 families per provider). Inclusion criteria are that children must: 1) be receiving EI services from a participating provider; 2) have a classification of ASD or high ASD risk as determined by the EI system; 3) child is not transitioning from EI services for at least 6 months; 4) caregiver speaks English or Spanish (Project ImPACT materials are available in Spanish); and 5) have a caregiver willing to participate in weekly coaching sessions. Based on current EI family demographics, we anticipate the sample of parent-child dyads will be 45% African American, 26% Latino, 18% Caucasian, 6% Asian, 2% American Indian/Native American, and 3% multi-racial. Children will be less than 5 years of age and will either have a diagnosis of autism spectrum disorder or be identified as at-risk for autism by the early intervention system, as children under three years of age do not need a formal diagnosis to receive autism-specific treatment. We anticipate that 75% of the children will be male based on the sex distribution of autism. Participants will be excluded if they do not speak English or Spanish, as the published intervention materials are currently available in English and Spanish and the research team is able to communicate with participants in English or Spanish only. Participants will not be excluded based on their gender or past experience.

Data to be collected from Human Subjects

Early Intervention Providers				
Measure	**Baseline**	**Week 8**	**Week 16**	**Week 24**
Demographic	X			
Fidelity Observation		X	X	X
Acceptability and Feasibility				X
Qualitative Interview				X
Parents				
Demographics	X			
CHAOS	X			
Autism Impact Measure	X			X
Social Communication Checklist	X			X
10 minute recorded play interaction	X			X

Data will take the form of demographic questionnaires, direct observations, and audio and video recordings. Data will be obtained directly from participants in the proposed research projects. No data will be obtained from existing records.

Field Observations: We will collect direct observation ratings of provider's coaching fidelity using the *Peace Caregiver Coaching Fidelity Tool* and the *Project ImPACT Fidelity Checklist*. Session recordings will be of usual early intervention sessions, approximately 1 hour long. We will record 3 sessions with each family enrolled in the study (at 8 weeks, 16 weeks, and 24 weeks of intervention).

Demographic Questionnaires: We will collect sociodemographic information for each participant including information related to race/ethnicity, socioeconomic status, and education level at baseline.

Questionnaires: We will collect parent surveys regarding the home environment using the *Confusion, Hubbub, and Order Scale* (CHAOS), and surveys regarding children's social communication skills using the Autism Impact Measure and the *Social Communication Checklist* (SCC). Parents will complete the CHAOS scale at baseline and the *Autism Impact Measure* and the Social Communication Checklist at baseline and after 24 weeks of intervention. We will survey providers on the acceptability, appropriateness and feasibility of the PEACE Implementation Toolkit at 24 weeks of intervention.

Assessments: We will collect direct observation ratings of caregiver responsiveness using the *Parenting Interactions with Children: Checklist of Observations Linked to Outcomes* (PICCOLO) from 10-minute recordings of a parent-child play interaction at baseline and after 24 weeks of intervention.

Interviews: We will conduct qualitative interviews with 20% of the early intervention providers in each cohort. We will interview them using an interview guide with questions eliciting feedback on the PEACE Implementation Toolkit and the implementation supports that were provided. Interviews will be recorded on Zoom for audio or over the phone based on participant preference.

Use of Toolkit: We will gather data on utilization of the online resource library and chat by self report by provider participants. During a randomly selected week of the intervention, providers will report the amount of time spent accessing and utilizing the online resources.

Recruitment and Informed Consent

Recruitment

Clinicians

Clinician recruitment will occur through participating agencies. We will provide information about the study to agencies participating in Philadelphia's Project ImPACT training initiative and invite them to participate. Recruitment and retention strategies are based on our prior community trials in which we recruited 80-95% of eligible practitioners and experienced 5-7% attrition. Agencies will distribute flyers and a short video describing the study to EI providers employed in their agency. Agency leaders will also describe the study at staff meetings. Research team members will attend professional development and informational meetings to answer providers' questions, address their concerns and garner support. If a provider agrees to participate, they will speak with study staff over the phone to discuss the study and review the consent form. The consent form will be provided to the provider to sign either through an electronic link or mailed to them, based on their preference. There will be a local number and e-mail address for staff to contact with any study-related questions.

Families

After a provider has agreed to participate in the study, agencies will then distribute flyers and a short video to parents on the providers' caseload describing the study. Interested parents will sign a permission to contact form using a secure electronic survey link. Initial contact with families will be made by telephone during which eligibility will be confirmed, the study will be described in detail utilizing the consent form, and all questions about the study will be answered. A secure electronic link to the study consent form will be emailed or texted to the parent to review and sign. If a parent prefers and requires it, the consent form can also be mailed to the parent to sign. Once the signed consent form is received, a member of the research team will begin data collection. Consent will be obtained from both providers and families before data collection begins. There will be a local number for families to call with any questions related to the study protocol.

Consent Process

The amount and complexity of data to be collected warrants affirmation of consent from study participants at several steps in the process. The entire study will be described during the

invitation phone call to the provider or parent who has indicated interest in the study. Interest in moving on to the consent process will be obtained verbally at this time. Informed consent will be obtained electronically through a link sent to the provider or parent or on paper via a mailed consent form. The provider or parent will be able to review the consent form and sign if they agree to participate. In addition, informed consent will be affirmed at each step of data collection. The participant will have the opportunity to ask questions about the consent forms prior to giving written informed consent.

A written informed consent for the study will be sent in an electronic email or mail for participant's review prior to the start of data collection. The document and link includes a description of the entire study and expected roles and responsibilities of the provider, primary caregiver and child, risks and benefits to participants, and confidentiality procedures. The consent document will also clearly state that participation in the study is completely voluntary, and participants can drop out of the study without penalty at any time. Study staff will review this consent form over the phone. At this time, study staff will answer questions and obtain verbal confirmation of interest to review the consent form and sign through the electronic link, or that they would like the consent form mailed to them with a return envelope. The consent forms explicitly outline the voluntary nature of participation in this research study. Easy channels of communication to study staff if a participant wishes not to participate will be clearly outlined. Specifically, the contact information for the PI and study coordinator will be listed on the consent form, expectations for participation, compensation, and further outlines of confidentiality practices specific to information collected. All participants will be given the option to consent to receiving text messages from the research study team. Text messages will be used for sending study updates and confirming study procedure appointments. Text messages will be sent from the research study team's email. Participants will be informed that standard text message rates apply if they agree to allowing the research team to contact them via text messages.
All consent documents follow the guidelines outlined by the Office of Human Subjects Protection of the National Institutes of Health, the University of Pennsylvania, the Philadelphia Department of Public Health, and ethical guidelines set forth by the state and federal governments. Documentation of subject consent will be stored in a locked file in the PI or designee's locked office.

<u>Subject Compensation</u>

Participating providers and families will be compensated for time spent completing specific data collection time points.

Field Observations and Survey Completion: Providers will be compensated $25 for participating in each fidelity observation. This will be a total of 6 observations (3 time points with 2 families), for a total of $150. Families will be compensated $75 for participating in the parent-child play interaction observations and completing questionnaires at two time points for a total of $150.

Professional Development: Providers will receive professional development training credits for their participation in group facilitation meetings and for completing the training. In addition, they will receive training in Project ImPACT and the option to receive certification in Project ImPACT at no cost, which is a considerable cost benefit for the provider.

Data Sharing

If providers believe that their performance in the study may be evaluated by their agency or the EI system they may become anxious and thus make them unlikely to participate in the study. Videotaping provides concrete examples of coaching techniques that enable efficient and accurate measurement of the strategies used during intervention sessions; however, there is potential that such videotaping will provide concrete examples of intervention techniques or other behavior that could negatively influence staff performance review if administrators or supervisors in the EI system were to view it. For this reason, there will be no disclosure of videotaped performance or self-reported information about provider fidelity, especially to these personnel. As a result, the research team will keep all identifiable and individual participant data confidential from all administrative personnel, including agency executive and clinical directors. However, upon conclusion of data analysis, the research team will provide anonymous and aggregate results of the study to the Philadelphia Department of Public Health, the department of Intellectual and Disability Services within DPH, Philadelphia Infant and Toddler Early Intervention, Elwyn Preschool Early Intervention, as well as any participating community agencies. Anonymous and aggregate results provided to community agencies will be aggregate data from all participants, not exclusively those from any single community agency. This procedure acts in the interest of participant confidentiality and job security.

Potential Risks to Subjects

Risk to parents and children

Parent and child involvement in the proposed study involves direct observation measures of children and parents in their homes, completion of a demographic survey, and completion of surveys regarding the child's social communication skills. The study therefore involves minimal risk to children and their families. The risks include:

1. Respondent burden associated with the time and effort to complete the observations and surveys:
    a. We estimate time burden to be an average of 3.5 hours of total data collection for parents during observations (10-minute parent-child interaction observation at 2 time points, 1- hour fidelity observation at 3 time points).
    b. We estimate time burden to be an average of 30 minutes for survey completion at 2 time points.
2. The possibility of breached confidentiality by disclosure of personal information.
3. The risk of distress caused by the videotaped observation and/or questionnaires:
    a. The proposed measures include a number of sensitive items related to children's clinical presentation and family characteristics. Answering certain questions on the proposed measures may cause some distress. Some questions asked of parents (such as those about income or stress) may cause parents some discomfort.

b. Parents may feel anxious by observations or videotaping, especially if they believe that the research team is evaluating their performance. Videotaping provides concrete examples of teaching techniques that are vital to the measurements proposed in this research. However, there is potential that such videotaping will provide examples of behavior that the research team believes endanger the parent or child. For this reason, there will be no disclosure of observed or videotaped information to those outside of the research team unless there is a suspicion of child abuse or neglect. Parents will be informed during the consent process that all study personnel are mandated reporters. All staff are trained in mandated reporting. In cases of suspected abuse or neglect, the research staff member suspecting the abuse or neglect will contact one of the two licensed psychologists on the study. They will review the situation together and determine if it meets criteria for reporting.

4. The risk that the intervention may have some iatrogenic effect.
   a. There is a small chance that the proposed intervention may have negative consequences. The majority of evidence suggests that the components of the proposed intervention are the most efficacious in treating young children with ASD. However, to protect against this risk, we will monitor outcomes and potential adverse events, as described below, to identify any iatrogenesis.

<u>Risk to Early Intervention Providers</u>

Early intervention providers' involvement in the proposed study involves direct observation measures of intervention fidelity, completion of 1 sociodemographic survey, brief measures on the acceptability and appropriateness of the toolkit, and participation in qualitative interviews. The study therefore involves minimal risk to providers. Possible risks include:

1. Respondent burden associated with the time and effort to complete the training, observation, interviews, and questionnaires:
   a. We estimate time burden to be an average of 22 hours for completing Project ImPACT training before baseline.
   b. We estimate time burden to be an average of up to 16 hours for participation in group facilitation meetings, if providers are assigned to the implementation group.
   c. We estimate time burden to be an average of up to 8 hours for participation in individual facilitation meetings, if providers are assigned to the implementation group.
   d. We estimate time burden to be an average of 6 hours of total data collection for providers during observations (1 hour observation at 3 time points with 2 families).
   b. We estimate time burden to be an average of 15 minutes for survey completion at baseline and 24 weeks.

2. The possibility of breached confidentiality by disclosure of personal information to administrative personnel at the early intervention system linking individual providers to their performance.
3. The risk of distress caused by the videotaped observation, interview content, and/or questionnaires:
    a. Providers may be made anxious by videoing, especially if they believe that their performance in the study may be evaluated by their agency or the EI system. Videotaping provides concrete examples of coaching techniques that are vital to the measurements proposed in this research; however, there is potential that such videotaping will provide concrete examples of intervention techniques or other behavior that could negatively influence staff performance review if administrators or supervisors in the EI system were to view it. For this reason, there will be no disclosure of videotaped performance or self-reported information about provider fidelity, especially to these personnel. To help minimize this risk, we will provide EI administrative personnel, including agency executive and clinical directors, written notification that these measures are confidential and at no time and under no circumstances will be shared with EI personnel.
    b. Potentially more distressing are emotional responses to fidelity measures. The fidelity measures are designed to quantify EI providers' adherence to the intervention protocol. EI providers may feel as though their willingness or ability to treat children with ASD is being challenged. Specifically, documenting providers' performance may cause feelings of insecurity regarding effort or ability.

Protection against Risks

Interaction with research participants. To minimize distress associated with respondent burden and distress associated with the interview, both parents and providers will be told at the beginning of each observation or have stated at the beginning of the questionnaire that they may refuse to participate in any part of the study and skip any question at any time. We will accommodate parents' wishes with regards to the timing of the observations, will break up data collection into stages if requested, and will train research staff to be sensitive to the well-being of parents, children, and providers. Participants will be reminded that information will be kept confidential and will never be published in any manner that would identify them. All participating families will be reminded that all clinical data will be collected for research purposes only. Children's distress is most likely to arise from stress or fatigue associated with observations. Frequent breaks will be offered as well as the ability to reschedule for a more optimal time. Families will be encouraged to contact their pediatrician, school evaluation center, or local developmental specialists if they desire further evaluation.

Data Management and Access. To minimize risks associated with breaches of confidentiality, all data pertaining to study participants will remain confidential at all times. The exposure of the identity of study participants will be avoided wherever possible. An 11-digit identification number will be employed to encode the participant identity on study materials, including data collection forms. Providers will be assigned a unique identification number as well. The Penn Center for

Mental Health at the University of Pennsylvania, where data will be stored, has a 20-year history of conducting research using protected health information and linking it with other datasets.

Center protocols for data management and protection have been developed and implemented for all datasets that include protected health information. Data records will be labeled confidential, use only unique identification numbers and be kept on a secure server that is only accessed by those on the study team. The research team will handle the original media on which data are kept. Media will be labeled confidential, use only unique identification numbers and be kept in a locked filing cabinet. Penn's Technology Support Services employs a number of security and privacy technologies and best practices in order to deliver services that provide "security in depth".
We plan to maintain access to the video and audio recorded data of participant field observations and interviews for approximately 3 years (or until analyses are complete) from the end of data collection. We will ask participants that consent to the study to sign a video release form to indicate whether they will allow us to keep video files beyond the 3 year expiration date for training and presentation purposes. Data will be maintained for the purpose of coding and analysis to inform the primary aims of the study.

To ensure the privacy and confidentiality of data for this project we will only store and use the identifiable data at the following locations: 1) Password-protected PCs; 2) A server at the University of Pennsylvania within the facilities managed room in the data center. A Senior LAN Consultant will upload the data onto the secure production servers. Videos will be sent from Penn to Dr. Ingersoll's lab at Michigan State University for coding. Videos will be sent via Penn Box, Penn's secure file sharing service. When viewing videos at MSU, staff will keep the video copy in Penn Box and not make copies to other media. Lastly, all output containing individual identifiable information is treated as confidential data. This information is never transferred electronically via email or other protocols. Any printed material containing individual identifiers is shredded.

Physical Security – Servers are hosted in dedicated virtual machines running on Dell SAN hardware in the Information Systems and computing facilities managed computer room. The hosting environment SAN and Host Bus Adapters are in a locked Dell rack housed in the Computer Room with restricted door card access to authorized personnel only. There is 24-hour camera surveillance.

Business Continuity – Server environments get redundant power from independent power feeds. In addition, each of the power sources is UPS protected. There is a Halon fire suppression system, with alarm points below the raised floor and in the ceiling. The virtual machines are hosted in VMWare ESX environments connected to a Dell SAN for shared storage. All virtual machines are stored on the SAN. To minimize downtime caused by hardware failure, the environment is configured for redundancy with multiple ESX hosts, multiple Host Bus Adapters, multiple SAN Switch ports, multiple storage processors, and RAID 5 storage. The server environments are replicated to a secondary site at 3650 Chestnut Street, which has equivalent physical security and also employs all of the security best practices outlined below.

Server Administration and Maintenance – The servers are administered by a team of four full-time professional IT staff. The team has over 50 years of combined experience configuring and

supporting Windows servers, and all of the staff attend technical training regularly to stay current in best practices for configuring and securing Windows and VMWare environments.

Server Security Best Practices – In keeping with SANS and Microsoft best practices, all software services and corresponding ports on the servers that are known to be substantial security risks and which are not used by CMH resources are disabled including telnet, and ftp. Security patches are applied promptly and there are standard processes in place for preventive maintenance and monitoring of the servers.

Hardware Firewalls - All servers reside behind a cluster of Juniper SSG520 firewalls. A Juniper SSG520 appliance configured in high availability mode acts as a secure gateway between PennNet/Internet (Untrusted Zone) and server resources behind the firewall. A custom firewall policy is developed for each resource hosted on each of the virtual machines. All policies are developed based on service port and PennNet only IP addresses.

VLAN - A Foundry Switch in the TSS managed rack is configured for 4 VLANs to support traffic segmentation behind the SSG520. LTS has access to each VLAN, giving us the ability to place each virtual machine in the appropriate VLAN for another layer of security.

SSL Encryption for Web Services - When hosting web servers we only support the use of HTTPS with an SSL certificate to minimize vulnerabilities and exploits common on the standard HTTP port. All port 80 traffic is re-directed to port 443.

Password Policy - A complex password policy, meeting Microsoft complex password requirements, is in effect in the CMH domain. The password policy requires all CMH domain users to change their domain password every 180 days.

Preparation of Staff for Data Collection

All study personnel will have Patient Oriented Research certification from the University of Pennsylvania. The PI will oversee the additional training and ongoing review of interviewers and coders. Clinical research staff who oversee assessments will be trained to reliability and supervised by the clinical psychologist on staff. In order to become reliable, staff will score videotaped treatment sessions. The PI will then score the same videotaped sessions and the PI's results will be compared with the examiner's results. The PI will calculate inter-rater reliability rates; inter-rater reliability should be no less than 80%. The PI will also provide all research assistants with training regarding culturally sensitive practices and maintaining professional boundaries while interacting with families.

Adverse Events

All unexpected adverse events will be reported by study personnel to the Philadelphia Department of Public Health IRB, the Project Officer at IES, and the IRB at Penn via standard adverse event reporting procedures. All adverse reactions will be noted and discussed thoroughly with the PI, investigative team, and IRB to determine proper reporting procedures on a case-by-case basis.

Potential Benefits of the Proposed Research to the Participants and Others

There are some benefits to family/child and clinician participants. Families in the treatment conditions will receive training in intervention techniques considered best practice for young children with ASD. In addition, clinicians in the two treatment conditions will receive considerable training and support throughout their participation that has the potential to benefit the children they treat. The potential exists for great benefits to child-serving systems at large. Potential risks are reasonable given the safeguards proposed and the valuable information to be yielded regarding interventions for children with ASD.