

**Title:** Optimizing a School-Based Therapeutic Play Intervention for Preschool Students: A Factorial Experiment Protocol

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**NCT Number:** NA

**Document Date:** 5/19/2026

**IRB Approval Date:** 7/05/2024 (Study number 1376935; WCG IRB)

## Abstract

### Background

Primary Project is a long-standing school-based prevention program, based on the tenets of child-centered play therapy, designed to support young children at risk for school adjustment difficulties. Although there is strong evidence for the kindergarten through third grade model, the Pre-K adaptation has not been systematically evaluated. The Pre-K Primary Project model is a multi-component intervention that aims to strengthen young children's social and emotional competencies through individual play sessions, structured peer play sessions, and classroom push-in sessions with a trained school-based interventionist.

### Methods

This study is grounded in the Multiphase Optimization Strategy (MOST) framework for intervention science. As such, we aim to optimize the multi-component intervention for effectiveness and feasibility within the primary school setting. We will recruit approximately 150 preschool children from multiple school districts through universal social-emotional screening. Children will be randomized individually within schools to one of eight conditions in a  $2 \times 2 \times 2$  factorial design. The experimental factors include length of individual sessions (8 versus 12 weeks), peer play sessions (on/off), and classroom push-in sessions (on/off). All children will receive at least one active intervention component. Primary outcomes are children's social-emotional adjustment as reported by teachers, parents, and paraprofessional child associates. Secondary outcomes include school connectedness, attendance, anxiety symptoms, and administrative records. Parents will also report on contextual risk and protective experiences. Analyses will use a factorial ANOVA framework to test main and interaction effects of the intervention components. We will use a community-engaged approach to decision making to identify the most optimized (i.e., effectiveness, affordable, scalable, and efficient) intervention.

### Discussion

This is the first optimization trial of the Pre-K Primary Project model. Findings will advance understanding of which components are most effective, both independently and in combination, and will provide evidence to guide schools in implementing efficient and sustainable models of early prevention. By identifying optimal configurations of the program, this study aims to improve social-emotional outcomes for preschool children and inform broader dissemination of the intervention.

### Keywords

Preschool, Prevention, Social-emotional development, School-based intervention, Factorial design, Randomized controlled trial, Child-centered play therapy, Play therapy, Early childhood education, MOST framework, Multiphase Optimization Strategy

### Administrative information

Title	Optimizing a School-Based Therapeutic Play Intervention for Preschool Students: A Factorial Experiment Protocol
Protocol version	Protocol version 3.0, September 2025

Funding	This research was supported in part by the New York State Education Department [grant numbers: C013777, C015274].
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Role of sponsor	The funder does not have authority in research activities including study design, data collection, data management, analysis, interpretation of data, writing, or research dissemination.

## Introduction

### Background and rationale

There are a growing number of children in the United States with mental, emotional, or behavioral health concerns (1,2). Left untreated, these difficulties may persist through development and contribute to a wide range of negative outcomes in adolescence and adulthood. Consequently, there is a critical need to identify effective strategies that promote protective factors, enhance resiliency, and disrupt the causal processes that facilitate the emergence of subsequent mental health problems. Prevention programs that enhance young children's social and emotional competencies can both alleviate present difficulties and protect youth against future mental health problems (3,4).

Early childhood is a critical developmental period for social and emotional growth, with key developmental milestones including the growth of peer social skills and self-regulation abilities. Educational settings are important contexts for fostering young children's social and emotional development. Children who adjust well to the school setting are more apt to thrive in terms of their social and emotional skill development, whereas children who struggle with the transition to the early school years may face challenges across multiple domains (5). It is these elevated symptoms detected within the general student population, not diagnoses of specific childhood disorders, that best predict adult mental health outcomes (6). Consequently, preventive interventions that include universal screening and encourage social and emotional skill development, while also facilitating a positive transition to the educational environment, are ideal.

School-based interventions are well positioned to strengthen children's social and emotional competencies and reduce future risk (7). Schools serve as a context for growth in multiple domains of socioemotional development, including interpersonal skill development with peers and adult figures, intrapersonal awareness of academic and non-academic skills, coping with difficulties, and managing the simultaneous demands of curricular and extracurricular activities (8). Further, recent evidence indicates that school-based interventions grounded in child-centered play therapy (CCPT) are related to reductions in children's behavioral, emotional, and academic problems (9). There is also some growing evidence that non-clinical preventive interventions grounded in the tenets of CCPT (i.e., Child-Centered Play Interventions; CCPIs) are effective for children's social and emotional development (10). CCPIs are often more feasible and sustainable for schools – for

instance, they are facilitated by a specially trained school-based paraprofessional (i.e., child associate) who is supervised by a licensed school-based mental health professional (11). However, research based on CCPIs is limited.

Primary Project is a long-standing CCPI that targets children in kindergarten through third grade (approximately ages 5 – 9) who are having school adjustment difficulties (11,12). The program provides structured play sessions with trained paraprofessional child associates under the supervision of mental health professionals to support children with early school adjustment difficulties. The goals of Primary Project are to enhance school-related social and emotional competencies (e.g., task orientation and peer social skills) while reducing behavioral and interpersonal adjustment difficulties in children.

Prior research has established the effectiveness of Primary Project in improving school adjustment outcomes in young children (13) and a recent study demonstrated positive effects on children's school attendance (14). A recent randomized controlled trial supported the program's effectiveness for improving children's social skills and self-regulation (Aaron et al., forthcoming).

Building on this foundation, Primary Project was adapted for preschool-aged children (approximately age 4) by adding developmentally appropriate components, including a greater focus on peer-play skills. The Pre-K Primary Project model includes three core components: individual play sessions, structured peer play sessions, and classroom push-in sessions wherein the paraprofessional child associate provides individual support to the child in a classroom setting. Conceptually, these three components act upon proximal mediators (e.g., increasing emotion regulation skills and self-efficacy; facilitating positive peer relationships; and promoting school connectedness) to enhance children's overall social-emotional adjustment (Figure 1).

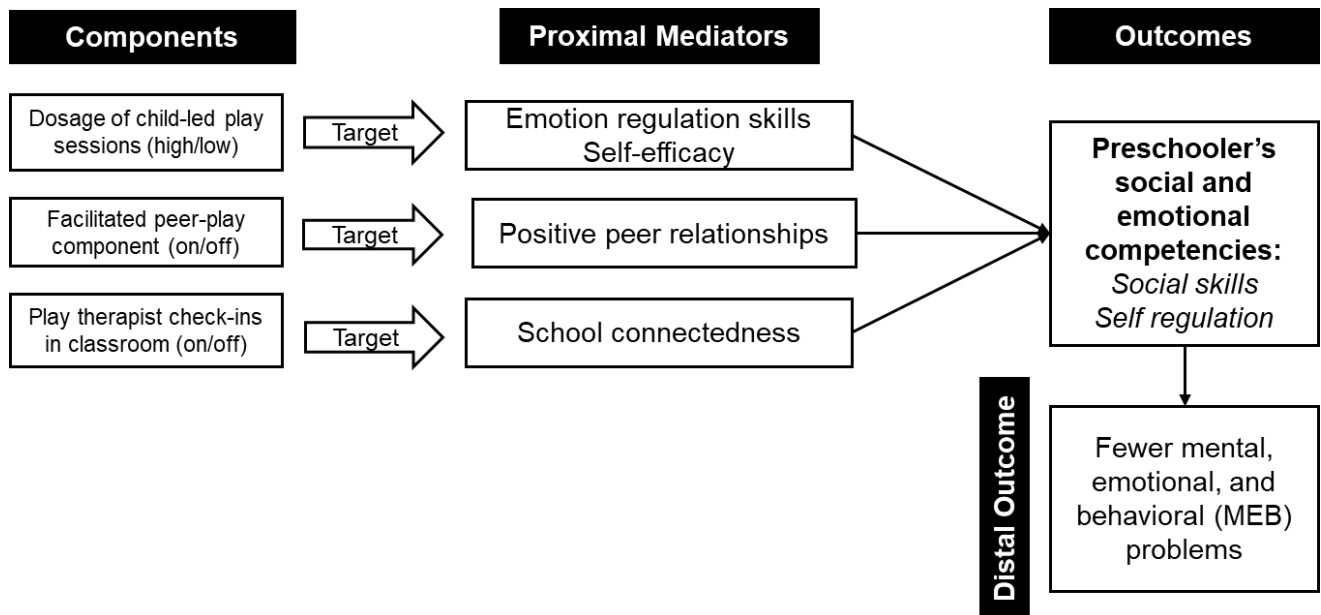
However, despite increasing implementation, the Pre-K Primary Project model has not undergone systematic evaluation to understand which components, and in what combination, are most effective. This represents a critical gap given the Pre-K model's multi-component nature. Understanding the individual and combined effects of its components is essential to guide schools towards efficient and sustainable program goals.

The current trial addresses this gap by using the Multiphase Optimization Strategy (MOST), an innovative translational framework (15) to develop and evaluate multi-component interventions (16,17). MOST involves three phases: preparation, optimization, and evaluation. In the preparation phase, investigators establish a conceptual model, identify candidate intervention components, and define an optimization objective that balances effectiveness with practical constraints. In the optimization phase, the goal is to empirically identify the *optimized intervention* via a randomized controlled trial (RCT), often using a factorial experimental design. The optimized intervention is the combination of candidate intervention components that achieves the best balance of intervention effectiveness with affordability, scalability, and efficiency (i.e., intervention EASE; (18). Finally, in the evaluation phase, the optimized intervention package is tested in a RCT, usually in a 2-arm trial, to confirm its effectiveness under real-world conditions compared to a suitable control.

The present trial represents the optimization phase of MOST. The specific optimization goal is to identify the combination of components that are most effective for improving children's social-emotional outcomes and school adjustment, while also being feasible in terms of program timing and resource constraints (e.g., ability to offer two full cycles per school year without incurring additional staffing costs). In sum, this trial examines whether individual play sessions, peer play sessions, and classroom push-ins, independently and in combination, improve preschool children's

social-emotional adjustment. The overall goal is to develop an optimized program model for broader dissemination.

**Figure 1**  
*Study Conceptual Model*



## Objectives

The primary objective of this trial is to *optimize* the Pre-K Primary Project intervention for strengthening preschool children's social-emotional adjustment. The first specific aim of this study is to determine the independent and combined effects of three intervention components (individual play, peer play, and classroom push-in sessions) on preschool children's social and emotional competence, using a factorial experimental design.

As an exploratory sub-aim, we also seek to explore the impact of intervention components on identified mediators including children's level of school connectedness, emotion regulation, and peer relationships. These exploratory analyses will inform iterative revisions to the conceptual model and future research studies.

Our second specific aim is to use a community-engaged approach to identify and disseminate the optimized version of Primary Project for preschool implementation. Specifically, we will work with school partners to consider the results from the optimization trial, balanced with the feasibility, sustainability, and affordability of different intervention packages (e.g., ability to offer two cycles per school year without incurring additional costs from staffing or other resources). These results will be disseminated via a new program manual and other materials targeted to both academic and non-academic audiences.

## Trial design

The trial design is a multi-site, randomized,  $2^3$  ( $2 \times 2 \times 2$ ) factorial experiment, meaning children will be randomized to one of eight conditions. The three experimental factors are: length of individual sessions (8 weeks versus 12 weeks); peer play sessions (present versus absent); and classroom push-in sessions (present versus absent). In this experimental design, the main effect of a

component is estimated by comparing the average outcome across all conditions that include the component with the average across all conditions that do not include it, and interactions are estimated as differences in a component's effect across the levels of the other components. The unit of randomization is the individual child, with random assignment stratified within each school to ensure balance across conditions. Due to the operationalization of the component levels, all children receive at least one active intervention component. See Figure 2 for a summary of the eight factorial conditions.

**Figure 2**  
*Factorial Design*

Condition	Component A: Individual sessions	Component B: Play pairs	Component C: Classroom Sessions
1	8 weeks	Yes	Yes
2	8 weeks	Yes	No
3	8 weeks	No	Yes
4	8 weeks	No	No
5	12 weeks	Yes	Yes
6	12 weeks	Yes	No
7	12 weeks	No	Yes
8	12 weeks	No	No

## Methods: Participants, interventions and outcomes

### Study setting

This study will be conducted with public school districts in New York State that have early childhood (i.e., pre-K) programs for 4-year-olds. There are currently five participating school districts that have been recruited to the study. The intervention will be implemented in school settings. Individual play sessions and peer-play sessions are conducted in a playroom that is private and separate from the classroom space. The classroom push-in component will be implemented in the classroom. A list of participating study sites will be available from the study team upon request.

### Eligibility criteria

**Participants.** Children will be eligible if they are enrolled in preschool classrooms at participating schools and identified as appropriate for intervention through universal screening. Screening will be conducted using the Teacher–Child Rating Scale (T-CRS; (19), a teacher-completed measure of social-emotional adjustment. Children who score in the target range indicating emerging adjustment difficulties (i.e., 15<sup>th</sup> to 30<sup>th</sup> percentile) will be eligible for participation in the trial. Children will be excluded if they demonstrate severe developmental impairments that would prevent participation in the intervention.

**Study centers.** Participating sites will be public preschools that have adopted (prior to the trial) the Pre-K Primary Project model as part of their early childhood programming.

**Intervention providers.** The intervention will be delivered by a trained paraprofessional (i.e., child associates) under the supervision of licensed school-based mental health professionals. All staff will complete program training and adhere to established Primary Project implementation standards.

**Who will take informed consent?**

Parents or legal guardians of children identified through the universal screening process will be approached for consent. Families will first receive the routine school-based permission form that allows their child to participate in Primary Project services. In addition, after a child is screened and selected as a participant for Primary Project, parents will receive a separate research permission form describing the purpose of the current study, study procedures, and data collection processes. Members of the study team are available to provide information upon request about both forms, answer questions, and ensure that parents fully understand what participation entails before making a decision. Written informed consent for the research study will be obtained by school teams and shared with the research team, prior to randomization. Refusal to participate in the study does not affect a child's eligibility to receive Primary Project services.

**Additional consent provisions for collection and use of participant data and biological specimens**

No biological specimens will be collected as part of this study. Consent procedures apply only to the collection and use of participant data. Parents will be informed that their child's de-identified study data may be used for future research related to program evaluation and child development. Any such use will be subject to Institutional Review Board approval, and all identifying information will be removed prior to data sharing.

**Interventions****Explanation for the choice of comparators**

This study will use a factorial design in which all participating children receive at least one active intervention component of Primary Project. The comparators will therefore be levels of the candidate intervention components that differ in either dosage or the presence or absence of specific components: individual play sessions of varying length (i.e., 8 versus 12 weeks); peer play sessions (i.e., present versus absent); and classroom push-ins (i.e., present versus absent). This experimental design allows for the estimation of the independent and combined effects of each component on the outcome of interest. By comparing children who receive a component/combination of components with those who do not, the study will identify which elements contribute to improvements in social-emotional outcomes while maintaining equity in service delivery across participants. Importantly, this approach will avoid the ethical concern of withholding the intervention entirely, as all children will receive some form of active support.

**Intervention description**

Primary Project is a school-based preventive intervention designed for children in kindergarten through 3<sup>rd</sup> grade. The Pre-K version of Primary Project was adapted from the established model and contains three components (i.e., individual play sessions, peer play sessions, and classroom push-in sessions). The program is delivered by trained paraprofessionals (i.e., child associates) under the supervision of licensed school-based mental health professionals. All intervention components will be delivered over the fall or spring semester of the pre-school year. The intervention is intended for 4-year-old pre-K programs. Child associates receive standardized training prior to implementation and ongoing supervision from licensed school-based mental health professionals. Fidelity to intervention protocols will be monitored through session logs, supervision meetings, and periodic consultations with program staff.

The three components of the Pre-K Primary Project model are described below. More details and materials for Primary Project program implementation are available by visiting the Children's Institute website or by contacting the corresponding author.

**Individual play sessions.** All children will receive individual play sessions with a child associate in a designated playroom within the school. Sessions will last 20-30 minutes and occur twice per week. All sessions are grounded in child-centered play therapy (CCPT) principles. Child associates use a non-directive approach, allowing children to choose from a range of developmentally appropriate toys and play materials (e.g., art supplies, blocks, puppets, and imaginative play sets) that encourage expression, problem-solving, and emotional regulation. The role of the child associate is to create a safe and supportive environment, verbally reflect on children's actions and feelings, and facilitate their self-directed play in ways that promote social and emotional growth. In the factorial design, children will be randomized to receive either 8 or 12 individual play sessions.

**Peer play sessions.** Children randomized to this condition will participate in structured play pairs, consisting of six, biweekly, 30-minute sessions with a peer and the child associate. Peers are non-study children who exhibit excellent social and emotional competencies, as observed and rated by their teachers during universal screening. Pairings will be determined collaboratively with teachers to ensure compatibility and opportunities for skill-building. Parents of play pairs give permission for their child to participate in regular Primary Project implementation. The sessions will be designed to promote social competence, cooperation, and peer connectedness by providing guided opportunities to practice skills such as sharing, turn-taking, communication, and conflict resolution. While maintaining a child-directed approach, the child associate will actively scaffold interactions by reflecting and reinforcing positive peer behaviors, providing gentle redirection when difficulties arise, and offering a variety of open-ended and expressive materials for children to choose during cooperative play such as blocks, pretend play items, or creative art materials.

**Classroom push-ins.** Children randomized to this condition will receive four, bi-weekly, classroom push-in sessions facilitated by the child associate. Push-in sessions will be scheduled weekly during regular classroom activities (e.g., circle time, free play, or small-group learning). During classroom push-in times, the child associate uses child-led therapeutic play techniques to help foster classroom engagement, positive peer interaction, and a sense of belonging for the target child. Child associates will coordinate with classroom teachers to integrate push-ins smoothly and to reinforce skills across settings.

### **Criteria for discontinuing or modifying allocated interventions**

Given that Pre-K Primary Project is a school-based, non-invasive preventive intervention, discontinuation or modification of an allocated intervention is expected to be rare. However, participation in intervention components may be discontinued under the following circumstances:

- **Parent or guardian request.** Parents may withdraw their child from the research study or any intervention component at any time without consequence.
- **Child request or distress.** If a child expresses unwillingness to participate or demonstrates significant distress that cannot be resolved within the session, the session may be paused or discontinued at the discretion of the child associate in consultation with the supervising mental health professional.
- **Teacher or school request.** School staff may request that a child's participation be discontinued if there are concerns about the child's ability to participate safely or if scheduling conflicts arise that cannot be accommodated.
- **Developmental or clinical needs.** If a child is identified as having developmental or behavioral needs that make participation inappropriate (e.g., severe impairment), the intervention will be discontinued.
- **Relocation.** The intervention may be discontinued if the child relocates to a different school.



Any discontinuation or modification will be documented in study records, and children will continue to have access to standard school services.

### **Strategies to improve adherence to interventions**

Several strategies will be in place to support adherence to intervention delivery and participation. Child associates will maintain weekly schedules for individual and peer play sessions to ensure consistency. Classroom push-ins will be coordinated with teachers to align with classroom routines and minimize disruptions. Intervention attendance and completion will be monitored through child associate logs, which document frequency, duration, and activities of each session.

To promote fidelity, child associates will complete a two-day (12-hour total) introductory standardized training before program implementation. The training consists of foundational knowledge and skills, including interactive activities and role playing with feedback from trainers. Primary Project supervisors also attend an additional foundational training that focuses on how to best support the child associate using supervision best practices. Additionally, child associates participate in ongoing, regular supervision with their supervisor (a school-based mental health professional). Supervisors will review session logs, provide feedback, and engage in joint problem solving.

To ensure adherence to the factorial experimental design and maintain fidelity to the intervention, child associates will complete structured session logs for each participating child. Session logs will be tailored to each child's assigned experimental condition and will include instructions for which intervention component to be delivered each session. Session logs will support child associates in maintaining protocol fidelity and will enable study staff to systematically monitor adherence to both intervention and research procedures. Child associates will upload their session notes at the end of every week to a HIPPA-compliant shared drive, for review by the study team.

### **Relevant concomitant care permitted or prohibited during the trial**

Children will be permitted to continue receiving all standard school and community services during the trial. Participation in Primary Project will not restrict access to other educational, behavioral, or mental health supports provided through the school district or external providers. No concomitant services will be prohibited. Documentation of additional services received will be collected when available to inform interpretation of study outcomes.

### **Provisions for post-trial care**

This is a minimal risk study. The probability and magnitude of potential harm or discomfort will not be greater than those ordinarily encountered in daily life. No specialized post-trial medical or ancillary care will be required. At the conclusion of the study, children will continue to have access to standard school services. Because of the minimal risk nature of the intervention, no specific compensation plan will be in place for harm. Any concerns that arise during or after participation will be addressed in collaboration with school personnel, with referral to appropriate school or community services as needed.

### **Outcomes**

**Primary outcome.** The primary outcome is children's social-emotional adjustment, assessed using teacher reports on the Teacher–Child Rating Scale, short-form (T-CRS-sf)(20). Scores will be aggregated as a continuous measure by averaging the subscales of behavior control, task orientation, assertive social skills, and peer social skills. The primary outcome was chosen because improved social-emotional adjustment is the central target of the Primary Project and is

conceptually linked to distal mental, emotional, and behavioral outcomes. As an exploratory aim, we will also explore specific subscale changes in behavior control, task orientation, assertive social skills, and peer social skills.

**Secondary outcomes.** Secondary outcomes will assess related aspects of children’s functioning and contextual influences. Attendance will be measured using school administrative records across the academic year, providing an objective indicator of school engagement. In addition, parents will complete surveys at baseline and spring follow-up, reporting on their child’s anxiety symptoms, social-emotional competencies, and contextual family risk and protective experiences. Together, these outcomes provide a multi-informant and multi-method perspective on the broader impact of the intervention.

**Exploratory/longer-term outcomes.** With parental consent, school records will be collected in subsequent years to examine longer-term outcomes, including attendance, discipline records, and academic performance. These data will allow evaluation of sustained intervention effects into later grades.

The selected outcomes capture both proximal intervention targets (e.g., social-emotional adjustment, school connectedness, and anxiety symptoms) and more distal indicators of school functioning (e.g., attendance and academic outcomes). Together, these measures provide a comprehensive assessment of the effectiveness of Pre-K Primary Project for improving early developmental competencies and reducing risk for later mental, emotional, and behavioral problems.

### Participant timeline

See Table 1 for participant timeline.

**Table 1. Participant timeline: Schedule of enrollment, interventions, and assessments.<sup>a</sup>**

TIMEPOINT	TRIAL PERIOD				
	Enrollment		Post-randomization		Close Out
	$-t_1$ to 0	0	$t_1$	$t_2$	
<b>ENROLLMENT:</b>	X				
Eligibility screen	X				
Informed consent	X				
Randomization		X			
<b>INTERVENTIONS:</b>					
Individual Session (8 Weeks) + Play Pair + Classroom Sessions			→		
Individual Session (8 Weeks) + Play Pair			→		
Individual Session (8 Weeks) + Classroom Sessions			→		
Individual Session (8 Weeks)			→		
Individual Session (12 Weeks) + Play Pair + Classroom Sessions			→		
Individual Session (12 Weeks) + Play Pair			→		
Individual Session (12 Weeks) + Classroom Sessions			→		
Individual Session (12 Weeks)			→		
<b>ASSESSMENTS:</b>					

Demographics	X				
Teacher-Child Rating Scale (T-CRS)	X			X	
Associate-Child Rating Scale (A-CRS)			X	X	
Parent Report Measures			X	X	
School Attendance and Administrative Records					X

*Note.* Table based on SPIRIT 2025 recommendations (Chan et al., 2025)

### Sample size

Power was estimated using the MOST package (21) in R version 4.4.2 with the FactorialPowerPlan function. We assumed that random assignment would occur within five clusters (school districts) with an average size of 45 (i.e., total  $N = 225$ ). We used pilot data to assume an intraclass correlation of .05 and a pre-post correlation of .6. The smallest meaningful effect size was set at  $d = .3$ . Given these assumptions, the calculated power was .80.

### Recruitment

Children will be recruited through a universal screening process in preschool classrooms at the beginning and middle of the academic year. As part of regular program implementation, teachers complete the Teacher–Child Rating Scale short-form (T-CRS-sf) for all children, and scores are used to identify those within the target range of emerging school adjustment difficulties. Parents or legal guardians of eligible children will then be contacted by the study team and provided with both the standard school permission form for Primary Project services and a separate research consent form describing the study.

To maximize enrollment, study staff will work closely with school administrators, teachers, and child associates to ensure that screening and consent procedures will be well integrated into school routines. Parents will be provided with clear written and verbal information about the program and study, opportunities to ask questions, and adequate time to return consent forms. In addition, study staff will remain available throughout the consent process to address parent concerns and encourage participation. These procedures have been successfully used in prior evaluations of Primary Project and will be expected to yield the target enrollment of approximately 150 preschool children across four districts.

### Assignment of interventions: allocation

#### Sequence generation

The allocation sequence will be generated by the study statistician using a computer-based randomization procedure. Eligible children are randomized at the individual level within schools to one of eight conditions in the  $2 \times 2 \times 2$  factorial design. Allocation is equal across conditions (1:1:1:1:1:1:1:1) and stratified by school.

#### Concealment mechanism

The randomization sequence will be maintained centrally by the statistician and will not be accessible to school personnel or study staff responsible for enrollment. Intervention assignments will be released only after a child is enrolled and consented, ensuring that group allocation remains concealed until the point of assignment.

#### Implementation

The study statistician will generate the randomization sequence and oversee assignment. Members of the study team will enroll participants following universal screening and parental consent. Once

enrollment is complete, the statistician will assign children to intervention conditions according to the concealed randomization sequence.

## **Assignment of interventions: Blinding**

### **Who will be blinded**

Because Pre-K Primary Project is a behavioral intervention delivered in classroom and playroom settings, it is not possible to blind participants, parents, teachers, or child associates to intervention allocation. However, data analysts will remain blinded to group assignments during primary analyses, and outcome measures will be collected from multiple informants to reduce bias. Teachers and parents complete standardized rating scales without being informed of the child's specific intervention condition.

### **Procedure for unblinding if needed**

Given that intervention allocation will be visible in the school setting, unblinding will not be applicable for participants, parents, or intervention staff. For data analysts, unblinding to intervention conditions will occur only after the primary analyses are completed. No other circumstances requiring unblinding are anticipated due to the minimal risk nature of the intervention.

## **Data collection and management**

### **Plans for assessment and collection of outcomes**

Throughout the trial we will aim to maintain data quality and consistency through the use of structured and standardized procedures for data collection and management. All study measures have established reliability and validity to ensure that data collected is accurate and meaningful.

Baseline demographic information will be collected at pre-intervention using a student information questionnaire completed by schools, including child age, grade, and other core student characteristics necessary for sample description and analytic adjustment.

The primary outcome is social-emotional adjustment, which will be assessed before and after the intervention using the Teacher-Child Rating Scale (T-CRS), which is a teacher-reported measure of children's social skills and self-regulation (20). Data on social-emotional adjustment will also be collected via the Associate-Child Rating Scale (A-CRS), a child associate-reported measure assessing social skills, behavior control, and task orientation, developed by the Children's Institute, and the Parent-Child Rating Scale (P-CRS), a parent-reported measure that evaluates social skills, behavior control, and task orientation through parent reports (13).

At pre- and post- intervention, additional set of validated measures will be completed by parents to assess related domains of functioning including: (1) the Child Anxiety Life Interference Scale (Preschool Version), a validated parent-reported scale assessing children's anxiety symptoms related to school contexts (22); (2) the School Refusal Assessment Scale-Revised, a validated 24-item parent-reported measure examining children's refusal behaviors regarding school attendance (23); (3) the Emotion Regulation Checklist (ERC), which assesses children's regulatory skills and emotional lability (24); (4) the pilot Preschool School Connectedness Measure, a parent reported measure developed by researchers at Children's Institute, which captures children's sense of belonging and connectedness at school; and (5) the Children and Families Experiences Survey (CAFEs), a measure of adverse and protective childhood experiences (25), which will be administered at post-intervention to capture contextual factors relevant to children's experiences during the study period. At the conclusion of the school year, secondary outcomes will also be obtained from school administrative databases, including disciplinary and attendance records.

Fidelity of program implementation will be monitored using multiple tools. The child associate or their mental health supervisor completes a tool (i.e., Pre-K Child Log) following the duration of each student's program to record session frequency, duration, and related activity information. The child associate will also maintain qualitative session notes to document unusual occurrences and participant progress.

To promote data quality and integrity, all study personnel will receive comprehensive training on administering and scoring instruments, as well as standardized data entry instructions. An ongoing quality control check will be conducted by the study coordinator to detect any inconsistencies or errors in the data and correct them as soon as possible.

<b>Table 2. Description of measures and data collection timeline</b>			
<b>Variable</b>	<b>Measurement</b>	<b>Description</b>	<b>Informant</b>
<b>Demographics</b>	Student information questionnaire		School
<b>Primary and Secondary Outcomes</b>			
Social-Emotional Adjustment	Teacher-Child Rating Scale (T-CRS)	Teacher reported measure on children's social skills and self-regulation (Weber et al., 2017)	Teacher
	Associate-Child Rating Scale (A-CRS)	Child associate reported measure on children's social skills, behavior control, and task orientation	Child Associate
	Parent-Child Rating Scale (P-CRS)	Parent reported measure on children's social skills, behavior control, and task orientation	Parent
	Child Anxiety Life Interference Scale – Preschool Version	18 item parent report on child's anxiety symptoms in regards to the school setting (Gilbertson et al., 2017)	Parent
School connectedness	Pre-K School Connectedness Measure	Parent-reported pilot items about children's feelings of connectedness and belonging to their class and school.	Parents
	School Refusal Assessment Scale-Revised (24 items)	24 items; parent reports on child's refusal to attend school (Kearney, 2002)	Parents
Other Outcomes	Discipline / Other administrative data	Deidentified administrative data	School database
	Attendance	Deidentified administrative data	School database
Emotion regulation	Emotion regulation checklist (ERC)	Parent-reported measure about children's emotion regulation skills and lability/negativity in emotional situations (Shields & Cicchetti, 1997)	Parents
<b>Contextual Factors</b>			
Adverse and protective childhood experiences	Child and Family Experiences Survey (CAFES)	Parent-reported measure about adverse and protective childhood experiences (Gongye et al., 2025)	Parents
<b>Implementation Measures</b>			
Fidelity and Implementation	Pre-K Child Log	Primary Project measure to monitor number of sessions, length of	Child associate

		sessions, and other implementation data.	
	Child associate session notes	Session notes written by child associates to monitor any unusual occurrences and to track progress in the program.	Child associate

### **Plans to promote participant retention and complete follow-up**

Several strategies will be employed to ensure high participant retention and maximize follow-up completion. Parents will receive reminders via email and text-messaging (i.e., short message service [SMS]) to complete surveys on time. The study team will also work closely with the school-based Primary Project team to ensure participant retention and completion of study materials. Throughout the study, staff will maintain consistent and supportive communication with parents to facilitate engagement and address any issues that may arise. Parents receive a \$20 gift card for each survey they complete.

If a participant discontinues or deviates from the intervention protocol, all data collected up to the point of withdrawal will be retained for analysis. With parental consent, follow-up data will be collected, including primary and secondary outcome measurements, via online surveys distributed by email or SMS. This method is designed to minimize participant burden, while maintaining the integrity of the intention-to-treat analysis.

### **Data management**

School-based data will be collected using an internet-based data management system managed by COMET Informatics, LLC. Parent survey data will be collected and managed using Qualtrics. All written materials will be scanned and uploaded by school teams to a secure and FERPA-compliant shared drive via Microsoft's enterprise-level cloud servers. For parent surveys that are filled out via paper, a trained research assistant will enter the data on Qualtrics, and data entry will be checked by a supervisor.

All research data will be stored on Microsoft's enterprise-level cloud servers, which are encrypted and access-controlled. Data access will require authorization and password protection, and only approved study personnel will be granted credentials. Potential risks of disclosure will be minimized through adherence to appropriate authorization of access to all data. Any inadvertent disclosures will immediately be reported to those affected.

Data will be checked regularly to ensure data quality and accuracy, including checking ranges of valid values and identifying inconsistencies. At the conclusion of the study, we will remove personal identifiers from all datasets in place of an anonymized identifier for each student. Only anonymized identifiers will be used during analysis.

A data codebook will be generated that lists all variable names, corresponding items and measures, and any pertinent notes from data collection.

### **Confidentiality {27}**

The study will protect the confidentiality of all data at all stages. Parents are informed during the consent process that all responses are confidential and are only for research purposes. This is a minimal or less-than minimal risk study. All measurements are completed by adults about the children and/or about the intervention. The data collected is not of a sensitive or controversial nature and

largely reflects data routinely gathered in schools.

Only the investigator and authorized study personnel will have access to identifiable information. Data is stored on password-protected servers compliant with FERPA and all personal identifiers will be removed prior to analysis. Each participant will be assigned an anonymized study identifier consistent across all analytic files. Deidentified datasets are stored permanently in Microsoft enterprise-level cloud-based servers. Analyses will be performed locally on centrally-managed devices with encrypted hard drives with tiered permissions and dual-factor user authentication.

After data collection is complete, only deidentified data will be retained for analysis and long-term storage. These deidentified datasets will be stored on encrypted cloud-based servers with access restricted to the study team.

Data will be reported on in the aggregate, and we will not report on any subgroups with fewer than 10 individuals.

## **Statistical methods**

### **Statistical methods for primary and secondary outcomes**

Prior to our main analysis, we will investigate group equivalence to determine successful randomization. Specifically, we will use chi-square tests to investigate differences in groups by child sex and race, and we will use ANOVAs to investigate differences in groups by age and by baseline T-CRS scores (overall score, peer social skills, assertive social skills, task orientation, and behavioral control). If differences exist between groups, these will be adjusted for in subsequent analysis.

Primary analyses will use a factorial ANOVA framework to examine the main effects of components on a composite score for social-emotional adjustment. In a 2x2x2 factorial design, there are 3 main effects (i.e., length of individual sessions, play pairs, and classroom sessions), three two-way interactions, and one three-way interaction. In factorial designs, the main effect of a component is estimated by collapsing across the levels of the other factors. For example, to determine the main effect of session length, outcomes will be compared between participants in conditions with 8-week sessions and those in conditions with 12-week sessions, collapsing across the presence or absence of the other components.

Prior to conducting the factorial ANOVA, we will test the data for necessary assumptions, including normal distribution of residuals and homoscedasticity. Then, the factorial ANOVA will be conducted using the lavaan package (26) in R version 4.4.2. We will covary for length of time each student is in their condition, by weeks, to account for student absences and other variations in program timing. We will use effect coding with two levels at each component (+1, -1), as recommended for factorial analysis within the MOST framework (27). Note that effect coding, rather than dummy coding, results in uncorrelated main and interaction effects (partial eta-squared), lending to increased interpretability.

The primary outcome is social-emotional adjustment (composite score) measured by the Teacher-Child Rating Scale. We will also conduct analysis to explore the impact of intervention components on four subscales of the T-CRS (peer social skills, assertive social skills, task orientation, and behavior control). Secondary outcomes will include school belongingness, emotion regulation, and anxiety symptoms. All *p* values will be adjusted using the Holm correction for multiple comparisons.

Exploratory analyses will examine long term school outcomes (e.g., attendance, disciplinary events, academic performance) to compare students who participated in different dosages and configurations of Pre-K Primary Project.

**Interim analyses**

N/A. No interim analyses will be conducted.

**Methods for additional analyses (e.g. subgroup analyses)**

In a sensitivity analysis, we will also explore, using a structural equation modeling framework, whether family contextual risk (as reported on the Children and Families Experiences Survey), moderates overall change in social-emotional competence from pre- to post-intervention. The Child and Families Experiences Survey is a measure of childhood adversities, and will result in an index of adverse childhood experiences.

**Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data**

All primary analyses will follow an intention-to-treat (ITT) framework, including all participants as randomized, regardless of their level of adherence to assigned intervention components. Sensitivity analyses may also be conducted to examine outcomes for children who complete the majority (>80%) of their assigned intervention sessions versus those who do not.

Prior to conducting substantive analyses, we will investigate patterns and potential mechanisms of missingness to determine whether data are missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR)(28). Descriptive analyses will summarize the proportion and distribution of missingness across variables and study conditions. Little's MCAR test will be used to evaluate whether data are MCAR. Specific follow-up missing data procedures will be determined based on patterns of missingness, such as logistic regression analyses or correlational tests to determine whether missingness is associated with observed demographic, study condition, baseline, or outcome variables, consistent with MAR mechanisms.

Because the intervention is embedded in the school day, missing outcome data are expected to be minimal. Attendance and disciplinary records will be available for nearly all children, even if they discontinue participation in intervention sessions. Survey data from parents and teachers may have higher rates of missingness, but retention strategies (e.g., reminder messages, consistent study team communication, and small incentives for survey completion) are designed to minimize nonresponse. These procedures will help ensure that analyses remain robust and that conclusions reflect both planned intervention exposure and real-world patterns of adherence.

If data are MCAR or MAR, missing data will be addressed using full information maximum likelihood (FIML) estimation in mixed-effects models, which allows the inclusion of participants with partially missing outcome data under the assumption that data are missing at random (29,30). As a robustness check, multiple imputation methods may be employed to evaluate whether findings are consistent across analytic approaches.

**Plans to give access to the full protocol, participant level-data and statistical code**

The full protocol, statistical code, and covariance matrix will be available to the public. Participant-level datasets will not be available due to lack of consent.

**Additional Methods****Community-engaged approach**

Our second aim is to use a community-engaged approach to identify and disseminate the optimized version of Primary Project for preschool implementation. We will develop a community advisory



board consisting of at least one representative (e.g., principal, teacher, and/or paraprofessional) from each participating school district. We will also include at least one Primary Project caregiver in the community advisory board. Following analyses, we will present results to each school team and gather feedback on implications of our findings. We will then hold a series of meetings with our community advisory board to identify the combination of components that are most effective for improving children's social-emotional outcomes and school adjustment (using results from our factorial experiment), while also being feasible in terms of program timing and resource constraints (e.g., ability to offer two full cycles per school year without incurring additional staffing costs).

Once the optimized intervention has been identified in conjunction with the community advisory board, we will disseminate our findings in multiple ways, including a fact sheet for schools and integration into all future training and implementation materials.

## **Oversight and monitoring**

### **Composition of the coordinating center and trial steering committee**

The trial is coordinated by the research team at Children's Institute, which serves as the central coordinating center. The PI will oversee the research team. This team is responsible for day-to-day management of the study, including participant recruitment, randomization, data collection, data management, and oversight of intervention delivery. The coordinating center will meet weekly during active recruitment and data collection periods to monitor progress and address operational issues, and at least monthly during other phases of the trial. Oversight of the trial will be provided by a team composed of senior investigators and project staff from Children's Institute, with representation from partnering school districts. This team is responsible for ensuring that the trial adheres to the approved protocol, monitoring study implementation, reviewing study progress, and resolving any barriers to recruitment, intervention delivery, or data collection. Additionally, research personnel from the Children's Institute will comprise the data management team which will be responsible for overseeing data entry, quality control, and secure storage. Given the minimal risk nature of the trial, no independent endpoint adjudication committee is required.

### **Composition of the data monitoring committee, its role and reporting structure**

Given the minimal risk nature of this behavioral, school-based trial, an independent Data Monitoring Committee has not been established. Oversight of study conduct, data quality, and participant safety will instead be carried out by the coordinating research and data management teams at Children's Institute. These groups are responsible for monitoring adherence to the protocol, ensuring fidelity to intervention delivery, and addressing any operational or ethical issues that arise. Because no sensitive clinical outcomes or safety concerns are anticipated, formal interim analyses and external safety monitoring are not required. Should unexpected risks or adverse events occur, they will be reported promptly to the Institutional Review Board in accordance with regulatory requirements. This approach is consistent with guidance that independent DMCs are not required for minimal risk, non-clinical intervention trials.

### **Adverse event reporting and harms**

The Pre-K Primary Project is a non-invasive, school-based preventive intervention and is classified as minimal risk. No adverse medical events are anticipated. However, any unintended effects of participation, such as a child displaying significant distress during a session or a parent expressing concern about study procedures, will be documented by child associates and reported to the supervising mental health professional. Supervisors will review such events and determine whether modifications to intervention delivery are necessary. All reported adverse events will be reviewed by the study coordinator and principal investigator, and any event that meets criteria for an

unanticipated problem involving risks to participants will be reported promptly to the Institutional Review Board (IRB) in accordance with regulatory requirements.

Because of the minimal risk nature of the intervention, no formal system for soliciting adverse events will be used beyond staff monitoring and supervision procedures. Any identified concerns will be addressed collaboratively with school personnel and, if appropriate, referrals will be made to school-based or community services.

### **Frequency and plans for auditing trial conduct**

A formal trial audit will not be conducted due to the minimal risk nature of the study. Adherence to study protocol will be monitored continuously by the Principal Investigator.

### **Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees)**

Any substantial modifications to the protocol, such as changes to eligibility criteria, outcomes, or analytic approaches, will be submitted for approval to the Institutional Review Board (IRB) prior to implementation. Approved amendments will also be communicated to the study team through regular coordination meetings and updated study documentation. In the event that modifications directly affect participants or their families (e.g., changes to consent procedures or data collection burden), families will be notified through revised consent forms or supplemental communication from the study team. Any protocol changes of relevance to the scientific community will also be documented in publications and reported according to SPIRIT guidelines.

### **Dissemination plans**

To ensure the findings are accessible and reach a diverse group of stakeholders, the trial results will be disseminated through multiple channels. First, the findings will be submitted to peer-reviewed academic journals for publication and presented at relevant academic conferences. Further, our partners will receive a one-page summary that summarizes key findings and implications to ensure direct communication about practical applications. We will proactively distribute the findings to schools already implementing the intervention, enabling them to incorporate evidence-based practices into their daily operations. Then, we will embed the key findings and implications into the program implementation materials to manualize the findings within the best practices framework. There are no restrictions on publication or dissemination anticipated.

### **Discussion**

This trial represents the first optimization trial of the Pre-K Primary Project and is designed to identify the most effective and efficient combination of intervention components for preschool children. The factorial experimental design selected for this study offers an efficient way to examine main and interactive effects of multiple components. By embedding the program within school contexts, the study reflects real-world conditions and enhances the potential for sustainable implementation.

The success of this trial requires attention to several practical considerations. Because the intervention is delivered by paraprofessionals (i.e., child associates) under professional supervision, consistent training and treatment integrity are essential for ensuring high-quality implementation across multiple schools. Integration of intervention activities into the preschool schedule also requires careful coordination with teachers and school staff to minimize disruption to daily classroom routines. Engaging parents in survey completion presents another operational challenge, which the study addresses through regular communication, reminders, and modest incentives.

The trial also faces methodological considerations common to school-based research. Although randomization within schools reduces bias, variability in classroom and school contexts may influence outcomes, and analytic approaches must account for nesting of children within classrooms. The study takes place across five school districts, which each have different environmental and demographic characteristics that must be accounted for. Additionally, school districts were recruited based on prior implementation of the Primary Project Pre-K model, which has limited the scope of recruitment. Although ranging in socioeconomic status, many of the schools are predominantly White. At the same time, these districts represent urban, suburban, and rural geographies which increases the overall generalizability of our results. Last, while the study uses multiple informants and validated measures, outcomes rely largely on adult reports, which may introduce informant bias.

Despite these challenges, the trial is expected to generate important insights into which components of the Pre-K Primary Project most strongly promote social-emotional development, school connectedness, and resilience in early childhood. Findings will guide future evaluation in a larger randomized controlled trial of the optimized intervention and will inform dissemination efforts to schools and districts adopting the program.

### **Trial status**

This paper reflects the most recent protocol (version 3.0) as of September 3, 2025. Recruitment began in September 2024 and is expected to conclude in March 2027.

### **Abbreviations**

MOST = Multiphase Optimization Strategy  
ANOVA = Analysis of Variance  
CCPT = Child-centered Play Therapy  
CCPI = Child-centered Play Intervention  
Pre-K = Preschool  
T-CRS = Teacher-Child Rating Scale  
A-CRS = Associate-Child Rating Scale  
P-CRS = Parent-Child Rating Scale  
CAFEs = Children and Families Experiences Survey  
ERC = Emotion Regulation Checklist  
SMS = Short Message Service  
FERPA = Family Educational Rights and Privacy Act  
ITT = Intention-to-treat  
MCAR = Missing Completely at Random  
MAR = Missing at Random  
MNAR = Missing Not at Random  
FIML = Full Information Maximum Likelihood  
IRB = Institutional Review Board

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