HRP-503E– Protocol for Social or Behavioral Science or Educational Research
(2017-1)

Protocol Title: Comparing a Fatherhood Focused Individual Intervention to Batterer Intervention to Reduce IPV and Child Maltreatment

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(*If applicable*) Clinicaltrials.gov Registration #: NCT04165291

INSTRUCTIONS
This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:** 1. Use this protocol template for a PI initiated study that includes direct interactions with research subjects. Additional templates for other types of research protocols are available in the system Library: • If the study involves genetic testing, blood draws, or MRIs, do not use this form. Use the biomedical protocol template. • If the study involves secondary analysis of data, use the Secondary Analysis of Data protocol. • For activities that may qualify as exempt research, use the Request for Exemption form (which includes a decision tree to determine whether or not your study qualifies as exempt). 2. If a section or question does not apply to your research study, type "Not Applicable" underneath. 3. Once completed, upload your protocol in the "Basic Information" screen in IRES IRB system.

Glossary of Acronyms

IPV	Intimate Partner Violence
CM	Child Maltreatment
PFDP	Parent and Family Development Program
UCONN	University of Connecticut
F4C	Fathers for Change

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BIP	Batterer Intervention Program
RF	Reflective Functioning
ER	Emotion Regulation

SECTION I: GENERAL INFORMATION

1. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities.

9 years (for both Phases I and II)

2. **Study location:** State where the study will take place and in what setting.

Yale University Child Study Center and the Department of Psychiatry will be the locations for this research study. Participants may l be recruited, consented, assessed and receive study treatments at the Parent and Family Development Program (PFDP) Clinic at 350 George St, a licensed adult and child mental health clinic on the Yale School of Medicine Campus or via Zoom secure conferencing is in person meetings are not feasible.

If international, complete and submit **International checklist** (http://your.yale.edu/policies-procedures/forms/450-ch-1-international-research-checklist) Note: If your research involves interactions with any embargoed countries you should contact the Director of Corporate Contracts and Export Control Licensing (Donald.Deyo@yale.edu or call 203.785.3817) for guidance on how to proceed.

3. **Help us categorize your research**. Are you using any of the following?

☐ Class Project
☐ Participant Observation
☒ Interviews
☒ Surveys
☐ Focus groups (study is not anonymous)
☐ Research in K-12 schools (submit a School Agreement form for the study)
☐ Deception (submit a Debriefing sheet)
☒ Audiotaping, videotaping or photography of individuals (study is not anonymous)
☐ Public viewing of videotapes or photographs
☐ Yale Psychology Pool (study does not qualify for exemption)
☐ International research sites (attach the International Checklist)
☐ Online (web-based) activities
☐ Social networks

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SECTION IV: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

This project proposes to conduct important Stage I and Stage II treatment development steps to test the efficacy of Fathers for Change (F4C) compared to Batterer Intervention Program (BIP).

Aims for Phase I:

1. Develop a revised BIP manual for individual treatment delivery as a comparison treatment.
2. Develop a fidelity measure to distinguish F4C from BIP for therapist fidelity coding.
3. Establish acceptability and feasibility of F4C compared to traditional group BIP (BIP-G) and an individually delivered BIP (developed in aim 1 above; BIP-I). We will test the following specific research hypotheses:
   i. Fathers randomized to F4C will have higher completion rates than those in either the BIP-I or BIP-G treatments.
   ii. Fathers will report greater working alliance and satisfaction with F4C than either BIP condition
4. Assess initial intervention signal of F4C compared with BIP-I (developed in aim 1 above) and a group format BIP-G (current standard of care) program of comparable length. We will test the following specific research hypotheses:
   i. Fathers receiving F4C will evidence greater improvement in reflective functioning (RF) and emotion regulation post-intervention compared to fathers receiving BIP-I or BIP-G.
   ii. Fathers receiving F4C will show greater reductions in intimate partner violence (IPV) and child maltreatment (CM) over the 18 weeks of treatment compared to fathers receiving either BIP condition.
   iii. Fathers receiving F4C will maintain reductions in IPV and CM in the 3 months following treatment.

Exploratory aim Phase I:

5. Test whether improved RF and emotion regulation are associated with reduced IPV and CM consistent with the F4C mechanisms of change We will test the exploratory hypothesis:
   i. RF and emotion regulation will mediate the association between treatment group and IPV and CM outcomes at follow-up.

Aims for Phase II:

AIM 1. Compare F4C to a standard BIP in its efficacy to reduce FV by decreasing fathers' violent behavior, improve father-child interactions, and reduce child mental health symptoms. *Hypotheses.* Children of fathers who receive F4C (n=140), relative to BIP (n=140), will: (1a) experience less FV, (1b) have more positive father-child interactions, and (1c) have lower FV-related mental health symptoms (PTSD, internalizing/externalizing) at post treatment and 6- and 12-month follow-ups. The effects of both treatments on father and coparent mental health outcomes will also be examined (1d *exploratory*).

AIM 2. Identify and compare latent change profiles of therapeutic targets (RF, ER) in F4C and BIP fathers across the 18-week intervention. *Hypotheses.* Compared to BIP, more F4C fathers will show profiles of healthy change in therapeutic targets: (2a) masked coding of in-session RF/ ER (i.e., increased RF and adaptive ER, decreased maladaptive ER), and (2b)

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between-session self-reported RF/ ER (i.e., increased RF and adaptive ER, decreased maladaptive ER). F4C change profiles will reveal critical junctures in treatment that precipitate change, thereby serving to optimize timing/delivery of treatment components (2c, *exploratory*).

AIM 3. Examine the mediating role of therapeutic change targets (RF, ER) on child-related outcomes in F4C and BIP families. *Hypotheses.* Profiles of healthy change in RF and ER will mediate the treatment effect of F4C over BIP on: (3a) FV (3b) father-child interactions, and (3c) child mental health symptoms (PTSD, internalizing/externalizing) at post-treatment and at 6- and 12-month follow-ups.

2. Background: Describe the background information that led to the plan for this project. Provide references to support the expectation of obtaining useful scientific data.

Eighteen percent of children in the United States witness Intimate Partner Violence (IPV) in their homes[1] with significant immediate and long-term consequences to physical and psychological health.[2, 3] Exposure to IPV perpetrated by fathers is common among children referred to child protective services with both national and state level data indicating between 30-40% of child welfare reported children are exposed to IPV, which is most often perpetrated by a father figure.[1, 4] Child protective service systems have long focused on mothers in their interventions for both safety and treatment of IPV. Mothers have been tasked with protecting their children from witnessing IPV or risk losing their children. [5, 6] Further, all the treatment requirements and opportunities are provided to and expected to be carried out by mothers. Fathers are not held accountable nor are they expected to participate in treatments often due to a belief that interventions do not work for this population. This belief comes from several meta-analyses that report near zero effect sizes of current batterer group intervention programs (BIPs).[7-9] the only broadly available treatment for IPV perpetrators, in reducing violence. Beyond negligible effects, attrition rates, even for court-mandated programs, are high (30-60%) indicating a significant service need. Importantly, even among intervention completers, recidivism rates for BIPs can be 20-30% indicating high intervention failure. [10] Often, men who continue to use violence following completion of a group BIP are re-referred to the same program or another similar group program of greater length. [11] Others may serve a short jail sentence with no other treatment provided. Families with IPV are frequently involved with child protective services because it is well known that exposure to IPV is detrimental to children and increases their risk for psychosocial and psychiatric difficulties. [12-14] Despite their ineffectiveness child protective services and the courts in many states continue to use completion of BIPs as sufficient to grant child visitation or as evidence that child protective oversight is no longer needed.[15, 16]

Why focus on fatherhood to engage men? Given the current "one size fits all" approach to batterer intervention has shown limited impact on the outcome of repeat violence and re-arrest,[8, 17] there is urgent need for alternative intervention approaches. Psychoeducational group interventions have been the standard with the belief they are more effective for the population. They focus on societal influences that condone violence against women, power and control and teach skills for anger management. Evidence suggests that tailoring IPV interventions specifically for men who are fathers may improve outcomes.[18, 19] Indeed, studies suggest fatherhood is a motivator for change among men who perpetrate IPV.[20, 21] Rothman and colleagues 36 found that nearly 2/3 of biological fathers who perpetrated IPV believed that their violence negatively affected their parent–child relationship and many worried about the long-term impact of IPV on their children. These data suggest that interventions that build on fathers' commitment to and empathy for their children may be a particularly promising approach. In their study of interparentally violent fathers, Perel and Peled[21] concluded that most fathers desired greater warmth, involvement, and connection in their relationships with their children. Other studies[18]

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similarly revealed that men experienced shame, guilt, and remorse when thinking about the harm they may have inflicted upon their children and they report a wish to shield them from their anger.[22] There is evidence that fear of losing family relationships and worry about harm to their children were influential in fathers' decisions to change their behavior and engage in intervention.[23] Therefore, developing IPV interventions that approach men as fathers who can have a positive impact on the health and development of their children rather than as "batterers" could be a more effective way to engage men in treatment leading to better clinical outcomes. Treatment engagement is the first step to intervention success. If individuals do not attend treatment they cannot benefit. Following engagement, to reduce IPV and CM, an intervention must target an appropriate mechanism of change.

What Intervention Mechanisms Could Reduce IPV and CM? Current Batterer Interventions target beliefs about the roles of women and power and control behaviors with limited impact on IPV.[7-9] Recent research indicates BIPs that more carefully consider psychopathology and psychiatric needs or incorporate mindfulness and psychological flexibility instead of power and control may be more effective in reducing IPV.[7, 24-26] RF describes the capacity of individuals to understand their own and others' actions as a function of underlying psychological and emotional states and motivations.[27] Individuals with high levels of RF are better able to recognize their own and others' thoughts, emotions, intentions, and desires.[27] Poor RF is associated with increased violent and aggressive behavior[28-30] and emotional dysregulation. Studies by the PI have indicated fathers with histories of IPV have very low levels of RF.[22, 31] Studies in mothers indicate a significant association between poor RF related to their children and maltreatment.[32, 33] While there is less research on the relationship between paternal RF and child maltreatment, poor RF is a potential core element driving male perpetrated IPV[34] Reading of the larger literature suggests a common and potentially modifiable pathway to IPV and CM through RF. Men at risk for IPV/CM often misperceive threat (acute threat sensitivity) especially from their partners 48 and instead respond to innocuous or ambiguous stimuli with hostility and emotion dysregulation and violence.[26, 35-41] Lack of RF is important to this chain. Poor RF can result in: 1) misperceptions of partners and children's' intentions or behaviors and 2) lack of understanding of one's own emotions, triggers, thoughts, and behaviors and 3) poor regulation of emotion that can result in violence. The PI has demonstrated low RF in fathers with histories of IPV[22, 31] and experimental studies have indicated that improving emotion regulation reduces violence.[24, 25] Therefore, intervention like F4C that can increase RF could reduce IPV and child maltreatment.

F4C as an Intervention for IPV and CM: F4C approaches men through their roles as fathers to increase engagement in the RF focused work that is central to the intervention. F4C is offered individually by master's level therapists to fathers with histories of IPV, defined as threatened or actual sexual or physical violence against an intimate partner in the past 12 months. F4C addresses 9 individually focused core topics, 4 co-parent topics, and 5 father-child focused topics in 60-minute individual therapy sessions over 26 weeks to achieve: (1) reduction of IPV and (2) decreased child maltreatment. In the context of a strong working alliance developed through focus on fatherhood,[42, 43] F4C intervention employs a continual focus on RF and emotion regulation skills. Improvement in these targets in turn leads to reduced IPV and child maltreatment. In concert with the IPV literature.[44, 45] F4C motivates the father to change by continually recognizing his desire to be a better parent and facilitating his ability to reflect on the experiences of his co-parent and children and learn new skills to manage his own affect and thinking to improve outcomes for his family. This is an innovative treatment approach that fills a significant gap in the field of IPV interventions.

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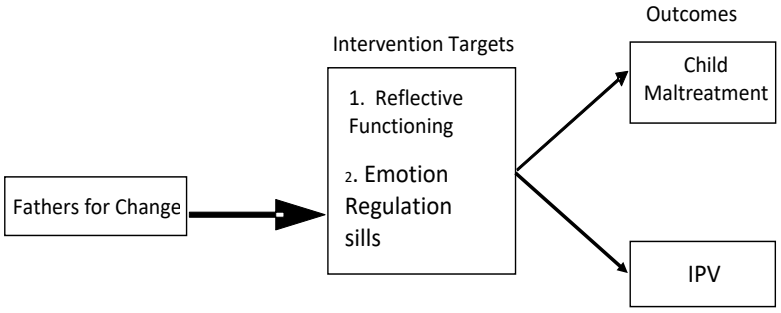
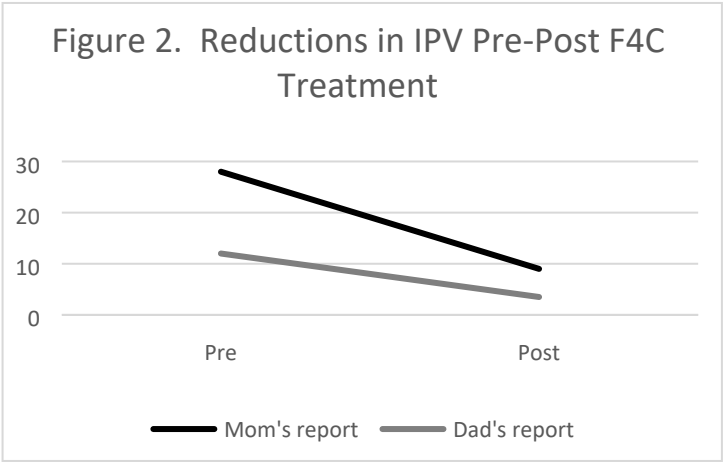


Figure 1. Working Theoretical Model of Fathers for Change

Why design an individual approach instead of group? Although programs for both IPV and CM have been implemented using a group approach[8, 46-48] F4C is an individual treatment approach. We chose this approach because: (1) IPV group approaches have been generally ineffective;[8, 9] (2) there is evidence that antisocial individuals in a group can have a contagion that limits the effectiveness of the group as a whole[49, 50] and may be iatrogenic;[51] (3) interventions for aggressive adolescents were more effective delivered in an individual format compared to group;[52] (4) the therapist needs to understand each client's own childhood history of exposure to violence, hostility triggers, and their intimate relationship patterns to optimally tailor role play, practice reflective functioning, and teach affect regulation skills; (5) our clinical experience with the population raises the concern that some men may be unwilling to share this information in group treatment; and (6) the co-parent and father-child focused components require the therapist to carefully assess RF, emotion dysregulation, and communication patterns based on the type of prior difficulties, whether the couple is still in a relationship, and the developmental age of the children in order to provide appropriate support. This is difficult in group treatment and does not allow for the individualized work and practice in session that is provided in F4C as one-on-one treatment.

Preliminary Studies F4C development. First, F4C[53] was developed and piloted by the PI in an outpatient clinic setting. A sample of 10 fathers were referred by child protection and the courts to participate in an open trial of initial feasibility. Completion rates were 80% and all fathers who completed the program remained non-violent during treatment with very high satisfaction indicating good potential for intervention acceptability.[53] Next, using content, treatment manuals, and training materials developed during the pilot study outlined above, Dr. Stover trained 12 clinicians in community mental health clinics to deliver F4C to child protection involved families through a statewide initiative in CT. Based on session fidelity reviews it is clear clinicians have successfully implemented the intervention using the manual and training curriculum. Based on a sample of 73 fathers referred to F4C, 74% completed the program. Importantly 68% of those referred to F4C had previously participated in a BIP. Additionally, fathers self-reported significant improvements



in the intervention targets of emotion regulation and reflective functioning from pre to post intervention (p<.05). There were significant reductions in IPV post-intervention based on mothers and fathers reports[54] (see Figure 2) and significant reductions in child maltreatment risk based on the Parental Acceptance Rejection Questionnaire[55] (t (67) = 6.44, p < .00) These data support F4C's ability to improve hypothesized intervention targets and IPV and child maltreatment outcomes. The current study is needed to provide an initial randomized test of F4C compared to an individually delivered BIP and group BIP. The randomized three group study will allow us to test F4C compared to BIP-I and Group BIP (BIP-G) and indicate whether the individual treatment format is the driving factor OR the content OR both.

3. Research Plan: Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. If working with a Non-Government Organization (NGO) or other organization, be sure to highlight which are research-only activities and which activities would occur regardless of the research. If working with survey firms, please specify what research activities the research firm will be responsible for.

Phase I: Seventy five fathers of children aged 6 months to 11 years will be referred by the Department of Children and Families to the Parent and Family Development Program at Yale, recruited and randomized to either F4C BIP-I or BIP-G (n = 25 per group) following an initial screen and baseline assessment.

Phase II:
Two hundred eighty fathers, the female *coparent of their youngest child,* and their youngest biological child aged 9 months to 12 years will participate for a total of up to 840 participants in this Phase 2 randomized controlled efficacy trial.

Initial screen:

Referred fathers will be asked to complete an initial brief screening if they are interested in participation in the study, which will include demographic matching information such as age, ethnicity, city of residence, income, employment history, substance abuse history etc. He will be told that his screening questionnaire will be reviewed, and he will be contacted to set up further assessment sessions if he is found to be eligible. This will provide the opportunity for contact with the mother to conduct phone screening with her related to IPV and assess her willingness for herself and their shared child to participate.

Fathers will be told that their female co-parents (and if different current intimate partners of more than 6 months) will be contacted but they will not be told when (day or time) this will occur. Female co-parent contact information will be provided on the referral from DCF so that fathers are not providing this information, and this will limit the possibility of coercion. The phone screening with female co-parents will include IPV specific questions (e.g. severity of IPV and status of protective orders). If the father is not eligible based on screening due to severe IPV that involves admitted hospitalization or strangulation, or a current full protective order related to his child, he will be informed that he does not meet our demographic criteria based on his initial screening. No mention of contact with mother will be made. If the father agrees to the study and he is eligible following screening of his female co-parent and she agrees to participate to provide information about their shared child, he will schedule a time to complete the second assessment with the child. Fathers will be able to participate even if their co-parent refuses participation of their shared child as long as he meets other eligibility criteria (no severe IPV involving hospitalization, no full contact protective order with child, mother consents to participate in providing symptom

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information about their shared child) to ensure there is no coercion or retaliation toward female co-parents for their decisions about child participation.

Baseline assessments:

Each father who agrees to participate based on recruitment screening described above will be invited to a 2-hour baseline interview either in person or via a password protected Zoom meeting to ensure security. He will complete standardized questionnaires in interview format with a trained research assistant to assess (a) history and severity of IPV, (b) psychiatric symptoms, (c) self-reported emotion dysregulation, (d) adverse childhood experiences (e) substance use (g) relationship status with the coparent and frequency of contact with his children and (g) reflective functioning (RF). We have successfully used all the included measures in prior studies with the target population without any adverse events.

Fathers will also be asked to attend a second appointment with their child for a structured play assessment. These will take place at 350 George Street, New Havenor 65 Kane Street in West Hartford following all safety protocols outlined by Yale will be followed regarding COVID-19 precautions or via a zoom video conference if in person is not feasible. The father-child play session takes 25 minutes and child questionnaires administered to youth 7 and older will take less than 20 minutes..Mothers will be contacted before for consent for participation of their child and as collateral informants on study assessments. If indicated, current female partners will also be invited as collateral informants. Mothers and female intimate partners may complete study questionnaires via telephone, zoom, or secure online survey link via the Yale Research Electronic Data Capture *(*REDCap).

The second session with the father will include the target child and include self-report measures of symptoms for children aged 7 and up followed by free play session with their father. This portion will be video recorded with the father and the target child. Fathers will be asked to play with their children for 15 minutes with a set of age appropriate toys. Upon completion of the play time they will be instructed to have their child clean up the toys. These interactions will be video-recorded either at the study offices or via the Zoom secure platform and coded by trained blind, RAs using the Child Interactive Behavior Rating Scale. The scale has age specific coding criteria for infants, toddlers, preschool, and school aged children.

The RA will complete study assessments in person or via zoom with fathers, mothers and partners at baseline, immediately following intervention completion, at 6 and 12 month follow-ups. Each measure and timing of assessment are outlined in Table 1.

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Table 1. Assessment Schedule	**Rater**	**Baseline**	**Weekly During Intervention**	**Monthly During Intervention**	**Post-intervention**	**6& 12 Month-FU**
IPV Outcomes						
Family Socialization Interview Revised (FSI-R)[96,108] – IPV module	Masked Coder	X			X	X
Time-line follow-back for IPV (56, 57)	Father, Mother, Current Intimate Partner		X			
Abusive Behavior Inventory (ABI)	Father, Mother, Current Intimate Partner	X			X	X
Court and Arrest Records	N/A	X				X
Child Maltreatment and Parenting Outcomes						
Child Protective Services Records	N/A	X				X
Family Socialization Interview Revised (FSI-R)[96,108] – Parenting Risk module	Masked Coder	X			X	X
Timeline Followback-CM Risk	Father and Mother		X			
Conflict Tactics Scale-Parent Child	Father and Mother	X			X	X
Father-Child Free Play coded using Child Interactive Behavior Rating (CIB)+	*Masked Coders*	X			X	X (12 month only)
Child Symptoms						
Children's Emotions Scale (RCES)	Mother and Father					
Brief Infant Toddler Social Emotional Assessment (BITSEA) Trauma Symptom Checklist for Young Children (TSCYC) or Trauma symptom checklist for children (TSCC) appropriate for child age	Mother and Father Children >7-Self Report	X			X	X
Kiddie Diagnostic Interview Schedule PTSD Module OR Diagnostic Infant and Preschool Assessment (DIPA) modified PTSD module	Mother and Father	X			X	X
Satisfaction Outcomes						
Client Satisfaction Questionnaire 8 (58)	Father				X	
Intervention Targets (Mechanisms)						
Unified Protocol Skill Use Scale (UPSUS)122 and select items from the 28-item Brief COPE	Father		X			
Difficulties in Emotion Regulation Scale (59) DERS Short Form	Father	X	X		X	X
Reflective Functioning Questionnaire-8 (RFQ)(60)	Father	X	X			
Parent Reflective Function Questionnaire (PRFQ) (61)	Father	X	X			
Intervention Process Variables						
Working Alliance Inventory (62)	Father and Clinician			X		
CHANGE Coding	Trained Reliable Coders			X		
Motivation to Change	Father			X		

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Therapist Session Report Form	Clinician		X			
Other variables to classify the sample						
STRESS Trauma History and PTSD Scale	Father	X				
Alcohol Use Disorders identification Test (AUDIT) – Self report(66)	Father	X				
Drug Abuse Screening Test- 10 (DAST-10)(67)	Father	X				
TimeLine Follow Back-Substance Use	Father		X			X
Father Contact and Engagement Scale(68, 69)	Father and Mother	X			X	X
Brief Symptom Inventory (BSI) (70)	Father and Mother	X			X	
CoParent Relationship Scale Children's Exposure to Violence Only	Father and Mother	X			X	X

Measures during baseline

Child Maltreatment Risk: We will collect official records of child maltreatment from the Department of Children and Families. We will also collect logs of child maltreatment risk behaviors (harsh discipline and hostility toward the child) as reported on time line follow-back calendars during treatment. Parents will report on their harsh/hostile behavior on the Conflict Tactics Scale-Parent Chlid Version. These will be used to inform masked coder ratings on the Family Socialization Interview (FSI-R; our primary outcome measure). The FSI-R assesses severity of child maltreatment risk based on a compilation of data from self- report, collateral reports and records.

Parent-Child Interaction Tasks.[(75)] Each Father-child dyad is video-taped in a semi-structured 20-minute play session. It consists of 15 minutes of free-play and a 5-minute clean-up. Each play session will be coded using the Child Interactive Behavior Coding[(72)] which has been validated with children aged birth to 13 years. Infant, Preschool or Child coding guidelines will be used depending on child age. The following codes are used across ages: 1) parental hostility/intrusiveness, 2) dyadic reciprocity, and 3) child's relationship behavior toward the parent (avoidance, anxiety). Parents and children will be rated by trained blind coders who have attained .75 reliability to the task author Ruth Feldman; 15% of the tapes will be double coded for reliability checks. The video recording of play assessments with the child pre and post treatment is necessary for coding father-child interactions before and after the treatment.

Child Mental Health. Symptom dimensions will be derived from father and mother reports on surveys with established reliability, validity, and developmental sensitivity. For <u>data reduction</u> purposes, continuous latent constructs will be identified via measurement models and second-order factor models conducted in Mplus[127] using standard fit criteria.[128,129] If necessary, we will use other methods to reduce these data, e.g., latent constructs formed by principal components analysis. The TSCYC and TSCC includes 8 subscales assessing trauma symptoms and more common childhood symptoms and are used for children aged 3 to 17. For infants and toddlers, we will have parents complete the Brief Infant Toddler Social Emotional Assessment (ITSEA)

Stratified Randomization. To increase the likelihood treatment groups are balanced on important variables (i.e., , residence with target child, protective order with coparent, *substance use)* participants will be assigned to treatment through stratified randomization. Following randomization, fathers will be assigned to either 18 sessions (once per week) of Fathers for Change or18 sessions of Duluth Batterer Intervention delivered in an individual format . We anticipate 140 participants in each treatment group. Research assistants managing the data Dr. Sullivan will be blind to treatment condition assignment during analysis. Participants will be recorded as receiving either "treatment 1", or "treatment 2" . The research assistants and Dr. Sullivan will not be aware which treatment protocol "treatment 1" or "treatment 2" correspond to until analyses are complete.

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Treatment Phase.

Each treatment will be delivered weekly over 18 weeks. Male participants will meet online or be contacted via phone weekly with the RA to complete self-report assessments of IPV behaviors, father-child interactions and *substance use*. The RAs will be blind to the participants' treatment conditions.[79] Study therapists will complete weekly session reports of session content and skill acquisitions based on completed homework.

***Fathers for Change**:* F4C focuses on: 1) the fathering role to facilitate engagement, 2) RF to understand self, partner and children and emotion regulation skills to reduce IPV and child maltreatment[80, 81] F4C focuses on understanding of emotional experiences, how they impact thinking and behaviors related to partners, co-parents and children. F4C clients will meet individually with their F4C therapist for 50 minutes per week over 18 weeks.

Batterer Intervention Program:[82, 83] The BIP is a psychoeducational intervention that will be delivered in 50- minute individual sessions over 18 weeks. The intervention focuses on the impact of violence on victims, power and control tactics, and societal influences supporting men's violence toward women. The intervention includes didactics and experiential exercises including role plays to teach anger management skills.

BIP is typically delivered in a group format, however will also be adapted to an individual format as part of the current study. Therapies will be delivered either in person or via secure/password protected zoom virtual sessions. All Yale safety protocols with regard to COVID-19 will be followed.

Therapist Training. Master's level clinicians will be trained to deliver the study interventions. Dr. Stover will utilize the therapist training manual, slides and videos generated from her pilot studies to train F4C therapists. She will meet weekly with F4C therapists for supervision. BIP-I and BIP-G therapists will be trained by Dr. Sullivan using the BIP manual[82, 83] and training materials modified for individual treatment delivery. BIP clinicians will meet weekly with Dr. Sullivan for supervision and intervention adherence.

Treatment Fidelity. Each intervention session will be video recorded. Trained coders will rate 20% of sessions for fidelity and change in emotion regulation/reflective functioning during therapy sessions using the F4C/BIP Fidelity Measure and the CHANGE coding system. Tape raters for fidelity will be trained by the PI coding a set of 6 practice tapes. Fidelity feedback will be provided by Drs. Stover (F4C) and Sullivan (BIP) in their respective supervision sessions with study therapists to ensure fidelity and allow corrective feedback. Tape raters will be trained by Adele Hayes for the CHANGE session coding system and will be supervised by Dr. Hayes at the University of Delaware and Dr. Grasso at the University of Connecticut. The *Change and Growth Experiences Scale* (CHANGE; Hayes, Feldman, & Goldfried, 2007) is an observational coding system that assesses processes of change during psychotherapy, including factors that facilitate and inhibit therapeutic change. The CHANGE has been used to code audio and video recordings of sessions or narratives from clinical trials of trauma-focused cognitive behavioral therapy (TF-CBT) for youth (Alpert et al., 2021; Canale et al., 2021; Ready et al., 2015; Yasinski et al., 2016), prolonged exposure, written exposure therapy (WET), and cognitive processing therapy (CPT) for adult PTSD (Alpert, 2021; Alpert et al., 2020; Sloan et al., 2021), as well as cognitive-behavioral treatments for depression (Abel et al., 2016; Adler et al., 2013; Hayes, Feldman, Beevers et al., 2007; Yasinski et al., 2020) and personality disorders (Hayes & Yasinski, 2015). The CHANGE has been used to identify key predictors of treatment dropout and outcomes in each of these clinical trials.

Weekly and Monthly Measures During Treatment

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The RA will meet with fathers via password protected zoom link or in person to complete logs of IPV, substance use and interactions with their children and monthly assessments of working alliance and treatment motivation via computerized survey at the time of their weekly clinical appointment. If fathers do not show for their appointment RAs will phone him to collect the information or email a secure survey. All data will be entered into a secure web-based REDCap database.

TimeLine Follow-back-Spousal Violence, Child Maltreatment Risk, & *Substance Use* (TLFB-SV/SU/CM)[57] will be used to assess specific types of IPV (physical, sexual, psychological) toward partners on any given day, contact with the target child and child maltreatment risk behaviors (yelling, swearing, spanking, slapping, ignoring, harsh punishment). The TLFB-SV/SU/CM will be administered weekly to assess violence, substance use and CM risk behaviors during treatment. This is a reliable and valid instrument that has been used to assess relationship violence over time and links to substance use. [57] Participants, *the mother of their youngest child and if different their current female partner* will be asked to report IPV and CM throughout treatment.

Measures of Treatment Targets: Fathers will complete items from the Parental Acceptance Rejection Questionnaire, COPES and Unified Protocol Skill Use Scale to assess intervention coping skill use and emotion regulation/RF changes during treatment.

Measures of Treatment Process: Fathers will complete the **Working Alliance Inventory,** [84] **Motivation to Change** (85) on a monthly basis and the **Client Satisfaction Questionnaire** at the end of treatment[86] to document (a) the quality of their relationship with their clinician, (b) their perceived motivation for change, and (c) satisfaction with treatment.

Post intervention:
Follow-up interviews will be conducted post-treatment to assess changes in IPV, child maltreatment risk, and child mental health. This will also be done via zoom or in person. Fathers will be offered $60 for post-treatment assessments and mothers $35. These will include the same assessments of reflective functioning, emotion dysregulation, IPV, and child maltreatment risk administered at baseline. Father-child interactions will be assessed via a coded free-play interaction with the target child at baseline and post-treatment. Fathers will be recorded playing with their children with an age appropriate set of pretend play toys for 15 minutes and then during cleanup time.

Follow-up:
6 and 12 months post-intervention, fathers and coparents will participate in follow-up interviews to assess IPV, child maltreatment risk, father engagement and parenting. Participants will complete these interviews over zoom or telephone. They will be paid $50 and mothers $35.

Analytic Plan.
We will use Research Electronic Data Capture (REDCap™), a widely used secure web-based software package designed for clinical trials[87] to collect study data.

Preliminary Analysis: A series of preliminary analyses will be conducted to: (1) characterize the sample, (2) document the internal reliability of measures, (3) check for logical consistency among related variables, (4) identify outlying values that should be considered for truncation, and (5) assess whether there are significant differences in outcomes based on study therapist. Although urn randomization procedures will be used to balance distribution of specific characteristics across treatment groups, we will explore between-group differences in urn variables and other demographics and possible moderators. Data analyses will be done independently and without

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knowledge of group assignment, with the participant's group assignment anonymized to "treatment 1" or "treatment 2".

Phase I Hypotheses:

i. Fathers randomized to F4C will have higher completion rates than those in the BIP-I or BIP-G treatment. Chi-square analysis will be used to examine between group differences in treatment completion.
ii. Fathers will report greater working alliance and satisfaction with F4C than BIP-I or BIP-G. Analysis of variance will be used to test between group differences in working alliance and client satisfaction.
iii. Fathers receiving F4C will evidence greater improvement in RF and emotion regulation, IPV, and child maltreatment(CM) compared with fathers receiving BIP-I or BIP-G post-intervention. Mixed effects regression will be used to test for between-group differences in RF, emotion regulation, IPV, and CM representing treatment effects associated with F4C versus BIP over time. Separate IPV and CM sum scores will be created. Any instance of IPV or CM by any report (self, co-parent or current partner report on the Timeline Follow Back, child protection or arrest records) will be counted to create a sum score across reports. The Child Interactive Behavior Codes[75] of Intrusiveness and Child Avoidance will be used as our observational measures of CM risk. Total coded RF score as measured by the PDI and self-reported emotion regulation on the DERS will be used to test impact mechanisms of F4C.
iv. Exploratory hypothesis: Test whether improved RF and emotion regulation are associated with reduced IPV and CM consistent with the F4C mechanisms of change. We will test path models: treatment group (dummy coded F4C, BIP-I or BIP-G) to each mediator (RF, emotion regulation) to the two outcomes (IPV and CM). See Statistical Analysis section for further details.

Power Analysis: A sample of 75 with planned 63 participants with complete data will provide 80% power to detect group differences with a modest effect size of .45 (see Statistical Design and Power Section).

Phase II Hypotheses:

AIM 1 Hypotheses: Children of fathers who receive F4C (n=180), relative to BIP (n=180), will: (1a) experience less family violence (FV), (1b) have more positive father-child interactions, and (1c) have lower FV-related mental health symptoms (PTSD, internalizing/externalizing) at post treatment and 6- and 12-month follow-ups. The effects of both treatments on father and coparent mental health outcomes will also be examined (1d exploratory). Hypotheses will be evaluated with the broad family of latent (growth) curve models (LGM),[138] which estimate and compare trajectories of change for each case in the data. Group differences in changes will be tested in multiple group LGM models.[139] Following analyses for our primary study hypotheses, we will examine whether child sex moderates child mental health outcomes between the F4C and BIP groups. **Power**. The planned sample size of 140 F4C and 140 BIP cases provides power of .91 to detect a small to moderate effect size (d = 0.12). The current study with 140 per group (even 126 per group assuming a conservative 30% attrition at follow-up) has sufficient power to determine small differences in changes between intervention groups on outcomes. LGM models for changes in latent rather than observed scores, for three or more waves of data, have the advantage of partialing out measurement error, and increasing the statistical power by at least 20%.[140] See Statistical Design and Power Section for estimation method.

AIM 2 Hypotheses. Compared to BIP, more F4C fathers will show profiles of healthy change in therapeutic targets: (2a) masked coding of in-session RF/ ER (i.e., increased RF and adaptive ER, decreased maladaptive ER), and (2b) between-session self-reported RF/ ER (i.e., increased

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RF and adaptive ER, decreased maladaptive ER). F4C change profiles will reveal critical junctures in treatment that precipitate therapeutic change, thereby serving to optimize timing and delivery of treatment components (2c, *exploratory*). Group-based trajectory modeling from the family of latent growth mixture modeling (GMM)[141] will be used first to examine the number of different trajectory groups and their profiles (e.g., stable low or high adaptative ER, gradual increase or decrease in RF level, initial increase, then stable RF level, rapid decrease followed by gradual decrease of maladaptive ER, etc.) during the intervention period, as well as determine whether F4C vs. BIP treatment conditions influence trajectory group membership. Initially, trajectories of each in-session and between-session therapeutic change target will be modeled separately. Because data are expected to have unequal measurement intervals, we will use a new feature in Mplus 8.8 for analyzing such data (i.e., *tinterval and dynamical SEM*[142]), and explore a new Stata 17 module for irregular time spacing measurements (i.e., *xtusreg*).[143] Subsequent models will simultaneously examine various combinations of these six related targets to identify appropriate group membership for the fathers. This therapeutic change grouping will be modeled as the mediating variable in subsequent mediation analyses. **Power.** Determining power in group-based trajectory modeling with unequal time gaps is complex and not well explored. Given that some applications have used the classical, similar analytic method, mixture LGM (with equal time gaps), to extract three classes with a sample size as low as 45,[144] the current target sample size of 360 (or 252 with attrition) will be adequate to identify trajectory groups and test further differences between F4C and BIP groups.

AIM 3. Hypotheses. Profiles of healthy change in RF and ER will mediate the treatment effect of F4C over BIP on: (3a) FV (3b) father-child interactions, and (3c) child mental health (PTSD, internalizing/externalizing) at post-treatment and at 6- and 12-month follow-ups. LGM mediation models will be used to evaluate the mediating effect of therapeutic change classes on the treatment impact on both the fathers' use of FV and children's outcomes. In particular, the baseline predictor will be father's randomly assigned intervention group: F4C vs. BIP, with father's therapeutic change in RF and ER trajectory groups from Aim 2 entered as a categorical mediator into a structural equation model framework to investigate the mechanisms of change in child outcomes at post-intervention and up to two subsequent follow-ups. **Power.** Power analyses for mediational LGM models with categorical mediators are rare.[145] The specialized Mplus 8.8 SEM software however has been advancing the toolbox available for such complex models, and its recent capabilities promise to provide adequate statistical power with the proposed sample size.[146]

4. Participant Population: Provide a detailed description of the types of participants who will be recruited into this study.

Phase I:

Seventy-five fathers of a biological child between 6 months and 11 years who are referred by the Department of Children and Families due to use of domestic violence in the last 12 months, the female co-parent of their youngest child and if different their current female intimate partners of more than 6 months, and their youngest biological child aged 6 months to11 years will participate for a total of up to 240 participants in this Phase 1B randomized controlled trial.

Female intimate partners who are not the co-parent of the youngest child will be contacted if they have been in a relationship with the father for at least 6 months at the time of consent.

Phase II:

The target sample is 280 father-coparent dyads and their 9 months to 11 year-old children recruited from CPS-involved families referred to the Parent and Family Development Program (PFDP) at Yale or the UCONN Health Center Outpatient Psychiatry Clinic. Participants will be randomized to either F4C (n = 140) or BIP (n = 140) following a baseline assessment. Half of F4C and BIP families will be treated at Yale and half at UConn Health. Yale will serve families in

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Greater New Haven region, while UConn Health will serve families in the Greater Hartford region. The two sites are approximately a 45-minute drive apart.

5. **Describe** how access to the population will be gained in the study.

Fathers referred to the Parent and Family Development Program or UCONN Health Center by the CT Department of Children and Families (DCF) or the community due to IPV or child maltreatment risk will be provided information about the study and asked to complete an initial brief screening if they are interested in participation. He will be told that his screening questionnaire (which will include demographic matching information such as age, ethnicity, city of residence, income, employment history, SA history etc.) will be reviewed and he will be contacted to set up further assessment sessions if he is found eligible by the PI based on our study's requirements. This will provide the opportunity for contact with the mother to conduct phone screening with her related to IPV and her willingness for their shared child to participate. Female co-parent and intimate partner contact information will be provided on the referral from DCF or community referral source so that fathers are not providing this information, and this will limit the possibility of coercion.

6. **Participant classification:** Check off all classifications of participants that will be specifically recruited for enrollment in the research project. Will participants who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of participants requiring special safeguards and provide a justification for their involvement.

☒ Children	☒ Healthy	☐Fetal material, placenta, or dead fetus
☐Non-English Speaking	☐ Prisoners	☐Economically disadvantaged persons
☐Decisionally Impaired	☐ Employees	☐Pregnant women and/or fetuses
☐Yale Students	☐ Females of childbearing potential	

Click or tap here to enter text.

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential participants? ☒Yes ☐ No

It is possible that the children of some enrolled fathers will be placed in foster care and under the guardianship of the Department of children and families at the time of referral. These children would only be enrolled if there was planned reunification with the father.

7. **Inclusion/Exclusion Criteria:** What are the criteria used to determine participant inclusion or exclusion?

Inclusion Criteria. Men who (1) report an incident of IPV (pushing, slapping, kicking) within the last 12 months prior to screening (based on court/police records, partner or self- report); (2) have at least one biological child aged 9 months to 12 years with whom they have contact in person or by phone/facetime etc. at least monthly; (3) are able to complete assessments in English; and (4) agree to have their female coparents (mother of the youngest child) contacted as collateral informants and for consent for participation of their shared child. If a participant has more than one child in the age range, the youngest will be the target of assessment. Female coparents (the

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target child's biological mother who does not need to be in a relationship with the father at the time of the study) will be contacted to consent for participation of herself and their shared child. If the coparent declines participation of the child the father may still participate in the study if he meets eligibility criteria to prevent any possible retaliation against co-parents for not consenting to child participation. No information about contact with co-parents or their responses will be provided to the fathers

Exclusion Criteria. Men will be excluded who have: 1) an active full/no contact protective order pertaining to their child since this will preclude participation in the father-child play assessment (many men will have full no-contact orders with their partners, but it is more common for men to still be allowed at least supervised contact with their children even with a full/no contact order with their partner); 2) physiological addiction to a substance that requires detoxification. Fathers will be evaluated using the AUDIT and DAST . If fathers report difficulties with physiological withdrawal from substances (e.g. delirium tremens, shaking, nausea) they will be referred for detox services. They can be re-evaluated following a detox program with documentation from the detox center of successful completion and clean urine screen.; 3) cognitive impairment that will not allow for understanding of the study interventions (a mini mental state score <25); 4) current untreated psychotic disorder; 5) currently suicidal or homicidal based on screening using the BSI; 6) Are currently enrolled or have previously received F4C or BIP; 7)coparent declines to provide collateral information about their child's symptoms.

SECTION V: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. Recruitment Procedures:

a. Describe how potential participants will be identified and contacted, and by whom.

Fathers will be provided information about the study at the time of referral by DCF to the Parent & Family Development Program at Yale or the UCONN Health Center. Contact information for co-parents will be provided by DCF or other referral sourc at the time of the referral (which is current practice). Each father will be recruited and given initial screening by a study RA in person or over the phone. If a father expresses interest, an in-person or virtual Zoom appointment will be scheduled to complete informed consent and baseline measures.

Mothers of the fathers' youngest child will be contacted for initial screening and to assess her willingness to allow participation of herself and their shared child in the study.

All research staff reaching out to female co-parents or current intimate partners will be trained on phone recruitment strategies used in previous studies by the PI and others to ensure safety of victims of IPV. These include: 1) asking whether she is free to talk now: 2) asking if it is ok to call back again; 3) asking if it is safe to leave messages on her voicemail or via text; and 4) during informed consent, making a plan for the safest way to contact her for follow-up data collection throughout treatment.

Mothers will be interviewed via zoom or in person on different days and encouraged to ensure their safety by choosing a location where they feel safe and away from the father to take the call. Fathers will not be informed of mothers' agreement to participate or the time or location of any contact the study team has with them. They will complete baseline interviews about their relationship history with the father, IPV in the relationship and the father's child maltreatment risk behaviors (hostility, yelling, spanking) toward the child. Mothers and intimate partner baseline interviews will take approximately 1-1 1/2to complete Mothers will be offered $50 for completion of baseline interviews.

Dr. Stover will not be involved in the consent, recruitment, or enrollment of participants.

Are you collecting any information about the individuals prior to their signing a consent form?
Yes ☒ No ☐

If yes, indicate what information you will be collecting and how it will be gathered *(phone screen, paper questionnaire, etc.)*

An initial screen will be done with both Father and his co-parent. The RA will administer initial screen to father and co-parent either over the phone, in person or via Zoom. Fathers screen will include demographic matching information such as age, ethnicity, city of residence, income, employment history, substance abuse history etc. Co-parent screen will include IPV specific questions (e.g. severity of IPV and status of protective orders)

2. Indicate recruitment methods below. Attach copies of any recruitment materials that will be used.

☐ Flyers
☐ Posters
☐ Letter
☐ Through local NGO or other local contact
☐ Table set-up / in-person recruitment of public
☐ Classroom recruitment
☒ Other: Referral by DCF case workers or IPV specialists
☐ Internet/web postings
☐ Mass email solicitation
☐ Departmental/Center website
☐ Departmental/Center research boards
☐ Snowball sampling
☐ Social Media (Twitter/Facebook):
☐ Radio
☐ Telephone
☐ Television
☐ Newspaper

3. Targeted Enrollment: Give the number of participants:

a. Targeted for enrollment at Yale for this protocol: Phase I: 180 Phase II: (180 fathers, 180 coparents and 180 children) =540

b. If this is a multi-site study, give the total number of participants targeted across all sites (280 fathers, 280 coparents and 280 children) = 840

4. How was this estimate derived?

Phase I: Seventy-five fathers, the female co-parent of their youngest child, and their child will participate for a total of up to 225 participants. We intend to include all 75 fathers assigned to study interventions for intent to treat analysis. The planned sample size of 75 participants who will provide data for inclusion in our intention-to-treat analysis should provide sufficient power to detect clinically meaningful differences between and within treatment conditions as specified in our primary aims. A sample of 63 people provides power of 80% to detect a standardized treatment group differences at 18 weeks of d = 0.45. For purposes of power estimates, we assumed d = 0.45 will represent a potentially meaningful clinical difference in both our primary and mechanism outcomes. In a pilot study examining F4C on participant IPV effect size for outcome was d = 0.86. We will enroll 75 participants to accommodate a 16% loss to follow-up.

Phase II:

Using these procedures in prior studies, our rate of successful follow-up has ranged from 70-90%. With 280 participant families randomized and an aim of at least 70% completion, we expect to have 196 cases with complete treatment and follow-up data.

4. Process of Consent/Assent *(NOTE: When a study includes minors, parent provide permission [not consent] for the child's participation, and the child provides assent for participation)*

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Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure participants' independent decision-making.

Fathers will complete informed consent either in person or online via Yale's REDcap data system, in line with guidance on obtaining informed consent during the COVID-19 pandemic. Each will agree to have their female co-parent contacted for consent of participation of their shared child.

Mothers will complete informed consent related to their own participation and the participation of children in which they are the primary guardian. This will be completed online via Yale's REDcap system..

Children in the study will be up to age 12 so will not sign informed consent but an assent will be used. For children under the age of 7 a verbal assent only will collected. The study procedures will be explained to them and their verbal assent to participate in play with their dads will take place prior to beginning the play assessment. Children 7 and older will complete a signed assent.

5. Evaluation of Participant(s) Capacity to Provide Informed Consent/Assent: Indicate how the personnel obtaining consent will assess the potential participant's ability and capacity to consent to the research being proposed, if applicable.

All potential participants (mothers, and fathers) will receive an explanation of the study, risks, benefits, and procedures with a trained research assistant in an individual, secure online Zoom meeting or in person. Research assistants who are attaining consents will be trained by the PIs. This will include observing Dr. Stover conducting practice informed consent procedures and then conducting the procedures in role play with them for practice. Participants will be asked to sign the compound consent form in person or via Yale REDcap, if they wish to participate following resolution of any questions and clear indication that the participants understand the nature of the study and the consent. We routinely use an informed consent quiz to assure all prospective participants understand all aspects of the protocol and its requirements. Fathers will have study interventions explained and options for participation explained. Fathers' treatment at the PDFP, or other treatments offered by the CT Department of Children and Families will in no way be influenced by their participation in the study. If they opt not to participate or decide to withdraw, they will continue to receive care as usual. The certificate of confidentiality will ensure that information collected as part of the research evaluation cannot be subpoenaed. This detail will be explained to participants and be part of the informed consent quiz to ensure understanding by participants.

Children will be recruited into this study to participate in brief self-reports of their symptoms (for those 7 and older) and father-child observational assessments. This will provide an observational measure of father-child interactions providing an additional measure of change related to parenting and child maltreatment risk. Fathers will be able to participate without their children to reduce any risks to the children for retaliation for their lack of participation. Study research assistants will describe the study procedures to the child and ask if they would like to participate. Verbal agreement to participate and behavioral compliance without undue pressure from the father will be taken as assent from children under 7. For those over 7 a written assent will be collected. If a play session cannot begin or must be ended, father and child will be compensated for the attempt to provide data to minimize risk to the child for being uncooperative. If a play session

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or child report assessment does not proceed, the father will continue in the study to randomization and treatment assignment.

6. Documentation of Consent/Assent: Specify the documents or verbal scripts that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given or spoken to participants.

A script to introduce the play assessment to children is included with the protocol. RAs will use this script with children prior to beginning the sessions.

7. Non-English Speaking Participants: Explain provisions in place to ensure comprehension for research involving non-English speaking participants. Translated copies of all consent materials must be submitted for approval prior to use. Do you speak the local language? Will you require a translator? (If so, please elaborate on how the translators will be trained).

N/A this study will include English speaking only participants.

8. Are any of the study procedures likely to yield information subject to mandatory reporting requirements? (e.g. HIV testing – reporting of communicable diseases; parent interview -incidents of child abuse, elderly abuse, etc.). Please verify to whom such instances will need to be reported.

It is possible that procedures will result in information subject to mandatory reporting of child abuse or harm to self or others. Participants will clearly be informed of the limits of this confidentiality, which are in cases of suspected child abuse or neglect, and imminent risk for harm to self or others (particularly intimate partner or child).

Confidentiality regulations and limits to these regulations will be adhered to as follows: The MPIs, along with co-investigators Sullivan, Silverman and have extensive experience in directing and running clinical programs. All five investigators are licensed clinical psychologists who are mandated reporters and are required to report child abuse as required by law. They are also required to break confidentiality regulations in the event a participant is suicidal or homicidal.

<u>Report of Suspected Child Abuse and Neglect:</u>
If a participant discloses abuse of a child to the research assistant during a research interview, he/she will immediately contact the PI at their site (or co-investigators in her absence) who will facilitate calling the CT Child Protective Services Hotline and writing a written report to be filed within the guidelines for reporting in the State of CT. This would include information about neglect, physical, sexual or psychological abuse of a child. Fathers self-reports of child maltreatment risk behavior will be monitored carefully for evidence of behaviors that reach the level of reportable child abuse. Incidents of yelling or spanking may not rise to the level of a child abuse report based on CT law. Further, CT law does not require reporting of IPV to child protective services, unless the IPV incident described included the child. Men reporting about their past incidents of IPV will not alone trigger a child protective services report. Reports of new incidents of IPV or child maltreatment risk behaviors during the course of the study will be assessed to determine if they meet the child abuse reporting laws outline by CT statute. In all cases of new disclosures of abuse, reports will be filed with protective services. We will provide support to the father following the report through his assigned clinician or through other services available at the PFDP, or in the community. What data are available suggest that sensitive mandated reporting of potential child abuse and neglect does not necessarily threaten the integrity of recruitment or participation

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Suicidal or Homicidal Ideation or Intent:
Upon report of suicidal intentions or the threat of harm to others, the participant will be secured to a higher level of treatment (e.g. hospital setting) while the female participant will be notified for her safety if necessary (e.g., as in a Tarisoff report, if her safety is threatened). Our team has expertise in dealing with high-risk behaviors and abides by all state and federal regulations. If a research assistant learns of homicidal or suicidal ideation or intent, they will immediately contact the PI at their site who will assess the participant and facilitate a higher level of care if needed. Drs. Stover are licensed clinical psychologists in the state of CT as are Drs. Sullivan, Silverman

9. Waiver of Consent/Documentation of Consent: In certain circumstances, the IRB may grant a waiver of documentation of consent, or a full waiver of consent, depending on the study. If you will request either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☐Not Requesting any consent waivers

☐Requesting a waiver of signed consent (e.g., verbal or online consent only):

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ Entire Study (Note that an information sheet may be required.)

For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☒ NO ☐
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☒ NO ☐

OR

- Does the research pose greater than minimal risk? YES ☐ NO☐
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☐

☐ Requesting a waiver of consent (if you are not obtaining ANY consent):

☒ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

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☐ Entire Study

For a waiver of consent, please address all of the following:

- Does the research pose greater than minimal risk to subjects?
  ☐ Yes *If you answered yes, stop. A waiver cannot be granted.*
  ☒ No
- Will the waiver adversely affect subjects' rights and welfare? YES ☐ NO☒
- Why would the research be impracticable to conduct without the waiver?
  Conducting a full informed consent on any possible participant who comes into the PDFP without assessing their eligibility will put undue burden on clinic and study staff and participants. Informed consent for this study will take time to ensure clients understand procedures and to complete the informed consent quiz. Doing this with ineligible clients is burdensome for all involved and may be annoying for clients who are then ineligible.
- Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date? If the father is not eligible based on screening due to severe IPV that involves hospitalization or strangulation, or a current full protective order related to his child, he will be informed that he does not meet our demographic criteria based on his initial screening. No mention of contact will mother will be made. The study team will retain de-identified information about clients screened and reason for ineligibility for Consort Diagram purposes but no information about individual clients will be retained. Screening forms will be shredded as soon as fathers are notified of their ineligibility or if they decline participation in the study following informed consent.

10. Assessment of Current Health Provider Relationship for HIPAA Consideration:
Does the Investigator or any member of the research team have a direct existing clinical relationship with any potential subject?
☐Yes, all subjects
☐Yes, some of the subjects
☒No

If yes, describe the nature of this relationship. *Write here*

11. Request for waiver of HIPAA authorization: (When requesting a waiver of HIPAA Authorization for either the entire study, or for recruitment purposes only. Note: if you are collecting PHI as part of a phone or email screen, you must request a HIPAA waiver for recruitment purposes.)
Choose one:
☐ For entire study
☒ For recruitment/screening purposes only
☐ For inclusion of non-English speaking subject if short form is being used and there is no translated HIPAA research authorization form available on the University's HIPAA website at hipaa.yale.edu.

i. Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data: We will be contacting participants by phone to provide

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information about the study and screen for eligibility. Conducting full HIPAA authorization to ask clients screening questions would be impractical to conduct and collect during the screening process.

ii. If requesting a waiver of **signed** authorization, describe why it would be impracticable to obtain the subject's signed authorization for use/disclosure of this data: *Write here*

The investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the "accounting for disclosures log", by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.

SECTION VI: PROTECTION OF RESEARCH PARTICIPANTS

1. Confidentiality & Security of Data: Describe the steps that will be taken to secure the data during storage, use and transmission as outlined in the below sections. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses to the below sections.

Confidentiality with regard to completed research forms will be maintained via a numbered reference system maintained by the PI and Project Directors. Participants' names will appear only on the consent form, HIPPA authorization form, and "key" form in a password protected file only assessable by the PI. All data will be identified by participant ID only. All measures, video and recordings will be labeled by participant ID only. Subjects who decline participation in the study or those who wish to withdraw from the study can continue in their treatment at the outpatient facilities as they would if they were not approached to participate in a study. As stated above to further protect against potential risks to confidentiality for this population, a Certificate of Confidentiality will be obtained. Participants will clearly be informed of the limits of this confidentiality, which are in cases of suspected child abuse or neglect, and imminent risk for harm to self or others (particularly intimate partner or child).

Therapy sessions will be video recorded to ensure that the therapists administer the study treatments within manual guidelines and are engaging the intervention targets of emotion regulation and reflective functioning. To assure the confidentiality and protection of participants with respect to video and audio recording, the following steps will be taken:

- Participants have the right to refuse recording. Participants who consent to recording will be informed that they have the right to stop at any time during any session.
- Each therapist will conduct the recording him/herself. All recording will take place in the treatment facility in private offices.
- During treatment sessions the therapist's behavior is of primary interest for process assessment, the camera will be directed at the therapist.

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- Each digital recording will be labeled with the participant's study identification number and a coded session date.
- The therapist or RA will then store the digital recording on a password protected server. Yale utilizes a HIPAA compliant, encrypted and fire wall protected server called One Drive. Once the files are uploaded onto the One Drive server, the session will be deleted from the video camera data cards.
- Access to the recordings will be limited to specially trained research raters who will rate the tapes according to established process rating systems. All ratings will be done in esearch offices at Yale, UCONN or U of Delaware.
- Upon completion of these ratings, the recordings will be deleted.

Aside from video recordings of sessions, all other study data will be de-identified and stored within the REDCap database. Consent forms and releases of information for the study will be kept in a secure file on a password protected computer.

The treatments provided could be an option for mandated treatment. If clients wish their study therapist to provide information to court support services or some other entity related to their participation in treatment, the study therapist and/or PI will do so with a signed release from the client. A form letter will be created that indicates the dates of program attendance, nature of the treatment being provided and completion of treatment. No information about the research data collected or study components will be provided only their attendance and successful or unsuccessful completion of treatment. If a client wishes for other information to be disclosed, they can indicate this on the release form.

Criminal and child protection records will be collected by providing an excel sheet with participant names and dates of birth to the Court Support Services Division of the State of CT and the Department of Children and Families along with signed releases of information from participants to provide their names to the agency to provide data to us. We will provide no other information to DCF or CSSD about the participants. Data will be entered into the excel sheets by CSSD or DCF staff and returned to the project director. These will be transferred from the agency to the project director using secure data transfer (OneDrive).

2. What participant information will you be collecting? Describe the identifiers that will be included or associated with the data and/or specimens (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.)

We will collect names, birth dates, criminal records, Department of Children and Families records and contact information (phone numbers, addresses and email addresses) from study participants. If a participant drops out of the research study we will make efforts to retain them in the study for intent to treat analysis. This information will be kept with the signed informed consent in a locked cabinet in the PI's office. It will not be linked to study measures which will be locked in another office space under the participants study ID number.

Other potentially identifying information to be collected:

☒Audiotapes

☒Videotapes

☐Faces (focus groups, photographs or other way that an individual would be physically recognized)

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☒Potential for identification from the bulk of the information, even if direct identifiers are not collected (deductive disclosure).

3. How will the research data be collected and recorded?

Data will be collected via interview and entered directly into an on-line REDCap data system. REDCap is an on-line, secure data capture. Responses to the PDI will be recorded via audio recorders. They will be downloaded onto a secure password protected servers that only study team members will have access. Digital recordings will be conducted by the therapist and stored on a HIPAA secure server. They will be rated by trained therapy fidelity coders. All data will be stored on a password protected and encrypted HIPAA compliant server at the Yale School of Medicine and entered on a secure REDCap database.

Collection of records from DCF and criminal records: Fathers will sign a release of information for collection of data from DCF related to his arrests for family violence related incidents and reports of IPV and child maltreatment to DCF. An excel spread sheet will be created that will include the names of study participants and their dates of birth. These will be sent to the contact person at DCF who will search records via a secure data transfer (encrypted and firewall protected using Yale's secure file transfer). The contact person who will be a state employee with approved access to the DCF and state arrest databases will search the names and dates of birth. The state employee will fill in the excel spread sheet with the data requested (number of reports to DCF for IPV and CM over the 26 weeks of treatment and number of IPV or CM related arrests over the 26 weeks of treatment). If an incident appears in both databases this will be noted to prevent double counting of a single incident of IPV multiple times due to reporting to both the police and DCF. The completed dataset will be returned to Dr. Stover via the same Yale secure file transfer. DCF will not keep any records of this data once transferred back to Dr. Stover. The excel sheet will then be updated by Dr. Stover with participant study ID numbers and the names and dates of birth will be deleted from the file. This ID only dataset will be saved for merging with other study data for analysis. This will ensure that arrest and DCF data will not be attached to participant names once it returns to Yale. The data will be stored on a password protected server only assessible by the study team.

4. If identifiers will be associated with the data and/or specimens, describe whether a record or list containing a code (i.e., code number, pseudonyms) will be used, where the list will be stored, who will have access to the list and when it will be destroyed.

The only file that will link the study participants to their study ID number will be an excel file kept on a password protected and encrypted computer in the PI's research lab. Only the PI and study RAs will have access to this file.

5. Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored. Study data will be retained for 10 years from study completion to allow for analysis and use of data to answer research questions and the development of F4C. Video and Audio recordings of fathers sessions will be destroyed based on their wishes at the time of consent. If fathers will allow us to retrain their videos for training or research, these will be kept indefinitely. Using these videos for training purposes has been useful previously to train clinicians. Fathers will be reminded that their videos will be kept indefinitely at the time of recording. The fathers will not be identified in the videos as IPV offenders. They appear as fathers interacting with their children only. If fathers want their video and audio recordings deleted at the completion of the study, these will be

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deleted from all servers following fidelity coding of session videos/supervision and following transcription of audio files for analysis.

All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu

6. Identify who will have access to the data and/or specimens. *If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred.*

Only study team members will have access to the data. Dr. Adele Hayes will have access to video recorded sessions stored on a One Drive folder. They will oversee trained coders who will rate therapy sessions for focus on emotion regulation and reflective functioning important to the intervention. They will access recordings on this server. They will not be removed from this server at any time nor shared with others via download. Dr. Hayes has received IRB exemption from her university IRB for this work. Letters to this regard are uploaded with this protocol.

7. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data or the link to personal identifiers? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured. The data will be stored in a de-identified dataset on the Yale secure server. Only Drs. Stover, their research team will have access to the data. No personal identifiers will be retained.

8. Will a Certificate of Confidentiality be needed? (*See also the NIH Certificate of Confidentiality Kiosk, http://grants.nih.gov/grants/policy/coc/index.htm)* Yes a certificate of confidentiality will be attained from NICHD which is now standard for studies that involve collection of information that participants may not want disclosed to the court.

SECTION VII: POTENTIAL RISKS AND BENEFITS

1. **Risks:** Describe the reasonably foreseeable risks, including risks to participant privacy, discomforts, or inconveniences associated with participants participating in the research. *Note: All studies have the potential for risk, if not physical, there may be psychological, reputational, or financial risks or risks to breach of confidentiality.*

Potential risks to confidentiality: There is a risk of breach of confidentiality, however we will implement safe guards to prevent this as outlined above in sections related to confidentiality.

Potential risks of Behavioral therapies: Although Fathers for Change is a newer approach, other programs and agencies have worked with maltreating parents and their children and used play observations.[72] Additionally, we had no adverse events related to the intervention in our pilot studies of Fathers for Change. Psychological risks are minimal and not different from those of equivalent non-study psychotherapeutic interventions.

Potential risks of Rating scales and questionnaires: To participate in this study, subjects are asked to complete various forms and questionnaires during their initial enrollment, during treatment and post-treatment. All of the questionnaires are standardized and should add no risk to the subjects. Some of the questions are personal in nature and may be upsetting

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2. Minimizing Risks: Describe the manner in which the above-mentioned risks will be minimized.
Potential risks to confidentiality:

Potential risks to confidentiality: As detailed above, every effort will be made to maintain participant confidentiality. Confidentiality with regards to completed research forms will be maintained via numbered reference system maintained by the PI and Project Director. Participants names will appear only on the consent form, HIPPA authorization form and "key" form in a password protected file only accessible by the PI and project director. Subjects who decline participation in the study or those who wish to withdraw from the study can continue in their treatment at the outpatient facilities as they would if they were not approached to participate in a study. As stated above to further protect against potential risks to confidentiality for this population, a Certificate of Confidentiality will be obtained. Participants will clearly be informed of the limits of this confidentiality, which are in cases of suspected child abuse or neglect, and imminent risk for harm to self or others (particularly intimate partner or child).

Potential risks of Behavioral therapies: For the treatment conditions, frequent monitoring (at least weekly) of the participants' clinical status by therapists and research staff will ensure identification and withdrawal from the study of participants who show significant psychological or symptomatic deterioration. If a participant shows significant symptomatic deterioration such that they are a danger to themselves or others or are in need of crisis intervention, the clinician, RA or project manager working with the participant will contact Drs. Stover or Sullivan immediately. Both are licensed clinical psychologists with extensive clinical experience with IPV offenders, victims and children who have witnessed violence or experienced maltreatment. Drs. Stover, and Sullivan have over 15 years experience working with men with histories of IPV, victims and children who have experienced violence and maltreatment. Dr. Silverman is also clinical psychologists with decades of experience with clinical populations. Senior clinical supervision will be available at any time a client is being seen. Drs. Stover, Sullivan, or will assess the situation and assist with crisis stabilization, treatment planning, or facilitate inpatient psychiatric hospitalization if indicated. Participants who chose to withdraw or not participate in the study will have access to usual care at the facilities where the study is offered.

Rating Scale and Questionnaires. Participants will be instructed that they can choose to skip any question or item if they do not want to answer. All the measures have been used in previous research with this population and in the pilot studies conducted by the PI or her co-investigators. The major disadvantage is the time taken to complete them. Our previous experience indicates that the baseline assessment will take 2 hours. A research assistant will meet with the participant online via zoom independent of their clinician and conduct all assessments. Only participants' code numbers will be recorded on the forms themselves to protect confidentiality. Also, careful efforts aimed at maintaining confidentiality have been effective in previous research, and only participants' code numbers will be recorded on the forms themselves to protect confidentiality. *The study team (Drs. Stover and Sullivan) have extensive experience collecting IPV related data longitudinally from victims of IPV and have safely done so in previous studies.*[88-90] *Procedures recommended in the literature and used in our prior studies of phone/text/email follow-up will be carefully adhered.*

Additional Safety and Comfort: All research staff will receive substantial training and supervision to ensure that their interactions with all participants are not only professional, but also warm, friendly, non-confrontational, and respectful to all participants. We will take all precautions to ensure the safety of female co-parents of our male participants including: a) ensuring that partners' responses to all screening items are confidential from one another; b) allowing a male participant to remain in the study even if his female partner declines participation for herself or the child (he will not be informed of her decision instead he will be told the research team has decided to continue

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with him individually); c) as outlined in the limits to confidentiality section of the study consent form (see above), in the event of any credible threat (harm towards life) made against a female partner, confidentiality will be breached per legal requirements and she and the police will be notified and informed of the potential danger to her; d) providing all female partners referral numbers to the CT Domestic Violence Services a 24 hour crisis support line and other treatment and community resources as needed if she contacts project staff with concerns. Drs. Stover and Sullivan all have strong working relationships with the Connecticut Coalition Against Domestic Violence (CCADV) and the services provided by the statewide system of supports for victims of IPV.

Protection of Child Participants: Children will be recruited into this study to participate in father-child observational assessments and for those over 7 answer self-report questions about their mental health symptoms. These will provide an observational measure of father-child interactions providing an additional measure of change related to parenting and child maltreatment risk and child self-report of symptoms to corroborate the parent report data we will collect. Fathers will be able to participate without their children to reduce any risks to the children for retaliation for their lack of participation. Study research assistants will describe the study procedures to the child and ask if they would like to participate. Verbal agreement to participate and behavioral compliance without undue pressure from the father will be taken as assent from children given their young age. If a play session cannot begin once a father and child are at the research center or must be ended, father and child will be compensated for the attempt to provide data to minimize risk to the child for being uncooperative. If a play session does not proceed, the father will continue in the study to randomization and treatment assignment. Children will participate in free-play using age appropriate toys with their fathers for 15 minutes and then complete clean-up of used toys. Research assistants will be observing the session through a one way mirror or video in another room and will be trained to assess children's distress level. If at any time, the child becomes overly distressed from being in the room with their father or wishes to end the session, the session will be stopped and they will be offered their small toy to take home. If ending the session and choosing their toy does not help them calm, Ras will call Dr. Stover, Sullivan or . A senior member of the research team will always be available at the time of a father-child assessment in the event of distress of the child. All are licensed clinical psychologists with expertise in child development and child mental health treatment. They will be available to assess any child and provide crisis intervention, make referrals for needed services or treatment and provide support. Given the play focus and limited demands of the assessment, there is limited risk for distress of the child participants.

3. Data and Safety Monitoring Plan: Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HSC will make the final determination of the risk to subjects.).

   a. What is your assessment of the overall risk level for subjects participating in this study?

   Greater than minimal risk.

   b. If children are involved, what is your assessment of the overall risk level for the children participating in this study?

Risk to children is minimal as their only participation is in play assessment with their fathers. These assessments will be observed through a one-way mirror.

   c. Include an appropriate Data and Safety Monitoring Plan. Examples of DSMPs are

available here http://your.yale.edu/policies-procedures/other/data-and-safety-monitoring-plan-template for

i. Minimal risk
ii. Greater than minimal/moderate risk

d. For multi-site studies for which the Yale PI serves as the lead investigator:

i. How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed? Click or tap here to enter text.
ii. What provisions are in place for management of interim results? Click or tap here to enter text.
iii. What will the multi-site process be for protocol modifications? Click or tap here to enter text.

Summary of the Protocol

As detailed in the research plan and the protection of human subjects sections this study involves a randomized controlled trial of Fathers for Change compared to Batterer Intervention Program. For further details on the sample and inclusion/exclusion criteria, see the Human Subjects section. The Yale School of Medicine Child Study Center Parent and Family Development Program clinic will serve as the participating site. The clinics will recruit participants, allow for data collection/assessments by study staff and offer space for provision of the study treatments.

Roles and Responsibilities

Dr. Stover and the study team will review data integrity and safety during weekly team meetings. The post graduate associate and research interns will review assessment data and bring any concerns to Dr. Stover immediately if needed or in the context of weekly study review. Drs. Stover (Fathers for change) and Sullivan (Batterer Intervention) will also provide weekly supervision to study therapists, where they can report any concerns or safety considerations related to study interventions. Any significant study safety concerns related to participants will result in an immediate phone call to Dr. Stover and if needed Drs. Sullivan and Silverman. Dr. Stover will not participate in data analysis. Dr. Silverman or another team member masked to participant treatment group will carry out all statistical analyses related to study intervention comparisons.

In accordance with Federal and Institutional regulations, a Data Safety and Monitoring Board (DSMB) for this study will meet quarterly to review aggregated study outcomes data and adverse events. The DSMB will be composed of three clinical investigators with expertise in working with men/fathers, forensic populations, and IPV victims/child witnesses who are not affiliated with this study. Dr. Stover will present these aggregated data on study outcomes and adverse events quarterly in a blinded fashion.

Trial Safety

Participants would be excluded from further participation in the intervention if any of the following occur:
1) psychosis, 2) a domestic dispute or incident of child maltreatment that results in a full no contact order pertaining to the child, 3) suicidal ideation requiring hospitalization. Overall, subjects will be dropped from the study if they show severe symptom deterioration, which would warrant transfer to another level of intervention.
Mechanisms for trial safety and security have been detailed in the Human Subjects Section of this proposal.

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The trial would be stopped if study interventions resulted in increased violence toward co-parents or children.

Yale requires disclosure of any conflict of interest for study personnel. Prior to beginning work on the study, all staff will complete a conflict of interest survey. If a conflict is identified, prior to commencing work on the study a conflict of interest plan will be developed by the Yale Research Compliance Administrator, Conflict of Interest Program to ensure faculty or staff are in no way influencing the findings of the research.

Reportable Events

The data with respect to adverse event (AE) severity and attribution of any adverse outcomes to study interventions or procedures will be based on coding procedures endorsed by the YALE IRB, as follows:

Coding of Severity:
0 = No adverse event or within normal limits
1 = Mild adverse event
2 = Moderate adverse event
3 = Severe, resulting in psychiatric or medical hospitalization
4 = Life-threatening adverse event
5 = Fatal adverse event

Coding of Attribution:
1 = Unrelated to study interventions
2 = Unlikely relationship to study interventions
3 = Possible relationship to study interventions
4 = Probable relationship to study interventions
5 = Definite relationship to study interventions

Event attribution may include the following study components: 1) Interventions; 2) Research Assessments; or 3) Study Procedures. On the basis of this review, after Dr. Stover excuses herself, the DSMB's outside reviewers will deliberate, and submit a written report to the P.I., the Yale IRB and the Program Officer within 48 hours of these meetings, suggesting any recommendations for protocol modifications, or a recommendation to terminate the trial. While no unblinded interim data analysis is planned, if the DSMB independent reviewers suggest that an unblinded interim analysis is required, we will consult with the program official and the IRB, and a statistical penalty for this interim analysis may be taken if it is decided that the trial can continue. All adverse events graded 3 or higher in severity and attribution will be considered as serious adverse events (SAEs), and will be reported within 48 hours to the Yale IRB HIC, and NIH. Reasons for terminating a subject's participation (e.g. "stopping rules") will include: 1) serious adverse reaction to study intervention Fathers for Change or BIP. Anticipated adverse events include increased negative mood, increased danger to female partner or child, and/or rearrests related to IPV or CM offenses or other non-family violence criminal charges. These will be assessed with rating scales. As these scales are assessed at baseline and during the experimental procedure, we will be able to determine if the event is attributable to the research. Otherwise, routine reporting of adverse events data will be done on a quarterly basis corresponding to the quarterly meetings of this study's DSMB, using the following summary table which includes AE severity and attribution, as well as whether or not such AEs were anticipated (ATP) or unanticipated (UNATP).

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4. **Potential Benefits:** Identify any benefits that may be reasonably expected to result from the research, either to the participant(s) or to society at large. (*Payment of participants is not considered a benefit in this context of the risk benefit assessment.)*

The major potential benefit of this study is the development of a feasible, evidence-based intervention that may be integrated into treatment clinics that addresses the intersecting issue of IPV and CM especially for those that have already failed the standard treatment as usual group Batterer Intervention program. The proposed intervention may decrease IPV and CM, which will benefit the men their co-parents and children. Additionally, male participants will be offered free treatment.

SECTION VIII: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. **Alternatives:** What other alternatives, if any, are available to the study participants outside of the research?

Participants will be able to receive intervention as usual offered at the Parent and Family Development Program if they do not want to participate in research.

2. **Payments for Participation (Economic Considerations):** Describe payments that will be made to participants, if any, the amount and timing of payments, and the conditions for receiving this compensation (if applicable). If you plan to hold a drawing, be sure to include the following on any consent or recruitment materials mentioning the lottery: 1) the value of the prize; 2) the sponsor of the prize (this cannot be a federal funding source); 3) the odds of winning; and 4) that there are no restrictions to winning.

Fathers and coparents will be paid $50 for their completion of baseline assessments. Children younger than 7 will receive a small toy (worth $5-10) for completing play assessments. All children in a family within the age range will be offered the toy to prevent any conflict within the family. Children over 7 will receive $20 for completing play assessments and symptom questionnaires.
During Treatment: Fathers and coparentswill receive $5 for each completed weekly log over the 18 weeks of treatment.

Follow up interviews:
Fathers and coparents will be offered $600 for post-treatment assessments, $60 for 6 month and $60 for 12-month follow-ups. Payments for pre-post assessments and assessments during treatment will be paid in cash to participants when they attend in person treatment sessions. Alternatively, the participant will also be offered the option of receiving a reloadable Bank of America debit card which will be topped up by research assistants. For the mothers who will only have remote contact with RAs and clinicians in order to reduce contact and risk associated with COVID-19, they will be offered a reloadable debit card sent via post.

3. **Costs for Participation (Economic Considerations):** Clearly describe the participant's costs associated with participation in the research, if any, and the interventions or procedures of the study that will be provided at no cost to participants.

There will be no costs to participate in this study. Male participants will be offered free treatment.

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