Study Protocol and Statistical Analysis Plan

Promoting Effective Coping by Children Exposed to Post-divorce Interparental Conflict to Reduce Risk for Mental Health Problems

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Document Purpose

This document presents the final approved and as-conducted study protocol and the statistical analysis plan used for ClinicalTrials.gov results reporting. It is based primarily on the ClinicalTrials.gov registration and the final IRB-approved protocol dated May 20, 2025. Material changes from the originally approved protocol are identified in the relevant sections.

No participant names or other direct identifiers are included.

Protocol History

Version	Date	Description
Original IRB protocol	July 6, 2022	Originally approved study protocol
Final IRB protocol	May 20, 2025	Final approved operational protocol
Final as-conducted protocol	August 8, 2026	Draft prepared for ClinicalTrials.gov results reporting

Protocol Summary

The purpose of this study was to identify components for inclusion in a digital coping intervention intended to reduce risk for mental health problems among children exposed to high interparental conflict following parental separation or divorce.

The study used a randomized and counterbalanced 2×2×2 factorial design. Three candidate digital intervention components (Reappraisal, Distraction, and Relaxation) were each independently assigned as present or absent. This produced eight experimental conditions representing every possible combination of the three candidate components. All participants received a common Education/Introduction component.

The planned randomized-trial enrollment was 144 children between 9 and 12 years of age, with 18 children planned for each condition. A total of 148 children were ultimately randomized.

The study evaluated the main and interactive effects of the three candidate components on coping efficacy, emotional security, and child internalizing and externalizing problems. Outcomes were assessed at baseline, posttest approximately 30 days after the last assigned intervention component, and follow-up approximately 120 days after the last assigned component.

PRE-REGISTRATION CHANGE

The target sample was revised from 164 participants in the original K01 application to 144 participants. This provided a balanced factorial design with equal cell sizes and counterbalanced component order while retaining adequate power to detect a medium-sized effect. The revised target also aligned with the MOST decision-priority approach, in which components were evaluated using prespecified meaningful-effect thresholds rather than statistical significance alone. A total of 148 children were randomized because four previously randomized participants did not initiate the intervention. Sensitivity analyses with and without the four additional participants produced no substantive differences in the results.

Background and Rationale

Children exposed to high levels of conflict following parental separation or divorce are at increased risk for emotional and behavioral problems. Lower emotional security and coping efficacy may contribute to this risk. Although interventions that teach adaptive coping strategies can improve children's adjustment, prior programs have not focused specifically on children experiencing high levels of post-separation interparental conflict.

Because children generally cannot control interparental conflict, the study sought to identify coping strategies suited to this specific context. Reappraisal, distraction, and relaxation represent different evidence-based approaches to managing thoughts, emotions, and physiological arousal during or after interparental conflict. Each strategy was developed as a separate digital intervention component.

The 2×2×2 factorial design allowed the study to estimate each component's main effect and its interactions with the other components. Consistent with the Multiphase Optimization Strategy (MOST) framework, the objective was to identify components demonstrating meaningful effects for possible inclusion in a future optimized intervention package.

Study Objectives

The primary objective was to estimate the main and interactive effects of the Reappraisal, Distraction, and Relaxation components on children's interparental and family emotional security, coping efficacy, and child- and parent-reported internalizing and externalizing problems.

Secondary objectives were to estimate component effects on children's daily cognitive appraisals, emotional distress, physiological arousal, and coping behaviors during the six-week assessment period. Exploratory analyses examined whether changes in children's cognitive, emotional, and behavioral responses to interparental conflict accounted for component effects on the primary outcomes.

Study Design

This randomized, single-masked 2×2×2 factorial optimization trial evaluated three candidate intervention components (Reappraisal, Distraction, and Relaxation) each assigned as present or absent. Participants were randomized to one of eight conditions representing every possible combination of the three components.

All children received the Education/Introduction component and received 0-3 candidate components according to their randomized condition. Within conditions containing more than one candidate component, the order of the components was counterbalanced.

Condition	Education	Reappraisal	Distraction	Relaxation
1	Yes	No	No	No
2	Yes	Yes	No	No
3	Yes	No	Yes	No
4	Yes	No	No	Yes
5	Yes	Yes	Yes	No
6	Yes	Yes	No	Yes
7	Yes	No	Yes	Yes
8	Yes	Yes	Yes	Yes

The planned sample was 144 children, with approximately 18 children assigned to each condition. A total of 148 children were ultimately randomized, as described in the enrollment clarification in Section 1.

The study was conducted remotely with families living in the United States. Screening, consent, assessments, intervention activities, daily reports, and twice-weekly calls were completed using approved electronic and remote communication systems.

Participants

Inclusion Criteria

Children and participating parents were eligible when:

- The child was 9–12 years old and the child's parents were separated or divorced.

- The child and participating parent were fluent in English and lived in the United States.
- The participating parent had the legal authority to permit participation, agreed to complete study assessments, and had contact with the child for at least four overnights or 12 daytime visits per month.
- The parent's identity and telephone number could be verified during the remote screening process.
- The child's mean standardized score across two child-report measures of interparental conflict was at or above the 40th percentile of the reference distribution.
- The child had internalizing or externalizing problems in the borderline range or higher according to either child or parent report on the Brief Problem Monitor.

Exclusion Criteria

Children were excluded when:

- The child was actively participating in therapy or counseling.
- The child was unable to complete study tasks.
- The child scored at or above the 99th percentile on an internalizing- or externalizing-problems subscale of the BPM.
- The child or parent endorsed specified items indicating child self-harm or suicidality.
- The participating parent's identity or telephone number could not be verified.

Families excluded because of elevated symptoms or safety concerns were provided appropriate referral information.

PROTOCOL MODIFICATION

The upper exclusion threshold for internalizing and externalizing problems was revised from the 97th to the 99th percentile to reduce unnecessary exclusions and support recruitment while continuing to exclude children requiring a higher level of care. Safety screening was also revised to focus on specified CBCL and YSR items directly addressing self-harm and suicidality. Children meeting the revised exclusion criteria remained ineligible and were referred to appropriate resources.

Recruitment

Children were recruited through their parents using court, school, community, university, professional, and digital outreach. Recruitment also included families who had expressed interest in related research, public court records, participant referrals, targeted advertising through BuildClinical, and printed or electronic study materials.

Interested parents were directed to the study website to complete a web-based pre-screening survey and were generally notified of their preliminary eligibility within 48 hours. Potentially eligible families were then invited to schedule a remote screening session and complete the identity-verification procedures described in Section 8.

PROTOCOL MODIFICATION

Recruitment was expanded because pandemic-related changes substantially reduced attendance in the local court program, parental interest, and the number of eligible families, making the original local strategy insufficient to reach the target sample. Because study procedures were already conducted remotely, recruitment was broadened nationally through community, court, school, university, professional, and digital channels to improve enrollment and geographic diversity.

Consent, Parental Permission, and Child Assent

Consent occurred in three separate stages so that families could decide independently whether to participate in pre-screening, screening, and the full trial.

1. Before the parent-only pre-screening survey, the participating parent provided consent to complete the survey and to the research use of the pre-screening responses.
2. Before the remote screening session, the participating parent provided informed consent for their own screening participation and separate parental permission for the child to complete the screening and baseline assessment. The child separately provided assent to participate in screening. These forms authorized only the screening and eligibility-determination procedures.
3. After eligibility was confirmed, the participating parent provided new informed consent for their own enrollment in the full trial and separate parental permission for the child's enrollment. The child provided new assent to participate in the intervention and follow-up procedures.

At each stage, trained study personnel reviewed the applicable procedures, answered questions, and explained confidentiality and its limits. Forms were completed electronically using the REDCap eConsent framework, and participants received electronic copies of the signed forms.

If a parent appeared unable to provide informed consent because of acute distress or apparent substance use, the consent process was stopped and rescheduled. Participation at every stage was voluntary, and parents and children could decline to answer individual questions or discontinue participation without penalty.

Study Procedures

Pre-screening

The participating parent completed a 5–8-minute web-based survey assessing preliminary eligibility and demographic characteristics. Parents who appeared preliminarily eligible were generally notified within 48 hours and invited to schedule a remote screening session. Before scheduling, the parent submitted a photograph with valid picture identification through a secure REDCap form.

PROTOCOL MODIFICATION

Formal identity and telephone-verification procedures were added after the study encountered individuals misrepresenting their eligibility or identity. Parents were required to submit a photograph with valid identification, appear by video during screening, and validate their telephone number before enrollment.

Screening and Baseline Assessment

The parent and child attended an approximately two-hour remote screening session. During the session, study personnel verified the parent's identity and telephone number, obtained informed consent and assent, administered separate parent and child baseline assessments, and determined final eligibility.

The parent and child completed their assessments separately to protect the privacy of their responses. The child reported on interparental conflict, emotional security, coping, coping efficacy, and internalizing and externalizing problems. The parent reported on interparental conflict and the child's internalizing and externalizing problems.

Families who completed the baseline assessment but were ineligible were informed of the determination, compensated for the assessment, provided nationally accessible mental health and separation/divorce resources, and offered access to the digital games.

Study Orientation

Eligible families ordinarily completed an approximately 15-minute orientation immediately after the baseline assessment. When a family required a study-provided telephone, the telephone was mailed to the family and a second remote meeting was scheduled to complete the orientation after the device arrived.

During orientation, study personnel reviewed the intervention and assessment schedule, study technology, communication procedures, safety resources, and participation-point system. Families could use their own compatible device or a study-provided telephone with restricted functionality.

Randomization and Masking

After orientation, authorized study personnel randomized eligible children to one of the eight factorial combinations using the REDCap randomization module. A prespecified allocation table containing 144 assignments was placed in random order and uploaded to REDCap. The table allocated 18 children to each factorial combination and did not use stratification.

After the original target of 144 children had been enrolled, four randomized children had not initiated the intervention. Recruitment was therefore extended by four participants. The four corresponding factorial combinations were placed in random order, and the final four children enrolled were assigned sequentially according to that order.

Component order was counterbalanced within conditions containing multiple components. Each two-component combination was allocated equally between its two possible orders, with nine assignments per order. The condition containing all three candidate components was allocated equally across its six possible orders, with three assignments per order.

Children were told how many games they would complete but were not told the content of their assigned games or the content of components they were not assigned to receive. Staff conducting telephone interviews and reviewing or following up on daily reports and intervention responses were masked to condition. To maintain masking, experimental conditions were identified in REDCap using non-descriptive fruit names rather than intervention-component labels.

Digital Intervention Components

Children completed one digital game per week and completed between one and four games, depending on their randomized condition. Each game lasted approximately 30 minutes.

All children first completed the Education/Introduction game, which presented basic information about parental separation or divorce and explained connections among thoughts, feelings, and actions.

The Reappraisal component, presented to children as “Helpful Thoughts,” taught children to identify and use alternative, more helpful ways of thinking about stressful situations. The Distraction component, presented as “Distraction Actions,” taught children to redirect their attention temporarily toward appropriate activities when they could not immediately change a stressful situation. The Relaxation component, presented as “Relaxation Exercises,” taught strategies intended to reduce physiological arousal and promote calm responding.

Each candidate component game included psychoeducation, skill instruction, examples, interactive practice, application to the child's experiences, encouragement to practice the skill during the following week, and preparation for possible barriers to practice.

Intervention Feedback and Home-Practice Review

After each game, children were invited to complete a brief survey assessing the game's usability, acceptability, and relevance and providing an opportunity to suggest improvements. Approximately five days after each assigned coping game, children completed a brief home-practice review describing whether and how they had used the skill and any barriers to practice.

Longitudinal Assessments

During the six-week assessment period, children were asked to complete 42 online daily reports and 12 twice-weekly calls (twice per week). Parents were asked to complete 42 online daily reports during the same period.

Children's daily reports assessed interparental conflict events and their related cognitive, emotional, behavioral, and symptom responses. When no interparental conflict event occurred, children reported on another challenging experience and their responses to it. Parent reports provided information about relevant events and the child's adjustment, while twice-weekly telephone interviews collected additional event-specific information from children.

Posttest assessments were sent to the child and parent approximately 30 days after the last assigned intervention game. Follow-up assessments were sent approximately 120 days after the last assigned game, or approximately 90 days after the posttest. The latter assessment is referred to as the three-month follow-up because it occurred approximately three months after the posttest.

Participant Burden

Across all study procedures, children were expected to spend approximately 6.5–11 hours participating, and parents were expected to spend approximately 5–7 hours.

Schedule of Activities

Activity	Parent	Child	Timing
Pre-screening consent and survey	Yes	No	Before screening
Identity and phone verification	Yes	No	Screening session
Consent/permission/assent	Yes	Yes	Screening session
Baseline assessment	Yes	Yes	Before randomization
Consent/permission/assent	Yes	Yes	Enrollment
Orientation	Yes	Yes	After enrollment and before randomization
Randomization	No	Yes	After orientation
Education/Introduction game	No	Yes	Intervention period

Assigned coping games	No	Yes	One per week
Game feedback	No	Yes	After each game
Home practice review	No	Yes	About five days after each coping game
Daily reports	Yes	Yes	Up to 42 reports over six weeks
twice-weekly calls	No	Yes	12 interviews over six weeks
Posttest	Yes	Yes	~ 30 days after the last assigned game
Follow-up	Yes	Yes	~ 120 days after the last assigned game

Outcomes

Higher emotional-security and coping-efficacy scores indicated better outcomes, whereas higher internalizing- and externalizing-problem scores indicated worse outcomes. For statistical analysis, adverse outcomes were reoriented so that positive component effects consistently represented improvement. The seven registered outcomes were assessed at baseline, posttest, and follow-up. Component effects were analyzed separately at posttest and follow-up.

Outcome	**Reporter**	**Measure**
Interparental emotional security	Child	Security in the Interparental Subsystem Scale–SF, 17 items
Family emotional security	Child	Security in the Family System Scale, 24 items
Coping efficacy	Child	Coping Efficacy Scale, 7 items
Internalizing problems	Child	Brief Problem Monitor Internalizing, 6 items
Internalizing problems	Parent	Brief Problem Monitor Internalizing, 6 items
Externalizing problems	Child	Brief Problem Monitor Externalizing, 7 items
Externalizing problems	Parent	Brief Problem Monitor Externalizing, 7 items

Baseline outcomes were assessed before randomization. Posttest assessments were sent approximately 30 days after the last assigned intervention game, and follow-up assessments were sent approximately 120 days after the last assigned game. Secondary intensive outcomes assessed during the six-week period included conflict-specific and general cognitive appraisals, emotional distress, physiological arousal, and conflict-specific and general coping behaviors.

Compensation

Parents and children each received $50 for completing each major assessment: baseline, posttest, and follow-up. Children also earned participation points for completing daily reports, twice-weekly calls, digital games, and home-practice reviews. At 10-point increments through 70 points, children could select an age-appropriate toy, activity, or electronic gift card valued from approximately $5 to $20 (up to $88); physical prizes were selected to have an approximate value comparable to the electronic gift card offered at the same point level. Participants who completed the baseline assessment but were subsequently found ineligible received the applicable baseline compensation.

PROTOCOL MODIFICATION

The original protocol provided $10-20 for each major assessment (up to $45), additional $5 payments for child twice-weekly calls, and entries into a prize drawing. The final protocol provided $50 for each major assessment and replaced the drawing with a tiered participation-point system. These changes were intended to align compensation with participant burden and post-pandemic inflation, support enrollment and retention, and eliminate delays associated with maintaining a prize drawing during an extended recruitment period.

Risks and Safety Monitoring

Anticipated Risks

The study involved no more than minimal risk. Foreseeable risks included temporary discomfort when answering questions about interparental conflict, coping, emotions, or mental health and the possibility of a breach of confidentiality. Participants could skip individual questions or discontinue participation without penalty.

Safety Screening

Specified CBCL and YSR items concerning self-harm and suicidality were automatically flagged in Redcap for review by trained study personnel. Relevant responses were reviewed at baseline, posttest, and follow-up.

Children's daily reports, twice-weekly calls, and free-text intervention responses were also monitored for potential safety concerns. Study personnel reviewed these materials daily, with a maximum intended interval of 24 hours between submission and review.

Study personnel were trained in basic safety assessment using the NIMH Ask Suicide-Screening Questions toolkit. Participants reporting risk of harm to themselves or others were warmly transferred to the 988 Suicide & Crisis Lifeline. Families of children with mental health scores above the 99th percentile were connected with SAMHSA's National Helpline, and suspected abuse or neglect was referred to the Childhelp National Child Abuse Hotline. Critical incidents were reported to the IRB as required.

PROTOCOL MODIFICATION

Clinical oversight procedures were revised after recruitment expanded beyond Arizona because the original consulting clinician was licensed only in that state. The revised safety plan used continuously available national services to provide timely and geographically appropriate responses to safety concerns among participants throughout the United States.

Potential Benefits

Direct benefit was not guaranteed. Children may have benefited from learning and practicing coping strategies, including possible improvements in coping efficacy or emotional security or reductions in mental health problems. Families also received mental health and separation/divorce resources.

Privacy, Confidentiality, and Data Management

Study information was collected and transmitted using approved electronic systems, including REDCap, text-message services integrated with REDCap, a custom study application, and the digital intervention platform.

Each participant was assigned a study identification number, which was used to track research data across study systems. The file linking participant identities with study identification numbers was stored separately in REDCap and was accessible only to authorized study personnel. When necessary, authorized personnel used limited linkage information to connect intervention activity or safety-related responses with the correct participant record.

Photographs and identification images submitted for identity verification were stored securely in REDCap and destroyed after the participant completed or was discharged from the study. Analysis datasets did not contain direct identifiers. The linkage between participant identities and study identification numbers was retained for five years. Participant requests to delete eligible data were addressed within 30 calendar days, subject to applicable research and record-retention requirements.

The study was protected by an NIH Certificate of Confidentiality. Findings were reported only in aggregate or deidentified form.

PROTOCOL MODIFICATION

Unanticipated maintenance costs associated with the original intervention platform required the study to transition to a different learning-management system. The replacement system required user accounts, which were created using study-specific codes rather than children's names or email addresses; limited linkage information allowed authorized personnel to connect responses with study records and respond to safety concerns. Data retention, deletion, and identity-image procedures were further clarified in response to IRB requests during continuing review.

Data Quality

Study personnel received training in informed consent, assessment, safety monitoring, and data management procedures. Electronic surveys used programmed range checks and automated safety alerts when appropriate.

Data-quality reviews addressed potentially duplicate or fraudulent records, eligibility determinations, measure scoring, missing data, and consistency between randomized assignments and recorded factorial-condition codes. Analysis datasets were reviewed for valid values, scoring consistency, and completeness before the statistical models were fitted.

Ethical and Regulatory Oversight

The Arizona State University Institutional Review Board reviewed and approved the study. Material protocol modifications were implemented only after receiving the required IRB approval. Parents provided informed consent for their participation and permission for their child's participation, and children provided informed assent.

The trial was registered on ClinicalTrials.gov as NCT05822687. Study results and required supporting documents will be submitted in accordance with applicable reporting requirements.

Dissemination

Study findings will be disseminated through ClinicalTrials.gov, peer-reviewed publications, conference and community presentations, blog posts, and podcast interviews. Audiences may include researchers, mental health professionals, policy makers, family-law professionals, and community members.

Deidentified data may also be shared with qualified researchers when permitted. No participant will be identified in any report, presentation, publication, or shared dataset.

Statistical Analysis Plan

Study Design and Objective

This randomized, counterbalanced 2×2×2 factorial optimization trial evaluated the main and interaction effects of three digital coping components: Reappraisal, Distraction, and Relaxation. Each component was independently assigned as present or absent, producing eight experimental conditions. All participants received the common Education/Introduction component.

The primary objective was to estimate the main and interaction effects of the candidate components on emotional security, coping efficacy, and child- and parent-reported internalizing and externalizing problems.

Primary Outcome Measures

The registered primary outcomes were child-reported interparental emotional security, family emotional security, and coping efficacy and child- and parent-reported internalizing and externalizing problems. These outcomes were measured using the SIS-SF, SIFS, CES, and BPM, respectively, yielding seven reporter-specific outcomes.

The outcomes were assessed at baseline, posttest, and follow-up. The corresponding baseline score was included as a covariate, and component effects were estimated separately at posttest and follow-up. The 120-day follow-up was the principal endpoint for ClinicalTrials.gov results reporting.

Analysis Population

The primary analysis followed the intent-to-treat principle by analyzing participants according to their randomized factorial assignments, regardless of intervention completion. Of the 148 randomized participants, 147 were included in the adjusted models. One participant could not be included because the required baseline coping-style covariate was missing and was not imputed.

Primary Statistical Analysis

Each of the seven reporter-specific outcomes was analyzed separately at posttest and follow-up using Bayesian Gaussian regression, producing 14 primary models. Each model included the main effects of Reappraisal, Distraction, and Relaxation; all two-way interactions; the three-way interaction; the corresponding baseline outcome; child age and gender; baseline exposure to interparental conflict; and baseline primary-control coping.

The components were effect-coded as −1 for absent and +1 for present. Each reported component-present versus component-absent contrast was calculated as twice the corresponding regression coefficient and represented the component effect averaged across the levels of the other components.

Emotional-insecurity and mental-health-problem outcomes were reoriented for analysis so that positive component effects consistently indicated improvement.

Bayesian Estimation and Missing Data

Population-level regression coefficients were assigned weakly informative Normal(0,1) priors. Default priors were retained for the model intercepts and residual standard deviations. Posterior means and 95% credible intervals were reported.

Models were estimated using four chains of 6,000 iterations, including 3,000 warmup iterations per chain, for a total of 12,000 post-warmup draws per model. Convergence was evaluated using R-hat, effective sample size, and sampler divergences. R-hat values below 1.01, bulk and tail effective sample sizes above 400, and no divergent transitions were considered acceptable.

Missing posttest or follow-up outcomes and missing values of the corresponding baseline outcome were jointly estimated within each outcome-specific Bayesian model. Age, gender, baseline interparental conflict exposure, and baseline primary-control coping were not imputed. Participants missing any of these required covariates could not contribute to the adjusted model.

PROTOCOL MODIFICATION

The registered analysis plan specified frequentist linear mixed models with multiple imputation. Before reviewing the outcome results, we revised the analysis to use Bayesian factorial models and a posterior expected-value approach based on methodological advances in MOST published after the trial was registered. This approach retained information from the full posterior distributions of the main and interaction effects and used it to estimate expected outcomes for all eight conditions, leaving the factorial estimands, effect coding, and covariate set unchanged. A sensitivity analysis comparing weakly informative and flat priors indicated that the substantive conclusions were not driven by selected priors.

Standardized Effects

Component effects were reported in the original outcome units and as standardized effects. Because the components were coded −1 for absent and +1 for present, the component-present versus component-absent contrast was calculated as (2\beta). The standardized effect was calculated by dividing this contrast by the pooled observed standard deviation of the corresponding outcome at the applicable timepoint. The same transformations were applied to the limits of the 95% credible intervals.

Optimization Decision Procedure

The registered analysis plan proposed screening components using standardized-effect thresholds of at least 0.33 for coping efficacy, 0.18 for emotional security, or 0.20 for internalizing or externalizing problems. Under the final Bayesian approach, these thresholds were retained as descriptive benchmarks but were not applied as automatic component screen-in rules.
Instead, the posterior distributions of all main and interaction effects were used to estimate the expected outcome under each of the eight candidate intervention conditions. Expected outcomes were calculated separately for each primary outcome at posttest and follow-up, with baseline outcomes and other covariates held at representative values. Because these predictions incorporated the full factorial model, they accounted for both favorable and antagonistic interactions among components.

For each outcome, the posterior probability that a condition produced the best expected outcome was calculated as the proportion of posterior draws in which that condition had the most favorable expected value. The 120-day follow-up results were prioritized for ClinicalTrials.gov reporting. Optimization decisions

considered the pattern of expected outcomes and probability-of-best estimates across the primary outcomes rather than relying on a single statistical-significance test or deterministic component threshold.

Prior Sensitivity Analysis

To evaluate whether the weakly informative priors materially affected the conclusions, the follow-up coping-efficacy model was refitted using the software's default flat priors. Component estimates from the weakly informative and flat-prior models were compared. The substantive conclusions were not sensitive to the prior specification.

Multiplicity

No formal adjustment for multiple outcomes or factorial effects was applied. Results were interpreted using the posterior effect distributions, 95% credible intervals, expected-outcome estimates, and optimization summaries collectively rather than using a familywise null-hypothesis significance threshold.

Forthcoming Analyses

Analyses of reliable change, mediation, and the intensive longitudinal daily-report and telephone-interview data are forthcoming. These analyses were not included in the primary outcome analyses or optimization results reported in this statistical analysis plan.