Pathways for Parents After Incarceration Feasibility Study

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NCT04525703

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Child Health and Human Development (NICHD)

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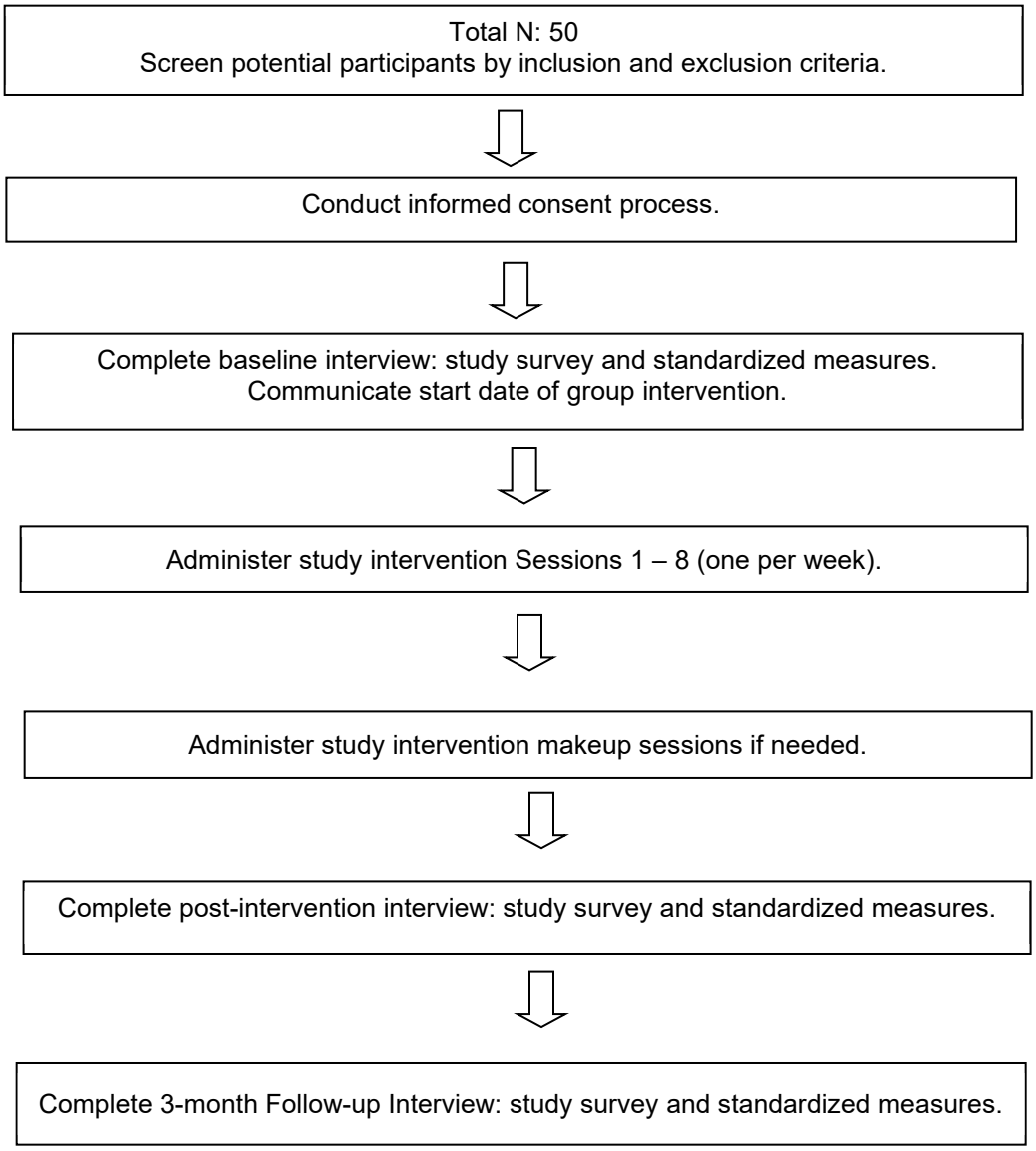
1.0 STUDY SUMMARY

1.1 Synopsis

Full Title	Intervention Feasibility Study - Fatherhood After Prison: Healthy Children and Families
Short Title	Pathways for Parents After Incarceration Feasibility Study
Protocol Number	MRR IRB 2020-0144
ClinicalTrials.gov Identifier & Summary	NCT04525703 The purpose of this study is to learn how to better support fathers and their families after incarceration. It will test an intervention that promotes healthy development for children of previously incarcerated fathers and the caregivers of their children for empirical promise through a pilot feasibility trial. About 15 families (15 fathers, 15 caregivers, and 15-20 children, totaling 45-50 participants) will be in the study.
Number of Site(s)	UW Madison
Phase	NA
Main Inclusion Criteria	Fathers: • being able to speak and read English • having at least one child between the ages of 3 and 17-years-old • having been released from incarceration within the last 5 years (from county jail or state/federal prison) • play a parenting role in at least some way (e.g., residence, contact, phone, etc.) Caregivers: • able to speak and read English • at least 18-years-old
Main Exclusion Criteria	• have been convicted of a crime against any of his children • are prevented from having contact with their child
Objective(s)	The aims of the pilot are to demonstrate: • a) client acceptance of the treatment (e.g., retention) • b) ability to recruit sufficient numbers of participants • c) feasibility of delivery with the clients and therapists in the designated treatment settings
Endpoints	Key outcome measures will assess father involvement, extended family relations, and child outcomes in addition to self-report criminal behavior, substance use, and recidivism for the fathers.
Study Design	Feasibility of a behavioral intervention
FDA Regulatory Overview	NA
Study Intervention	The Pathways for Parents after Incarceration program uses eight key lessons, including topics on effective listening, speaking, and problem-solving skills, lessons on emotion regulation, and issues surrounding family engagement. The program (both classroom and therapeutic peer support) will be offered virtually and weekly for 8 continuous weeks.
Total Number of Subjects	47

Study Population	Children of previously incarcerated fathers and the caregivers of their children.
Statistical Methodology	Descriptive statistics (univariate analyses) and inferential statistics to assess differences between pre and post-test variables (bivariate analyses)
Estimated Subject Duration	The duration of the study for each subject is approximately 21 weeks including follow-up survey.
Estimated Enrollment Period & Study Duration	Study enrollment and follow-up will occur over 19 months with the total expected duration of the trial to be 19 months.

1.2 Schematic of Study Design



2.0 INTRODUCTION

2.1 Purpose

The purpose of the overall study, Promoting Healthy Development among Children of Fathers with Antisocial Behavior, is to build and test a preventive family-focused intervention in a feasibility study that promotes healthy development for children of previously incarcerated fathers and their children. The study has three specific aims, two of which have already been completed. The first was to conduct secondary data analyses to explore a series of questions that explored topics including fathers' history of antisocial behavior and criminality, children's psycho-social and behavioral health outcomes, father engagement and parenting behavior, maternal parenting practices, quality of parental relationship, and extended family involvement. The second aim included conducting semi-structured interviews with fathers, mothers, and relatives to improve understanding of the barriers to father engagement and challenges that families face as fathers return to the community following incarceration.

To that end, this protocol situates itself within the third and final aim, that of specifying treatment procedures (e.g., develop manuals, select measures, specify therapist training and adherence procedures) and establishing feasibility of the intervention (e.g., recruitment, enrollment, fidelity, adherence, retention, and safety). Specifically, this protocol is in regard to the feasibility of the intervention. The purpose is to test the intervention for empirical promise through a pilot feasibility trial. The aims of the pilot are to demonstrate: a) client acceptance of the treatment (e.g., retention), b) ability to recruit sufficient numbers of participants, and c) feasibility of delivery with the clients and therapists in the designated treatment settings.

The family intervention is based in a family systems model that includes all members of the family. Multiple family groups are used because previous research has found they are efficient forms of service delivery, build social support among participants, and improve parent-child interactions. Feasibility of the pilot must include all participants anticipated in the program model to test strategies, logistics, and measures. Drawing from the framework of dissemination and implementation science, another central purpose of the pilot is to refine the operational methods that will facilitate translation and implementation in the future should the intervention be found efficacious and effective. This pilot will answer questions that are pertinent to intervention development, as well as the success of dissemination and implementation in the future.

2.2 Name and Description of the Study Intervention

Pathways for Parents after Incarceration is a community-based program that seeks to equip fathers with the skills both for positive father engagement and reentry success. It uses a manualized curriculum that is adapted from a prison-based program, Parenting Inside Out (PIO). PIO is an evidence-based, cognitive-behavioral parent management skills training program created for incarcerated parents through a six-year collaboration of scientists, policy makers, practitioners, and instructional designers. Both the information in the program and the way that information is presented were informed by knowledge derived from research and practice. Extracted from the full 90-hour version, the Pathways for Parents after Incarceration program uses eight key lessons from one of the original versions (PIO-48) that have been identified by the research team and those with lived experience as being most beneficial to them. These include topics on effective listening, speaking, and problem-solving skills, lessons on emotion regulation, and issues surrounding family engagement. The course is led by 2 parent coaches who will be hired and formally trained to deliver PIO by the PIO parent organization, The Pathfinder Network. The classroom-based PIO sessions will be delivered over 8 weeks in two- to two-and-a-half hour sessions. These classes will be held entirely virtually using a web-based video software. All participants will utilize computers with cameras and audio in order to join the class remotely. At no time will audio or video be recorded. All classroom components, including small group break outs and activities, will be done remotely.

In addition to the classroom component that PIO provides, the program will offer a therapeutic component. These sessions will also be done virtually. Weekly, those receiving services from Pathways for Parents after Incarceration will be invited to take part in a remote peer support group-style group session led by a provider within the community, Anesis Family Therapy. This component of the program is rooted in systems therapy and uses narrative therapy, trauma focused cognitive therapy, and motivational interviewing techniques. This aspect promotes fathers' and caregivers' ability to identify their values and skills so they can effectively confront the challenges (both instrumental and relational) that they face during their reentry period and as family members working to support the fathers. These sessions will run for 45-60 minutes following the classroom portion (PIO).

The program (both classroom and therapeutic peer support) will be offered weekly in virtual, remote format on for 8 continuous weeks (the 9th week will be a class graduation/celebration). Any participant that does not have access to a computer will be loaned laptops or tablets and internet hotspots. The structure of the sessions are as follows:

5:00pm - virtual classroom opens and PIO course activities begin
7:00pm - PIO class concludes and 30 minute break begins
7:30pm - therapeutic peer support
8:30pm - wrap up

These sessions will provide gift card or cash incentives for attending and completing class material. Food will be delivered to their home in lieu of providing food in person during group meetings as was originally planned before COVID-19.

The third and final piece of the program includes the opportunity for fathers and their families to partake in family engagement activities. Prior research pointed program development to the need to support fathers in their ability to spend time with their children engaged in prosocial activities. Pathways for Parents after Incarceration will offer monthly activities to program participants and their families which will provide families the opportunity to enhance their interactions with each other and other families in a safe way. This may include kits that the research team drops off for families centered around art, literacy, or games. It may also include virtual gatherings or outings in socially distanced venues. All decisions related to activities will be guided entirely by recommendations of Madison and Dane County Public Health Department in Wisconsin. The plan is to develop all virtual activities and then only if other formats are allowed, would we do something else.

3.0 STUDY OBJECTIVES AND ENDPOINTS

The aims of the pilot feasibility trial are to demonstrate:

a) client acceptance of the treatment (e.g., retention)

b) ability to recruit sufficient numbers of participants

c) feasibility of delivery with the clients and therapists in the designated treatment settings

Specified measures will be collected at various times (e.g., client experience and satisfaction at post-intervention time points; outcome measures at pre- and post-intervention time points). Key outcome measures will assess father involvement, extended family relations, and child outcomes in addition to self-report criminal behavior, substance use, and recidivism for the fathers. Waves of data collection will occur: 1) prior to beginning the program, 2) immediately following the program, and 3) 3-months after completing the program. Data collection will be done with the father, caregiver, and child. This will be done virtually either by phone with research team members reading prompts to participants or by video conferencing where team members can virtually share screens and walk through documents together, or virtually with

research team members reading prompts and writing down answers. If not possible, it would take place in a private setting (ideally outdoors) where researchers and participants can be safely socially distanced.

4.0 STUDY DESIGN

4.1 General Design

The purpose of this pilot feasibility trial is to specify treatment procedures and establish feasibility of an intervention with the goal of identifying elements required for a randomized control efficacy and effectiveness trial in the future. The focus is on intervention procedures and assessment of feasibility as outlined in the Stage 1a and Stage 1b steps of new treatment procedures. No randomization of participants occurs. The focus is on demonstrating 1) client acceptance, 2) ability to recruit, and 3) feasibility of delivery. Data are collected from participating fathers, caregivers, and children.

4.2 End of Study Definition

The end of the study is defined as the date of the final visit completed by the last remaining subject in the study. This may be either the date of the last visit or the date of the final visit completed before that subject's participation ends (e.g., withdrawal, lost to follow-up, expiration).

5.0 SUBJECT SELECTION

5.1 Inclusion & Exclusion Criteria

Inclusion Criteria - Fathers
1. being able to speak and read English
2. having at least one child between the ages of 3 and 17-years-old
3. having been released from incarceration within the last 5 years (from county jail or state/federal prison)
4. play a parenting role in at least some way (e.g., residence, contact, phone, etc.)
5. being able to speak and read English
6. having at least one child between the ages of 3 and 17-years-old
Inclusion Criteria – Caregivers
1. able to speak and read English
2. at least 18-years-old

Exclusion Criteria
1. have been convicted of a crime against any of his children
2. are prevented from having contact with their child

5.2 Vulnerable Populations

It is important to document and mitigate the effects of incarceration on individuals and families, and thus we are focusing our intervention on previously incarcerated parents and their children. We are also interested in decreasing recidivism, which is a significant problem in the United States. Children with incarcerated parents are at risk for a host of problems and one of the hypothesized mechanisms is related to positive father involvement, improved parenting practices, and broader familial support.

The study seeks to enroll fathers previously incarcerated in jail or state/federal prison. This is a group of individuals who face significant barriers to being successful and engaged with their family after prison or jail, largely because of racially discriminatory practices used in society that results in disproportionate numbers of minorities incarcerated in prison and jail. Research to promote positive father involvement is needed to help improve fathers' own outcomes (e.g., reduced substance abuse and criminal activity), as well as the outcomes of their children (e.g., reduced stress, internalizing and externalizing behavioral problems).

We make sure that the reading level of all materials is at or below the 8th grade reading level. We read items out loud to all participants and pause to make sure that they understand the material. We have an NIH Certificate of Confidentiality to protect participant responses to sensitive questions and to questions that might elicit information about illegal behavior that should remain confidential. We remind participants that they can skip any items that they do not wish to answer. We conduct extra training with research staff so that they understand the importance of confidentiality and sensitivity to vulnerable populations.

While compensation will be provided, the amount of compensation we believe is not high enough to be considered overly attractive by participants as to take unwarranted risks or to affect the voluntariness of consent. We will also inform all study participants during the consent process that their participation will not in any way affect their parole or probation status, their sentence, or anything else related to their status as a formerly incarcerated individual.

For any participants that are on probation or parole, we will not notify their probation or parole agent of their participation - unless if the participant requests/requires that we do so - and would not share any information obtained in the study should we be asked. We have a Certificate of Confidentiality to ensure this safety mechanism can be fully implemented. In the event that a participant were to ask if we can inform their probation or parole agent of their participation in the study or if the probation or parole agent were to inquire as to their participation, we would simply provide that the individual is participating. We will abstain from providing any specific details of the participant or their time in the study beyond enrollment.

5.3 Subject Recruitment

The first tier of recruitment will be with fathers. Our first avenue for recruitment will be reaching out to participants from previous focus groups conducted with a congruent sample, as previously approved by the University of Wisconsin-Madison ED/SBS IRB (Study #: 2019-0409, PI: P. Charles). Participants in these focus groups filled out future contact forms which the study team will use to invite them to the community intervention. This recruitment will take place through phone calls, text messages, or email communications.

Second, we will advertise with a flyer that is posted in places that individuals in the study might frequent (e.g., social service settings, clinics, community centers, libraries). Similarly, the study team will be creating a Facebook page to post flyers on. As per the IRB guidance (https://kb.wisc.edu/sbsedirbs/page.php?id=42376) simply posting recruitment materials through online platforms is generally not considered "Use of New Media" and since it will not be a means of data collection no privacy statement, terms of use, or consent is required. Again, these mechanisms of recruitment will not require any face-to-face communications and thus will fit any socially distanced guidelines that public health officials may have in place. In addition, we will host a Facebook Live Event using an already approved group recruitment script. Prospective participants will have the option of providing their name and contact information in a UW-M Qualtrics survey that will be available only to the research team. This will ensure confidentiality instead of the person providing the information publicly.

A third avenue of recruitment will come from recruitment with partner agencies, such as JustDane referrals through their Journey Home, Phoenix groups, Renewal After Prison group, or service fair that is offered to individuals recently released from prison; The Beacon (day shelter for homeless populations) with their

array of services provided to vulnerable groups; Nehemiah's Man Up group for currently and previously incarcerated men; and the Urban League with their fatherhood and child support initiatives. We will post flyers at these agencies if allowed or send flyers via email, but also work with program staff there to identify and recruit potential participants if allowed. Through these processes, we will invite people to call or to meet virtually with the research team to get information about the community program and screen them for study participation upon initial contact. We will follow the lead of each individual community organization as to how they have been delivering services during the pandemic. For those holding groups virtually, we will inquire as to joining a session virtually, as well, to advertise and to tell interested/eligible individuals about our study and ask that they reach out to us via phone or email.

Anyone who contacts the study team via email will be provided with the study flyer and basic email text with study details.

Stated explicitly, through each of these approaches, interested participants will be invited to contact the study team (most likely via phone call, but also through email or text message via Google phone) for screening at a later time if not available to be screened on the spot at the time of original recruitment contact. During these contacts, research team members will provide more details and information regarding the community intervention and check inclusion criteria. As alluded to, group recruitment methods may also be used. For example, if a Phoenix group meeting is occurring at JustDane (previously Madison-area Urban Ministry) remotely, participants will be asked by staff ahead of time for their voluntary participation in a 10-minute group presentation in which one of the research team members will also join the group virtually to inform individuals of the study and possibly to participate if they are interested and meet the eligibility criteria. A project phone number will be given to participants to call to get more information. Flyers, group recruitment scripts, and phone scripts are all attached herein.

Once a study team member verifies that a father is eligible for participation and he agrees, he will provide the name and contact information of the primary or secondary caregiver (depending on the status they currently hold, themselves). The caregiver will be contacted if the child is cared for primarily by the caregiver and not the father. Individuals who are caring for the focal children of participating fathers are identified as caregivers. Based on previous research, we expect most of these caregivers to be either the other biological parent or a relative of the child.

The study team will then reach out to the caregiver to confirm interest in enrolling the child in the study through phone, text message, or email. If the caregiver does not respond or does not wish to have their child enrolled, we will notify the father that he may still enroll but that we will not be able to collect data from their child. We will place initial calls or send initial emails no more than 3 times to caregivers before ceasing communication. At that time, we will assume they are not interested in having their child participate, or themselves, and notify the father.

If a father has more than one qualifying child, one child will be randomly chosen for participation. We will not require that a child be the biological child of the participating father.

While staff at JustDane, the Beacon, Nehemiah, or the Urban League may help refer potential participants to the study, as would other service providers who have recruitment flyers at their locations, they will not actively recruit. If a potential participant were to inquire about the study or express interest, the staff at the respective agency would be instructed to refer the prospective participant to the study team for information.

All participation will be voluntary for the study respondents.

In addition to posting flyers at social service institutions, businesses, community centers, clinics, libraries, and churches with their permission, the research team will work directly with staff at community organizations (e.g., Just Dane) to share flyers and information about the study with individuals served at their agencies who might be eligible and interested. At no time, however, will staff at community agencies be asked to answer questions about the study or to explain study procedures. Instead, prospective

participants will be guided to contact the study team directly at the email address or phone number on the flyer.

6.0 BEHAVIORAL/SOCIAL INTERVENTION

6.1 Study Behavioral or Social Intervention Description

The Pathways for Parents after Incarceration Program (P4P) is an 8-week intervention that focuses on strengthening parenting skills, building constructive co-parenting strategies, providing therapeutic social support, and connecting families to needed specialized services. P4P is based on an adapted version of Parenting Inside Out (PIO), a cognitive behavioral parent management skills training program originally designed for parents in prison.

P4P is delivered remotely over Zoom (owing to the COVID-19 pandemic) but in real time. Participants first pick up materials needed for the intervention (e.g., intervention manual, laptop/tablet, office supplies, other materials), and then participate from home or other location of their choice. Eight didactic sessions (once per week for eight weeks) are completed along with eight therapeutic sessions (these run back-to-back). Trained PIO coaches deliver the didactic classroom portion and trained therapeutic clinicians deliver the therapeutic sessions. The PIO or classroom portion lasts 2-2.5 hours each, and the therapeutic session is 1 hour each week (total time = 3-3.5 hrs/week).

Staff who will administer the intervention must first complete a PIO training offered by the organization who owns the curriculum rights to the intervention, The Pathfinder Network (*https://www.thepathfindernetwork.org/*). Clinical staff who facilitate the therapeutic sessions must be trained and licensed clinicians in social work, counseling, psychology or related fields. Intervention fidelity will be monitored using the Parenting Inside Out Group Observation Feedback Form Score. Domains scoring in the low category (1=remediation is needed or 2=a growth area) will signal inadequate fidelity requiring re-training and further monitoring. This will be done through individual meetings with the interventionist and with written feedback.

6.2 Study Intervention Compliance

Adherence to the protocol will be assessed by documenting the number of participants recruited, consented and enrolled, and attendance of participants in weekly PIO and therapeutic sessions. Completion of study interviews (measures and qualitative interviews) will also be tracked. To remain an active participant in the study, participants must attend all PIO sessions and if any are missed, attend a makeup session with a coach. Attendance records are carefully monitored and tracked. Participants who drop out of the study once the sessions begin will not be replaced.

7.0 STUDY VISITS AND PROCEDURES

7.1 Screening and Enrollment

[The Screening and Enrollment visits and procedures are described in detail below.]

Informed Consent

Father respondents will participate in an oral consent process to take part in the screening process. Using an oral consent script, the researcher will describe the purpose of the study, the screening process and its purpose, what questions will be asked on the screening instrument, and that the information collected during the screening process will be retained for research purposes regardless of whether they enroll in the study. Participants will then be asked whether or not they wish to participate in the screener to see if they will be eligible to participate in the full study.

The potential participants who respond to community postings or to information materials that are provided by community partners will be instructed to email or call the study team. Contact details will be provided on information sheets and flyers. Potential participants who respond to the posted flyer or the

provided information will be asked to set up an over-the-phone time to complete the brief screening form and obtain contact information for the formal invitation and subsequent reminders for the intervention. If eligibility and exclusion criteria are met, they will be invited to participate in the full consenting process after the screening.

Researchers will determine if they are legally eligible to provide parental consent for their child. If so, participating fathers will take part in the consenting process for the eligible child. Children will participate in the consenting process after the father consents.

If the father is unable to legally provide parental consent for the child, researchers will determine if the caregiver is legally able to provide parental/legal guardian consent. If so, the caregivers will participate in the consenting process for the eligible child, children under the age of 5 will not provide assent, children 5-10 years old will participate in an oral assent process, and children aged 11-17 years old will participate in a written assent process. If neither the jailed parent nor the caregiver is legally able to give parental consent for the eligible child, based on the exclusion criteria the family will not be able to participate.

The consent process will take place virtually or in person (assuming COVID safe) prior to baseline data collection. If the father is legally able to provide consent for the child, the study team member will meet with the father and child virtually (by video call or phone) or in person, prior to the first session. The research team member will read each consent form out loud to the participant to which it pertains. Following that, the team will ask for written consent on the forms.

If the father is not the legal guardian and cannot consent for the child, the study team member will meet with the caregiver and child virtually or in person (similar to the procedure for fathers). The research team member will read each consent form out loud to the participant to which it pertains. Following that, the team will ask for written consent on the forms.

Participants will receive the forms either through mail, email, or delivery through a safe procedure in which there will be no contact during the consent drop off. Once signed, participants will be allowed to either scan, take a picture and send, or coordinate for a safe and secure pick up in which a research team member obtains the form with no contact (e.g., taking it from a mailbox). If consent is done in person, the signed consent form will be obtained at that time.

Fathers will sign a consent form that includes signed parental permission for the child. Children younger than 5 years old will not provide assent as we believe children ages 3-4 years old will not be able to understand the study. When developmentally appropriate, the researcher will describe the activity (asking interview questions) using language that is accessible to young children before engaging in the activity with the child. Children ages 5 to 10 years will be asked to provide verbal assent. Children ages 11-17 will be asked to provide written assent. When the father is not able to give consent for the child to participate, the caregiver will be asked to provide consent instead.

Screening Visit

Once a prospective participant indicates interest in learning more about the study, the researcher sets up an appointment over the phone or over video chat (e.g., Zoom) and screens the participant for eligibility using an established screener form. Once determined eligible, the participant is asked if they would like to continue and complete the consent process. This session lasts approximately 20-30 minutes.

Baseline

A baseline or pre-test survey is completed after the participant is deemed eligible and they complete the consent process. This is either done in the same session as the screener and consent or at another time. The baseline survey is estimated at 1.5 hours.

Enrollment

A research participant will be defined as “enrolled” in the study when they meet the following criteria:

- The subject and study staff have completed all screening documentation and the person is deemed eligible.
- The PI has verified that the subject meets all of the inclusion criteria.
- The PI has verified that subject meets none of the exclusion criteria.
- The subject has been consented by study staff.

7.2 On-Study/Follow-up Visits

Each intervention visit consists of (1) participation in a parenting skills class followed by (2) participation in a peer support therapeutic group. The 8 sessions of parenting class include:

1. Getting Acquainted and Destination Adulthood
2. Effective Speaking Skills
3. Effective Listening Skills
4. Effective Problem Solving Skills
5. Connecting with Your Child: (a) Bonding Through Play and Reading, (b) Parenting Adolescents
6. Bonding through Emotion Coaching
7. Directions and Encouragements
8. Advocating for Your Children

Parenting skills classes last 2-2.5 hours. They are delivered by two trained facilitators. They are delivered remotely over Zoom. Participants are at home or other location of their choice. Attendance is tracked.

A 30-minute break is provided after the end of the parenting skills class. Then participants return to the remote Zoom session and participate in a therapeutic peer support group. These groups last one hour. They are facilitated by trained and licensed clinicians (e.g., social workers, counselors, psychologists).

All procedures and activities are provided solely for research purposes.

The final study visit for the intervention itself occurs after the final parenting skills class, usually one week later, where a graduation ceremony and celebration takes place. The final study interaction occurs three months after the post-test interview is completed when the 3-month follow-up interview takes place.

7.3 Early Termination/Withdrawal Visit

Subjects who terminate or are withdrawn early from the study will have one final visit to follow up regarding adverse events, collect study materials that are on loan (e.g., computer or tablet), and if applicable, to refer person or family to appropriate support services in the community.

7.4 Long-Term Follow-up | Re-contacting Subjects

Follow-up occurs three months post-intervention for final data collection. Otherwise, there is no further follow up that takes place.

8.0 DATA HANDLING AND RECORD KEEPING

8.1 Data Collection

We will retain de-identified screening data (which includes the initial 11 eligibility questions as well as the remaining demographic questions) so that we can determine who among those screened were ineligible for participation and why. To help protect a person's identification, we will omit the day of someone's birthday (MM/DD/YYYY) from the record for anyone who is screened but does not participate in the study. This will be informative to future studies about general interest in studies of this kind and screening criteria that might need to be changed.

Potential participants will also be asked whether or not they would like to be contacted for future studies. Individuals who agree to this will provide their contact information to be recontacted over the phone or in person. The study team will store their contact information for future study eligibility. Contact for future studies would include other future studies not yet planned or funded. Retaining these data will be helpful for future study recruitment.

Preliminary screen data regarding eligibility criteria will be stored in a locked file cabinet in a locked room at the School of Social Work. Only approved study personnel have access to the files.

Individuals who agree to be contacted in the future will have their contact information stored in a secure, password -protected file with only their name and contact information.

Participants who do not enroll in the study and do not wish to be recontacted for future studies will have their contact information destroyed.

8.2 Confidentiality and Privacy

Data collection conducted with fathers, caregivers, and children will generally be done on an individual basis (either alone or the father (or caregiver) and child together as appropriate). In most cases, survey completion will be done virtually. This will ideally be conducted through a virtual video-call in which research team members can share their computer screen with data collection instruments pulled up to walk the participant through the documents together. In other cases, this may be done through a phone call where the researcher reads prompts to the participants to answer. In as few cases as possible and as a last case scenario, survey completion may be completed in participant's homes, in private rooms located at local libraries, or in office space provided by partner community agencies through safe and socially distanced protocols. In all cases, the utmost precaution will be taken to ensure that other individuals are not in the vicinity and cannot overhear the researcher asking, or the participant answering questions.

If someone else is in the location, we will continue with the interview only if other individuals are at a sufficient distance so as to be unable to hear the questions and responses. In no situation would an interview be continued or conducted if the privacy of the respondent would be compromised by the specific circumstances of the interview.

8.3 Records Retention

The few questions audio recorded in the interviews will be digitally recorded and transcribed by the study team. Once the transcription has been verified by the PI, the audio file will be deleted. The use of audio recordings is important to allow for the interviewer to focus on the questions with the participants without having to take detailed notes that could yield less accurate data.

Transcripts will be stored on campus resources for at least 7 years after the project ends per the research records retention policy.

Subjects will be notified in the consent form about the use of photos. The PI also has a photo release form that could be used in addition to obtaining permission to use photos of participants when disseminating findings. Photos, like the audio data, will be retained for at least 7 years after the project ends.

8.4 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol or investigational plan requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the Principal Investigator/site investigator/study staff to use continuous vigilance to identify and report deviations. The Principal Investigator is responsible for assessing whether the deviation constitutes noncompliance as defined by the reviewing IRB and if so, reporting it within the required time frame(s). The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

8.5 Publication and Data Sharing Policies

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central (https://www.ncbi.nlm.nih.gov/pmc/) upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 5 years after the completion of the primary endpoint by contacting the PI, Pajarita Charles, *paja.charles@wisc.edu*.

9.0 STUDY ANALYSIS

9.1 Statistical Hypotheses

- **Primary Efficacy Endpoint(s):**

For feasibility and acceptability measures, we are not testing hypotheses. We are examining elements of the intervention to assess client acceptance of the treatment, ability to recruit sufficient numbers of participants, and feasibility of delivery with the clients and therapists in the treatment settings.

- **Secondary Efficacy Endpoint(s):**

We hypothesize that participants who are in the intervention will have improved relationship, parenting, parent-child, and mental health outcomes after completing the intervention. Alternatively, our null hypothesis is that there will be no difference in the effects of the intervention for relationship, parent-child, parenting, and mental health outcomes.

9.2 Sample Size Justification

The sample size for this feasibility pilot study is based on previous research and not to formally test hypotheses. Its purpose is largely to develop an intervention, identify measures, and assess logistical nature of the proposed intervention. The secondary outcomes, while they can be tested in pre- and post-test analyses, are included to determine trends or patterns of responses.

9.3 Subject Population(s) for Analysis

Participants who completed the full intervention and the pre- and post-test interview (including both father and caregiver participants) will be included in the analyses.

9.4 Statistical Methods

Primary outcomes will be assessed using descriptive statistics. Specifically, count data (e.g., number of enrolled participants who complete the intervention) are presented using percentages. Continuous measures presented as a score on a scale (e.g., provider adherence scores) are presented with means and standard deviations, and minimum and maximum scores.

Secondary outcomes will be assessed using paired sample t-tests to estimate changes between the scales at baseline and post-test. Two-tailed tests with .05 p-values will be used.

9.5 Handling of Missing Data

Complete-case analysis will be used and participants with missing data (i.e., missing post-test interview) will be excluded from the analysis.

10.0 RISK/BENEFIT ASSESSMENT

10.1 Known Potential Benefits

There are no direct benefits to subjects. However, there are potential benefits to participants which include the parenting strategies that the fathers will learn in the community-based program.

The potential benefits for society derive from the scientific advances that may occur as a result of this study through intervention development and future efficacy and effectiveness trials. There is the possibility of public benefit because of the potential to positively influence previously incarcerated parents and their children. Additionally, information learned in the study may be used to inform the research and social welfare policy community to improve services provided to incarcerated parents that could prevent or reduce further criminal justice involvement and criminal behavior post-prison.

10.2 Known Potential Risks

There is a risk of a confidentiality breach.

Participants may be upset by aspects of the research or content of the intervention program.

Participants may reveal personal, sensitive, or identifiable information when responding to open-ended questions.

Participants may reveal illegal behaviors due to the nature of the questions.

Participants may become fatigued or frustrated due to the length of the study.

10.3 Risk/Benefit Analysis

Data will be stored securely according to campus policy; when necessary, identifiable or sensitive information will be stored separately from other study data and participant identities will be masked in publication and any other dissemination of study results.

Participants will be informed about all aspects of the study during consent and have the option to skip or withdraw from any activities that make them upset or uncomfortable, including skipping any questions in surveys or measures.

Personal, sensitive, or identifiable information is necessary to answer the research question(s) but it will be stored separately from other study data.

If a participant reveals illegal behavior, it will either be removed from the research record. If the information is shared as part of an answer to the research question and is needed for the purposes of the study, the data will be protected by way of secure storage according to campus policy, as well as by a Certificate of Confidentiality that will be obtained after the PI receives IRB approval.

Participants will be informed of the approximate length of study activities during the consent process and will be offered the opportunity to take breaks during the study activities if needed.

Participants will be informed that although groups will be held virtually, sessions will never be video or audio recorded.