Title: Researching Resiliency in Stressful Experiences (RISE) Program for Men Leaving Incarceration

NCT #: NCT04785677

Date: 4/14/2020

Study Summary

Study Title	Multisite Randomized Controlled Trial of Comprehensive Trauma Informed Reentry Services for Moderate to High Risk Youth Releasing From State Prisons
Study Design	1:1 Randomized Control Trial
Primary Objective	Determine whether the TARGET program helps young men released from prison improve their mechanisms of change.
Secondary Objective(s)	Determine whether the TARGET program helps young men released from prison improve their community stability and decrease their odds or recidivating.
Research Intervention(s)	Trauma Affect Regulation: Guide for Education and Therapy (TARGET**)**
Study Population	Incarcerated men aged 18-35 who have experienced at least one traumatic event in their lifetime. .
Sample Size	400
Study Duration for individual participants	Up to 18 Months
Study Specific Abbreviations/ Definitions	Lifetime Traumatic Events (LTE), Trauma Affect Regulation: Guide for Education and Therapy (TARGET), Department of Corrections (DOC).

1.0 Objectives*

1.1 The purpose of this study is to evaluate the impact of a comprehensive trauma-based reentry program for moderate- to high-risk young incarcerated males between the ages of 18-35 on post-release outcomes. We will assess changes in key mechanisms of change (i.e. mediators) as well as post-release outcomes. The key mechanisms of change include: trauma symptoms (PTSD, depression, anxiety, and substance abuse), coping, impulsivity, and aggression. Post-release outcomes include community stability (i.e., housing and employment), and recidivism (i.e., re-arrest and re-incarceration for technical violation or new crime; time to re-incarceration).

1.2 Research Questions

- RQ1: Does a comprehensive trauma-based reentry program improve key mechanisms of change for moderate- to high-risk young incarcerated males?
- RQ2: Does a comprehensive trauma-based reentry program improve community stability for moderate- to high-risk young incarcerated males?
- RQ3: Does a comprehensive trauma-based reentry program decrease rates of recidivism for moderate- to high-risk young incarcerated males?

2.0 Background*

2.1 More than 2.2 million young males have some contact with the criminal justice system each year; nearly 50% of Black males and 40% of White males are arrested for non-traffic related crimes by age 23.[1] Close to 200,000 young males are currently incarcerated in state and federal prisons across the nation; just under 20% of the total state prisoner population are young males at time of release.[2,3] Younger age at prison intake and release are potent predictors of increased risk level; thus, young males are disproportionately identified as moderate- or high-risk for recidivism on standardized assessments. After release from incarceration, young males have the highest recidivism rate of any age group - 76% are rearrested for a new crime within 3 years.[4] In a recent recidivism analysis, 90% of young men at time of release were re-arrested within nine years, with 52% of arrests occurring within the first year.[5]

The existence of an inverse, curvilinear relationship between age and both arrest and incarceration is treated as an "iconic fact" in the field of criminology,[6] a fact which suggests that young males essentially "grow up" and grow out of committing crime.[7,8] However, current recidivism rates among this group in particular indicate that some critical facet of young males' experience is missing from existing correctional interventions.[9] One potential driver of young males' recidivism may be the unaddressed mental health symptoms and substance abuse which result from extremely high prevalence rates of lifetime traumatic experiences (LTEs).[10-13] According to the American Psychiatric Association (2013), LTEs include direct personal experiences of victimization, threat or experience of serious injury, threat of death, learning of a serious injury

or death occurring to a loved one, or witnessing an event that involves death or serious injury/threat to another person in childhood, adolescence, or adulthood.

Across samples and study design, 62-98% of incarcerated males report at least one LTE (prior to incarceration)[14-16] compared to 22-47% of men who have never experienced incarceration.[17,18] Specifically, 58% of incarcerated males report physical abuse and 17% report sexual abuse in childhood - 2-3 times the estimated prevalence among males in community-based samples.[19-21] Further, while discussions about LTEs typically center on the experiences of women and girls, incarcerated and formerly incarcerated males and females report equally high numbers of LTEs, although the nature of LTEs differ between the genders. Although incarcerated females report 2.5-4 times the rate of sexual abuse/assault as incarcerated males, incarcerated males report witnessing extreme harm to others at nearly double the rate as incarcerated females (60% vs. 34.8%).[22] Incarcerated males also report interpersonal nonsexual trauma in adolescence at nearly twice the rate as incarcerated females (63.2% vs. 34.8%).[22]

Addressing LTEs among incarcerated males is important because more than 95% of those who are incarcerated are eventually released[23] and trauma symptoms and risks for recidivism are correlated. Trauma symptoms include increased sensitivity to stress, high levels of negative emotionality, sensation seeking (i.e., pursuing risky, stimulating experiences),[24,25] aggression, impulsivity, dissociation, impaired ability to adequately assess risk, and unrealistic expectations of interpersonal relationships.[26-28] Rates of posttraumatic stress disorder (PTSD) are higher among males with incarceration histories (21%) when compared to both males in the general population (4%–5%) and male veterans (7%)[16,21,29,30]; incarcerated males with substance use disorders are 80% more likely to have experienced two or more LTEs[31] including previous physical or sexual assault.[12] These individuals struggle to remain abstinent from drugs and alcohol after release from incarceration[12,32,33] and are more likely to be re-arrested when compared to their non-victimized peers.[10,34,35]

Moreover, trauma symptoms predict violent and nonviolent criminal behavior[13,36] and formerly incarcerated males who have experienced LTEs are significantly more likely to have used violence prior to their incarceration and have a higher risk of engaging in violence after release when compared to their non-victimized peers.[16,37-39] For young incarcerated males, frequent victimization is associated with onset of aggression early in life.[10] Indeed, incarceration itself may exacerbate symptoms associated with untreated LTEs.[11,40,41] For incarcerated individuals, the number of LTEs is highly correlated with the number of incarcerations.[13,31,34] Experiences of trauma increase the odds of arrest, incarceration, and recidivism, which, in turn, contributes to a higher likelihood of additional trauma.[42,43]

A substantial body of neuroscientific and psychological research identifies why intervening with young offenders is particularly important. The adolescent and young adult (ages 10-25) brain is actively developing, growing at a rate comparable to that of infancy.[44] The young brain is engaged in a highly sensitive dual process of pruning and myelination to maximize efficiency and integration. This process of neural pathway development is responsive to and

dependent on the environment, making young people particularly sensitive to LTEs.[44,45] The frontal lobe develops through age 25 and controls all executive functions including memory, judgment, impulse control, and planning, often resulting in impulsivity and risk-taking among young adults. Further, the hypothalamic-pituitary-adrenal (HPA) axis, a central part of the stress-response system, undergoes significant development during this time; young adults release greater amounts of the stress hormone, cortisol, when faced with highly stressful challenges and demonstrate higher levels of activity in the amygdala, part of the brain responsible for responding to threat.[46] Due to the vulnerability of the developing brain and stress response systems, witnessing or experiencing violence during this time decreases impulse control and retards growth toward future orientation which underscores the urgent need to intervene at this particularly malleable developmental stage.[47]

Gaps in Current Knowledge. Despite incarcerated males' extremely high rates of trauma exposure, research to date has focused nearly exclusively on providing trauma treatment to incarcerated females. Only 28 states provide any correctional-based trauma treatment[81]. Of those states, 13 offer trauma treatment to men, meaning that 75% of incarcerated males have no access to any interventions designed to reduce the impact of LTEs, despite males and females reporting nearly equivalent rates of trauma exposure, albeit different types of LTEs. Further, the existing evidence supporting trauma-based correctional interventions is limited by a lack of randomized controlled trials (RCTs) conducted with incarcerated or formerly incarcerated males. Findings from a recent meta-analysis[48] suggest that there are gender differences in response to psychological interventions, with women reporting greater reductions in mental health symptom burden when compared to men post-intervention and at follow-up. This strongly suggests that intervention adaptations and tailored content need to be developed to more effectively respond to the trauma treatment needs of men. Finally, nearly all trauma-based correctional interventions are delivered during custody; only one published study provides any treatment post-release.[49] Therefore, the unique complexities of the reentry period, and the changing needs of individuals as they leave incarceration and return to their communities are not integrated into existing trauma-based interventions. This gap means that little is known about how to implement trauma treatment for young males during reentry, when stress is heightened, and they must manage housing instability while searching for employment. Interventions that span prison-to-community are essential to improving well-being and reducing recidivism among this population.

Although trauma-based interventions are rarely delivered to this population, cognitive-behavioral group-based interventions have been successfully implemented among samples of racially diverse criminal justice-involved or at-risk young males.[50-52] In a recent systematic review of individual and group-based psychological interventions designed to address both criminological (crime specific) and psychosocial risks [53], these approaches were identified as especially potent for reducing risk and improving well-being among the highest-risk, highest-need, hardest-to-engage offenders. Further, robust

associations between LTEs and both homelessness and unemployment have been noted for a range of high-risk populations. For example, LTEs have been significantly associated with increased days of homelessness (β =.18), poorer physical health (β =-.23), and drug use (β=.22) among homeless veterans.[54] Additionally, homeless patients with co-occurring mental health and substance use disorders were significantly more likely to attend substance abuse treatment when compared to those diagnosed only with a substance use disorder.[55] Individuals in a nationally representative sample who experienced childhood LTEs were twice as likely to be unemployed (OR=2.0) compared to those with no history of LTEs. Unemployment rates were amplified for those who experienced childhood physical abuse (OR=2.4) and multiple forms of trauma (OR=2.9).[56]

Interventions which begin during custody and extend in the community after individuals have released from incarceration have shown the strongest short- and long-term effects.[57-61] Adding a community aftercare component to prison-based substance abuse treatment positively impacts recidivism, with RCTs demonstrating a 48% reduction in 3-year recidivism for individuals who received both in-prison treatment and aftercare (27%) compared to individuals who only received in-prison treatment (75%).[62] Including post-release services extends the protective benefits of in-prison treatment, increasing sobriety and decreasing re-arrest.

We propose a comprehensive trauma-based reentry program for moderate- to high-risk young incarcerated males between the ages of 18-35 on post-release outcomes. Combining evidence-informed trauma treatment for LTEs with a holistic reentry approach focused on community stabilization factors will catalyze the reduction of trauma symptoms, impulsivity, and aggression, while increasing coping, housing stability, and employment – all factors critical to reducing recidivism. Beginning the intervention during custody allows for the development of a therapeutic and trusting relationship between group members and clinicians, increasing post-release treatment retention. Building on the reentry planning work pre-release, post-release groups will focus on the tangible needs of housing and employment, while simultaneously addressing the after-effects of LTEs as they arise in real time during this critical phase of brain development and reentry phase transition. Thus, we propose that participation in comprehensive trauma-based reentry program will increase housing stability and employment, based on the established relationship between trauma symptoms, coping, impulsivity, aggression, housing, and employment.[53-62] Decreased trauma symptoms, impulsivity, and aggression paired with increased coping and community stability will reduce recidivism among this sample of moderate- to high-risk young males as they leave incarceration and return to their communities.

3.0 Study Endpoints*

3.1 Comprehensive trauma-based reentry program group members will show improvements in key mechanisms of change compared to TAU control group members.

3.2 Comprehensive trauma-based reentry program group members will have increased community stability compared to TAU control group members.

3.3 Hypothesis 3: Comprehensive trauma-based reentry program group members will have lower rates of recidivism and those who do recidivate will spend more days in the community prior to recidivism compared to TAU control group.

4.0 Study Intervention

4.1 The comprehensive trauma-based reentry program has two primary components: a trauma-based intervention paired with community stabilization reentry efforts. Consistent with evidence-based reentry approaches,[66] the proposed intervention will use trauma-trained reentry practitioners to deliver he intervention and provide reentry supports including coordinating substance abuse treatment, assisting with housing, and providing employment services.

Trauma-Based Intervention Component. Trauma Affect Regulation: Guide for Education and Therapy (TARGET) is a manualized, cognitive-behavioral, trauma-based group program designed for both young men and young women with a history of LTEs who are experiencing trauma symptoms. TARGET has an established evidence base.[67-71] Up to fourteen TARGET sessions will be paired with the specialized reentry supports. Up to four sessions will occur prior to release and up to ten sessions will be delivered in the community post-release.

TARGET helps participants understand and manage trauma memories and affective dysregulation and provides psychoeducation and skills-based learning on how to process and manage trauma-related reactions to stressful life situations, including PTSD symptoms, traumatic grief, and shame. The goal of TARGET is to increase emotional regulation and coping, helping participants gain control of intense emotions and posttraumatic stress reactions while simultaneously solving daily stressors and maintaining sobriety. Like other present-focused, cognitive-behavioral interventions, TARGET provides a systematic approach to processing trauma that does not require memory processing or risk re-traumatization. The comprehensive trauma-based reentry program pairs trauma-based components with community stabilization reentry efforts. Consistent with evidence-based reentry approaches, the proposed intervention will use trauma trained reentry specialists to deliver the intervention and provide reentry supports to help improve community stabilization.

The comprehensive trauma-based intervention component will be delivered across up to 19 sessions and each session will simultaneously include a focus reentry planning, community stabilization, and trauma treatment. Up to four sessions will take place in prison before release and up to 15 sessions will take place in the community upon release from prison. Sessions delivered during custody will provide psychoeducational information on trauma and reentry, and facilitate reentry planning with a focus on community stabilization and service identification and access. Sessions in the community will be delivered post-release and will focus on emotion awareness and regulation, recognizing and

positively responding to their triggers, evaluating their thoughts, and identifying positive emotions. Post-release sessions will also enable the participants to develop healthier coping skills, manage their mental health symptoms, impulsivity, and aggression, and decrease substance abuse.

5.0 Procedures Involved*

6.1 The proposed 5-year study is a two-armed 1:1 Randomized Controlled Trial (RCT) implementing and evaluating the effectiveness of a comprehensive trauma-based reentry program for young men releasing from prison to the community evaluated as moderate- to high- risk for recidivism. A total of 400 18-35 year old males releasing to one of the four participating urban and rural counties in Florida (Columbia, Duval, Leon, and Suwanee) will be randomly assigned to participate in the comprehensive trauma-based reentry program or a treatment-as-usual (TAU) control group. Participants in the comprehensive trauma-based reentry program will participate in up to four group sessions while incarcerated and up to15 group sessions in the community after release. The effectiveness of the comprehensive trauma-based reentry program for 18-35 year old males will be evaluated on the following constructs: key mechanisms of change, community stability, and recidivism. Participants assigned to the treatment-as-usual control group will remain eligible to participate in all reentry services they normally would have received.

The purpose of this study is to evaluate the impact of a comprehensive trauma-based reentry program for moderate- to high-risk young incarcerated males between the ages of 18-35 on post-release outcomes. We will assess changes in key mechanisms of change (i.e. mediators) as well as post-release outcomes. The key mechanisms of change include: trauma symptoms (PTSD, depression, anxiety, and substance abuse), coping, impulsivity, and aggression. Post-release outcomes include community stability (i.e., housing and employment), and recidivism (i.e., re-arrest and re-incarceration for technical violation or new crime; time to re-incarceration).

5.2 Research team members are trained interventionists in order to assess if there are adverse behaviors or thoughts during service delivery (treatment group) and during data collection interviews (all participants). All interviews are conducting one-on-one so the research team member can assess for adverse reaction to the data collection or treatment delivery

5.3 Research team members have experience working with people with trauma histories. This is important so they can successfully assess if there are adverse behaviors or thoughts during service delivery (treatment group) and during data collection interviews (all participants). All interviews are conducting one-on-one so the research team member can assess for adverse reaction to the data collection or treatment delivery.

6.4 Data will be collected from participants during one-on-one interviews. Interviews will occur in a private space, where the conversation between the team member and individual cannot be

heard. Data will be recorded in RedCap computer software. Potential participants will complete 12 -count trauma checklist as a screener for assessing for presence of at least one LTE. Eligible participants will plan to release to one of our four Florida counties. Participants will be consented using a Florida State University IRB consent form. If the individual meets screening criteria and consents into the study, the research team member will complete the baseline interview.

All consented participants (treatment and control) will complete a series of interviews. Baseline interviews will occur immediately after consent and occur in prisons. Follow-up interviews will be conducted in the community and timepoints include (1) after the conclusion of the program period, (2) three months after the conclusion of the program period, and (3) nine months after the conclusion of the program period.

6.5 Measures were selected based on the quality of established psychometric evidence and use with criminal justice-involved or other at-risk populations.

- Risk Assessment. Spectrum is the assessment tool used by FDC that identifies risk factors for criminal behavior. Scores on Spectrum range 1-5. The assessment is given to individuals at intake, periodically throughout incarceration and then again under a year before they release and measures an individual's risk to recidivate.
- Trauma screener. A dichotomous Yes/No measure of 12 LTEs s from the Trauma Assessment for Adults serves as the trauma screening tool. Participants are identified as eligible if they have experienced at least one LTE.
- Demographics. Age, race/ethnicity, marital status, level of education at release, age at first offense, number of prior incarcerations, most serious offense, and current sentence length will be collected from FDC administrative databases.
- Trauma. The 24-item Trauma History Questionnaire (THQ)[72] was designed to assess LTEs among general, community, and clinical populations. Each item examines a specific traumatic experience under the categories of interpersonal violence, accidents and disasters, serious illness, traumatic loss, and criminal victimization. Participants indicate whether they experienced the event, and if so, they provide age at time of exposure and a brief description. The THQ operationalizes *Diagnostic and Statistical Manual of Mental Disorders, 5th edition* (*DSM-5*) criteria for LTEs. The THQ is a reliable measure of trauma exposure (3-month test-retest coefficients=.51-.91) and has strong convergent validity to other measures (k=.61-1.00).
- PTSD. The 20-item PTSD Checklist for DSM-5 (PCL-5)[73] will be used to assess PTSD symptoms at all interview timepoints. All items are scored on a 5-point Likert scale with 0= "not at all" and 4= "extremely". Scores above 33 indicate current incidence of PTSD. The PCL-5 has

strong reliability (α=.94), test-retest correlations (*r*=.82), and has strong convergent validity and discriminant validity.

- Depression. The 11-item major depressive disorder subscale of the MINI International Neuropsychiatric Interview (MINI)[74] assesses current incidence of depression at all interview timepoints. Items are rated on a dichotomous Yes/No scale and follow *DSM-5* psychiatric guidelines. The MINI has strong interrater reliability and the kappa value for the major depressive disorder construct was adequate (k=.72).
- Anxiety. The 7-item anxiety subscale of the MINI assesses current anxiety disorders at all interview timepoints. Items are rated on a dichotomous Yes/No scale and follow psychiatric guidelines of the *DSM-5*. The MINI has strong interrater reliability and kappa values for anxiety disorder constructs were adequate (k=.69-.84).
- Substance Use Disorder. The 9-item substance use disorder subscale of the MINI assesses current incidence of substance use disorders at all interview timepoints. Items are rated on a dichotomous Yes/No scale and follow psychiatric guidelines of the *DSM-5*. The MINI has strong interrater reliability and the kappa value for the substance use disorder construct was adequate (k=.74).
- Coping. The 26-item Coping Self-Efficacy Scale[75] assesses self-efficacy and confidence in coping with stress at all interview timepoints. The C-SES is reliable and valid (α=.80-.91).
- Impulsivity. The 30-item Barratt Impulsivity Scale (BIS)[76] assesses general impulsiveness at all interview timepoints on six first-order factors (attention, motor, self-control, cognitive complexity, perseverance, and cognitive instability impulsiveness) and three second-order factors (attentional, motor, and non-planning impulsiveness). The BIS was validated among community, clinical, and correctional samples (α=.79-.83).
- Aggression. The 12-item Brief Aggression Questionnaire (BAQ)[77] evaluates physical aggression, verbal aggression, anger, and hostility at all interview timepoints. The BAQ has stable test-retest reliability and convergent validity with behavioral aggression measures.
- Housing. A 7-item housing measure will assess housing stability at all post-release timepoints. Sample items include, “Have you had to “double up” with friends or relatives?”, “Do you consider yourself homeless?”, and “Where are you living or staying now?”
- Employment. A 10-item employment measure assesses employment at all interview timepoints. During the initial in-prison interview, the participant will be asked to think about their employment six months prior to their current incarceration. In all post-release interviews, the participant will be asked to reflect on their employment in the previous three months. Sample items include, “What was your work situation right before your current incarceration/over the past 3 months]?” and “How long have you been at your current employment?”

- Recidivism. Recidivism data on arrests in Florida, incarceration in a Florida state prison, the number of days to arrest or incarceration, and the reason for incarceration (i.e., commission of new crime or violation of the terms of release) will be collected from FDC and Florida Department of Law Enforcement databases annually for three years.

6.0 Data and Specimen Banking*

6.1 Collected data is stored in REDCap, and research team members and data analysts have access to the system. Data is protected and HIPPA compliant. Data collected is the interview assessment data using the tools listed in 6.4 for the initial interview and the 3 follow-up interviews.

7.0 Sharing of Results with Subjects*

N/A

8.0 Study Timelines*

8.1 *Describe:* Individuals will be recruited approximately four to six months prior to release and then we will remain in contact with them to collect primary data from them for 9 months after the conclusion of the intervention. Thus, participants can end up being engaged with the study for a maximum amount of 18 months.

Research Activities	Related Timelines
Recruitment of Study Participants:	May 2020-October 2021
Programming inside facilities:	June 2020-December 2021
Community Programming:	September 2020 -March 2022
TI (Completion of programming period):	November 2020-March 2022
T2 (3 Months post completion of program period)	February 2021-June 2022
T3 (9months post completion of program)	August 2021-Ducember 2022

8.2 Based on a recruitment goal of 400 and the number of staff and students that will be used to recruit study participants, it is anticipated that it will take eighteen months to enroll all study subjects into the study.

9.0 Subject Population*

Commented [A1]: Eligibility : Age, Risk Factor Identification (spectrum?), Screening for Lifetime Traumatic Experiences, Conversational English, Cognitive Consent, Release to Leon or Duval

Random Number generator (randomization)

9.1 Participant inclusion requirements include: (1) male; (2) age 18-35; (3) identified as having risk for recidivism; (4) screened as experiencing at least one LTE; (4) releasing from incarceration to one of our four study counties within six months; (5) conversational English; and (6) being able to cognitively consent into study participation.

9.2 Participants may be excluded if: they (1) identify as women; (2) younger than 18 or older than 35; (3) no demonstrated any risk; (4) not cognitively able to understand what it entails to be a research participant.

10.0 Vulnerable Populations*

10.1 The research team has reviewed the checklist relating to studies involving incarcerated individuals and have designed the study to be in consideration of these guidelines for the population.

11.0 Local Number of Subjects

11.1 400 individuals will be recruited into the study to participate. Participants will be returning to the following four county area: Leon, Columbia, Duval, and Suwanee.

12.0 Recruitment Methods

12.1 In order to enroll participants into the study, the research team will obtain regular lists of prospective participants from the Florida department of corrections (FDC) in each state. The list includes the name, age, sentencing county, prison location, scheduled release date, risk score, and offense history so that research team members can randomly identify prospective study participants. Then, the research team member emailed the primary contact person at each prison site the list of prospective participants' names and DOC ID numbers using a password protected and encrypted Excel database to schedule individual information and screening sessions.

The primary contact person at each prison site nor any other correctional official has a role in selecting the prospective participants that will be eligible for an information and screening session. Researchers schedule days to meet with prospective participants at the prisons. On those days, researchers will arrive at the prison and will meet with corrections officials to confirm with the official the names of those participants that the researchers met with to tell them about the study. Every member of the research team will be trained in the Prison Rape Elimination Act (PREA).

The day of the visit for recruitment, the correctional official can say that the visitor is from the Florida State University, but otherwise will not tell the prisoner that the visitor is there to see him/her about a research study. The prisoner can refuse to meet with the visitor. We do not want the correctional officer talking to the prisoner about

the study for several reasons: a) reduce potential for coercion; b) because it is not feasible to train all correctional officers in the prison on research protocol; and c) to protect confidentiality of the prospective participant.

Once the prisoner arrives to the visit in a private meeting room, the researcher will tell the prisoner about the study. The private room is one in which correctional officers may be able to see into the room for security purposes, but they cannot hear the content of the meeting. First, the researcher will confirm whether the returning prisoner intends to live in one of the designated study counties. Those individuals who do not intend to live in a study county will be thanked for their time and told they are not eligible for study participation.

The researcher will conduct consent procedures. The researcher will read aloud the consent form and allow for participants to have time to read the consent form on their own. The researcher will assure participants that their supervision will not be affected by their choice to participate or not participate in the study. The participants will also be told they can discontinue the study at any point or refuse to answer any questions without consequence. The benefits and risks of the study will be reviewed as will the expectations and limitations to breaches of confidentiality. Participants will be provided with two copies of the consent form – one for the participant to sign, either esign or paper signature, and return to the researcher and the other for the participant to keep. However, the participant is not obligated to keep the consent form. The participant is offered a copy to keep so they will have information about how to contact the research team with further questions and the IRB contact information. If participant chooses not to keep the consent form, they will be told that they can always request a consent form after release if they so choose. No aspect of the study will proceed until the consent process is completed. A researcher will inform participants that if they decide not to be in this study, or stop participating at any time, they will not be penalized or lose any benefits for which they otherwise qualify. A researcher will also inform participants that their sentence, program participation, employment opportunities, or any other aspects of their supervision by the DOC will not be affected by their choice to participate. Participants will be informed that their responses will be kept confidential to the fullest extent of the law. If a participant discloses they are the perpetrator or victim of sexual assault within the prison milieu, the incident will be addressed in accordance with PREA guidelines.

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12.2 Participants receive $30.00 for completing each of the three post-release interviews. The three follow-up interview timepoints are: (1) after the conclusion of the program period (post-test), (2) three

months after the conclusion of the program period, and (3) nine months after the conclusion of the program period. Research participants will not get money for completing the baseline measurement packet while incarcerated.

13.0 Withdrawal of Subjects*

13.1 The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include: Will release from prison after recruitment for study participation ends, lost eligibility to be a research participant; or interfered with ability to complete study protocol.

13.2 If a subject is to be withdrawn, an IRB approved withdrawal letter with the reason for withdrawal is sent to the participant. Subject withdrawals are tracked and reported to the IRB.

13.3 If a subject is withdrawn from the study by the research team for one of the reasons listed here, the research team will use information collected during the interviews to help determine whether the TARGET model is effective in helping people released from prison. Participants are informed of this protocol during the informed consent process.

14.0 Risks to Subjects*

14.1 Participants may become emotionally distressed when thinking and talking about the following: their history of participation in crime; history of incarceration; social relationships; services history; behavioral health problems; education attainment; employment status; or transition back to the community. Probability of these risks are low. Our staff is trained to work with participants if they feel emotionally distressed during interviews or service delivery.

All legally available protections will be in place to protect confidentiality of data shared. However, if participants disclose an intent to harm themselves or someone else, this information will be reported to the proper authorities. This procedure will be disclosed in the consent form. However, if people do disclose these intents, it could result in legal or social risks. The same procedure follows if a participant is found to need minor medical or psychological referral, the participant will be encouraged to share this information with research team members. If the medical or psychological need appears to place the participant at risk of harming himself or others, the researcher will immediately share the medical or psychological risk information with the participant's practitioners. The consent form will describe this procedure. If the medical or psychological need appears to place the participant at risk of harming himself or

others, the researcher will immediately contact local authorities about the concern. The consent form will describe this procedure.

Participants may feel distressed by the random assignment process and about the group to which they are randomly assigned. The consent form clearly describes the randomization process and chances of being in the control group, thus the probability of emotional distress is low.

A risk of participation in this study is a breach of confidentiality through the accidental disclosure of the participants' private, identifiable information. Probability of this is low due to use of secure data management systems and constant training with Prison and Research staff on the importance of confidentiality. All interviews are conducted in confidential settings. To minimize risk of accidental disclosure of identifiable private information, a meaningless code number will be established for all participants immediately following consent. That code number will be attached to all interview tools rather than identifying information. A separate document linking identifying information and meaningless ID numbers will be stored apart from consent forms in a locked cabinet in the research team office.

15.0 Potential Benefits to Subjects*

15.1 Possible benefits from the study include discussing the relationships between previous experiences, mental health issues, and criminal offending. The participants may also benefit by thinking about the influence of violence and victimization on your patterns of on patterns of offending, perhaps providing space for you to make difference choices after release. All Participants (Control and Treatment groups)

These participants may benefit from DOC services that include educational and vocational preparation, transition preparedness programming, 12 step groups, behavioral health services, religious programming, and case management.

16.0 Data Management* and Confidentiality

16.1 Data analysis will include statistical techniques such as t-tests, correlations, chi-square testing, ANOVA, survival analysis, structural equation modeling, and multilevel modeling.

16.2 To minimize risk of accidental disclosure of identifiable private information, a meaningless code number will be established for all participants immediately following consent. That code number will be attached to all interview tools rather than identifying information. A separate document linking identifying information and meaningless ID numbers will be stored apart from consent forms in a locked cabinet in the research team office.

16.3 Research team members are all trained on using REDCap to store, encrypt, and protect the data. REDCap servers are housed in a local data center at Florida State University and all web-based information transmission is encrypted. REDCap was developed specifically around HIPPA-Security guidelines. All identifiable information is replaced with a meaningless code number for the sake of confidentiality.

The researchers will obtain the participants department of corrections' identification nm

16.4 Data collectors all have tablets with REDCap. They collect information from the participants on their tablets using REDCap, which is housed in a local data center at FSU. We will maintain all study records, including signed and dated consent documents for six years after completion of the study.

16.5 Data will be stored in REDCap for six years after completion of the study. Research team members have access to the data and are responsible for receipt or transmission of the data..

17.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

N/A There are minimal risks to subjects in this research project

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 Research participants are not ever required to meet with somebody whom they do not want to interact. If the participant would like a different interviewer, or a different person to facilitate the TARGET sessions if they are in the treatment group, then the research team will grant them that wish if possible. The participant will be informed at consent, and reminded throughout the study, that they can choose to stop any interview or intervention session at any time without any consequences or repercussions whatsoever. The participant has the option to not answer any questions that they find too personal and do not want to share with the interviewer. This information is all discussed with the participant during the informed consent process at the beginning of the study.

18.2 Research team members are trained in interviewing skills, including how to talk with the research participant in an empathic manner that helps put them at ease, which is particularly important considering the sensitive nature of some of the questions. Regarding the TARGET program for those in the treatment groups: all of the interventionist are trained counselors who are trained in working clinically with participants and have experience talking with our research participants in an empathic manner.

18.3 The only information the research team will access that does not come directly from the participants are the administrative data collected from department of corrections databases. This includes the following:

- race/ethnicity
- release dates;
- type and length of supervision being released into;
- if you are on court mandated treatment during incarceration or post-release, and what type of treatment is required;
- custody levels at initial assignment and release;
- prison identification number;
- date of birth;
- both community and institutional (at time of entry into facility and final) risk scores, and which assessment tool is used;
- treatment and program participation;
- Protected Health Information from the Department of Corrections database;
- criminal history, including length of sentence, number of priors, age of first arrest, age at present offense, list of convictions, and what you are serving your current sentence on;
- recidivism data, including dates and number of: rearrests resulting in a 48 hour stay, jail time, incarceration for a new conviction, re-incarceration from state prison for a new offense or technical violation, residential sanction facility;
- technical violations, including what the violation was and the result of violation;
- sanctions, including type, number received and reason for sanction;
- education level at admission and at release;
- employment status on admission and for those on parole;
- home plan upon release and housing status for those already released;
- program treatment referral or receipt by parole, including your need, services received and services completed

Commented [A3]: Are these all applicable?

19.0 Compensation for Research-Related Injury

19.1 N/A.

20.0 Economic Burden to Subjects

20.1 The only potential economic burdens include travel time and/or expense related to transportation to research site. However, the research team is mobile and usually conducts interviews in the participants' home community.

21.0 Consent Process

21.1 The consent process takes place in prison for eligible participants released to our participating counties in the study window. Research team members facilitate the consent process. Consent is obtained electronically with the tablets that store REDCap. The consents are discussed and obtained in person at the prison after the research team member introduces the project to the potential participant and explains why they have been selected. Potential research participants are given as much time as they need to make a decision on whether to participate in the research.

The research team is following the "SOP: Informed Consent Process for Research (HRP-090) for the consent process.

22.0 Process to Document Consent in Writing

22.1 The consent process takes place in prison for eligible participants released to our participating counties in the study window. Research team members facilitate the consent process. Consent is obtained electronically with the tablets that store REDCap. The consents are discussed and obtained in person at the prison after the research team member introduces the project to the potential participant and explains why they have been selected. Potential research participants are given as much time as they need to make a decision on whether to participate in the research.

The research team is following the "SOP: Informed Consent Process for Research (HRP-090) for the consent process.

23.0 Setting

23.1 Below are the participating prisons in the research study. Please go to the Local Research Locations in RAMP to see more details about each facility.

- Apalachee Correctional Institution,
- Baker Correctional Institution,
- Bay Correctional Facility,
- Blackwater Correctional Facility,
- Columbia Correctional Institution,
- Florida State Prison,
- Gadsden Reentry Center,
- Graceville Correctional Facility,
- Holmes Correctional Institution,
- Jackson Correctional Institution,
- Lake City Correctional Facility,
- Liberty Correctional Institution,
- Northwest Florida Reception Center,
- Reception and Medical Center,
- Taylor Correctional Institution,

- Wakulla Correctional Institution
- Cross City Correctional Institution
- Lake Correctional Institution

24.0 Resources Available

24.1 Research team members will schedule in advance with the primary contact person the days to go to the prison for recruitment and baseline data collection. Each interview will last for between 1.5 and 2 hours and will take place in rooms where the conversation can be confidential.

24.2 Participants will be referred to mental health staff in the prisons if the research team member assesses they need counseling as a result of answering the questions on the interview packet. Specifically, the research team member will make a referral through the classification officer and/or primary contact person at the prison. Additionally, the informed consent contains resources for the participant if they are feeling emotional distress or need immediate assistance.