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Intimate Partner Violence and Fatherhood Intervention in Residential Substance Abuse Treatment

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Study Rationale and Background Information
Substance use and intimate partner violence (IPV) are two severe problems that often co-occur (Centers for Disease Control & Prevention, 2013; Centers for Disease Control, 2012; Shorey, Stuart, & Cornelius, 2011) and can lead to poor parenting behaviors (Gustaffson & Cox, 2012; McMahon, Winkel, & Rounsaville, 2008). Current treatments for co-occurring substance abuse and IPV are lacking (Stover, 2013). This study will test initial efficacy of a novel intervention for IPV and substance use among fathers in residential substance abuse treatment: Fathers for Change compared to a standard parenting intervention.

Research Hypotheses
This initial pilot will assess the feasibility, acceptability, and intervention signal of Fathers for Change compared to a Parent Education Condition within a residential treatment center for substance dependent men. We will test the following specific hypotheses:

1. Fathers in the Fathers For Change (FFC) group will have comparatively greater completion rates in both the residential and aftercare components of the program compared to fathers in the Dads 'n' Kids (parenting education-PE) program.
2. Fathers in the FFC group will exhibit greater improvement in hostile cognitions, emotion regulation and physiological arousal at the time of residential treatment discharge (12 weeks) and following aftercare sessions (16 weeks) than fathers in the Dads 'n' Kids group.
3. Men in the FFC group will experience comparatively less substance abuse relapse at the 3 month-follow-up than in the Dads 'n' Kids group.
4. Men in the FFC group will report fewer intimate partner violence (IPV) incidents and CM risk behaviors at 24 week follow-up than fathers in the Dads 'n' Kids group.
5. Exploratory Hypothesis: The relationship of Intervention (FFC versus PE) to substance abuse relapse, IPV, and child maltreatment risk behavior (at 24 week follow-up) will be mediated by reductions in hostile cognitions and emotion regulation (measured at 16 weeks).

Study Design
Sixty fathers, their female co-parent and youngest child will be recruited to participate in the study. At the time of intake at Westcare's Emerge Program and Salvation Army's Residential Substance Abuse Rehabilitation Program, fathers will be provided flyers about the study. Men who express an interest in participating in a parenting program as part of their treatment will fill out an initial interest form with their counselors (including their name, arrival and discharge date, information about how often they're in contact with their children) and have their counselors submit this form to the Project Coordinator. The Project Coordinator will schedule a screening with the potential participant and will be asked to sign a consent form,

and to sign a release of information to review their SA treatment and criminal history. Men will be told that his questionnaire and records will be reviewed and will be contacted further if considered eligible by the PI based on the study's requirements.

This will provide the opportunity to contact the mother to conduct a phone screening in regards to IPV history and willingness to participate. If the mother indicates an IPV history that involved hospitalization or strangulation or a current full no contact protective order, he will be notified that based on the demographic screening, he is not eligible for the study. If the father is eligible and agrees to participate in the study, the research assistant will contact the father to set up a baseline assessment and the co-parent will be contacted to set up a baseline interview by phone or in-person if she wants to participate. If the father is not eligible for the program we will remove the bottom portion of his screening form that includes personal information (name, arrival and discharge date, and WestCare or Salvation Army counselor information) and shred it. The top portion including de-identified information (IPV history and contact with children) will be kept to keep track of the number of referrals compared to the number of participants in the program.

Mothers of the father's youngest child will be recruited in several ways:

1. When she visits the facility she will be approached by study staff in person.
2. She will be mailed study flyers asking her to contact the research office.
3. Westcare or Salvation Army staff will call mothers and ask permission for study staff to contact them to tell them about the study.

Following completion of baseline assessments, subjects will be randomly assigned to the FFC intervention or the Parenting Education (Dads 'n' Kids) condition. To increase the likelihood that treatment groups are balanced with respect to demographic variables, and moderators, subjects will be assigned to treatment conditions through urn randomization using a Microsoft Access-based program. In urn randomization, an algorithm modifies ongoing randomization probabilities based on prior composition of treatment groups and maximizes multivariate equivalence of groups

Fathers in each treatment group will meet individually with their assigned therapist once per week for 50-60 minutes of treatment. The Fathers for Change Intervention has three phases: individual focused, co-parent relationship focused and restorative parenting focused. Beginning with motivational interviewing, the clinician and father will discuss child development, the impact of SA and violence on parenting, and the father's own childhood experiences of SA and violence and how he would like things to be different for his own children. The clinician will also provide skills training to reduce hostile cognitions and increase emotion regulation skills. In co-parenting focused sessions the clinician will teach communication and problem solving skills, these topics will be addressed with or without the co-parents participation. In family sessions the clinician focuses on restorative parenting to

rebuild the father-child relationship. These phases can be delivered either individually to the father or together with his children present. The decision whether family members are invited to participate will be made on a case by case basis dependent on safety of the co-parent and child, their wish to participate and their ability to come to the treatment facility.

The Dads n' Kids (Parenting Education-PE) Program will provide individual sessions only. PE was developed to provide parent education and support that is typically available to SA parents at risk for child maltreatment. This program was selected as the comparison condition because PE and FFC are equivalent in terms of treatment dose, duration, client expectation for a parenting intervention, and formation of a helping alliance with a caring professional. The clinician will provide assistance in solving problems related to family basic needs (e.g. health care, child care, housing and education). The clinician will also provide topic pamphlets that will focus on creating routines and rituals, ages and milestones to be aware of, alternative to spanking, and nutrition/fitness. The intervention is a behaviorally focused intervention to build parenting skills.

Participants in both groups will be asked to complete a baseline interview once they have been enrolled in one of our programs. Short, monthly interviews will take place to assess the client's motivation to change and working alliance with their assigned clinician. The research assistant will also conduct three post-assessment interviews: 1. Post-residential interview at 12 weeks; 2. Post-intervention interview at 16 weeks; and 3. A 3-month follow-up interview at 24 weeks from baseline. Co-parents will be asked to complete a baseline assessment and a 3-month follow-up assessment.

A complete list of study measures are outlined in Table 1. Fathers will meet in a confidential office to complete study measures that will be administered in interview format. Following administration of paper and pencil measures, fathers will complete the Articulated Thoughts in Simulated Situations Task. They will listen to audio recorded scenarios and vocally speak their thoughts into an audio recorder. Their statements are transcribed for coding by trained, blind coders. Upon completion of hearing these potentially stressful scenarios, research assistants will guide participants through a debriefing relaxation exercise of guided imagery and deep breathing to ensure men are calm prior to leaving the assessment session. We have successfully used all the included measures in prior studies with the target population without any adverse events.

Fathers will meet the following Inclusion criteria: (1) current DSM-5 criteria for substance use disorder of alcohol, cocaine, marijuana, amphetamines, or opiates at the time of admission to Westcare or Salvation Army; (2) report physical or psychological violence in an intimate relationship within 12 months of admission to the program (based on court/police records or self- report); and (3) be expecting his first biological child in the next 6 months (current or former partner is pregnant), have at least one biological child under the age of 15 with whom they

lived or had at least once per month contact prior to admission to Westcare or Salvation Army. Each will agree to have their female co-parents contacted for participation as collateral informants and will provide the contact information. If a participant has more than one child in the age range, the youngest child will be the target of assessment. Female co-parents (the target children's mothers) will be invited to participate as collateral informants on research assessments and to participate in a portion (2 -4) of the intervention sessions. If a female co-parent does not consent to participate, a male participant will still be allowed to enroll in the study if he meets eligibility criteria.

Individuals will be excluded who: 1) Have histories of severe physical violence against a female partner (e.g. strangulation, causing hospitalization) based on police records, self or partner reports; 2) Men who have an active FULL/NO CONTACT protective order pertaining to their partner or child (Westcare and Salvation Army have access to criminal record/court information for all of its residential clients. Participants will sign releases of information during informed consent to allow the study team to access this information to determine eligibility); 3) Have cognitive impairment (a mini mental state score <25); 4) Have major medical complications such as a head injury or HIV dementia that may also be a confound in the study interventions; 5) Have current untreated psychotic or bipolar disorder (reported by history, as part of the Westcare or Salvation Army record, or self-report); or 6) Are currently suicidal or homicidal. If potential participants have a prior diagnosis of bipolar or psychotic disorder that is currently treated and symptoms are well managed based on initial study interview and after collateral contact with the Westcare or Salvation Army treatment teams, they may participate in the study.

Table 1. Standardized Measures and administration for Randomized Trial

Instrument	Rater	Reliability	Base -line	Monthly During Intervention	Post Residential Intervention 12 weeks	Post Intervention 16 weeks	3 month follow-up 24weeks
SA Outcomes							
Timeline follow-back for SA	Father and Mother	.91		X	X	X	X
Urinalysis Drug Panel	Father	NA	X	X		X	X
IPV Outcomes							
Conflict Tactics Scale Revised (CTS2)	Father and Mother	.79 to .95	X				X
Timeline follow-back for IPV	Father and Mother	.91		X	X	X	X
Court and Arrest Records	N/A	N/A	X				X
CM Risk Outcomes							
Parental Reflective Functioning Questionnaire (PRFQ)	Father	.82	X			X	X
Adult Adolescent Parenting Inventory (AAPI)	Father and Mother	.74 to .98	X			X	X
Father-Child Free Play coded using (CIB)+	Blind Coders						X
Quality of Co-Parental Relationship Scale	Father and Mother	F: .66 - .88 M: .80 - .83	X			X	X
Satisfaction Outcomes							
Client Satisfaction Questionnaire 8	Father	N/A				X	
Mediators							
Articulated Thoughts in Stimulated Situations (ATSS) and HR/SC	Blind Coders	N/A	X		X		
Difficulties in Emotion Regulation Scale (DERS)	Father	.93	X		X	X	X
State-Trait Anger Inventory (Staxi)	Father	.84 - .93	X		X	X	X
Rumination-Reflection Scale (ARQ)	Father	.88 - .91	X		X	X	

Working Alliance Inventory	Father and Clinician	.79 - .97		X			
Motivation to Change (URICA-DV)	Father	.85 - .87		X			
Moderators							
Childhood Trauma Questionnaire	Father	.80 - .97	X				
Self-Report Psychopathy Scale 3	Father	.60	X				
Life Change Index Scale	Father	N/A	X				X
Brief Symptom Inventory (BSI)	Father	.74 - .89	X			X	X
Addiction Severity Index	Father	.89	X				
Father Interview	RA	N/A	X			X	X
Treatment Services Review	Father	N/A				X	X
PhenX Measure: Self-Report HIV Testing	Father	N/A	X				
FRPN FATHER ENGAGEMENT SCALE_v1	Father	N/A				X	X
FRPN FATHER ENGAGEMENT SCALE_v2	Father	N/A				X	X
FRPN FATHER ENGAGEMENT SCALE_v3	Father	N/A				X	X
Measure of Contact-Fatherhood Research and Practice Network	Father	N/A				X	X
Domestic Violence Quiz	Father	N/A	X		X		
Co-Parenting Quiz	Father	N/A	X		X		

At the 3 month follow-up, fathers will be asked to attend a play assessment with their child. This will be a 30 minute appointment in which they will play with toys or games with their child for 15 minutes, clean up and then complete several puzzles with their child. These session will be audio recorded and coded using the Child Interactive Behavior Rating Scale by trained blind coders.

The PI, co-investigator Stover, and study coordinator will be the only ones who have access to the data, and data will be stored in locked file cabinets and on password protected computers. Data will be analyzed in aggregate to investigate study hypothesis (stated above).

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Urinalysis Data Collection

To ensure urine screening data is available for all participants, including those who are no longer receiving services and providing urine samples at Westcare, Inc., or Salvation Army, any participants who have not given urine drug screens at Westcare Inc. or Salvation Army within a week of the post-treatment and 3 month follow-up assessments, Integrated iCups from Instant Technologies will be used for urine drug screening at the time of their assessment interviews. RAs will provide clean test cups taken from the packaging just prior to collection. Participants will be asked to provide the urine sample at the end of the assessment session. They will go into a private bathroom at the location of the interview. They will be instructed to place the sample in the cup and close it. RAs will wear rubber gloves when handling test samples. They will immediately read the urine test results by peeling the test panel on the side of the cup and reading the results. They will document the results on the Urine Screening Form. The urine sample and rubber gloves will be immediately disposed of in the waste bin at the location.

Sample Size

The study will be recruiting 60 male participants that are in a 6 month residential treatment, their female co-parents (youngest child's mother) and their youngest child for a total sample of 180.

Study Population

Sixty male participants of the WestCare Community Involvement Center or the Salvation Army Adult Rehabilitation Center who are residents.

Inclusion criteria: 1. Is the father (biological or adoptive) of a child under 15 years old (including an unborn fetus expected in the next 6 months); 2. Reports some verbal or physical aggression in his current or former co-parenting relationship; 3. Is diagnosed with substance use of alcohol, cocaine, amphetamines, opiates, marijuana at the time of intake at Westcare or Salvation Army.

Exclusion criteria: 1. Participants with significant cognitive delays will be excluded as study questionnaires are not intended for those with a reading level below grade 8; 2. Participants with active psychotic or suicidal symptoms will be excluded due to the severity of those issues. 3. Participants will be excluded if there is an active no-contact protective order pertaining to the child or the co-parent; 4. Individuals who cannot speak English because study measures have not been translated into other languages; 5. Have cognitive impairment (a mini mental state score $\leq$25); 6. Have major medical complications such as a head injury or HIV dementia that may also be a confound in the study interventions;

Female co-parents of the father's youngest child and his youngest child will also be recruited into the study.

Equipment:

During the Articulated Thoughts in Stimulated Situations (ATSS) we will be assessing heart rate and skin conductance with a BioLog device. Participants will be asked to wear three (3) receptors that will be placed on their chest by the client to measure heart rate. They will also be asked to wear two skin conductance sensors that they will place on two of their fingers. These receptors and sensors are attached to a small device that will allow the research team to assess heart rate and skin conductance throughout the 30 minute audio recording. This device is being used to measure their stress level and biological reactions to each scenario that they'll be listening to. Although there is minimal risk if they choose to participate in this task, they will have the option of completing the ATSS recording with or without wearing the BioLog device. Participants will not be forced to use the device if they do not want to.

Expected Results

We expect that:

1. Men in the FFC group will have significantly higher completion rates than PE fathers.
2. Men in the FFC group will have significantly lower scores on the STAXI, DERS, ATSS and lower physiological arousal during stress tasks than PE fathers post intervention and at 24 week follow-up.
3. Men in the FFC group will have a significantly greater understanding of co-parenting and the impact of violence on their children compared to the PE group post-intervention.

5. Men and co-parents in the FFC group will report higher treatment satisfaction than the PE group.

Principal Investigator

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Louis de la Parte Florida Mental Health Institute
Department of Mental Health Law and Policy

Risks

The risks of this study are minimal. Participants may find it difficult to talk about stressful events that have happened to them and their families. They may experience some discomfort answering questions or talking about these things. Participants will be allowed to withdrawal from the study at any time. Participants may request a short break or discontinue any questionnaire at any time. If the child seems distressed or does not want to participate during play sessions, they will be discontinued. Additionally, male participants will be receiving residential treatment at WestCare or Salvation Army and have an individual therapist at the facility in addition to individual sessions as part of the research program. The support of the residential program and their individual therapist will provide them with support if discomfort arises at any time during the study.

Risk to female collateral informants is also minimal. Men are enrolled in residential substance abuse treatment so are not in the community or living with their families at the time of enrollment and the bulk of the study. Female co-parents will be contacted individually and safety of her participation will be assessed. If she feels her participation will put her at any risk for retaliation or violence by the father, she will not be enrolled. Prior to initiating co-parent treatment sessions with both partners for those in the FFC group, the clinician will assess the safety of the co-parent and ensure both want to participate. If significant symptoms or difficulties of female co-parents are revealed, this information will be reviewed with the study co-investigator, Dr. Stover, and appropriate referrals will be provided to mothers who participate in the study. Mothers will be interviewed individually and confidentially on different dates and locations from the fathers in the study.

A. Behavioral therapies

Psychological risks are minimal and not different from those of equivalent non-study psychotherapeutic interventions. For the treatment condition, frequent monitoring (at least weekly) of the participants' clinical status by the therapist 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 study clinical consultant, Ms. Kisha Miller, a licensed clinical social worker and certified addiction counselor, will assess the client in consultation with the participants primary counselor or clinical director at Westcare or Salvation Army. A determination will be made about whether a higher level of care is needed beyond what is provided in the residential treatment setting. If significant symptoms or difficulties of female co-parents are revealed, this information will be reviewed with the study PI, Dr. Moore and co-investigator Stover, and appropriate referrals will be provided to mothers who participate in the study.

B. Rating Scale and Questionnaires and ATSS Task.

To participate in this study, subjects are asked to complete various forms and questionnaires during their initial enrollment and post-treatment. All of the questionnaires are non-invasive and standardized and should add no risk to the subjects. They have been used in previous research with this population. The major disadvantage is the time taken to complete them. The ATSS paradigm has been used with the study population by the PI in her previous pilot studies and by others doing IPV research without adverse events. We will follow practices typically used with laboratory anger and distress tasks to debrief participants. As stated above, research assistants will guide participants in a relaxation session including guided imagery and deep breathing to ensure men are calm and not leaving the sessions aroused, distressed or angry. In the event that a participant remains agitated following the implementation of diaphragmatic breathing and a guided imagery scenario, the RA will contact the study clinical consultant, Ms. Miller, Westcare, or Salvation Army clinical director to assess risk and next steps.

Our past experience with these measures indicates that they are acceptable to patients. The initial baseline assessments for the study will take approximately 2 hours for completion for men and 1 hour for women. Post-treatment assessments will take approximately 1 hour for completion. A research assistant will meet with the patients independent of their clinician and conduct all assessments. Only patients' code numbers will be recorded on the forms themselves to protect confidentiality.

Benefits

Participants will receive an individual intervention to address parenting and co-parenting. As such, their mental health, physical health, and familial functioning may improve as a consequence of participation. Furthermore, this research will inform interventions for fathers with substance abuse and violence histories in residential treatment, enabling us to better treat these problems.

Compensation

Male participants in both the FFC Program and the Dads 'n' Kids Program will receive $35.00 for their post-intervention interview at week 16 and will be paid $50.00 for completing the 3 month follow-up interview with the research assistant. Female co-parents will receive $25.00 for completing a baseline assessment and $50.00 for completing a 3 month follow-up interview with the research assistant.

Human Subjects Considerations

Informed Consent

The P.I. and study coordinator will give flyers to the WestCare and Salvation Army staff, who will distribute them to male residents at intake into the facilities. They will be provided a screening sheet to complete and turn in if they are interested in participating. Volunteers who meet the study criteria will be taken on a first come - first serve basis. The study coordinator will then set up confidential meetings with volunteers individually to obtain informed consent. Consent forms will be given to participants and reviewed verbally by the study coordinator. Consents will clearly outline confidentiality and the limits that apply (see below). Potential participants will be allowed to ask questions at this time and take as long as necessary to give consent.

Female co-parents will receive flyers mailed from the facility. They will be asked to call the research team to learn about the study. They will also be approached by study staff in-person when they visit the facility to ask if they would like to learn about the study. Either in person or on the phone, participants will talk privately with a study staff member to learn about the study and to complete informed consent.

Safeguards for Vulnerable Subjects

It will be made clear to all potential volunteers that participation in this study will in no way affect participants' legal standing or the services they receive at WestCare or Salvation Army. Additionally, limits to confidentiality will be clearly outlined to participants as noted below.

Suicidal or Homicidal Ideation or Intent:

Upon report of suicidal intentions or the threat of harm to others, the PI and clinical consultant Ms. Miller will be notified immediately. Ms. Miller, a licensed clinical social worker, in conjunction with the residential treatment staff at Westcare or Salvation Army will determine what steps are need to protect the safety of the participant and any others in the community. The PI, co-investigator Stover and clinical consultant Ms. Miller have extensive experience in dealing with high-risk behaviors and abides by all state and federal regulations.

Additional Safety and Comfort. All research staff will receive substantial training and supervision to ensure that their interactions with all male participants and female collateral informants are not only professional, but also warm, friendly, non-confrontational, and respectful to all participants.

Privacy and Confidentiality

The limits to confidentiality will be clearly explained to participants. These limits include any report of previously unreported child or elder abuse or any indication that the participant is a harm to themselves or someone else. In these instances, Dr. Moore, will assess the situation in collaboration with the treatment team at Westcare or Salvation Army and notify the appropriate authorities (e.g. Child Abuse Reporting careline). Participants will also be informed of the limits of confidentiality with regard to disclosure of substance use while in the program. Westcare and Salvation Army policy will require that this information be shared with the participants' primary therapists so this can be addressed in the context of the clients' ongoing residential treatment at Westcare or Salvation Army.

All data will be kept private and confidential. All participants will be given a unique ID number, such that their data cannot be tied back to them in any way. The PI, co-investigator Stover and study coordinator will be the only ones who have access to the data, and data will be stored in locked file cabinets and on password protected computers. Data will be analyzed in aggregate to investigate study hypothesis (stated above), with identifying information withheld.

To assure the confidentiality and protection of participants with respect to videotaping, the following steps will be taken:

- Participants have the right to refuse videotaping. Participants who consent to videotaping will be informed that they have the right to stop taping at any time during any session.
- Each therapist or RA will conduct the taping him/herself. All taping will take place in a confidential treatment room at Westcare or Salvation Army.
- Each video file will be labeled with the participant's study identification number and a coded session date.
- The therapist or RA will be log and store the tapes in locked files in secure research offices at USF.
- Access to the video files will be limited to specially trained research raters who will rate the files according to established process rating systems. All

ratings will be done in our research offices. Upon completion of these ratings, the files will be erased unless participants agreed to have them used for training purposes.

Certificate of Confidentiality

To help us protect the participants' privacy, we have attained a Certificate of Confidentiality from the National Institutes of Health. We can use this Certificate to legally refuse to disclose information that may identify the participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify the participant, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality does not prevent the participant or a member of the participants' family from voluntarily releasing information about the participant or the participants' involvement in this research. If an insurer, employer, or other person obtains the participants' written consent to receive research information, the researchers may not use the Certificate to withhold that information