

Trauma-informed intervention to reduce substance use and to support community transition [TRUST]: Study protocol for a type 1 effectiveness-implementation hybrid trial to reduce overdose risk among justice-involved women

Michele Staton

mstaton@uky.edu

University of Kentucky College of Medicine

Jaxin Annett

University of Kentucky College of Medicine

Pamela Carey

Texas Christian University

Yang Yang

Texas Christian University

Olivia Jones

University of Kentucky College of Medicine

Lacee Bills

Texas Christian University

TK Logan

University of Kentucky College of Medicine

Martha Tillson

University of Kentucky College of Medicine

Carrie Oser

University of Kentucky College of Medicine

Kevin Knight

Texas Christian University

Study protocol

Keywords: Justice-involved women, substance use disorder, trauma-informed care

Posted Date: March 12th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-8436515/v1>

License:  This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Additional Declarations: No competing interests reported.

Version of Record: A version of this preprint was published at Trials on April 20th, 2026. See the published version at <https://doi.org/10.1186/s13063-026-09715-2>.

Abstract

Background

The integration of trauma-informed interventions for justice-involved women into SUD treatment is a key strategy for mitigating overdose risk. Coupling the unique overdose risk factors for women with their histories of violent victimization and related trauma, overdose intervention approaches for women must be engaging, targeted, and trauma-informed.

Methods

This study utilizes a type 1 hybrid effectiveness and implementation trial to examine an innovative trauma-informed intervention for justice-involved women (N = 264) in corrections-based substance use treatment during the transition from jail to the community. By equipping women with relational, coping, and emotional regulation skills to manage trauma-related reactions, they are expected to gain the tools and strategies needed to reduce their risk of returning to substance use after release.

Discussion

The importance of knowledge gained through this study is grounded in the national public health crisis associated with overdose deaths, largely associated with the opioid epidemic, but also related to unique issues faced by women and the limited, targeted, trauma-informed overdose prevention interventions for this population. This study has the potential to significantly reduce overdose risk among justice-involved women with a history of violent victimization and related trauma.

Trial registration:

This study is registered in ClinicalTrials.gov under protocol identifier - NCT06651528 with an original submission date of October 16, 2024 and updated December 12, 2025 (clinicaltrials.gov/study/NCT06651528).

Structured summary {1b}

Item	Description
Primary Registry and Trial Identifying Number {4}	Clinicaltrials.gov; NCT06651528 https://register.clinicaltrials.gov/prs/beta/studies/S000EZNY00000170/recordSummary
Secondary Identifying Numbers	Unique protocol ID: 94956
Source(s) of Monetary or Material Support	n/a
Primary Sponsor and contact information {3b}	National Institutes of Health/National Institute on Drug Abuse; R33DA061365
Role of sponsor and funder {3c}	NIH ensures expertise of the investigator team to lead the proposed trial, as well as compliance and adherence to data safety and monitoring for the protection of human subjects.
Contact for Public Queries	Michele Staton, Ph.D., M.S.W. (Contact PI) mstaton@uky.edu
Contact for Scientific Queries	Michele Staton, Ph.D., M.S.W. (Contact PI) mstaton@uky.edu
Public Title	Trauma-informed Intervention to Reduce Substance Use and to Support Community Transition
Scientific title	Trauma-informed Intervention to Reduce Substance Use and to Support Community Transition
Countries of Recruitment	USA
Health Condition(s) or Problem(s) Studied	Substance Use Disorder; Trauma
Intervention(s)	TRUST
Key Inclusion and Exclusion Criteria	Inclusion criteria will include incarcerated women who: (1) are participating in corrections-based SUD treatment; (2) have an anticipated release date within 4 months; (3) self-identified history of experiencing or witnessing violent victimization; (4) willing to engage with at least one "Safe Support Person" (SSP) in the community, someone who is trusted to support recovery and willing to be contacted about participation; and (5) expressed willingness to participate.
Study Type	The study utilizes a type 1 hybrid effectiveness-implementation design (Curran et al., 2012) with single group in randomized waves to assess effectiveness of the TRUST

	intervention in reducing post-release overdose risk, while also examining key factors hypothesized to affect intervention implementation success (Aarons et al., 2011).
Date of First Enrollment	12/8/25
Sample Size	264
Primary outcome(s)	<i>Overdose risk</i> defined by any illicit substance use during the 6 months post-release from custody
Key Secondary outcome(s)	Trauma-related symptoms and connection through recovery supports, emotional regulation, and healthy coping
Ethics Review	University of Kentucky Institutional Review Board; FWA00005295
Individual Trial Participant Data sharing statement	De-identified data will be preserved and disseminated for scientific advancement. Data from this project will be archived at the Inter-university Consortium of Political and Social Research (ICPSR) under the National Addiction & HIV Data Archive Program (NAHDAP), contingent on NAHDAP approval.

Protocol version {2}

December, 12 2025; NCT06651528

Introduction

Background and rationale {9a): Overdose mortality among women has increased dramatically over the past two decades, with the death rate increasing 492% from 1999 (2.6/100,000) to 2017 (15.5/100,000), primarily driven by the proliferation of synthetic opioids¹. Women have been disproportionately impacted by the opioid crisis because of biological differences in pain sensitivity, historical overprescribing, and self-medication^{2,3}. Compared to men, women also progress more rapidly from opioids and other substance use exposure to the development of a substance use disorder^{4,5} (SUD) and other health consequences⁶.

While recent national data indicate that men have consistently higher overdose death rates than women⁷, the disparity is shrinking among individuals re-entering the community after incarceration⁸. Overdose risks are significantly increased because of reduced tolerance following periods of abstinence during incarceration, limited access to medications to treat opioid use disorder, and disruptions in support networks^{9,10}. Additionally, justice-involved women overdose more frequently than men,¹¹ as well as among women in the general community¹². Thus, women's threat for overdose following abstinence during incarceration is significantly heightened, and there is a need for research on strategies to address overdose risks that are specifically tailored for justice-involved women.

Factors that have increased overdose risk among women include history of interpersonal violence, untreated childhood trauma, low self-worth in relationships, and connections with others who use drugs.¹³ More specifically, exposure to violent victimization and associated trauma can lead to a myriad of problems for

women, including physical injury, the onset or worsening of chronic pain, and mental health issues such as PTSD.^{14,15,16,17} Prior research has demonstrated that women who experience intimate partner violence have higher rates of chronic pain¹⁸ and opioid use than the general population.^{19,20,21} Because PTSD and substance use are strongly associated, women who have experienced violence or other traumatic events may use substances to manage trauma-related psychological distress.²² One mixed-methods study found that a primary motivation for substance use among participants was to cope with anxiety, with several participants stating that they use substances to cope with distressing memories of traumatic experiences.²³ Hence, individuals often use substances to relieve physical and emotional pain.

Given the higher risk for overdose among justice-involved women with exposure to violent victimization,^{24,25} there is a need for interventions targeting this population. Additionally, the rate of incarceration among women has increased by 525% in the last 40 years.²⁶ Given the relationship between history of exposure to violence, PTSD and other mental health issues, dysfunctional relationships, and substance use, the period of community re-entry following release from carceral settings represents a particularly high-risk time for overdose for women. The risk is further amplified for those who lack adequate social supports, access to resources, and effective coping strategies and emotional regulation to mitigate trauma-related stress. This paper describes an intervention designed to address those risk factors among justice-involved women.

Limited intervention approaches target overdose prevention despite high risks for justice-involved women. Existing approaches primarily focus on overdose education and naloxone distribution (OEND), aiming to improve women's ability to respond when *witnessing* overdoses.^{27,28} Yet, overdose intervention strategies that target women most at risk for *experiencing* an overdose are critically needed, particularly because resuming substance use post-release from custody exponentially increases the likelihood of overdose fatalities.^{29,30,31} Having a plan to address factors associated specifically with *overdose risk* during re-entry, such as those driven by trauma-related experiences, is imperative. Particularly for women, this plan should include connection and active engagement with a safe supportive person in their network, taking steps to avoid risks for substance use, providing local resource referrals, and increasing self-awareness of targeted risk factors such as partner abuse, sexual assault, and other types of violence exposure.^{32,33,34} The plan also should address distinctive structural and social challenges that contribute to overdose risk (e.g., histories of interpersonal violence, associated trauma and post-traumatic stress, drug-involved romantic relationships, unequal gendered power dynamics, and parenting-related stress^{35,36,37,38,39}).

The integration of trauma-informed interventions for justice-involved women into SUD treatment is a key strategy for mitigating overdose risk. Coupling the unique overdose risk factors for women with their histories of violent victimization and related trauma, overdose prevention intervention approaches for women must be engaging, targeted, and trauma-informed. Integrating trauma-informed interventions into existing SUD systems and continuums of care (including correctional settings) is necessary to address the long-term effects of exposure to violent victimization and trauma among justice-involved women with SUD.⁴⁰

Research has identified important key components of existing trauma-informed approaches. For example, a promising approach that has been adapted for juvenile justice settings is the Texas Christian University (TCU) Trust-Based Relational Intervention (TBRI).^{41,42} TBRI is a trauma-informed intervention strategy designed to

address the effects of early adversity, including violent victimization, and relational trauma,⁴³ which is conceptually grounded in the pillars of trauma-wise care.^{44,45} These pillars of trauma-informed care (emotional regulation, felt safety, healthy connections) are also adaptable for adult women with a history of exposure to victimization and violence. These key components provide an overarching framework for the development of trauma-informed interventions because they build upon critical needs for connection and trust, which can be shattered in the wake of a traumatic experience. By equipping women with relational, coping, and emotional regulation skills to manage trauma-related reactions, they are expected to gain the tools and strategies needed to reduce their risk of returning to substance use after release. The Trauma-Informed Intervention to Reduce Substance Use and to Support Community Transition (TRUST) intervention, described in detail below, is designed to reduce overdose risk during community re-entry for vulnerable, at-risk women.

The TRUST curriculum builds upon the foundation of trauma-wise care for a re-entry intervention among incarcerated women with SUDs and trauma histories. Research has shown that trauma experiences can result in a wide range of negative emotional reactions such as anxiety and depression, which can trigger increased risk for substance use. This project focuses initially on helping women identify trauma-related reactions (physical and emotional) and the relationship of negative emotions to their own substance use. This protocol paper describes the methodology for testing the TRUST intervention, which is guided by the recently revised Standard Protocol Items - Recommendations for Intervention Trials (SPIRIT) framework.⁴⁶

Explanation for the choice of comparator {9b}: See section {15a} below.

Objectives {10}

This type 1 hybrid trial is guided by the following specific aims:

- *Effectiveness:* Examine effectiveness of TRUST to reduce overdose risk among women (N=264) being released from four corrections-based SUD treatment program sites, using random assignment of sites to start date. Comparisons will examine (1) Treatment as Usual (TAU, standard in-custody SUD treatment, n=88), (2) In-custody TRUST only (TAU + TRUST corrections-based sessions only; n=88), and (3) TRUST + Re-entry (TAU + corrections-based TRUST sessions + Re-entry recovery support; n=88). The primary outcome is *overdose risk*, defined as any illicit substance use (self-reported and urine drug screen; excluding alcohol and marijuana) during the 6 months after release from custody.
- *Implementation:* Examine implementation components linked with TRUST adaptation and study preparation, launch, and sustainability guided by the EPIS framework.⁴⁷

Methods: Patient and public involvement, and trial design

Patient and public involvement {11}: The study details will be reported through clinicaltrials.gov (NCT06651528); study recruitment is not open to the public.

Trial design {12}: The study utilizes a type 1 hybrid effectiveness-implementation design⁴⁸ to assess effectiveness of the TRUST intervention in reducing post-release overdose risk, while also examining key factors hypothesized to affect intervention implementation success.⁴⁷ Scientific rigor is enhanced through

integration of two robust methodologies including a delayed start⁴⁸ and cluster (sites within state) random assignment to start date.

Methods: Participants, interventions, and outcomes

Trial setting {13}: Two facilities in Kentucky (KY) and in Missouri (MO) were selected for testing TRUST based on previous collaborations across multiple NIDA-funded collaboratives, as well as having women’s corrections-based treatment programs grounded in therapeutic community modalities with sufficient numbers of incarcerated women. In addition, KY and MO rank in the bottom third of the country for overdose deaths among women (KY ranks 48th, MO ranks 37th ⁵⁰). The University of Kentucky (UKY) and TCU have long-established partnerships with these state organizations, providing the foundational infrastructure needed to successfully implement and carry out the study.

The study will be implemented in the following women’s correctional facilities (two sites in KY and two sites in MO): (1) **KCIW** - Kentucky Correctional Institute for Women in Pewee Valley, KY; all custody levels, 683 incarcerated women; 48 SUD treatment beds. (2) **FCRJ** - Franklin County Regional Jail in Frankfort, KY; medium/minimum security levels, 109 incarcerated women, 50 treatment beds. (3) **CCC** - Chillicothe Correctional Center in Chillicothe, MO; all custody levels, 2076 incarcerated women, 256 treatment beds. (4) **WERDCC** - Women’s Eastern Reception, Diagnostic and Correctional Center in Vandalia, MO; all custody levels, 1740 incarcerated women, 240 treatment beds. Each of the four targeted sites include SUD programming at the facility with consistency in the treatment modality (modified therapeutic community) and length of time in treatment (average 6 months).

Characteristics of the people who are needed for the trial: The following demographic information is based on previous studies with women incarcerated in jails.^{6,51}

Characteristic	The people we would expect to see included
Age	Age range from 18 – 99; anticipate mean 36.2.
Sex	It is anticipated that 100% of study participants will be female.
Gender	It is anticipated that the majority (~95%) of study participants will identify as women.
Race, ethnicity and ancestry	85% white; 10% African American; 5% other
Socioeconomic status	It is anticipate that the majority of participants (85%) will report low SES due to limited education, income, and employment.
Geographic location	All study sites are in the US; it is anticipate that participants will reside in urban (65%) and rural (35%) after release from custody.
Other characteristics relevant to the trial	n/a

Eligibility criteria for participants {14a}: For the effectiveness trial, inclusion criteria will include incarcerated women who: (1) are participating in corrections-based SUD treatment; (2) have an anticipated release date within 4 months; (3) self-identified history of experiencing or witnessing violent victimization; (4) willing to engage with at least one “Safe Support Person” (SSP) in the community, someone who is trusted to support recovery and willing to be contacted about participation; and (5) expressed willingness to participate through signed informed consent with research staff **{see section 32a}**.

Eligibility criteria for sites and those delivering interventions {14b}: Criteria for site selection is discussed in section {13}. The study will be implemented in corrections-based substance use disorder treatment in four facilities. Staff in those facilities will be delivering the intervention following strict training protocols and fidelity adherence checklists.

Who will provide informed consent {32a}: Informed consent will be provided prior to the collection of any study data. Informed consent will include a detailed review of any possible risks associated with study enrollment, including participating in the intervention in both the facility and in the community. The SSP will be given informed consent prior to the initial telehealth session, and a waiver of documented informed consent will be requested due to the nature of the telehealth session. The SSPs will be asked to complete web-based survey measures related to their perceptions of the woman’s emotional regulation, connection, and healthy coping skills.

Given the vulnerable nature of this incarcerated sample at the time of study recruitment, potential participants will be assured during the informed consent process that: (a) Decisions to participate or refuse participation in the study will not affect their legal parole status, if applicable; (b) No individually identifiable information collected as part of the study will be shared with any justice authority including correctional staff, parole officers, or community-mandated treatment programs; and (c) Declining to participate will have no impact on parole or other legal status. Women who choose not to participate will not be identified in study records, and non-participation will not appear in any official record or file. Informed consent procedures will cover participation in the screening session, baseline interview, intervention, follow-up interviews, and potential risks associated with involvement in both carceral and community settings, ensuring that participants are fully informed about all study procedures prior to deciding to enter the study.

Additional consent provisions for collection and use of participant data and biological specimens {32b}:

Additional detail on the use of participant data is included in section {26}. Biological specimens are not collected as part of this trial.

Intervention and comparator

Intervention and comparator description {15a}: Intervention components will be delivered as follows: (1) Treatment as Usual (TAU, standard in-custody SUD treatment, comparator, n=88), (2) In-custody TRUST only (TAU + TRUST corrections-based sessions only; n=88), and (3) TRUST + Re-entry recovery support (TAU + corrections-based TRUST sessions + Re-entry recovery support; n=88). Within each site, cohorts of women will first be recruited for the TAU condition, then after 3 months of the TAU condition, the site will add the TRUST in-custody sessions only approach and new cohorts of women will be recruited (TAU+TRUST only condition). A 6-month window will be provided to each cohort to allow for intervention delivery (approximately

3 months), that cohort to be released from custody, and logistic transition to the next cohort. Each site will add the TRUST + Re-entry recovery support approach, where new cohorts of women will be recruited, given 3 months to complete intervention delivery, be released, and complete the cohort transition. The total time frame for each condition is about 9 months.

Treatment as Usual (TAU, n=88): Women in the TAU condition (**Comparator [9b]**) will not receive the TRUST intervention sessions, but will receive traditional in-custody SUD treatment over 6 months as usual in the four targeted sites. Participating women's treatment programs are managed by the Department of Corrections (DOC, KY) and Gateway Foundation (MO). Treatment is consistent with modified therapeutic community programs with transitional support following release while on community supervision.^{52,53} The therapeutic community programs are separate units with the facilities and emphasize the overall goal of addressing substance use and criminal thinking. Although trauma and history of violence are addressed as part of the holistic group process approach in these programs, these topics are not addressed from an on-going systematic or relational perspective and are not specifically addressed as part of re-entry planning.

TAU + TRUST (TRUST only, n=88). The TRUST intervention will consist of a series of group modules (12 sessions, approximately 1-2 hours in length), delivered over the course of 3 months by the TRUST practitioner. Sessions are organized by the three pillars of trauma-wise care⁴⁴ including trauma and emotion management, safety, and relationships. There is a major focus throughout the curriculum on "connecting the dots" between negative emotional reactions such as anxiety and depression and women's patterns of substance use that can increase risk for overdose. The project also provides education and a toolbox of possible strategies for women to recognize these trauma reactions, evaluate threats to safety and relationships, and decide next steps to reduce their risk of returning to use after release.

TAU + TRUST + Re-entry (n=88). This condition includes TRUST corrections-based group sessions, along with ongoing re-entry recovery support from a Safe Support Person (SPP). Identification of the SSP will be grounded in approaches similar to those with justice-involved youth⁴¹ and with adults in SUD treatment.^{54,55} The SSP will be identified by the study participant as someone who will provide prosocial support during re-entry (e.g., support towards abstinence, establishing healthy recovery support relationships, rebuilding relationships with family and children) and in most cases will involve a close family member (parent, grandparent) or friend at the woman's identified home placement. This individual will be identified by the study participant as someone who is not involved in active substance use nor has a current justice system status (e.g., on probation). Within a month of anticipated release, the study participant and TRUST practitioner will meet with the SSP via telehealth videoconferencing for a TRUST orientation to discuss study involvement, core principles of TRUST, and best ways support the participant after release as part of re-entry planning. Once the woman is released, the TRUST practitioner will meet with her and the SSP via telehealth videoconferencing at least once per month (more often if desired) for recovery support sessions during the 3 months following community re-entry to continue to practice TRUST skills taught during the corrections-based program.

Criteria for discontinuing or modifying allocated intervention/comparator {15b): Due to the vulnerable nature of this participant population (women who are incarcerated), participation in study data collection and intervention activities is completely voluntary. Informed consent is provided prior to the initiation of any study

activities, and women are informed that if the intervention causes them any undue distress, they can withdraw at any time. Otherwise, it is not anticipated that the intervention assignment will be modified during the course of the trial.

Strategies to improve adherence to intervention/comparator {15c}: Data on sessions attended will be collected by TRUST interventionists, as well as fidelity monitoring checklists to ensure that core domains of each intervention session were delivered. In addition, participants will be asked to complete a brief pre/post survey to measure knowledge gained during each session.

Concomitant care permitted or prohibited during the trial {15d}: Study participants will receive the TRUST intervention sessions during their usual course of SUD treatment in the facility. Women will be encouraged to continue any additional medical or psychological services they are receiving in the jail as part of services as usual.

Ancillary and post-trial care {34}: While post-trial care is not a standard part of the TRUST intervention, study staff will maintain an up-to-date resource referral guide to refer study participants who want additional services at the conclusion of trial participation.

Outcomes {16}

The primary outcome is overdose risk as defined by any illicit substance use (other than alcohol or marijuana) during the 6 months post-release. This measure was specifically selected because 1) any use of specific substances after long periods of incarceration could be a risk due to tolerance loss and/or the presence of illicit fentanyl in many substances; and 2) women leaving custody in these facilities will be graduates of SUD treatment on parole, and any drug use would be considered a violation. Secondary measures of changes in trauma-related issues, connection and recovery supports, emotional regulation, and healthy coping will be used as indicators of application of core TRUST components and will be assessed with both the participant and the SSP. Other secondary outcomes will include measures associated with the effectiveness of corrections-based treatment alone, which may also influence overdose risk.

Harms {17}

Study procedures will be monitored closely by the IRB with all potential safeguards to protect against harm for this vulnerable population of incarcerated women. This study will use conventional clinical and social science research methods typical for behavioral intervention delivery. Potential psychological harms will be explained to during the informed consent process to aid women in making an informed decision about whether to participate in the study. Any potential risks are principally related to questions asked during the interview that may be uncomfortable. Participants may experience emotional distress, anxiety, or other negative reactions because of the challenging nature of the interview content and/or participation in the intervention, which may occur both in custody and/or during re-entry). Participants will be informed that they are not required to answer anything they are not comfortable answering and that they can withdraw from the study at any time. If the participant's anxiety becomes substantially distressing, the participant will be removed from the study and given a referral for mental health and substance use treatment, either within the facility or in the community, depending on her location at the time.

For participants assigned to the TRUST condition, there is the potential risk of a breach of confidentiality regarding study files. Every effort will be made to prevent this. After TRUST study records are completed, they will be securely and confidentially stored in the study field office. No study-related files, whether hard copy or electronic, will be stored in carceral facilities. All potential risks and safeguards will be explained to each potential study participant during the informed consent process.

Participant timeline {18}

Women in custody who provide consent will be screened for eligibility and complete a baseline interview. Across four experimental sites, start time to intervention condition (Treatment as usual, TRUST only, TRUST + Re-entry) is randomly assigned. Follow-up interviews are conducted in the community at 3-and 6-months post-release. The following table outlines the participant timeline including the schedule of enrollment, interventions, and research assessments.

Participant timeline: Schedule of enrollment, interventions, and assessments⁴⁶

TIMEPOINT ^a	PRE-Release					POST-Release					
	-4	-3	-2	-1	0	1	2	3	4	5	6
ENROLLMENT											
Eligibility screen	X										
Informed consent	X										
Baseline interview	X										
Randomization ^b	X										
INTERVENTION											
Wave 1 [TAU, Comparator]											
Wave 2 [TRUST Only] ^c		X	→	X							
Wave 3 [TRUST + Re-entry]		X	→					X			
FOLLOW-UP ASSESSMENTS:											
Overdose risk								X			X
Secondary outcomes								X			X

^a t₁ = 4 months prior to release; 0 = release date from institution; t₂ = 3 months post-release in the community; t₃ = 6 months post-release in the community.

^b Randomization is to start date of the intervention, determined a priori to study launch but reflected here since it determines study activities by block.

^c Arrow indicates continuous delivery of intervention (e.g., drug)

Sample size {19}

Power calculation is based on an attrition rate = 10% (based on other work with women re-entering the community after jail release⁵⁰), Bonferroni corrected p = 0.025, within-period/time ICC = 0.01 (based on treatment satisfaction ratings from a prior TCU study⁵⁶), a medium effect size (odds ratio = 0.60) indicating

that the odds of any illicit substance use for women in the treatment conditions is 0.60 times the odds for the TAU condition (unpublished). For 80% power, a medium effect size =0.60, attrition rate = 10%, ICC = 0.01, power analyses yield an estimated N=264 (88 per condition, 66 per site, 22 per condition per site).

Recruitment {20}

Corrections-based SUD treatment programs in KY and MO average about 6 months length of stay and are generally completed during the final 6 months of their sentence prior to release from custody. Approximately 4 months prior to their targeted release date, incarcerated women in corrections-based SUD treatment will be invited to an information session about the study with research staff. The session will include an overview of study procedures, voluntary participation, incentives, contact information, and assurance will be given that participation in the program will not affect their current participation in SUD treatment. After the information session, research staff will meet individually with each woman to collect informed consent and answer any questions. Following initial screening and determination of eligibility, a baseline assessment will be completed with each incarcerated woman who meets eligibility criteria and provides informed consent.

Assignment of interventions: Randomization

Who will generate the sequence {21a}: In this trial, the randomization of start date for conditions is based on two levels: 1) state, and 2) facilities within the state. The sequence will be randomized by research study personnel. Integrity of the randomization process will be protected by coding each of the states and facility sites in order to reduce bias for preference of start date.

Type of randomization {21b}: Scientific rigor is enhanced through integration of two robust methodologies including a delayed start⁴⁸ and cluster (sites within state) random assignment to start date. Specifically, each state, as well as which facility within each state, will be randomized to start date for implementing study interventions. This design will allow for examining the effectiveness of experimental conditions by layering 2 incremental intervention components (quasi-experimental design) and account for potential history effects by staggering start times for conditions.⁵⁷

This design can be counted as a quasi-experimental design with “non-equivalent groups” because there are multiple groups and multiple waves of measurement, but the groups are not necessarily equivalent (although expected to be similar). The adoption of this design over a standard 1:1 random assignment was chosen since it allowed for scientific rigor while accommodating pragmatic limitations (e.g., having enough participants to be able to run 3 concurrent conditions within each site) and reducing potential contamination due to correctional-based SUD programs operating within a confined unit. Because the participants are nested under sites, we will use rigorous methods such as multi-level analysis (SAS PROC MIXED; SAS, 2002-2012; HLM⁵⁷) to examine effectiveness of TRUST components. This analytic model addresses the issue that participants within the same site are likely to be more similar to each other than to those from other sites, as they are exposed to the same selection attributes, as well as general treatment service goals.

Allocation concealment mechanism {22}: Because study sites are randomized to start dates, it is not possible to conceal allocation.

Implementation {23}: Because study sites are randomized to start dates, those who enroll participants will have access to the randomization allocation.

Assignment of intervention: blinding

Who will be blinded {24a}: The TRUST study is an unblinded trial.

How will blinding be achieved {24b}: n/a

Procedure for unblinding if needed {24c}: n/a

Data collection, management, and analysis

Plans for assessment and collection of outcomes {25a}: Outcomes for the effectiveness trial are measured through data collection at baseline and follow-up in the community. Research staff are trained in both the study protocol and correctional facility visitation procedures, and will travel to each site for baseline data collection. Training and supervision of the data collection staff will be conducted by the MPIs and study director at each site who have experience in supervising data collection staff in correctional settings. Research staff will be instructed study protocols and important facility policies and procedures. Baseline assessments will be a face-to-face assessment completed in confidential rooms in each facility. No correctional staff will be present during data collection, but may monitor participant entrance and exit into the room.

At the conclusion of the baseline assessment, participants in all three conditions will be offered the opportunity to review an overdose education video on how to revive someone experiencing an opioid overdose with naloxone. If the participant agrees, a naloxone nasal spray (Narcan®) kit will be made available to them upon release. Although naloxone is specific to opioid overdoses, recent data suggests that heroin (80%) and fentanyl (71.5%) are the most common drugs associated with overdoses in the 90 days before incarceration.⁵⁸ However, research staff will clarify that overdoses associated with other drugs (e.g., methamphetamines) will not be reversed by naloxone.

Plans to promote participant retention and complete follow-up {25b}: Follow-up data will be collected at 3 and 6 months post-release. To the extent possible, data collection will be face-to-face with all participants. Phone or videoconferencing may also be used if needed for the convenience of the participant. To minimize attrition, tracking procedures will utilize phone calls, internet and social media (particularly Facebook) searches, letters, and in-person field visits.

Data management {26}: Self-reported data from women will be collected during study screening, baseline, and at the 3 and 6 post-release follow-up. Sources of research material from study participants will focus on the primary outcome of overdose risk defined by any illicit substance use (other than alcohol or marijuana) using self-report and urine drug screens (follow-up only). All self-report data will be collected using REDCap. In addition, data will be collected by research staff on participation in the TRUST intervention, number of sessions completed, session content, and any needed referrals. Implementation science surveys (administered to *key stakeholders* at four assessment points) will be programmed and distributed through

REDCap. Justice administrators (community supervision staff) will not receive any clinical data (including missed sessions).

Data will be collected and managed through REDCap across all study locations, and compiled in one data warehouse. Any intake documentation containing PHI is separately handled and stored from any research data collected from participants. For illustration, all written records containing PHI will be stored in a locked area, separate from all other de-identified data. Any codes linking the two will be securely locked. Electronic data with PHI will be kept in a database that is password-protected and only accessible to MPIs. All incidental material that contains subject identifiers will be destroyed. Regardless of study completion status, any participant may choose to receive assistance with linkage to ongoing community treatment services to further mitigate overdose risks.

Confidentiality {33}: All information and data provided by participants will be kept confidential and will not be released to anyone outside the scope of the study without prior written authorization from participants. Participants' identities will never be revealed in any research reports. A *Certificate of Confidentiality* will be obtained from the National Institute on Drug Abuse which, under federal law (PL 94-255), protects study data from being used in any legal or criminal proceedings. Participants will also be verbally informed about protections of confidentiality and given a copy of the signed informed consent outlining the study purpose and safeguards including the Certificate of Confidentiality. Accordingly, no self-reported data will be shared outside of authorized study key personnel. Justice authorities will not have access to self-reported data collected during interviews or the intervention.

Statistical methods

Statistical methods for primary and secondary outcomes {27a}: Three intervention conditions will be compared (TAU, TAU + TRUST, and TAU + TRUST + Re-entry) on the primary outcome (overdose risk defined by *any illicit substance use* during the 6 months post-release from custody), and secondary TRUST outcomes (*trauma-related symptoms* and *connection* through recovery supports, emotional regulation, and healthy coping) during both the 3 and 6 months post-release points, as well as TAU SUD treatment outcomes (recovery network support, utilization of treatment/recovery resources, employment, etc.).

Who will be included in each analysis {27d}: Descriptive statistics such as distributions, means and standard deviations, skewness, outliers and other factors on the entire sample, per site, and per condition will be examined. Data transformations will be used as needed. Sites randomly assigned to the 4 start times will be compared to test for equivalence on baseline measures. Specifically, groups will be compared on baseline characteristics (e.g., SUD severity, violent victimization, PTSD checklist scores) using ANOVA and chi-square. These will be included as covariates in analyses if significant baseline differences exist. An intent-to-treat ITT approach will be used, where all study participants will be included in analyses. Comparison of survival curves (time to substance use) for each group will be examined using SAS PROC LIFETEST using the log rank test with the Sidak multiple-comparison adjustment, with overdose risk as the dependent variable.

How missing data will be handled in the analysis {27c}: For clinical trial data, a log rank test will assess attrition related to dropout and multiple-imputation methods will determine maximum likelihood estimates,

account for ambiguity in missing values, and provide unbiased estimates for random missing values related to the treatment effect.

Methods for additional analysis {27d}: Between group differences on secondary outcomes will be explored using repeated measures ANOVAs (software: SAS 9.4, PROC MIXED), utilizing study site as random effects, with condition, time, and interactions as set factors. Because substance use rates, choices of substances, and violent exposures may differ among racial and ethnic groups of justice-involved women, race and ethnicity will be explored as moderator variables in predicting outcomes if subgroup sizes are sufficiently large enough. Putative change mechanisms will also be observed as mediators of the Intervention Group X Overdose Risk connection and use multi-group structural equation models (SEM; using MPLUS) to conduct moderated mediation analyses to reveal potential racial and ethnic differences in mediation.

In this hybrid type 1 trial, the implementation aim will use a longitudinal mixed method approach^{59,60,61} to describe the implementation process over time and to examine factors associated with TRUST sustainability. Key stakeholders will be invited to participate in quantitative surveys assessing core implementation constructs, like implementation climate (Implementation Climate Scale^{62,63}), organizational readiness (Organizational Readiness for Change⁶⁴), and leadership engagement (Implementation Leadership Scale⁶⁵). Surveys are during the Preparation phase (month 11), every year during the implementation phase (months 13-48), and 6 months post-completion of the implementation phase (months 53-60) for a total of 4 assessment points to evaluate changes in implementation processes over time. Quantitative data will be aggregated by data collection wave, and a series of qualitative focus groups with key administrator and practitioner stakeholders will be held at regular intervals to validate quantitative survey responses^{47,60}.

Interim analyses {28b}: There are no plans for an interim efficacy analysis. Accrual, ineligibility, and dropout rates will be assessed monthly.

Protocol and statistical analysis plan {5}: The plan for analysis of primary and secondary outcomes is described in section {27a}. In addition, analysis plans are available in ClinicalTrials.gov, and will be specified in each manuscript submitted for publication or included as an additional file to the submission, depending on the journal and level of complexity of analysis.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {3d}: This trial is led by MPIs Staton and Knight, along with a strong team of collaborative programs at the University of Kentucky (UKY) and at Texas Christian University (TCU) to provide the strongest research across multiple areas including opioid use disorder, multi-site RCTs, implementation research, justice system, SUD treatment and risk-reduction interventions for women, and community linkages after release from incarceration. We have combined our justice coalition infrastructures established by our previous CJ-DATS, JJTRIALS, and JCOIN studies, two decades of NIDA-funded Cooperative Agreement initiatives to improve outcomes for justice-involved individuals with SUDs.

The MPIs will ensure trial monitoring, which will be conducted under the NIH approved Data Safety Monitoring Plan. Each adverse event (AE) is reviewed and classified by a MPI or Medical Monitor as either *Serious* or *Non-*

Serious, with reporting procedures followed accordingly. Serious Adverse Events (SAEs) include a fatal event, immediately life-threatening occurrence, permanent or substantially disabling incident, events resulting in inpatient hospitalization, or congenital anomalies. SAEs also cover other medical events judged by investigators to be serious because it endangers the participant, requires intervention to prevent a reportable SAE (e.g., overdose), or suggest a significant hazard, contraindication, side effect, or precaution. In the event that a SAE occurs, the MPIs and the Medical Safety Monitor will conduct an immediate review of the experimental protocol to discuss continuation of the trial.

Composition of the data monitoring committee {28a}: This study's human subjects protection protocol will fully comply with special protections concerning behavioral research involving prisoners as participants (Protection of Human Participants, Code of Federal Regulations, 45 CFR 46, Revised March 8, 1983). This includes the composition of the IRB having at least one prisoner reviewer involved in each level of review. The trial is monitored by the UKY and TCU Institutional Review Boards under a single-site agreement (UK). Following IRB approval, an application including the research proposal and IRB application materials is forwarded to the Office of Human Research Protections (OHRP) for approval and prisoner certification. It will be up to the OHRP to determine if it meets criteria for any of the four categories of research authorized under HHS regulations at 45 CFR 306(a)(2). The study will also be reviewed and approved by the KY-DOC office of research integrity.

Frequency and plans for auditing trial conduct {29}: The UKY Office of Sponsored Projects Administration, the unit responsible for overall compliance in research and directly reporting to the Vice President for Research, has an internal policy and procedures in place to ensure that clinical trial registration and results at defined intervals reporting occur in compliance with NIH policy requirements. The UKY and TCU study teams will adhere to that policy. In addition, the IRB will require annual continuation review to audit the trial. MPIs will be monitoring adverse events at least monthly, along with accrual numbers, study drop outs, and fidelity to intervention sessions.

Protocol amendments {31}: Any potential amendment to the protocol will first be submitted to the UKY IRB under a single site IRB agreement for review. Acceptance of the proposed amendment by the IRB will be required before any change to the experimental protocol is implemented. MPIs will promptly inform NIDA's program officer of any major changes in the status of an ongoing protocol.

Dissimination policy {8}

All data will be reported and made available through ClinicalTrials.gov. Following peer-review publication, data generated through this project will be made available to investigators at academic institutions upon request. Data will be de-identified for publication and sharing. The final research data will also be made available to oversight or regulatory committees. The rights and privacy of individuals who participate will be protected at all times, and at no time will identifiers be included that would permit linkages to the individual participants and variables that could lead to deductive disclosure of the identity of participants. The TRUST intervention manual will also be available for dissemination at the conclusion of the study.

Discussion

The majority of incarcerated women have histories of violent victimization and untreated trauma,²⁴ and these factors have the potential to significantly increase their overdose risk upon community release in the absence of effective interventions.⁶⁶ To our knowledge, this is the first study to examine the implementation and integration of trauma-informed intervention (TRUST) with the goal of overdose prevention for women during community re-entry. Despite significant need, few evidence-based health interventions are delivered in correctional facilities;⁶⁷ thus, this project has potential to accelerate the translation of research into justice settings to establish a trauma-informed intervention for women before and after release from custody to reduce overdose risk during community re-entry.

The importance of knowledge gained through this study is grounded in the national public health crisis associated with overdose deaths, largely associated with the opioid epidemic, but also related to unique issues faced by women and the limited, targeted, trauma-informed overdose prevention interventions for this population. These unique risks are exacerbated when a woman has a history of violent victimization and has sustained long periods of incarceration where tolerance is diminished, and supportive networks are limited. Ultimately this study that has the potential to significantly reduce overdose risk among justice-involved women with a history of violent victimization and related trauma.

Trial status

Recruitment for this trial began December 8, 2025, and is anticipated to continue enrollment through December 2027.

Declarations

Acknowledgement: This research was supported by the National Institutes of Health/National Institute on Drug Abuse under award number R33DA061365. The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of the NIH, NIDA, or the participating sites. We would also like to acknowledge the contribution of our partners in the Kentucky Department of Corrections and Missouri Department of Corrections.

Authors contributions: M.S. and K.K. conceptualized and designed the study protocol, the manuscript draft, and overall responsibility for the finalized manuscript. J.A., T.L., and O.J. assisted with drafting sections of the manuscript, as well as overall review of the complete draft. P.C., Y.Y., L.B., C.O., and M.T. contributed to the overall review of study protocol updates and finalizing the manuscript draft. All authors approved the submitted version of the manuscript. All authors agree to be accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

Funding: This research was supported by the National Institutes of Health/National Institute on Drug Abuse under award number R33DA061365.

Availability of data and material: The datasets generated and/or analyzed during the current study will be publicly available upon study completion, or upon request from the corresponding author.

Ethics approval and consent to participate: This study is approved by full review of the University of Kentucky Institutional Review Board (Protocol #94956), in accordance with ethical standards established through the Belmont Report and protections for prisoners as a vulnerable population through the Office of Human Research Protections. The approved protocol includes an informed consent form which is reviewed with study participants prior to initiation of any research or intervention activities.

Consent for publication: Not applicable.

Competing interests: Not applicable.

References

1. VanHouten, J. P., Rudd, R. A., Ballesteros, M. F., & Mack, K. A. (2019). Drug overdose deaths among women aged 30–64 years – United States, 1999–2017. *MMWR. Morbidity and Mortality Weekly Report*, 68(1), 1–5. <https://doi.org/10.15585/MMWR.MM6801A1>.
2. Mazure, C. M., & Fiellin, D. A. (2018). Women and opioids: something different is happening here. *The Lancet (British Edition)*, 392(10141), 9–11. [https://doi.org/10.1016/S0140-6736\(18\)31203-0](https://doi.org/10.1016/S0140-6736(18)31203-0)
3. Springer, S. A., Biondi, B. E., Frank, C., & El-Bassel, N. (2020). A call to action to combat the opioid epidemic among women. *Journal of Addiction Medicine*, 14(5), 364–366. <https://doi.org/10.1097/ADM.0000000000000622>
4. Hernandez-Avila, C. A., Rounsaville, B. J., & Kranzler, H. R. (2004). Opioid-, cannabis- and alcohol-dependent women show more rapid progression to substance abuse treatment. *Drug and Alcohol Dependence*, 74(3), 265–272. <https://doi.org/10.1016/j.drugalcdep.2004.02.001>
5. Greenfield, S. F., Back, S. E., Lawson, K., & Brady, K. T. (2010). Substance abuse in women. *The Psychiatric Clinics of North America*, 33(2), 339–355. <https://doi.org/10.1016/j.psc.2010.01.004>
6. Staton-Tindall, M., Ciciurkaite, G., Havens, J. R., Peteet, B., Webster, M., & Oser, C. B. (2017). Preliminary outcomes of a brief intervention to reduce HIV and HCV risk among rural women. *Drug and Alcohol Dependence*, 171, e195–e196. <https://doi.org/10.1016/j.drugalcdep.2016.08.535>
7. Butelman, E.R., Huang, Y., Epstein, D.H., Shaham, Y., Goldstein, R.Z., Volkow, N.D., & Alia-Klein, N. (2023). Overdose mortality rates for opioids and stimulant drugs are substantially higher in men than in women: State level analysis. *Neuropsychopharmacology*, 48, 1639-1647. <https://doi.org/10.1038/s41386-023-01601-8>
8. Hartung, D. M., McCracken, C. M., Nguyen, T., Kempny, K., & Waddell, E. N. (2023). Fatal and nonfatal opioid overdose risk following release from prison: A retrospective cohort study using linked administrative data. *Journal of Substance Use and Addiction Treatment*, 147, Article 208971. <https://doi.org/10.1016/j.josat.2023.208971>
9. Joudrey, P. J., Khan, M. R., Wang, E. A., Scheidell, J. D., Edelman, E. J., McInnes, D. K., & Fox, A. D. (2019). A conceptual model for understanding post-release opioid-related overdose risk. *Addiction Science & Clinical Practice*, 14(1), 17. PMID: 30982468.

10. Sinkman, D., & Dorchak, G. (2022). Using the Americans with Disabilities Act to reduce overdose deaths. *Department of Justice Journal of Federal Law and Practice*, 70(1), 113-128.
11. Binswanger, I. A., Blatchford, P. J., Mueller, S. R., & Stern, M. F. (2013). Mortality after prison release: Opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009. *Annals of Internal Medicine*, 159(9), 592–600. <https://doi.org/10.7326/0003-4819-159-9-201311050-00005>
12. Waddell, E. N., Baker, R., Hartung, D. M., Hildebran, C. J., Nguyen, T., Collins, D. M., Larsen, J. E., & Stack, E. (2020). Reducing overdose after release from incarceration (ROAR): study protocol for an intervention to reduce risk of fatal and non-fatal opioid overdose among women after release from prison. *Health & Justice*, 8(1), 1–19. PMID: 32651887.
13. SAMHSA (2015) Substance Abuse and Mental Health Services Administration. *Substance abuse treatment: Addressing the specific needs of women* (Treatment Improvement Protocol Series, No. 51. HHS Publication No. 13-4426.) U.S. Department of Health and Human Services. store.samhsa.gov/sites/default/files/d7/priv/sma15-4426.pdf
14. Afari, N., Ahumada, S. M., Wright, L. J., Mostoufi, S., Golnari, G., Reis, V., & Cuneo, J. G. (2014). Psychological trauma and functional somatic syndromes: a systematic review and meta-analysis. *Psychosomatic Medicine*, 76(1), 2–11. PMID: PMC3894419.
15. American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). doi.org/10.1176/appi.books.9780890425596.
16. Koenen, K. C., Ratanatharathorn, A., Ng, L., McLaughlin, K. A., Bromet, E. J., Stein, D. J., Karam, E. G., Meron Ruscio, A., Benjet, C., Scott, K., Atwoli, L., Petukhova, M., Lim, C. C. W., Aguilar-Gaxiola, S., Al-Hamzawi, A., Alonso, J., Bunting, B., Ciutan, M., de Girolamo, G., ... Kessler, R. C. (2017). Posttraumatic stress disorder in the World Mental Health Surveys. *Psychological Medicine*, 47(13), 2260–2274. PMID: 28385165.
17. Ulirsch, J. C., Ballina, L. E., Soward, A. C., Rossi, C., Hauda, W., Holbrook, D., Wheeler, R., Foley, K. A., Batts, J., Collette, R., Goodman, E., & McLean, S. A. (2014). Pain and somatic symptoms are sequelae of sexual assault: Results of a prospective longitudinal study. *European Journal of Pain*, 18(4), 559–566. PMID: 34019249.
18. Wuest, J., Merritt-Gray, M., Ford-Gilboe, M., Lent, B., Varcoe, C., & Campbell, J. C. (2008). Chronic pain in women survivors of intimate partner violence. *The Journal of Pain*, 9(11), 1049–1057. PMID: 18701353.
19. Desmarais, S. L., Gray, J. S., Rade, C. B., Cohn, A. M., Doherty, S., & Knight, K. (2016). Medication-Assisted Treatment and violent outcomes in community-based offenders with alcohol and drug use problems. *Psychology of Violence*, 6(3), 378-389.
20. Sacks, S., Cleland, C. M., Melnick, G., Flynn, P. M., Knight, K., Friedmann, P. D., Prendergast, M. L., & Coen, C. (2009). Violent offenses associated with co-occurring substance use and mental health problems: Evidence from CJDATS. *Behavioral Sciences & the Law*, 27, 51-69.
21. Stone, R., & Rothman, E. F. (2019). Opioid use and intimate partner violence: A systematic review. *Current Epidemiology Reports*, 6(2), 215–230. doi.org/10.1007/s40471-019-00197-2
22. Smith, K. Z., Smith, P. H., Cercone, S. A., McKee, S. A., & Homish, G. G. (2016). Past year non-medical opioid use and abuse and PTSD diagnosis: Interactions with sex and associations with symptom clusters. *Addictive Behaviors*, 58, 167–174. PMID: 26946448.

23. Rigg, K. K., & Ibañez, G. E. (2010). Motivations for non-medical prescription drug use: A mixed methods analysis. *Journal of Substance Abuse Treatment*, 39(3), 236–247. PMID: 20667680.
24. Green, B. L., Dass-Brailsford, P., Hurtado de Mendoza, A., Mete, M., Lynch, S. M., DeHart, D. D., & Belknap, J. (2016). Trauma experiences and mental health among incarcerated women. *Psychological Trauma*, 8(4), 455–463. PMID:27065062.
25. Karlsson, M. E., & Zielinski, M. J. (2020). Sexual victimization and mental illness prevalence rates among incarcerated women: A literature review. *Trauma, Violence, & Abuse*, 21(2), 326–349. PMID: 29661117.
26. Monazzam, N., & Budd K.M. (2023). *Incarcerated women and girls* [Fact sheet]. The Sentencing Project. www.sentencingproject.org/fact-sheet/incarcerated-women-and-girls/
27. Gicquelais, R. E., Mezuk, B., Foxman, B., Thomas, L., & Bohnert, A. S. B. (2019). Justice involvement patterns, overdose experiences, and naloxone knowledge among men and women in criminal justice diversion addiction treatment. *Harm Reduction Journal*, 16(1), Article 46. <https://doi.org/10.1186/s12954-019-0317-3>
28. Wenger, L. D., Showalter, D., Lambdin, B., Leiva, D., Wheeler, E., Davidson, P. J., Coffin, P. O., Binswanger, I. A., & Kral, A. H. (2019). Overdose education and naloxone distribution in the San Francisco County jail. *Journal of Correctional Health Care*, 25(4), Article 1078345819882771. <https://doi.org/10.1177/1078345819882771>
29. Gan, W. Q., Kinner, S. A., Nicholls, T. L., Xavier, C. G., Urbanoski, K., Greiner, L., Buxton, J. A., Martin, R. E., McLeod, K. E., Samji, H., Nolan, S., Meilleur, L., Desai, R., Sabeti, S., & Slaunwhite, A. K. (2021). Risk of overdose-related death for people with a history of incarceration. *Addiction (Abingdon, England)*, 116(6), 1460–1471. <https://doi.org/10.1111/add.15293>
30. Park, T. W., Larochelle, M. R., Saitz, R., Wang, N., Bernson, D., & Walley, A. Y. (2020). Associations between prescribed benzodiazepines, overdose death and buprenorphine discontinuation among people receiving buprenorphine. *Addiction*, 115(5), 924–932. PMID: 31916306.
31. Ranapurwala, S. I., Shanahan, M. E., Alexandridis, A. A., Proescholdbell, S. K., Naumann, R. B., Edwards, D., & Marshall, S. W. (2018). Opioid Overdose Mortality Among Former North Carolina Inmates: 2000–2015. *American Journal of Public Health (1971)*, 108(9), 1207–1213. <https://doi.org/10.2105/AJPH.2018.304514>
32. Cole, J., Logan, T., Melvin, C., & McLouth, C. (2024). Associations of interpersonal trauma, distress intolerance, and posttraumatic stress disorder with recent problem opioid use among a non-clinical sample of women. *Journal of Drug Issues*. Online First <https://doi.org/10.1177/00220426241252336>.
33. Logan, T., Walker, R., Jordan, C., & Leukefeld, C. (2006). *Women and Victimization: Contributing Factors, Interventions, and Implications*. Washington, DC: American Psychological Association Press.
34. Logan, T., Walker, R., Cole, J., & Leukefeld, C. (2002). Victimization and substance use among women: contributing factors, interventions, and implications. *Review of General Psychology*, 6, 4, 325-397.
35. Ataiants, J., Roth, A. M., Mazzella, S., & Lankenau, S. E. (2020). Circumstances of overdose among street-involved, opioid-injecting women: Drug, set, and setting. *The International Journal of Drug Policy*, 78, 102691–102691. <https://doi.org/10.1016/j.drugpo.2020.102691>
36. El-Bassel, N., Marotta, P. L., Goddard-Eckrich, D., Chang, M., Hunt, T., Wu, E., & Gilbert, L. (2019). Drug overdose among women in intimate relationships: The role of partner violence, adversity and relationship

- dependencies. *PloS One*, 14(12), e0225854. PMID:31881035.
37. Harris, M. T. H., Bagley, S. M., Maschke, A., Schoenberger, S. F., Sampath, S., Walley, A. Y., & Gunn, C. M. (2021). Competing risks of women and men who use fentanyl: "The number one thing I worry about would be my safety and number two would be overdose." *Journal of Substance Abuse Treatment*, 125, 108313–108313. PMID:34016300.
 38. Scheidell, J. D., Hoff, L., Khan, M. R., Bennett, A. S., & Elliott, L. (2022). Parenting and childcare responsibilities, harm reduction service engagement, and opioid overdose among women and men who use illicit opioids in New York City. *Drug and Alcohol Dependence Reports*, 3, 100054. PMID: 35757568.
 39. Thumath, M., Humphreys, D., Barlow, J., Duff, P., Braschel, M., Bingham, B., Pierre, S., & Shannon, K. (2021). Overdose among mothers: The association between child removal and unintentional drug overdose in a longitudinal cohort of marginalised women in Canada. *The International Journal of Drug Policy*, 91, 102977–102977. PMID: 33129662.
 40. Covington, S. (2022). Creating a trauma-informed justice system for women. In S.L. Brown & L. Belsthorpe (Eds.), *The Wiley handbook on what works with girls and women in conflict with the law: A critical review of theory, practice, and policy* (pp. 172-184). John Wiley & Sons.
 41. Knight, D. K., Yang, Y., Joseph, E. D., Tinius, E., Young, S., Shelley, L. T., Cross, D. R., & Knight, K. (2021). Preventing opioid use among justice-involved youth as they transition to adulthood: Leveraging safe adults (LeSA). *BMC Public Health*, 21(1), 2133–2133. PMID: 34801009.
 42. Purvis, K. B., Razuri, E. B., Howard, A. R. H., Call, C. D., DeLuna, J. H., Hall, J. S., & Cross, D. R. (2015). Decrease in behavioral problems and trauma symptoms among at-risk adopted children following trauma-informed parent training intervention. *Journal of Child & Adolescent Trauma*, 8(3), 201–210. PMID: 26322149.
 43. Purvis, K. B., Cross, D. R., Dansereau, D. F., Parris, S. R. (2013). Trust-based relational intervention (TBRI): A systematic approach to complex developmental trauma. *Child and Youth Services*, 34(4), 360-386. PMID: 24453385.
 44. Bath, H. (2008). The three pillars of trauma-informed care. *Reclaiming Children and Youth*, 17(3), 17–21.
 45. Bath, H. (2015). The Three Pillars of TraumaWise Care: Healing in the Other 23 Hours¹. *Reclaiming Children and Youth*, 23(4), 5.
 46. Chan A-W, Boutron I, Hopewell S, Moher D, Schulz KF, et al. SPIRIT 2025 statement: updated guideline for protocols of randomised trials. *BMJ* 2025;389:e081477. <https://dx.doi.org/10.1136/bmj-2024-081477>.
 47. Aarons, G. A., Hurlburt, M., & Horwitz, S. M. (2011). Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Administration and policy in mental health*, 38(1), 4–23. <https://doi.org/10.1007/s10488-010-0327-7>
 48. Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, 50(3), 217–226. <https://doi.org/10.1097/MLR.0b013e3182408812>.
 49. Hemming, K., Haines, T. P., Chilton, P. J., Girling, A. J., & Lilford, R. J. (2015). The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ (Clinical research ed.)*, 350, h391. <https://doi.org/10.1136/bmj.h391>

50. America's Health Rankings (2023). United Health Foundation Annual Report. <https://www.americashealthrankings.org/publications/reports/2023-annual-report>
51. Staton M, Tillson M, Terrill D, Oser C, Leukefeld C, Fanucchi L, McCollister K, Dickson MF, Winston E, Annett J, Webster JM. (2025). Outcomes following two models of treatment linkage facilitation for women with a history of OUD following jail release. *Journal of Substance Use Addiction Treatment*, Jul;174:209702. doi: 10.1016/j.josat.2025.209702. Epub 2025 Apr 24. PMID: 40286856; PMCID: PMC12158640.
52. Knight, K., Simpson, D. D., & Hiller, M. L. (1999). Three-Year Reincarceration Outcomes for In-Prison Therapeutic Community Treatment in Texas. *The Prison Journal (Philadelphia, Pa.)*, 79(3), 337–351. <https://doi.org/10.1177/0032885599079003004>
53. NIDA [2015]. National Institute on Drug Abuse (NIDA). 2015. *Therapeutic Community*. Research Report Series. Bethesda, MD: National Institute on Drug Abuse. Retrieved September 20, 2023 from www.drugabuse.gov/publications/research-reports/therapeutic-communities/what-are-therapeutic-communities.
54. Dopp, A. R., Manuel, J. K., Breslau, J., Lodge, B., Hurley, B., Kase, C., & Osilla, K. C. (2022). Value of family involvement in substance use disorder treatment: Aligning clinical and financing priorities. *Journal of Substance Abuse Treatment*, 132, Article 108652. <https://doi.org/10.1016/j.jsat.2021.108652>
55. Osilla, K. (2023). How conflict, cohesion, and social support affect patients in buprenorphine treatment and their families. Presentation, Addiction Health Services Research meeting, October 19, 2023.
56. Yang, Y., Gray, J., Joe, G. W., Flynn, P. M., & Knight, K. (2019). Treatment retention satisfaction, and therapeutic progress for justice-involved individuals referred to community-based medication-assisted treatment. *Substance Use & Misuse*, 54(9), 1461–1474. PMID: 31030611.
57. Raudenbush, S. W. (2005). Hierarchical models. In B. Vidakovic, S. Kotz, C. B. Read, N. L. Johnson, & N. Balakrishnan (Eds.), *Encyclopedia of Statistical Sciences* (Vol. 5, pp. 3150–3158). John Wiley & Sons, Inc. <https://doi.org/10.1002/0471667196.ess1060>.
58. Annett, J., Tillson, M., Walker, M., Webster, J. M., & Staton, M. (2023). Adverse childhood experiences and mental health among incarcerated women: Self-esteem as a mediating mechanism. *Child Abuse & Neglect*, 146, Article 106486. <https://doi.org/10.1016/j.chiabu.2023.106486>
59. Flynn, P. M., Knight, D. K., Godley, M. D., & Knudsen, H. K. (2012). Introduction to the special issue on organizational dynamics within substance abuse treatment: A complex human activity system. *Journal of Substance Abuse Treatment*, 42(2), 109-115. PMID: 22154828.
60. Hunter, S. B., Ayer, L., Han, B., Garner, B. R., & Godley, S. H. (2014). Examining the sustainment of the Adolescent-Community Reinforcement Approach in community addiction treatment settings: protocol for a longitudinal mixed method study. *Implementation Science: IS*, 9(1), Article 104. <https://doi.org/10.1186/s13012-014-0104-1>
61. Shortell, S. M. (2004). Increasing value: A research agenda for addressing the managerial and organizational challenges facing health care delivery in the United States. *Medical Care Research and Review*, 61(3_suppl), 12S-30S. <https://doi.org/10.1177/1077558704266768>
62. Ehrhart, M.G., Aarons, G.A. & Farahnak, L.R. Assessing the organizational context for EBP implementation: the development and validity testing of the Implementation Climate Scale (ICS).

Implementation Sci **9**, 157 (2014). <https://doi.org/10.1186/s13012-014-0157-1>

63. Jacobs, S. R., Weiner, B. J., & Bunger, A. C. (2014). Context matters: measuring implementation climate among individuals and groups. *Implementation science : IS*, *9*, 46. <https://doi.org/10.1186/1748-5908-9-46>
64. Shea, C. M., Jacobs, S. R., Esserman, D. A., Bruce, K., & Weiner, B. J. (2014). Organizational readiness for implementing change: a psychometric assessment of a new measure. *Implementation science : IS*, *9*, 7. <https://doi.org/10.1186/1748-5908-9-7>
65. Aarons, G. A., Ehrhart, M. G., & Farahnak, L. R. (2014). The Implementation Leadership Scale (ILS): development of a brief measure of unit level implementation leadership. *Implementation science : IS*, *9*(1), 45. <https://doi.org/10.1186/1748-5908-9-45>
66. Lamonica, A. K., Boeri, M., & Turner, J. (2021). Circumstances of overdose among suburban women who use opioids: Extending an urban analysis informed by drug, set, and setting. *The International Journal of Drug Policy*, *90*, Article 103082. <https://doi.org/10.1016/j.drugpo.2020.103082>
67. Zaller, M., Staton, M., & Ramaswamy, M. (2023). Introduction to the special issue: Health and social drivers in the criminal justice system. *Journal of Clinical and Translational Science*, *7*(1): e69. PMID: 37745927.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SPIRIT2025checklist12026rev.docx](#)